**Biocides Human Health Exposure Methodology**

# Foreword

The Biocides Human Health Exposure Methodology Document contains the technical aspects on exposure estimation for the purpose of the Biocidal Products Regulation (BPR EU528/2012) and applies for the evaluation of the active substances within the Review Programme as well as for the evaluation during product authorisation.

It is complementary to the ECHA Guidance on Exposure Assessment (Chapter 3, Part B). The principles of Exposure Assessment are described in Chapter 3, Part B and should be read together with the methodology document.

The content of this document is largely based on the previous versions of the Technical Notes for Guidance on Exposure (TNsG) that were developed in the past for the technical implementation of the Biocidal Products Directive (BPD 98/8/EC) (TNsG 2002, TNsG 2007).

The content takes into account the opinions developed by the Human Exposure Expert Group (HEEG) and the current Ad-hoc Human Exposure Expert group by incorporating the decisions that have been agreed at CA level as available at the time the respective version of the document has been drafted.

Due to the size of the document, it is advised to “view” with the “navigation panel” enabled to allow having an overview of the structure of the document.

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| **Version History** | | |
| **Version Number** | **Publication Date** | **Modifications** |
| 1 | October 2015 | First edition |
| 1.1 | May 2024 | Exposure assessment methodology for TP14 rodenticide product individually packed in LDPP/LDPE sachets  Removal of out of date ECHA visiting address |
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# Introduction

Each biocidal product is applied by one or more procedures. These are "scenarios", and each is composed of phases:

* mixing and loading
* application
* post-application and
* disposal or removal

For the generation of an exposure scenario the essential information that needs to be provided can be summarised as follows:

* the product and its purpose;
* where, how and by whom the product will be used;
* expected exposure controls (for example, process enclosure);
* tasks, frequencies and duration’s for mixing and loading (primary exposure);
* tasks, frequencies and duration’s for application or use (primary exposure);
* tasks, frequencies and duration’s for post-application activities (primary exposure);
* who else may be exposed (secondary exposure).

The exposure of the biocide user is "**primary**" and occurs in all phases. The exposure of other people is "**secondary**" and can occur during application and in particular, post-application, but also during further processing of objects that have been treated with a biocide. Primary and secondary exposure can be related to professional as well as non-professional users (consumers). However, exposure patterns, application times and frequencies as well as the ability to use protective equipment properly can deviate significantly between these user groups.

For many applications of biocidal products, harmonised assessment approaches have been agreed, which should be followed when appropriate for the application to be assessed. Besides these harmonised approaches, other models for exposure assessment exist and may be used in cases where no suitable harmonised approach exists.

Thus, when choosing a model for exposure estimation, the following ranking shall be observed:

1. Recommendations of the Ad hoc Working Group on Human Exposure (HEAd-hoc)
2. Opinions of the Human Exposure Expert Group (HEEG)
3. Models and defaults formerly presented in the Technical Notes for Guidance (TNsG) and the respective User Guidance
4. Other Models, e.g., generic models, ConsExpo, RISKOFDERM, etc.

Any deviation from this ranking should be justified.

The present document simplifies the selection of the right model and defaults by collecting the approaches from the above mentioned sources and presenting them according to the required ranking.

**Section 2** presents Default parameters for exposure assessment which are applicable for all kinds of human exposure.

**Sections 3 and 4** give advice on primary (direct) and secondary (indirect) exposure, respectively. Both chapters contain an overview on the respective *Exposure Scenarios*, provide guidance on *Exposure Estimation* and present *Refinement Options* to be used when more elaborated assessments are needed. Due to the differences between professional and non-professional use outlined above, different models and default assumptions are commonly used for these groups. To reflect this practice, some of the chapters in this document are subdivided accordingly.

**Section 5** focuses on approaches for assessment of *Combined Exposures*.

The following schema provides an overview (in line with the Chapter 3 / Part B Human Health Guidance Document) of the main aspects of the exposure assessment steps and the linking to the relevant sections of this document; additional linking of the section is provided within each section where relevant:

**Combined Exposures**

**(Section 5)**

Identify relevant populations & Uses

**Primary Exposure Scenario Creation** (Section 3.1)

**Professional Users**

(Section 3.1 & 3.1.1)

**Non-Professional Users**

(Section 3.1 & 3.1.2)

**Exposure Estimation Professional Users**

(Section 2 & 3.2.1)

**Exposure Estimation Non-Professional Users** (Section 2 & 3.2.2)

**Refinement Options**

(Section 3.3)

* **Professional Users**
* **Non-Professional Users (consumers)**
* **Professional Users**
* **Non-Professional Users (consumers)**
* **General Public**

**Secondary Exposure Scenario Creation** (Section 4.1)

**Residential, Treated Articles, Dietary** (Section 4.1.1-4.1.5)

**Exposure Estimation**

(Section 2 & 4.2)

**Refinement Options**

(Section 4.2.4)

# Default Parameters for Exposure Assessment

In order to conduct exposure assessment a number of default values are used within Tier I and II approaches. These default values usually address factors like body weight, body surface areas, inhalation rates, activity patterns and defaults for the locations where activities can take place.

These defaults, unless stated otherwise, apply both for primary (direct) and secondary (indirect) assessment.

For the purpose of harmonisation they are presented in this section, and are referenced in the relevant sections of exposure estimation within this document.

Additional defaults that are specific for either primary or secondary assessment only are described within the respective sections of this document.

## Anthropometric Parameters

This section is based on the HEEG Opinion (2013, Default Human Factor Values).

In review of available data, the NEGh Final Report (’Existing Default Values and Recommendations for Exposure assessment – A Nordic Exposure Group Project 2011) concluded that the US EPA data was the most valid. The data in Table 1 and Table 2 in this section further below are based on those from the US EPA Exposure Factors Handbook (2011 Issue), which are derived from US EPA Analysis of NHANES 1999-2006. The values for body weights and body surface areas are 25th percentile values; those for females providing a worse-case exposure assessment.

The data points in the US EPA Exposure Factors Handbook are often for a series of human age groups. For biocides assessment it would be laborious, and in fact unnecessary, for exposure assessments to determine exposures for all age groups. Therefore, , in order to provide a snapshot of exposure to the human population as a whole, four representative groups have been selected: for bodyweight and body part surface area - infant *(based on female 6 to <12 months old)*; toddler *(based on female 1 to <2 years)*; child *(based on female 6 to <11 years)*; and adult *(based on female 30 to <40 years old)*. The inhalation rates are based on the age groups: infant *(0 to <1 years old)*; toddler *(2 years)*; child (6 *to <11 years),* and for the adult (*long-term exposure: 31 to 51 years old – for short-term exposure, see further section (ii) on definitions of toddler below)*.

For an assessment, an Assessor would need to determine which representative group(s) is (are) at risk in a particular exposure scenario. For some scenarios, in some circumstances – an exposure assessment for one of the groups might allay concerns for the other three groups, and consequently for the human population as a whole. If so, and if explained in the assessment, actual exposure and risk calculations for the other three age groups might not need to be undertaken.

In particular for the infant and toddler, their behavioural characteristics will influence the route, frequency and degree of exposure. Definitions of both groups are given below to aid decision making.

**(i) Definitions of infant:** child who is at least 6 weeks old but less than 12 months old (Age Group Definitions – Minnesota Statutes 245A.02, subd. 19, March 2008 on http:/www.dhs.state.mn.us/main/groups/licensing/documents/pub/dhs16\_143385.pdf); child under 12 months old (<http://www.proz.com/kudoz/English/education_pedagogy/1148644-infant_x_toddler.html>); child in earliest period of life, especially before he/she can walk (http/www.thefreedictionary.com/infant): child who is in the earliest stage of extra uterine life, a time extending from the first month after birth to approximately 12 months of age, when the baby is able to assume an erect posture (http://medical-dictionary.the freedictionary.com/infant)

From these definitions it is reasonable to infer that ‘infants’ cannot walk or crawl extensively away from the place they are put to explore their environment. An ‘infant’ could touch surfaces which are within reach or within a very limited distance if the infant has some crawling ability. However for airborne residue (e.g., in a room where residues are volatilising from a treated surface) an infant could potentially inhale the volatised residue for the whole of the period the infant is in the treated area.

**(ii) Definitions of toddler:**

* ‘toddling’ is the kind of unsteady walking associated with young children (<http://www.proz.com/kudoz/English/education_pedagogy/1148644-infant_x_> toddler.html); child who is at least 12 months old but less than 24 months old (Age Group Definitions – Minnesota Statutes 245A.02, subd. 19, March 2008 on http:/www.dhs. state.mn.us/main/groups/licensing/documents/pub/dhs16\_143385.pdf);

* a child between 12 and 36 months of age, during this period of development the child acquires a sense of autonomy and independence through the mastery of various specialized tasks such as control of body functions, refinement of motor and language skills (<http://medical-dictionary.thefreedictionary.com/toddler>.

* when children learn to walk, begin to explore their environment (<http://urbanext.illinois.edu/baabysitting/age-toddler.html>).

From these definitions it is reasonable to infer that ‘toddlers’ can crawl/walk away from the place they are put and move to explore their environment. For example, a toddler, held by an adult, could to learn to play on a treated climbing frame. For the purposes of this document a ‘toddler’ will be considered to be in the age range 1 to <2 years old.

**Inhalation Rates**

(i) There are no recommended 25th percentile values for either short-term or long-term inhalation exposure presented in the US EPA Exposure Factors Handbook (September 2011), only mean and 95th percentile values. Therefore, mean values have been adopted for the infant, toddler and child with short-term inhalation rates based on ’moderate intensity’ of activity. [ A ‘moderate intensity’ of activity being defined as:

Fast walking, 3.3 to 4 miles per hour, and slow running, 3.5 to 4 miles per hour (page 5-8, Table 5-6 of USEPA Exposure Factors Handbook August 1997);

and specifically for children, play (page 5-9, Table 5-7 of USEPA Exposure Factors Handbook August 1997);

For adults, ‘moderate intensity activity’ includes for males, mowing, wood working, yard work (page 5-9, Table 5-7 of USEPA Exposure Factors Handbook August 1997), and for all adults heavy indoor cleanup, performance of major indoor repairs/alterations and climbing stairs (page 5-18, Table 5-16 of USEPA Exposure Factors Handbook August 1997.]

(ii) For the adult, the default short-term inhalation rate is 1.25 m3/hour; this value is retained as it has been universally used to date in biocidal product assessments and to have harmonization with other EU regulatory frameworks. It is understood 1.25 m3/hour derives from a paper by Taylor (Taylor C., America Journal of Physiology November 30 1941, 135: 27-42). From the paper, a value of pulmonary ventilation of 1.7 m3/hour was the average value of a worker (man) performing light

work; liters per minute were measured and extrapolated to one hour. This makes this value of 1.7 m3/hour very conservative as the light work is not performed continuously. The value of 1.25 m3 tends to be used in industry for one hour (8m3 for ten hours) and falls within the measured limits. This rate takes in to account that work resulting in faster breathing is not continuous,which is probably more the case nowadays than in 1941. Thus 1.25 m3 is considered sufficiently conservative value, especially for women; using 1.7 m3/hour for persons of 60 kg would be unrealistic.

There may be situations where one or more of these default values do not make sense. In such cases, deviations from the agreed values may be used, but such deviations will need to be thoroughly justified in the assessment.

It is recognised every issue yet to be met in exposure assessment cannot be foreseen. As exposure assessments progress, the suitability of the human factor default values in this Opinion can be determined and if relevant can be amended; also, other human parameters/factors can be added.

**REFERENCES:**

Final NEGh Report: ’Existing Default Values And Recommendations for Exposure assessment – A Nordic Exposure Group Project 2011’ published by the Nordic Council of Ministers, Ved Stranden 18, 1061 Kǿbenhavn K; TemaNord 2012:505; ISBN 978-92-893-2316-1.

US-EPA, Human Factors Handbook (2011 Issue). EPA/600/R-090/052F Sept 2011/www.epa.gov

**Table 1**: Default values for body weight & body part surface areas for the infant, toddler, child & adult (US EPA Exposure Factors Handbook 2011)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | INFANT  irrespective of gender  *(based on female 6 to <12 months old)* | TODDLER  irrespective of gender  *(based on female 1 to <2 years old)* | CHILD  irrespective of gender  *(based on female 6 to <11 years old)* | ADULT  irrespective of gender  *(based on female 30 to <40 years old)* |
| Body weight | 8 kg | 10 kg | 23.9 kg | 60 kg |
| **Body Part Surface Areas** | | | | |
| Hands (palms and backs of both hands) | 196.8 cm2 | 230.4 cm2 | 427.8 cm2 | 820 cm2 |
| Hands (palms and backs of both hands) | 196.8 cm2 | 230.4 cm2 | 427.8 cm2 | 820 cm2 |
| Arms (both) | Upper = 352.6 cm2  Lower = 229.6 cm2  Total = 582.2 cm2 | Upper = 412.8 cm2  Lower = 268.8 cm2  Total = 618.6 cm2 | Upper = 772.8 cm2  Lower = 496.8 cm2  Total = 1269.6 cm2 | Upper = 1141.2 cm2  Lower = 1128.8 cm2  Total = 2270 cm2 |
| Head | 344.4 cm2 | 403.2 cm2 | 529 cm2 | 1110 cm2 |
| Trunk  (bosom, neck, shoulders, abdomen, back, genitals and buttocks) | 1533.4 cm2 | 1795.2 cm2 | 3376.4 cm2 | 5710 cm2 |
| Legs (both legs and thighs) | 1041.4 cm2 | 1219.2 cm2 | 2741.6 cm2 | 5330 cm2 |
| Feet (both) | 246 cm2 | 288 cm2 | 604.9 cm2 | 1130 cm2 |
| Total body surface area | 4100 cm2 | 4800 cm2 | 9200 cm2 | 16600 cm2 |
|  |  |  |  |  |

**NOTE:** Table 7-12 in US EPA/ Exposure Factors Handbook, Nov 2011 (data based on US EPS 1985, and NHANES 2005-2006) informs that the 25th percentile surface area for adult male forearms is 1320 cm2 which equates to 6.8 % of the 25th percentile for the total body surface area for the male (19300 cm2). Therefore, it is assumed that the 25th percentile for the surface area of the forearms for females also equates to 6.8 % of the female 25th percentile for the total body surface area. Thus for the adult female, the surface area of both forearms is calculated to be 16600 x 6.8/100 = 1128.8 cm2.

**Table 2:** Short- and Long-term exposure values for inhalation

|  |  |
| --- | --- |
| SHORT-TERM EXPOSURE VALUES FOR INHALATION | |
| Infant - irrespective of gender: *based on 0 to <1 years old* | 0.84 m3/h |
| Toddler - irrespective of gender: *based on 2 years old)* | 1.26 m3/h |
| Child - irrespective of gender: *based on 6 to <11 years old* | 1.32 m3/h |
| Adult - irrespective of gender: *see Inhalation Rates section(ii) above* | 1.25 m3/h |

|  |  |
| --- | --- |
| LONG-TERM EXPOSURE VALUES FOR INHALATION | |
| Infant - irrespective of gender: *based on 0 to <1 years old* | 5.4 m3/24-hour day |
| Toddler - irrespective of gender: *based on 1 to <2 years old* | 8 m3/24-hour day |
| Child - irrespective of gender: *based on 6 to <11 years old* | 12 m3/24-hour day |
| Adult - irrespective of gender: *based on 31 to <41 years old or 41 to <51 years old* | 16 m3/24-hour day |

## Activity Patterns

There are currently no agreed single harmonised default values for activity patterns across Europe.

It is recommended to consult the ConsExpo General Factsheet (2014) that outlines a list of values. The assessor can decide on their suitability depending on the type of the assessment.

## Room Sizes and Ventillations

There are currently no agreed single harmonised default values for room size, surface area and ventilation across Europe.

It is recommended to consult the ConsExpo General Factsheet (2014) that provides default values for Dutch houses, as well as some information from other countries. Adaptation to the defaults presented may be needed depending on the exposure scenario and its applicability across European countries.

# Primary (direct) Exposure

## Exposure Scenario Pattern of Use (Conditions of Use)

An exposure scenario consists of information regarding how the biocidal product is used, for how long, how often as well as infomation on how it is applied.

This information represents the pattern of use of a biocidal product and is the first step in the conduct of primary (direct) exposure assessment for industrial, professional and non-professional users.

In this section for each product type information on the parameters to be used for duration/frequency per method of application is provided for professional users (industrial, professional users) and for the non-professional users.

For a number of product types the information is provided via an Excel spreadsheet as developed within the TNsG 2007 Guidance on Exposure for Biocides (Human Health) together with the information from the TNsG 2002 Guidance. In case no specific values are mentioned (derived from the TNsG 2002 or from the HEEG Opinions or product specific data on representative product) the user should choose from the values provided within the Excel spreadsheet for the respective product type.

| **Data requirement** | **Priority** | **Comment** |
| --- | --- | --- |
| Product | | |
| - physical properties | Essential | liquid / solid / in-situ generation / particle size, aerosol, volatility |
| - package details | Essential | volume, material, closure, bulk delivery. |
| - formulation details | Essential | active substance and co-formulants |
| - site inventory | Desirable | amount, delivery frequency |
| - storage information | Desirable |  |
| Purpose of product |  |  |
| - where used | Essential | location / system treated |
| - description of tasks | Essential | how used, application rates |
| - equipment used | Essential | pressures, volumes |
| Use environment | | |
| - containment | Essential | barriers to exposure, ventilation |
| - pattern of control | Essential | full containment, LEV, segregation, dilution ventilation |
| - use pattern | Essential | closed system, within a matrix, non-dispersive, wide dispersive |
| Mixing and loading phase | | |
| - task | Essential | Description |
| - frequency per task | Essential | events per day |
| - duration of task | Essential | event duration |
| - quantity used per task | Desirable |  |
| - dilution rate | Essential |  |
| Application phase | | |
| - task | Essential | description, continuous / intermittent / event |
| - frequency per task | Essential | events per day |
| - duration of task | Essential | event duration |
| - quantity used | Essential | not always relevant |
| - area / volume treated | Essential | not always relevant |
| - timing | Desirable | seasonality etc. |
| Post-application phase | | |
| - task | Essential | description, continuous / intermittent / event |
| - frequency per task | Essential | events per day |
| - duration of task | Essential | event duration |
| Disposal | | |
| - task description | Desirable | e.g. strip old coatings, collect dead vermin |
| Primary exposure | | |
| User sector | Essential |  |
| - mode of exposure | Essential | inhaled / via skin / ingested, by task |
| - proximity to exposure source | Desirable | hand / arm’s length / more distant |
| - operators per task | Desirable |  |
| Data may be better expressed as ranges and likely values, rather than as single values. | | |

### Pattern of Use (Conditions of Use) for Professional users

The following sections provide information on the pattern of use (conditions of use) per biocidal product type regarding professional uses.

The information is compiled from the TNsG 2002 relevant parts but updated where relevant with the corresponding parts from HEEG/HEAdHoc opinions or the TNsG2007.

Where available, **Recommended Scenarios** are available at the beginning of each section for each product type. Assessors should consider these first (taking into account relevance for the exposure scenario that is built) and then also consider the **Additional Information** within the section for the generation of additional scenarios where relevant (it is noted that the section on additional information has been taken from the TNsG 2002 and it will be further revised when more experience is gathered for different product types assessments).

For each product type the corresponding excel spreadsheet from the TNsG2007 Pattern of Use Database is provided and can be used only in cases where no other information is available for the product type regarding conditions of use. Background information on the Excel spreadsheets Database is available in Section 8 of this document.

#### Product Type 1 Human hygiene products

This product type covers non-cosmetic and non-medical products intended for use in disinfecting skin. Examples are hand wipes prior to handling food or healthcare patients, moistened lavatory tissue and baby wipes. Additional examples are disinfectant hand soaps or hand rubs that are often alcohol based and can be used without rinsing.

The users are Professionals in food and healthcare.

Products are ready for use in packs or individual sachets. Soaps are marketed as liquid form or as a solid tablet.

|  |
| --- |
| **Recommended Exposure Scenarios** |

The following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1:

* **Hygienic and Surgical hand disinfection in health care facilities by hand rubbing without rinsing**
* **Hygienic and Surgical hand disinfection in health care facilities by hand washing with hand soap**

According to the BPC Ad hoc working group on human exposure (BPC Ad hoc WG Opinion on Hand Disinfection, 2014), the following is proposed regarding the duration and frequency of use (for further details see Section 9 of this document);additional details can be found in the Adhoc WG Opinion.

**Duration & Frequency for Disinfection Methods**

|  |  |
| --- | --- |
| **Disinfection method** | **Professional use (health-care worker)**  **Application of hand disinfectant per shift** |
| Hand rubs (e.g. alcoholic disinfectants) | 25 /per working day of 8hrs |
| Hand wash (e.g. soap, liquid soap with disinfectant) | 10/day |
| Use of tissues treated with disinfectant | use the information for hand rubs |

|  |
| --- |
| **Additional Information** |

**Application**

The user removes the wipe from its packing, wipes the hands or skin, and disposes of the wipe as normal or clinical waste. Washing hands and forearms is familiar and simple.

Soap formulations are used for surgical hand disinfection, hand washing with antimicrobial soaps and hand wipes resp. whereas alcoholic formulations as well as liquid formulations with peracetic acid or active chlorine are used for hygienic hand disinfection.

Regarding the existing sources of information for harmonisation of the frequency per day for exposure assessment the different kinds of disinfection formulations need to be distinguished.

An example of the scenario outline for this product type is provided below:

|  |  |
| --- | --- |
| **Scenario outline** | **Exposure route and controls** |
| **Mixing & loading phase** | |
| Open sachet or dispense soap | None |
| **Application phase** | |
| Wipe skin  Wash / bathe | Dermal. Inhaled for alcohol-based products.  Dermal – full skin area |
| **Post-application phase (includes disposal)** | |
| Disposal to refuse or drains | None |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 1 and is made available here for use if for any application of product type 1 the agreed values displayed in the summary table above are not applicable.



#### Product Type 2 Private area and public health area disinfectant

The professional user is a cleaner.

##### i.Disinfectants for medical equipment, biocidal products for accommodation for man or in industrial areas

|  |
| --- |
| **Recommended Exposure Scenarios** |

The following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1:

* **Professional hard surfaces disinfection (floors, walls, ceilings) by coarse spraying**
* **Professional hard surfaces disinfection (floors, walls, ceilings) by wiping/brushing/mopping**
* **Professional hard surfaces disinfection (floors, walls, ceilings) by single use wiping tissue – cleaning and disinfection of hard surfaces in private areas, public health care facilities, veterinary practices and laboratories)**
* **Professional use of immersion bath for dipping of equipments (e.g. small farmer equipment) in agricultural environment or medical equipment).**
* **Professional mixing and loading operations during manual or automated addition of biocidal product to treated articles.**
* **Professional mixing and loading, manual or (semi)automated addition of biocidal product to treated articles**

|  |
| --- |
| **Additional Information** |

**General considerations:**

Surface disinfection is done using a ready-for-use (r.f.u) product, e.g. wipe, trigger spray, or through diluting a concentrate, e.g. for scrubbing, mopping or wiping depending on the degree of soiling. The use of powered sprayers is possible for large areas (e.g. swimming pools).

Medical equipment disinfection is done in a trough or in dedicated cold sterilisation equipment (e.g. for endoscopes).

Space fumigation requires specific equipment to evaporate and disperse the fumigant, and to verify the space free of fumigant before re-entry.

It is anticipated that products for use by professionals are supplied in steel or plastic containers, ready for use in packs or individual sachets. Products for non-professional use are marketed in plastic containers up to 2 litres.

Hypochlorite, used in domestic situations, is normally supplied at 3-5% available chlorine, with typical in-use concentrations at 0.01 to 0.5%. Glutaraldehyde, supplied as a bisulphite addition compound, requires activation before use.

**Mixing and loading** for surface disinfection requires simple dilution of concentrate in a bowl or bucket. **Application** depends on the degree of soiling. **Post-application**, the surfaces are normally wiped or left to dry. Waste disinfectant is disposed to mains drainage. Professional cleaners use products on a prolonged basis, mopping, scrubbing and wiping. A TNO report (V96.314: Schippers et al., 1996) shows that surface disinfection in healthcare is an intermittent activity. Data for household cleaning activity are quoted by Weegels (TU Delft, 1997), involving mostly wiping and mopping.

**Mixing and loading** for equipment disinfection may be manual or automatic. Application is by immersion, also manual or automatic. **Post-application tasks** involve washing and disposal of used disinfectant to mains drainage. A Danish report states that immersion baths for medical equipment should be in well-ventilated areas.

Fumigation involves the evaporation of liquid in a space under "permit to work" procedures. **Mixing and loading** has an evaporator loaded with concentrate. **Post-application**, the space fumigated should be certified as free from fumigant residues before reoccupation.

Medical equipment disinfectant baths **disposal** is to mains drainage. A disposal event would take no more than an estimated 2 minutes, including washing a soaking trough.

Other **disposal** is to mains drainage, with exposure to dilute disinfectant by splashes only. Used ready-for-use containers are disposed to waste or for pack recycling.

Fumigants disperse to the external environment.

Cleaners normally wear protective gloves for mixing & loading and application. It is likely that such gloves are contaminated inside. Healthcare professionals would be likely to use disposable latex gloves for cleaning and disinfection of surfaces, and RPE to clear glutaraldehyde spills.

##### ii.Biocidal products to be used in swimming pools, etc.

The product type covers the treatment of indoor and outdoor public and private swimming pools, leisure centres (water-slides, wave machines), hydrotherapy pools and spa baths. Spa baths and leisure pools are high challenge environments. Swimming pool filtration equipment contains biocide fixed within the filter medium, to prevent accumulation of biological agents within the filters. As (possibly) Product Type 9, this is done during product manufacture and is discussed later. Procedures such as filter backwash are physical procedures and are not covered in this statement.

Professional users are employed at public pools and spa baths.

It is recommended to consult the ConsExpo Disinfectants Factsheet for potential scenarios/pattern of use regarding Swimming Pool Disinfectants as the scenarios available within the Factsheet for non-professional may also be applicable for professional users.

|  |
| --- |
| **Additional Information** |

**Mixing and loading**

Generating plant (for in-situ generation of chlorine dioxide), or metering plant for liquid and solid dissolution systems. Direct liquid addition is possible for private pools. Systems relying on residual chlorine may require pH monitoring and buffering systems. Outdoor pools may also require dosing with algaecide.

Chlorine gas is held in cylinders. There is no information about liquid or solid products, though some solid products are placed on the market as large, non-friable tablets. Liquids may be delivered by tanker or in an Intermediate Bulk Container (IBC). Indoor facilities containing residual chlorine as disinfectant are likely to have irritant nitrogen chlorides (e.g. NCl3) present in the air. Other products (quaternary ammonium compounds, biguanides) do not release NCl3.

Solid, bromine-releasing biocides are used in hydrotherapy pools.

Many public pools have automated dosing systems.

The mixing & loading phase is of prime importance for professional users. Over-dosing and accident have led to release of chlorine gas inside facilities.

Changing a cylinder, changing a delivery tube from a drum of liquid, or recharging a solid reservoir would likely to be a single event in a day, with short-term exposure to concentrate.

Shock dosing may be necessary following the discovery of faecal matter in the pool. Full drain-down, pressure cleaning, refilling and recommissioning is required from time to time. Liquid biocide monitoring equipment and concentrate dosing pump will require periodic maintenance. There are no data for the pattern of use of these activities

**Removal & disposal to main drainage**.

There is no information on protective equipment that may be used in changing liquid or solid dosing reservoirs.

**Table: Biocidal products - swimming pools, etc.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Professional dosing systems  Changing dip tube  Handling solids  Automated dosing  Private systems - pour in |  | <5%  <5% | Hands - |
| **Application phase** | | | |
|  |  |  |  |
| **Post-application phase (includes disposal)** | | | |
| Maintenance |  | - | Skin contact, inhalation |

##### iii.Biocidal products to be used in air-conditioning systems

There appears to be considerable overlap between this Type and Type 11, preservatives for liquid cooling and processing systems. The scope appears to be limited to dosing humidifying water sprays with biocide or controlling biological agents in air conditioning condensate sumps. There is no information available on the use of products within this type.

**Table: Products in air-conditioning systems**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Change dip tube |  |  | dermal |
| **Application phase** | | | |
| Dispense liquid |  |  | None |
| **Post-application phase (includes disposal)** | | | |
| Dispose to waste |  |  | None |

##### iv.Biocidal products for chemical toilets, treatment of waste-water or treatment of hospital waste

Chemical toilets are commonly installed on transport (aircraft, buses) and at temporary sites (construction, camping, pop concert).

So far as is known, biocides are not used in sewage treatment works for waste-water treatment.

Systems for combined heat and biocide treatment of clinical waste exist, but there is no information available. Hospital waste includes pre-dosed sharps bins.

The users are Professionals dosing and emptying chemical toilets as well as users of sharps bins.

It is recommended to consult the ConsExpo Factsheet for Disinfectants to identify potential exposure scenarios/pattern of use for disinfectants for chemical toilets and rubbish bins as these might be applicable also for professional users.

|  |
| --- |
| **Additional Information** |

Plant equipment: Water loading bowsers and effluent collectors (honey-wagon). Disinfectant supplied in sharps bins is non-volatile and remains contained within the bin.

Products include toilet additive fluids need to mask colour and odour, as well as rendering pathogenic organisms harmless.

Bus toilet fluids are supplied, typically, in a 25 litre plastic container fitted with a tap.

Aircraft toilets are either vacuum or recirculating toilets. Only the latter type uses biocide, recycling the fluid as flush water for the duration of the flight. Bus toilets are once-through and discharge to a holding tank. Concentrate is either automatically dosed into toilet water before loading into the flush water reservoir, or poured manually into the reservoir. Unloading is a process of connecting pipe work from the vehicle to drains, or to a honey-wagon for remote disposal at a treatment works.

Toilets are designed to minimise biocide aerosol generation or splashing during use. It is possible that someone could be using a bus toilet when crossing very bumpy ground.

There is no reliable information on the tasks in waste water or clinical waste treatment.

**Application:**

Frequency, duration & quantity

The following estimates are tentative:  
- one dosing episode per bus, aircraft or clinical waste treatment cycle.

Removal for disposal is part of the process.

**Table: Products for chemical toilets, treatment of waste-water or hospital waste**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Professional, dosing tank |  | 20% | Hands - |
| **Application phase** | | | |
| Secondary - splash |  |  | Dermal - wipe off |
| **Post-application phase (includes disposal)** | | | |
| Connect disposal pipework |  | 80% | Hands |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 2 and is made available here for use if for any application of product type 2 the agreed values displayed in the text available above is not available or applicable.



#### Product Type 3 Veterinary hygiene biocidal products

The demarcation between biocides and veterinary medicines is not clear. Some of the examples quoted may prove to be out of scope. The scope is assumed to include human and animal footbaths for disease control, baths for equipment immersion, cow udder and teat cleaning, egg hatcheries and animal housing and livestock market disinfection. Feed areas are addressed under Type 4. Hand disinfection (to limit the spread of mastitis) is addressed as Type 1.

Professional users comprise farmers and cleaning contractors.

When spraying of the animals is anticipated, from the use of veterinary hygiene biocidal products, animal welfare issues as well as the need to perform an assessment for residues in food should be taken into account.

|  |
| --- |
| **Recommended Exposure Scenarios** |

The following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1

1. **Professional use of immersion bath for dipping of equipment (e.g. small farmer equipment) in agricultural environment or medical equipment**
2. **Professional animal house disinfection by spraying**
3. **Professional hoof bath disinfection**
4. **Professional cow teats disinfection by coarse spraying**
5. **Professional manual cow teats disinfection by the use of dipping cups (liquid)**
6. **Professional cow teats disinfection by the use dipping cups (foam)**
7. **Professional cow teats disinfection by the use of dipping cups (drying of teats with dry paper towel after pre-dipping)**
8. **Professional cow teats disinfection by the use of a wiping towel**
9. **Professional cow teats disinfection by the use of dipping cups (liquid) - semiautomatic dipping**
10. **Professional disinfection foot bath for rubber boots (liquid)**
11. **Professional manual loading of buckets or powder to be used on animal beddings (manually or with machine) – powder**
12. **Professional surface disinfection by wiping (mop, brush, wet cloth, sponge) (liquid)**
13. **Professional surface disinfection by spraying (liquid)**
14. **Professional surface disinfection by fogging (liquid)**

|  |
| --- |
| **Additional Information** |

Plant and equipment: Footbaths and immersion baths are simple equipment. Egg disinfection is by fogging with CDA applicator, by fumigation, or by washing in disinfectant. Animal housing disinfection is through high pressure spraying after gross detritus has been removed by mechanical means (e.g. skid-steer loader).

Chlorine-release products are generally supplied as non-friable tablets. Liquids are in plastic containers of various sizes - peroxyacid containers may be fitted with a fixed-volume dispenser. Other products are supplied in 1 to 25 litre containers, and in tubs of sachets. Products for use in footbaths may be supplied in 200 litre drums.

Foot and immersion baths are filled and disinfectant mixed by manual dosing. CDA spraying uses a reservoir of mixed disinfectant, with manual mixing. High pressure sprayers operate from mains water with a concentrate reservoir, loaded before use with concentrate. Fumigant (for example formaldehyde) is applied by evaporating from a stock solution in an evacuated area.

**Application:**

Typical sizes for animal housing: 4000 m2 for poultry houses, 390 m2 for pig units and 201 m2 for pig breeding, with a usage rate around 0.15 l / m2 at a concentration around 40 g / litre for poultry houses and 2 g / litre for other animals. Animal transport is disinfected with chlorine-based disinfectants at a concentration around 0.2 g / litre.

The following information is from a UBA-INFU report, coupled with HSE information on high pressure spray operations.

Poultry units:  
- cleaned 3 times annually. Suggested duration 400 minutes.  
- quantity used - suggested 600 litres of spray fluid.

Pig units:  
- cleaned twice annually. Suggested duration around 40 minutes  
- quantity used - suggested 60 litres spray fluid.

Poultry unit:  
- cleaned several times a year, duration 400 minutes  
- quantity used - suggested 60 litres spray fluid.

Transport disinfection would not be expected to last more than 10 minutes.

Livestock market:

- pressure washing - 160 minutes per market day (HSL survey).

Egg disinfection:  
- daily - washing is practically continuous, fogging - 10 minutes suggested.  
- fumigation relies on exclusion.

Footbaths:

- typically, two footbaths: estimate 20 uses per worker, with hand exposure through scrubbing boots with disinfectant.

- typical footbath volume - 10 litres (boots), 1000 l (animals).

**Post Application**

For maintenance and cleaning there is no information, though pressure sprayers are normally cleaned before storage.

Footbaths are normally poured to slurry pits. Livestock market run-off passes to treatment pits before discharge to mains drainage.

**Exposure Controls**

It is expected that coveralls (polyester or waterproof), waterproof boots and gloves, and face protection would be used for high pressure spraying and fogging. Where irritant products are used, and in poultry sheds where there is a zoonotic infection or sensitisation risk, it is likely that respiratory protective equipment would be necessary. However, cleaners do not always use waterproofs when cleaning down livestock markets in hot weather.

Where skin sensitising biocides are used, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

**Table: Veterinary hygiene products**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Pressure washer filling - manual  Fogger filling - manual  Egg washer system filling - auto  Foot bath filling - manual  Fumigation - manual  Udder and teat cleaner - manual |  |  | Hand - Hand Hand - HandHand and inhalation Hand - |
| **Application phase** | | | |
| Pressure washing  Fogging  Egg washing  Foot bath use  Fumigation  Udder and teat cleaning |  |  | Dermal, inhalation - Dermal, inhalation - Dermal Hand No exposure  Hand - |
| **Post-application phase (includes disposal)** | | | |
| Equipment washing |  |  |  |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 3 and is made available here for use if for any application of product type 3 the values/conditions mentioned above are not applicable.



#### Product Type 4 Food and feed area disinfectants

The product type covers among other abattoir, poultry, fruit and vegetable processing, bakery and confectionery, brewery, and food retail. It includes feed area disinfection. The product type does not include preservation through use of salt, vinegar, etc. or through food preservatives. (Food area disinfection means a 5 log reduction in microbes in 1 minute).

Hand disinfection is addressed as Type 1. Domestic food area disinfection is addressed under Type 2. Machinery lubricant preservatives are addressed under Type 6. Feed water treatment is addressed under Type 11.

The users are professionals only. In food factories, the user is part of a cleaning team and has often been trained by the suppliers of disinfectant products. In retail establishments, users disinfect work surfaces, tables, etc. as part of their waiting duties. If the disinfectant is used in containers to wipe/clean shoes, the material may enter the shoes by penetration.

|  |
| --- |
| **Recommended Exposure Scenarios** |

The following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1

1. **Professional hard surfaces disinfection (floors, walls etc.) by wiping/brushing/mopping (liquid)**
2. **Professional use of an immersion bath for dipping of equipment (e.g small farmer equipment) in an agricultural environment or medical equipment (liquid)**
3. **Professional surface disinfection by wiping (mop, brush, wet cloth, sponge) (liquid)**
4. **Professional surface disinfection by spraying (liquid)**
5. **Professional surface disinfection by fogging (liquid)**

|  |
| --- |
| **Additional Information** |

There are seven main classes of equipment in use:

- ring-main fed hose or spray lance  
- mobile unit for pressure spray or foam application at over 3 Bar  
- portable applicator (knapsack, compression and trigger sprayers)  
- automatic systems, cleaning in place (CIP), e.g. for cream lines, bottling plant  
- manual application (soak tank, bucket and cloth, mop or brush, and pour on - wipe off)  
- fogging (manual or automatic)  
- ready-for-use disposable wipes for surfaces.

A survey in 2001 (CCFRA for HSE) showed that the most common type of product in use was the class of quaternary ammonium compounds (quats), alone or in combination with other agents. Alcohol and alcohol / quat combinations were usually supplied in r.f.u. trigger sprays or wipes. Hypochlorite was commonly used, most often as foam. Peracetic acid preparations were used mostly in CIP processes and fogging. Iodophors were used for soaking hoses.

Products are delivered in r.f.u. packs, in small containers, in drums up to 200 litres and in IBC at 1000 litres. Bulk delivery by tanker occurs for large scale users.

Cleaning gross contamination is always necessary before disinfection. This is done by physical means (scrubbing, pressure spraying, steaming). The disinfectants are supplied as concentrates or ready for use (r.f.u.).

Food disinfection (poultry and salad lines) is automated, with raw food conveyed through disinfectant tanks or past sprays. Food packaging disinfection is similarly automated.

Feed area disinfection is very similar in nature to animal housing disinfection (Type 3) and remedial masonry biocide spraying (Type 10), using high-pressure mobile spray units after removal of detritus. The hygiene standards are unlikely to match those found in food factories.

Total disinfection is needed in breweries when yeast strains become infected. Bottle disinfection (rather than thermal pasteurisation) is becoming more common, mainly on automated treatment lines.

**Manual mixing and loading** is found in 40% of uses, metered dosing and venturi mixing in 40% of uses, and r.f.u. packs in 20% of uses. Many companies use a combination of techniques, depending on the disinfection task and time of day. Deep cleaning frequently takes place during the night shift.

Where dosed or venturi mixing takes place, there is the need to handle the supply tube in changing the concentrate reservoir.

**The application phase** is by spraying, foaming, hosing down, fogging, brushing, mopping, wiping, soaking, and pouring into drains. Trigger sprayers hold up to 500 ml of r.f.u. disinfectant. Compression sprayers hold up to 10 litres, and knapsack sprayers between 10 and 30 litres. For ring-main and pressure sprayer operations, the application rate varied between 40 and 1780 mg in-use product per m2 of area for disinfection, and between 400 and 57200 mg in-use product per m2 of machinery. Machinery cleaning includes spraying inside restricted spaces.

Using hypochlorite products where there are protein deposits leads to nitrogen trichloride (NCl3) generation and exposure by inhalation.

**The post-application tasks** are to rinse deposits from surfaces, or simply to dry off. Microbe swab test samples are taken from disinfected surfaces.

**Frequency, duration & quantity**

The following values (ranges) are derived from a research project in UK. However these values do not overwrite the ones under the Recommended Scenarios for this product type. In particular for spraying and fogging applications the duration of 6hours as indicated in section 3.2 should be used.

The assessor should only use this section below if the recommended scenarios are not covering a particular exposure scenario.

ring-main fed hose or spray lance  
- mixing & loading - none  
- hose application - 1 per day (0.2 to 3), for 120 min (60 - 360 min)  
- low pressure spray - 2 per day (1 to 2), for 45 min (30 - 360 min)

mobile unit for high pressure (> 3 Bar) foam or spray application  
- mixing & loading - foam - 5 per day (0 to 14), for 2 min  
- mixing & loading - spray - 2 per day (0.5 to 0 4), for 2 min (1 to 10 min)  
- foam application - 1 per day (0.2 to 1), for 30 min (15 to 720 min)  
- spray application - 1 per day (0.2 to 4), for 30 min (10 to 360 min)

portable applicator (knapsack sprayer)

- mixing & loading - 1 per day (1 to 2), for 3 min (2 to 3 min)  
- application - 1 per day, (0.01 to 3), for 15 min (5 to 50 min)

portable applicator (compression sprayer)  
- mixing & loading - 2 per day (0.2 to 5), for 2 min (1 to 8 min)  
- application - 1 per day, (0.2 to 15), for 30 min (2 to 360 min)

portable applicator (r.f.u. trigger sprayer or from dosimeter) with cloth  
- mixing & loading - where done, 1 per day (0.1 to 3), for 2 min (1 to 10 min)  
- application - 3 per day, or 100 / day in restaurant (1 to 150),  
- application for 5 min, or 1 min (restaurant), 60 min (line cleaning) - (1-120 min)

fogging(likely to be fixed in place, but may be portable)  
- mixing & loading - 1 per day (0.2 to 1), for 2 min  
- application - 1 per day, (0.2 to 1), for 30 min (20 to 40 min)  
- 2-3 litres of product used per 100 m3 space, 10 to 20 micron particle diameter, settling time  
 around 1 hour

automatic systems, cleaning in place (CIP)  
- (manual systems) mixing & loading - 1 per day, 2 min (2 to 3 min)  
- application - 1 per day (0.5 to 4), 30 min (2 to 180 min)

manual application (soak tank)  
- mixing & loading - 1 per day (0.2 to 5), for 2 min (1 to 10)  
- application - 1 per day (0.2 to 3), for 30 min (3 to 60 min), exposure on removal from soak.

manual application (bucket and cloth, mop or brush)  
- mixing & loading - 2 per day (0.2 to 2), for 2 min (1 to 5)  
- application - 4 per day (0.2 to 100), for 40 min (5 to 400 min)

manual application (pour on, wipe off)  
- mixing & loading - none  
- application - 4 per day, for 5 min.

manual application (disposable wipes)  
- mixing & loading - none  
- application - 15 per day, (4 to 20), for 1 min (1 to 2 min)

**Maintenance, test & clean**

Portable applicators are generally cleaned after use and left to drain dry. Sprayer maintenance is sometimes done in-house (e.g. maintaining seals); otherwise, maintenance is undertaken by the disinfectant (and equipment) supplier.

**Removal & disposal**

Wastes pass to on-site treatment plant, or for small users, to mains drainage.

**Controls**

The sector has strict rules about hygiene to protect food from human contamination. A work uniform is ubiquitous. This includes waterproof boots, coveralls, gloves and head coverings, with disposable gloves. Certain disinfection tasks require the use of protective equipment such as face visors, aprons, full waterproof clothing, and respirators.

Where skin sensitising biocides are used, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

**Table: Food and feed area disinfectants**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Supply tube for automatic mixing  Dispense concentrate to equipment or rfu solution to applicator |  |  | Hand - InhalationHand |
| **Application phase** | | | |
| Spray and Foam application  Hose application  Fogging  Soaking  Wiping |  |  | Dermal, Inhalation |
| **Post-application phase (includes disposal)** | | | |
| Swabbing |  |  | None |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 4 and is made available here for use if for any application of product type 4 the values/conditions mentioned above are not applicable.



#### Product Type 5 Drinking water disinfectants

The shock disinfection and commissioning of domestic and office water systems for the supply of drinking water is covered under Type 11 (i). The Type 1 statement covers exposure through bathing.

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| **Additional Information** |

Professionals treat bulk supplies of water for consumption at industrial waterworks. Professionals (military) treat water batches during wild camping.

Industrial plant is used for bulk drinking water treatment. Wild camping treatments may use impregnated resin columns or additives.

Bulk chlorine is the most common disinfectant substance. Ozone, chlorine dioxide, chlorine dioxide and iodine have been reported, and permanganate pre-treatment though there is no useful information about these processes.

Control of organic residues in drinking water is necessary to suppress the unwanted generation of trihalomethanes and halogenated phenols.

Delivery of bulk chlorine is by tanker.

The principal process is large scale chlorination, using bulk chlorine. Industrial, often at Major Accident Hazard sites with extensive gas leak monitoring systems and contingency plans in case of disaster. Exposure is via inhalation to low concentrations of chlorine on a short-term basis.

Another system reported used is a silver ion treatment (which relies on residual chlorine).

Plant workers could be exposed by inhalation below 0.5 ppm for several 10-minute periods per day.

**Table: Drinking water disinfectants**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| **Industrial**  **Camping** |  |  | InhalationNone (tablet, resin column) or dermal: skin contact (if liquid concentrate) |
| **Application phase** | | | |
| **Consumption of water**  **Bathing or showering** |  |  | Ingestion  Inhalation and skin contact |
| **Post-application phase (includes disposal)** | | | |
| **None** |  |  |  |
|  |  |  |  |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 5 and is made available here for use if for any application of product type 5 the values/conditions mentioned above are not available or applicable.



#### Product Type 6 In-can preservatives

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| **Recommended Exposure Scenarios** |

It was recognised that an efficient way to assess the risks, from active substances contained in Product type 6, would be to try to determine from which uses exposure would be greatest, i.e. to try to determine which particular product – or small number of products – would give worst-case exposure assessments for the in-can preservatives use in PT6 products.

For this purpose the HEEG has developed an opinion (**An approach to identification of worst case human exposure scenario for PT6, September 2012**).

This Opinion does not take into account any revisions (subsequent to 10 September 2012) of human factor values and the agreed default parameters presented in section 2.1 of this document should be followed.

In-can preservatives might be added to a wide range of different products. A non-exhaustive list includes: waterborne coatings, polymer dispersions, filler dispersions, pigment slurries, solutions and dispersions of glues and thickeners, concrete additives, construction materials, detergents, cleaners, textile processing chemicals, paper and leather treatment agents and other aqueous formulations.

For the generation of an exposure scenario for product type 6 the reader should consult first the HEEG Opinion (see Section 9) Opinion.

In addition the following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1

* **Professional users exposed to during the mixing and loading operations during manual or automated addition (of the biocidal product to treated articles) (liquid)**
* **Professional users exposed to during the mixing and loading operations during manual or automated addition (of the biocidal product to treated articles)**

|  |
| --- |
| **Additional Information** |

The section below here presents the approach for the different products that can be envisaged to fall under PT6 as developed in TNsG 2002 as well as the Excel pattern of use database for this product type from TNsG 2007.

This section is only indicative of some expected reasonable applications (indicated also in the table with the scenario outline).

##### i.Preservatives for detergents

The product type covers industrial and domestic cleaning products, liquid soaps and detergents, and fabric conditioners, to prevent deterioration. The products are mainly placed on the market as fluids. Products such as rinse-aids, scale removers and caustic cleaners are not covered. Household bleach is addressed as Type 2.01. Laundry disinfectants may be Type 2.05.

Activities such as using preserved liquid soap for bathing and showering are addressed in a similar way to the statement for Type 1.

The manufacture of preserved products is not included in this statement. Professionals are in catering, laundry and fibre processing, etc.

Professional catering and laundry equipment is effectively enclosed.

Detergents contain typical concentrations of 0.05% w/w biocide.

There is no information about supply to the professional market. Retail size packs of laundry and washing products range from 500 ml to 5 litres.

A common misuse scenario is the use of neat washing up detergent with abrasive to clean dirty hands of oil, soil, etc. and rinsing off under running water.

**Table: In-can preservatives - detergents**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Washing up  Laundry  Cleaning |  |  | Hands  Hands Hands |
| **Application phase** | | | |
| Hand wash  Spot treatment  Brush and hand wash  Cleaning with cloth |  |  | Hands  Hands  Hands Hands |
| **Post-application phase (includes disposal)** | | | |
| Wipe down surfaces with used washing up suds |  |  | Hands |

##### ii.Preservatives for other products

This category covers a very wide range of products: - water-based paints, adhesives, dyes and inks, polishes, lubricants and fuels, enzyme solutions, starch sizes and concrete additives, (and water in water-beds). It includes preserved lubricant products used to coat yarn in spinning (spindle oil), in food conveyors and in paper-mills, etc. and preserved ceramic slurries used in pottery.

Detergent and cleaning products are Type 6(i). Building products (other than wood), impregnated with insecticide, are addressed as Type 18. Oil in tank farms may be treated with slimicide (Type 12 (iii)). Sealants are Type 7.

Manufacture of preserved products in not included in this statement. Most professional users will be unaware that the product in use contains a preservative.

There is a very wide range of application plant, including textile and printing plant and concrete batch plant. Application equipment varies from oil applicators to fuel pumps, and brush and roller, to direct application from the container in which the product is marketed (e.g. adhesive stick).

Products arrive at the point of use already dosed with biocide. It is unlikely that users will replenish products with biocide concentrate - products are used up rather than re-used. However, specific information from applicants for authorisation should make the supply criteria and fields of application clear.

These range from the heavy industrial scale through to domestic and recreational uses. Recreational uses include home decorating and vehicle refuelling. Industrial processes show the greatest exposure risk during start up and maintenance operations - this includes emulsion products applied as surface coatings on production lines.

Professionals will apply paints by brush and roller. It is possible that professionals would spray paint.

There is no information on exposure frequency or duration for industrial scale operations, though it may be expected that these take place daily. Tentative general values are proposed as:

**Brush and roller applications:**  
- Professionals - 240 min per day (the original value from TNsG2002 was 7hrs but the duration has been modified to be in line with the duration agreed also for brushing applications of PT08, agreed by the HEAdhoc group).

The following examples are based on data from Weegels (TU Delft, 1997) and US EPA Activity Factors Handbook.

**Household paints:** (40% of paints used were water-based)   
- general painting - 1 session per day (range 1 to 3 sessions), likelihood of use = 10%   
- duration - -29 min, SD 29 min, 90% of time applying paint. (Window-frames - 45 minutes)  
- quantity used - 75 g, range 10 to 500 g of water-based product.  
- 90% used brush; 20% used roller and brush. 10% used roller only.

US EPA data - professional painters  
- median 11 litres / day, 95th% 38 litres/day of water-based paint.

Regarding removal and disposal: Paint brush cleaning - 120 seconds, range 72 to 189 seconds (solvent-based). Suggested values for hand-washing a paint brush (water-based paint) is 5 minutes and for a paint roller is 10 minutes.

**Table: In-can preservatives - other products (paint)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Stir product |  |  | Hand |
| **Application phase** | | | |
| Apply product  Spray  Immersion (ceramics) |  |  | Hand, forearm, Dermal |
| **Post-application phase (includes disposal)** | | | |
| Clean brush / roller (non-professional only) |  |  | Hand |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 6 and is made available here for use if for any application of product type 6 the values/conditions mentioned above are not available or applicable.



#### Product Type 7 Film preservatives

The products include paints, mastics, sealants, fillers, and adhesives showing a preservative effect (e.g. wallpaper pastes). It also includes preservatives to prevent microbe infestation of plasticisers in plastics (e.g. flooring, shoes, vehicles, maritime equipment and toys). The most commonly preserved plastic is PVC. Carpet backing contains fungicide (product type 9).

|  |
| --- |
| **Additional Information** |

Users are professionals (decorators and builders).

The equipment used is expected to be simple - sprayer (exterior coatings), mastic gun, paint brush and roller. There is no information on the type of sprayer that would be used.

The industrial processes of manufacturing or moulding preserved plastics should be assessed for primary exposureSurface coating products are generally supplied ready for use, or lightly thinned. Wallpaper pastes are dispersed in water. The preservative is fungicidal in action, with up to 1% active substance in paint products (up to 2% w/w in the dry film). Sealants contain up to 0.5% w/w preservative.

Plasticiser preservatives include substances such as Kathon and OPBA.

From wholesale or retail outlets, liquid paints in up to 25 l tubs, sealants in mastic gun cartridges or in dispenser tubes for DIY use, and wallpaper pastes in liquid or solid form in plastic packs.

Professional users are exposed to film preservatives using e.g. paints or plaster.

**Mixing and loading** is minimal, e.g. product stirring, dispersion of paste in water.

**Application** of surface coatings and pastes is by brush (for more fluid products, rollers maybe used). Viscous products such as fillers are trowelled into place. Preserved silicone mastics are applied via a gun, and smoothed with a wetted finger. There is no information on sprayed products.

**Post-application** tasks include brush cleaning (non-professionals only).

Information is limited and the following data should be regarded as highly tentative.

Spray applications:  
- Professionals - 3 hours

Brush and roller applications:  
- Professionals - 7 hours per day

There is no information on film removal.

Removal of exhausted paint films by heat, chemical stripping or abrasive action may expose the worker to residual biocides.

Other than normal work-wear, there is little use of protective equipment, including hand protection, in the construction and decoration industries. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

**Table: Film preservatives**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | | **Exposure route and controls** |
| **Mixing & loading phase** | | | | |
| Product preparation - stirring  Dispersal in water |  | |  | Hand  Hand |
| **Application phase** | | | | |
| Spray application  Brush / roller application  Trowel application  Mastic gun and smoothing down  Manufacture of plastic articles |  | |  | Dermal, Inhalation  Hand and forearm  Hand  Hand -  Hand |
| **Post-application phase (includes disposal)** | | | | |
| Brush washing  Paint film removal |  | |  | Hand - no protection  Hand - no protection |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 7 and is made available here for use if for any application of product type 7 the values/conditions mentioned above are not available or applicable.



#### Product Type 8 Wood Preservatives

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| --- |
| **Recommended Scenarios** |

The following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1

1. **Professional automated dipping/immersion of wooden articles (liquid)**
2. **Professional fully automated dipping (liquid)**
3. **Professional (double-vacuum treatment of wood) (liquid)**
4. **Professional manual dipping of wooden articles (application) (liquid)**
5. **Professional brush treatment (liquid)**
6. **Professional spray treatment - Application including Mixing and loading (liquid)**
7. **Professional borehole impregnation (liquid)**
8. **Professional borehole pressure impregnation - Application including mixing and loading (liquid)**
9. **Professional borehole pressure impregnation (solid) - Application including Mixing and loading**
10. **Professional deluging (liquid)**
11. **Professional Mixing with glue and mortar (liquid) (only mixing and loading exposure scenario)**

|  |
| --- |
| **Additional Information** |

The following section originates from TNsG2002 but with modifications to ensure alignment with the HEEG opinions for PT08.

##### Pre-treatment in industrial premises (pressure and vacuum impregnation and dipping)

This type has been taken to cover all preventive treatments, including the use of antisapstain products. Much of the following statement has been condensed from an OECD review with modification as per the corresponding HEEG opinions.

Only professionals undertake preventive treatments in industrial plant.

**Industrial plant:**   
- vacuum-pressure plant, used with water-based preservatives for roughly shaped wood.  
- double-vacuum plant, used with solvent or water-based preservatives for shaped wood  
- pressure plant, used with hot creosote for utility poles, etc.  
- deluge / flood spray plant, used with water-based products for flat panels  
- dipping in water or solvent-based preservatives for wooden articles (mechanical or manual)

Other plant:   
- portable spray equipment and paint brushes to apply antisapstain products in forests  
- spray gun and ventilated workstation to apply preservative to finished articles.

There is little information on the application of antisapstain products in industrial plant.

**Products and Delivery:**

For cyclical processes, product delivery is as kegs of concentrate paste, or as liquid concentrate in IBC or by tanker. Any dilution of concentrates is done in industrial plant.

Dipping processes are supplied in 200 l drums or by tanker. Solvent-based products are ready for use; water based products are supplied as concentrates.

Delivery takes place as bulk, IBC, drum (200 litre) and kegs of paste (copper chrome arsenic preservatives).

**Operations:**

Vacuum and pressure plant are operated on a cyclical basis and other processes on a batch process with continuous treatment. Anecdotally, wood preservation processes are more intensive during the spring.

In vacuum-pressure processes, wood absorbs 150 litres of preservative solution per m3. In double vacuum processes, wood absorbs 10 to 50 litres of preservative solution per m3. In pressure processes, wood absorbs around 300 litres per m3. For dipping etc., wood appears to absorb 0.2 litres per 4 m2 fence panel.

In all operations apart from manual dipping and deluge processes, fresh and treated wood is moved using lift trucks. However, the operators are closely involved with handling restraining straps and treatment machinery, in maintaining the door seals of treatment vessels, in removing fallen wood and sawdust sludge. Sites normally had one or two workers engaged in preservation, and one or two treatment vessels.

The dipping processes fully automated dipping, automated dipping / immersion as well as manual dipping are differentiated and described in detail as per the corresponding HEEG opinions for exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping (2013) and on defaults and appropriate models to assess human exposure for dipping processes (PT8, 2009).

The following data according to frequency and duration have been taken from HSE surveys.

**vacuum - pressure process:**  
- daily use - cycle time 3 hours, 3 cycles per day.

**double-vacuum process:**  
- daily use - cycle time 1 hour, 6 cycles per day.

**pressure process:**  
- daily use - cycle time 4 hours or overnight, up to 2 cycles per day.

**deluge / flood spray process (conveyor line)**  
- used several days a week -, continuously for 2 hours

The duration and frequency for the different dipping processes are provided by the HEEG Opinion on Defaults and appropriate models to assess human exposure for dipping processes (PT8, 2009) :

- manual dipping: 30 minute per day (once a day)

- automated dipping: 4 dipping cycles per day (duration: several minutes – 60 min)

For maintenance, test and clean greasing door seals, collecting fallen timber as well as clearing sludge by professionals have to be considered.

The disposal of preservatives is normally as controlled waste.

**Controls:**

Personal protective equipment like work clothing (e.g. coveralls), protective gloves and footwear may be used for exposure control. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

The automated dipping process may be fully automated as per HEEG opinion for exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping (2013).

**Table: Wood preservatives - pre-treatment in industrial premises (preventive)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Connect tanker transfer lines  Dilute concentrates in plant |  |  | Hands  None |
| **Application phase** | | | |
| Treatment vessels & dipping  Load wood onto carrier  Secure  Push into treatment vessel  Seal door, operate process  Open door  Remove carrier from vessel  Release straps  Convey treated wood to store  Deluge  Unload treated wood (conveyor)  Manual dipping  Manual immersion  Pour and scrub with product  Remove to drip dry |  |  | Dermal  Dermal, inhaled  Dermal |
| **Post-application phase (includes disposal)** | | | |
| Treatment vessels  Grease / replace door seals  Remove fallen wood from vessel  Clear sump / sludge  Sampling  Disposal - tanker  Deluge  Clean spray nozzles |  |  | Hands  Dermal  Dermal  Hands  Hands  Hands |

##### Other wood preservatives

This type has been taken to cover all curative treatments. Much of the following statement has been condensed from an OECD review.

Professionals can undertake most of the processes. Some products are restricted to them.

**Plant & equipment:**

- Spray equipment can be hired, though professionals may own their own equipment.

- Fumigation equipment is held by professional fumigators.

**Products:**

- These are solvent or water based products, supplied as concentrates for dilution on site, or ready for use. The nominal concentrations of active substances (fungicides and insecticides) for in-use product are less than 1% w/w. Retail outlets supply non-professional products in 1 to 10 litre cans.

- There may be gasor volatile liquids.

**Delivery:**

- Products are normally obtained from wholesalers in containers up to 25 litres and ordered from suppliers.

Process and operations:

Spraying (treating structures for rot and insect infestation of wood):  
- low-medium pressure - 4 to 7 bars - electric or fuel driven pump and preservative reservoir  
- low pressure - 1 to 3 Bar, - compression sprayer, garden spray equipment or powered sprayer.

Hand-held tool application to wooden structures and fences:  
- brush for mobile fluids  
- trowel, float or caulking tool (local damage  
- wrapping with impregnated fabric (utility poles - professional use only, no use data)

**Other:**   
- injection into woodworm holes with hand-held aerosol can  
- preservative of furniture polishes  
- sub-soil injection to halt rot in wooden foundations

* fumigation of structure infested with wood destroying insects

Many professional activities require considerable site preparation, and the use of preservative is less than half the time spent at the job.

**Frequency, duration & quantity:**

Low to medium pressure spraying:   
- a few days a week, maximum 2 uses daily.  
- 40 minutes per use (range 6 to 100 minutes' spraying).  
- quantity used - 0.35 litres per m2 of wood surface, median quantity used per job, 47 litres.

Low pressure spraying (mostly non-professional uses):  
- once or twice only, duration estimate - 40 minutes  
- quantity used unknown, perhaps less than 10 litres.

**Manual dipping:**

* 30 minute per day (once a day) as per the HEEG Opinion on Defaults and appropriate models to assess human exposure for dipping processes (PT8, 2009)

**Fumigation:**

- Variable

**Other applications:**   
- polishes and woodworm sprays - no information  
- soil injection (mechanical) - one-off event

**Maintenance, test & clean:**

Maintenance comprises unblocking spray nozzles. Hired equipment maybe returned to the hire shop while contaminated with wood preservative residues.

**Removal & disposal:**

Fumigation cylinders are returned to supplier.

**Controls:**

Professionals may wear coveralls, protective footwear, gloves and may use eye and head protection. Where solvent-based products are used, they should wear RPE. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

For fumigation professionals have SCBA breathing apparatus; warning signs and restricted access to fumigated structures.

**Table: Wood preservatives - other (curative)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Dilution of concentrate  Loading sprayer  Priming pump and spray line  Stirring paint / paste |  |  |  |
| **Application phase** | | | |
| Spray (indoors)  Apply by brush  Apply by float / trowel etc.  Caulk gun  Fumigation |  |  |  |
| **Post-application phase (includes disposal)** | | | |
| Unblock spray nozzle  Wash brush or wipe applicator  Fumigation: aeration and re-entry |  |  |  |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 8 and is made available here for use if for any application of product type 8 the values/conditions mentioned above are not available or applicable.



#### Product Type 9 Fibre, leather, rubber and polymerised materials preservatives

##### i.Preservatives for textiles and leather

|  |
| --- |
| **Additional Information** |

Textile preservation covers preservation for storage, transport and use. Carpets contain insecticide and fungicide, tents and fabrics for outdoor use contain fungicide and shower curtains are also treated with fungicide. Carpet may be backed with latex which has been impregnated with fungicide, see Type 9.03. Textile spinning oil lubricant is Type 6.02. Mosquito net dipping is addressed under Type 18.02.

Leather preservation includes fungicides as part of the tanning process, as outlined below.

Professionals only operate the processes stated below.

Plant & equipment: Certain raw fibres may require disinfection before processing to assure that they are free from communicable disease (e.g. formaldehyde fumigation). Textile mills and textile scouring plants use biocides in yarn treatment and finished textile treatment.

Tanneries and fellmongers use biocides in soak pits and large rotating drums.

Products & Delivery: Textiles: Insecticides and fungicides are supplied in 50 kg kegs typically. Fellmongers use 25 kg kegs or 200 litre drums - some products are supplied as powders. Tanneries are more likely to receive products in IBC.

**Process & operations**

The information source is an HSL report.

**Textiles:**   
Insecticide and fungicide are applied to yarn as the final stage of dyeing. The concentration in finished fibre is 0.2 to 1.4% w/w. A stock solution of biocide is prepared manually, for metered addition to dye baths. Textiles made of woven fabric are either dipped in a biocide bath in the latter stages of manufacture, or biocide is applied as a spray or foam and dried in place. There is very little handling of treated fibre or fabric, though post-batch cleaning leads to significant exposure.

**Leather:**   
Animal hides are supplied in the natural state or dried, and in either case boric acid may have been added. Hides are soaked / tumbled in water containing bactericide. Fellmongers remove wool and hair from the hides following enzyme treatment (Note - enzymes may contain preservative, type 6.02). Tanneries add fungicide at an early stage of the chrome tanning process. Tanned leather may also be conditioned by passing it through a biocide spray. The residual biocide in finished leather is estimated at 1% to 2%.

There appears to be little use of dispensing equipment. Biocide is dispensed to buckets, and stock solutions prepared, transferred manually to the soaking drums. After soaking, the hides are tipped to the floor to drain. Conditioning (tanneries) involves manual dosing of biocide working solution into a sprayer, which sprays skins on conditioning tables. The hides are handled manually.

**Frequency, duration & quantity:**

**Textiles:**   
- Manual addition of stock solution to dye baths and machine minding - 1 per week   
- Duration - biocide for treating fibre, 11 to 155 min; for treating textile. 46 - 250 min.  
 general default 124 minutes.

**Tanneries and Fellmongers:**  
- concentrate use - daily, about four times per shift  
- concentrate handling, 10 minutes per use; diluted solution 120 minutes (68 to 163 min).   
- Treated skin handling, diluted biocide - full shift (default)  
- Conditioning - spraying - full shift.

**Maintenance, test & clean**: No information is available.

**Removal & disposal:** On-site effluent treatment plant and discharge consents in operation.

**Controls:** Coveralls, eye protection, gloves and wellington boots were worn. A respirator was used when dispensing powdered biocide. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

**Table: Preservatives for textiles and leather**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Textiles  Dilution of concentrate  Leather  Handling concentrate  Dilution of concentrate  Loading raw skins (boric acid) |  |  | Hand  Hand inhalation  Hand |
| **Application phase** | | | |
| Textiles  Addition to dye bath  Addition to dosing foam / spray  Leather  Addition to treatment drum  Draining treated skins  Conditioning |  |  | Hand  Hand  Dermal  Dermal Dermal and inhalation |
| **Post-application phase (includes disposal)** | | | |
| Handling treated fibre, textile and leather |  |  | Hand |

##### ii.Preservatives for paper

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| --- |
| **Additional Information** |

This product type is separate from paper mill slimicides (Product type 12). Products are used to control fungi on non-food packing materials. There is very little information available. It is not certain whether paper conservation products (museums) are included within this product type.

It is anticipated that users will be professionals only.

Plant & equipment: Industrial.

Products: These are supplied in drums and water-soluble packages.

Delivery: There is no information available.

**Process & operations:** Products are applied as the final stage in paper and cardboard manufacture. The products are applied at 0.1% to 1% of the paper by spray or roller. Where the mass of paper and cardboard requires preservation against challenging conditions, a 4% w/w loading is needed. However, there is no reliable information available.

**Frequency, duration & quantity:** It is anticipated that mixing and loading for spraying would be a daily, regular activity.

**Table: Preservatives for paper**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Mixing concentrate for application |  |  | Hands, forearms - Inhalation |
| **Application phase** | | | |
| Spray or roller coating |  |  | None |
| **Post-application phase (includes disposal)** | | | |
| Clean down |  |  | Handsforearms |

##### iii.Preservatives for rubber and polymerised materials, and other biocidal products covered by product type 09

|  |
| --- |
| **Additional Information** |

Rubber used in vehicle tyres, abrasive wheels, etc. does not contain preservative. Rubber and plastic products in contact with soil and water will contain preservative. Carpet backing, synthetic rubber geotextiles and pond liners, and water filtration and softening media contain preservatives.

Plasticiser preservatives are addressed under product type 7.

New rubber types, capable of activation with bleach to form biocidal rubber gloves, and products such as plastic chopping boards, doped with antimicrobial substances to kill surface bacteria, are not addressed within this product type.

Biocide is incorporated at the manufacturing stage and it is anticipated that users will all be professionals. Users of preserved articles would be unlikely to know about the biocide content.

**Table: Preservatives for rubber, polymerised materials, and other biocidal products**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Loading mixer |  |  |  |
| **Application phase** | | | |
| - |  |  |  |
| **Post-application phase (includes disposal)** | | | |
| - |  |  |  |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 9 and is made available here for use if for any application of product type 9 the values/conditions mentioned above are not available or applicable.



#### Product Type 10 Masonry preservatives

This addresses products used to control lichen, fungi and algae on and in masonry, stone and concrete, in buildings, on paths and on roofs. Concrete additive preservatives are addressed as Type 6.02 and preservative coatings as Type 7. The products may include building materials such as impregnated plaster, but there is no information on the use of such articles.

|  |
| --- |
| **Additional Information** |

Professionals undertake in-situ curative treatments for fungal infestation of masonry and brickwork. The activity is often indistinguishable from in-situ curative wood preservation (Type 8.02) except for fluid injection. Minor uses include cleaning of fragile roofs made of reinforced cement, cleaning headstones in graveyards, and removing seaweed on dock steps and boat slipways. Typically, work is peripatetic. Abrasive cleaning treatments are not within scope.

Spray equipment can be hired, though professionals may own their own equipment. Minor tasks such as headstone cleaning is with brush and bucket.

Professional products are, commonly, water-based concentrates. These are supplied in pack sizes up to 25 litres.

Delivery: Purchased at need from wholesale or retail outlets.

**Process & operations**

**Application**

**Spraying** (treating structures for professional treatment of fungal and algal infestation of masonry):  
- low pressure spraying for fragile roofs, paths  
- low-medium pressure - 4 to 7 bar - electric or fuel driven pump and preservative reservoir,  
- also used at medium pressure (7-10 bar irrigation) to inject fluid in drilled holes in masonry.

**Hand-held tool application:**  
- hand-brush or broom for small items  
- watering can for paths  
- trigger sprayer for bathroom and kitchen mould control

**Mixing and loading** is undertaken at the site of use, with products diluted for use in a spray reservoir or poured into a concentrate reservoir. Professional **application** is normally at sites where building redevelopment requires eradication of fungi. A considerable period of time is required at each site for lay bare the areas requiring treatment, so masonry biocide use is estimated to be only 10% to 50% of the time spent on site. In general, the entire diluted product is used up in the treatment. **Post-application**, people should be excluded from the treated areas until surfaces are dry.

**Frequency, duration & quantity**

**Professionals using spray equipment**:   
- Frequency - a few times a week, at two uses per day.  
- Duration - 40 minutes per use (range 6 to 100 minutes)  
- Quantity - 47 litres per job (range 6 to 600 litres

**Professionals using brush equipment**:   
- There is no information on frequency or duration. It is unlikely that more than 10 litres of in-  
 use product would be used on any occasion, with application lasting a suggested 30 minutes.

**Maintenance, test & clean**

Professionals do not normally clean spray equipment. Seals and spray nozzle replacement would be the limit of likely maintenance.

**Removal & disposal**

Killed algae (with biocide residues) are removed with a brush. This includes roofs of asbestos cement, where fibre release could occur through jet washing. Waste fluids from brushing are disposed to mains drainage or to the soil.

**Controls**

Professionals: coveralls, gloves and eye / face protection. RPE may be needed for solvent-based products. Persons should be excluded from treated areas until surfaces are dry.

**Table: Masonry preservatives**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Dilution of concentrate |  |  | Hands and forearms |
| **Application phase** | | | |
| Spraying / irrigation  Brushing (and broom)  Trigger spray and wipe |  |  | Dermal and inhalation  Hands and forearms (and lower legs) Hands |
| **Post-application phase (includes disposal)** | | | |
| Maintenance  Brush removal of dead algae |  |  | Hands  Hands, inhalation |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 10 and is made available here for use if for any application of product type 10 the values/conditions mentioned above are not available or applicable.



#### Product Type 11 Preservatives for liquid cooling and processing systems

##### i.Preservatives used in once-through systems

The products are used in assuring microbiologically clean water supplies to paper mills, food production, certain power station cooling systems, etc. The interface with Type 16 (molluscicides) is not clear. The shock disinfection and commissioning of domestic and office water systems for the supply of drinking water is covered here. There is very little information on the pattern of use but ozone (O3) use is not is scope.

|  |
| --- |
| **Additional Information** |

**User:** Professionals only. Dosing systems are likely to require minimal intervention once set up, though cleaning in place procedures for inlets and holding tanks will be needed for sensitive systems such as those used in food and drink factories.

**Plant & equipment:** There is no information on dosing systems. Shock disinfection is a manual intervention.

Common products include hypochlorite, in-situ generated vapour such as chlorine dioxide (ClO2), and gases such as ozone or chlorine. Silver ion treatment in conjunction with residual chlorine is used in healthcare water supply systems. Cleaning in place products could involve a range of substances including peroxyacids. Pulp waste water treated with ClO2 to remove effluent colouring is a non-biocidal use.

**Delivery:** There is no information - bulk delivery of dosing system products is probable.

**Process & operations**

There is no good information available on dosing and cleaning in place (CIP) other than under Type 4 disinfectants.

Shock disinfection is the introduction of elevated concentrations of biocide in order to disinfect existing pipework, and to recommission recirculating water systems. A measured quantity of biocide concentrate is mixed with the supply reservoir and the concentration profile determined through the water system over time.

**Frequency, duration & quantity**

Recirculating system strip-down, clean and recommissioning should take place twice a year. The water distribution systems in new homes are shock disinfected before first use. Office water pipes are disinfected at need.

**Maintenance, test & clean**

No information is available.

**Removal & disposal**

Used products in water are disposed to mains drainage or to the environment.

**Table: Preservatives for once-through liquid cooling and processing systems**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | | **Exposure route and controls** |
| **Mixing & loading phase** | | | | |
| Shock disinfection only:  Dosing system – dip tube  Addition of biocide, mixing |  | |  | Hand |
| **Application phase** | | | | |
| Permeation through system - bleed from discharge until biocide detected |  | |  | Hand, inhalation |
| **Post-application phase (includes disposal)** | | | | |
| Permeation through system - bleed from taps (domestic)  Monitor biocide decay curve |  | |  | Hand, inhalation  Hand, inhalation |

##### ii.Preservatives used in recirculating systems

The products are used to treat wet cooling towers and evaporative condensers that are attached to air conditioning systems, food cooling systems, industrial processes and power supplies. The agents controlled are bacteria, algae and fungi. Small units are attached to dry cleaning establishments and mobile skating rinks. The type includes the control of algae in decorative fountains and in circulating aquaria water. It does not include biofilm dispersants, scale and corrosion inhibitors, or products immobilised in deioniser units.

|  |
| --- |
| **Additional Information** |

Professionals only use such products.

**Plant & equipment**

Large and medium sized systems (500 to 1000 m3) are normally dosed from biocide reservoirs, with the supply and maintenance of dosing systems under the control of biocide suppliers. The suppliers may also train user company workers in use of their system.

Products are supplied in liquid form, and as solid tablets.

**Delivery**

Large systems have tanker delivery. Medium-sized systems' products are delivered in 200 l drums or 1000 l IBC.

**Process & operations**

Warm water (30 to 40 oC) is dispersed as a spray through an updraught of fresh air. The water cools by forced evaporation with aerosol drift minimised through the use of "drift eliminators" on cooling towers. Biofilms can form on wet surfaces, detritus within the cooling tower sump, and within scale. Biocide addition to medium sized systems is by intermittent (1 per week) or continuous dosing. For very small and very large systems, the biocides are added by shock dosing.

Biocide addition is by dosimeter, or by manual addition as a measured dose, e.g. by graduated jug or (for very large systems) pouring several entire drums into the sump. Exposure can occur through manual addition, or in metering systems, through changing the drum of concentrate, moving the dispensing tube.

Workers inspect and test the system to check for scale or biofilm accumulation, check that the heater and thermostat to prevent the sump freezing in cold weather is working, and to take dip-slides.

Systems are drained down before the biannual maintenance. The number of installations per site ranges from 1 to 20 or more. A default is proposed as 3 systems per site.

There is little information on the control of food cooling systems. For example, hot food is shock cooled by evaporation of water within the product into a partial vacuum. The condensate, recycled as part of the cooling process, is rich in nutrient and can carry a high microbiological load.

**Frequency, duration & quantity**

Biocide addition (concentrate):  
- manual - one per installation (3), once a week, for 2 minutes  
- dosing system drum change - service company, 4 installations per day, (12 units), 2 minutes

Plant workers:   
- no exposure.

**Maintenance, test & clean**

Plant workers (diluted in-use fluid):  
- inspect and test - one per installation (3) per week, for 2 minutes

**Removal & disposal**

Bleed-off water from cooling towers and drain-down waste are discharged to mains drainage. Drums are returned to the supplier for re-use.

**Controls**

Effective drift eliminators prevent exposure to cooling tower aerosols and volatilised biocides are released to the environment. Very large systems do not use drift eliminators, but the release source is many tens of metres above ground level.

Service personnel wear protective equipment and gloves, and where necessary, RPE, when changing the dosing drum supply tube. Maintenance of dosing pumps requires the cleaning of these items before dismantling.

Where skin sensitising biocides are used, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

**Table: Preservatives for recirculating liquid cooling and processing systems**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Manual dispensing into measure and into sump  Auto-dispense – change dip tube |  |  | Hands and forearms If volatile inhalation Hands and forearms (and if volatile, inhaled) |
| **Application phase** | | | |
| - |  |  |  |
| **Post-application phase (includes disposal)** | | | |
| Sample process liquid (dip slide)  Inspect interior of cooling tower  Clean dispensing pump for maintenance |  |  | Hands  Hands, inhaled  Hands and forearms - (and if volatile, inhaled) |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 10 and is made available here for use if for any application of product type 10 the values/conditions mentioned above are not available or applicable.



#### Product Type 12 Slimicides

##### i.Slimicides for paper pulp

The stages of paper-making involving biocide addition are fresh-water supply (Type 11.01), at pulp storage (virgin or recycled fibre), in stock preparation, in paper process water, in water recovery, and in additives and coatings (Type 6.02). Fibre contains a range of naturally occurring aerobic and anaerobic bacteria and fungi which, if not controlled, cause slime deposits, malodour, discoloration, corrosion and fungal mat formation.

Surface applied fungicides added to finished paper (Type 9.02), and to machinery lubricants (Type 6.02) are addressed elsewhere. Catalase inhibitors (e.g. glutaraldehyde, for peroxide de-inking in paper recycling) and biofilm inhibitors (e.g. biodispersants, surfactants, enzymes) are non-biocidal. Some specialised paper making processes use no biocide.

|  |
| --- |
| **Additional Information** |

There are two levels of professional user: service companies who manage the addition of concentrate, and wet-end paper mill workers, making and drying paper.

**Plant & equipment**

As an industrial scale operation, paper making consumes <10 to 100 tonnes of water per tonne of paper. A typical production rate is estimated at 500 to 1000 tonnes of paper per day.

**Products**

Supply is in liquid form, representing most of the biocide used in paper-making. A few products are supplied in granular form, dissolved on site. Chlorine dioxide is generated on site from sodium chlorite or hypochlorite, which are not biocides.

**Delivery**

Industry trends are towards returnable intermediate bulk container (IBC) and bulk (tanker) delivery. Drum (200 l) supply is reducing in importance.

**Process & operations**

Chemically and mechanically separated fibre is suspended in water as slurry, typically containing 4% solids. The slurry is deposited as a paper web, with the water (white water) recycled. Biocide addition involves decisions on what product to add (knowing the target micro-organism), when and where to add it, monitoring of microbial activity and deposit formation, and machine performance. This must be without harm to waste water treatments, etc. An estimated of the rate of biocide use is 20 to 200 g per tonne of paper.

Biocide addition is by dosimeter from a drum, IBC's or on-site bulk storage. Some mills add biocide manually as a measured dose, e.g. using a bucket. Automatic dosing is indicated if manual addition is required more frequently than once a week.

Exposure to biocide concentrate occurs in manual dispensing and addition, particularly where this involves dilution and mixing before addition; and moving the dosing pump inlet tube between drums or IBC's.

In almost all companies, biocide concentrate addition is managed by the specialist biocide supply and service company, using trained operators, service engineers and consultants. Where microbial populations shift or resistance development is suspected, process biocides may be alternated within the day or every other day.

Exposure to in-use process fluids containing dilute biocide involves all workers in the process.

**Frequency, duration & quantity**

Concentrate handling:   
- Manual addition frequency, 1 per week per site;  
- manual duration estimate - 5 minutes dispensing, mixing and loading.  
- Automatic dosimeter - frequency of changing reservoir, 1 per week (or less)  
- automatic dosimeter change dosing pump. 5 minutes maximum.

Process operation at in-use concentration:  
- several hours through the day - suggested value 4 hours;  
 elevated skin exposure if wet clothing dries on the body.

(Many biocides degrade in paper-making, so in-use concentrations are lower than the nominal values).

**Maintenance, test & clean**

Maintenance and repair of dosing pumps require decontamination before handling as protective equipment is not practicable for such tasks.

Maintenance workers are exposed to process water that has dried, with concentrations above the nominal in-use value.

Sampling for microbial counting and examination involves transient hand contact with process water.

Deep cleaning using pressurised washers etc. is undertaken during process shut-down. The duration of use is expected to be prolonged (e.g. full shift exposure to dilute biocide spray).

**Removal & disposal**

Process water is either recycled or discharged to waste treatment. Drums may be returned or recycled, and IBC's are returned to the supply company.

**Controls**

Exposure of exposure to concentrate requires the use of personal protective equipment suitable for the hazard. RPE may be needed for volatile biocides. Process workers may wear waterproof work clothing and wellingtons. Drying machinery vapour is ducted outside the workplace.

Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

**Table: Slimicides for paper pulp**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Manual dispensing, pouring – automixing  Change concentrate reservoir |  |  | Hand and forearm. Inhalation (product dependent).  Hand and forearmInhalation (product dependent) |
| **Application phase** | | | |
| Process operation |  |  |  |
| **Post-application phase (includes disposal)** | | | |
| Process water sampling  Equipment maintenance  Dispense pump - clean for maintenance  Shut down deep clean |  |  | Hand  Dermal , Inhalation  Dermal - Inhalation.  Dermal - Inhalation |

##### ii.Slimicides for mineral oil extraction

These products control slime forming organisms in drilling mud, and suppress the proliferation of sulphate-reducing bacteria within the well and in pipelines. This includes the use of biocides in well injection water to control iron-reducing and sulphate-reducing bacteria (SRB). An estimated 40% of drilling muds are water-based, and up to 25% of these are treated with biocide.

Onshore non-oil drilling also uses slimicides; these uses could be considered as similar.

|  |
| --- |
| **Recommended Scenarios** |

The following exposure scenario (including exposure estimation models) is recommended for this product type. Details are available in Section 3.2.1.

1. **Professional prevention bacteria growth in oilfield systems (both off-shore and on-shore) (liquid)**

|  |
| --- |
| **Additional Information** |

There are three levels of professional user.  
- Mud engineers, who manage the formulation of drilling mud and other specialist fluids  
 which includes concentrate handling;  
- Labourers - mixers who control mud supplies and operate the separation of mud from drilling   
 shale (shaker screens), and   
- Drill floor workers, who become extensively contaminated with drilling mud

**Plant & equipment**

An oil-rig may hold up to 4 mud pits (total volume around 60 m3), with 75 m3 of mud "active" in the drilling system at any time.

Products & Delivery

These are supplied in IBC's and drums, typically fitted with snap connectors.

**Process & operations**

From the pit, mud is pumped to the drill. On emerging from the well, mud passes over a shale shaker to remove debris and returns to the mud pit. Around 50 litres of biocide concentrate is added to a mud mix to give a biocide concentration around 0.1%.

Well injection brine is dosed to a concentration around 0.03%. Injection into oil pipelines and underwater storage tanks to suppress SRB is automated.

Oil-rig operators typically work 12 hour shifts. The labourers tend to blockages and keep the shaker screens operational. In this area there are substantial mud aerosols.

**Frequency, duration & quantity**

Mud **mixing**:   
- there is no information on the typical frequency or duration

Mud cycling screen operation  
- this is a daily activity - the duration of time working in shale shaker rooms is not known.

Drill floor  
- this is a daily activity with exposure to mud for 12 hours.

**Maintenance, test & clean**

There is little information available. Samples of mud and fluids are taken for testing.

**Removal & disposal**

Water-based drilling muds are disposed to the environment.

**Controls**

It is anticipated that labourers and drill floor workers wear impermeable work wear (for protection against drilling products and weather), gloves and impermeable footwear. The use of RPE is anticipated to occur in screen rooms, though there is no information on this.

Skin disorders are not uncommon. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording by a trained individual) is expected.

**Table: Slimicides for mineral oil extraction**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Mud mixing |  |  | Inhaled aerosol |
| **Application phase** | | | |
| Screening/separation |  |  | Dermal, inhaled |
| **Post-application phase (includes disposal)** | | | |
| Sampling |  |  | Hand |

##### iii.Other slimicides

|  |
| --- |
| **Additional Information** |

The type is not defined. It may include scenarios such as the control of microbial agents in water-backed spray booths and abrasive machinery, to minimise particulate emissions. Oil tank control of sulphate-reducing bacteria may be product type 6.

Professional - sprayer using spray booth; leather worker using abrasive machinery.

**Plant & equipment**

Water-backed plenum extraction system.

**Process & operations**

Particulate laden air is drawn through a water curtain before discharge outside the workplace. The water becomes progressively laden with organic residues.

**Table: Other slimicides**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
|  |  |  |  |
| **Application phase** | | | |
|  |  |  |  |
| **Post-application phase (includes disposal)** | | | |
|  |  |  |  |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 12 and is made available here for use if for any application of product type 12 the values/conditions mentioned above are not available or applicable.



#### Product Type 13 Working or cutting fluid preservatives

Biocides are added to water-based fluids, to preserve these in their action of cooling, lubricating and carrying cuttings from mechanical cutting operations. Metalworking fluids are supplied containing biocide. Biocide concentrate may be added at intervals to fluids as shock doses.

Users: Professionals in tool making and other metalworking operations.

|  |
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| **Recommended Scenarios** |

For the exposure assessment of professional users the Recommendation no.7: **“Professional Exposure assessment to biocidal products used in metalworking fluids (PT13)”** of the BPC Ad hoc working group on Human Exposure should be followed; the recommendation covers all tasks and scenarios for this product type for professional users. The recommendation is a revision of the HEEG Opinion No.5.

|  |
| --- |
| **Additional Information** |

**Plant & equipment**

Cutting fluids are used in lathes, milling machines and other machinery for cutting and shaping metal. These are of varying degrees of sophistication, but all require human intervention that implies exposure. Small and medium sized companies operate an average of 10 cutting workstations.

**Table: Metalworking fluids**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Diluting concentrate  Adding biocide |  |  | Skin |
| **Application phase** | | | |
| Metalworking |  |  | Skin |
| **Post-application phase (includes disposal)** | | | |
| Sump maintenance  Fluid monitoring |  |  | Skin  Skin |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 13 and is made available here for use if for any application of product type 13 the values/conditions mentioned above are not available or applicable.



#### Product Type 14 Rodenticides

The scope is limited to rodents; this product type is closely linked with Type 20, for the control of other vertebrates. Typical sites of use are domestic, retail, industrial and recreational premises, and near animal housing, and sewers, docks, waste sites and embankments.

|  |
| --- |
| **Recommended Exposure Scenarios** |

The following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1

1. **Professional application (loose grain, pellets, granules)**
2. **Professional application (wax block, paste bait in sachets)**
3. **Professional application (paste bait in cartridges)**
4. **Professional application (paste bait in bucket [with spatula])**
5. **Professional application (fumigation via application of tablets/pellets)**
6. **Professional application (foaming)**

|  |
| --- |
| **Additional Information** |

Professional pest controllers (private companies and local authorities).

Mechanical equipment used by professionals is limited to phosphide pellet dispensers and applicator. Other equipment includes bait stations protected from interference by children and non-target animals, such as bait boxes and tubes.

Grain bait is the most commonly applied product, loose, in pellet form, and in a waterproof sachet for use in wet environments. Wax blocks and caulks and phosphide pellets are available.

Delivery: Pellets of phosphide bait are supplied in moisture resistant tubes or canisters. Baits are delivered as loose grain, pellets or separately packed in sachet etc. in e.g. bucket. Also cartridges with baits are on the market.

**Process & operations**

Professional users place loose grain baits by scooping. All other solid baits are placed either manually or by pellet dispenser. Bait boxes are simply located and fixed in place.

**Pre-application phase** might be loading of application devices. For instance pellet dispensers require a reservoir to be filled with the pesticide.

**Application** is placing bait in bait stations, sewers, burrows, etc. and dispersive operations such as caulking.

**Post application** tasks include checking bait boxes, decontamination of applicator equipment, and the collection of uneaten solid and liquid baits, and dead animals, to minimise the risks to non-target animals and uninvolved third parties.

**Frequency, duration & quantity**

For placing of baits the number of manipulations for professional users is proposed by HEEG opinion 10 (“Harmonised approach for the assessment of rodenticides (anticoagulants)”). The following harmonised figures for placing of baits per day and professional user (application) are recommended:

* Loose grain, pellets, granules: 63
* Wax block / Paste bait in sachets: 60
* Paste bait in prefilled cartridge: 11

For further details please refer to HEEG opinion 10(Harmonising the number of manipulations in the assessment of rodenticides; See section 9).

**Removal & disposal**

Collection of uneaten bait (post application), empty packages and dead animals, disposed as controlled waste. For disposal of baits the number of manipulations for professional user is proposed by HEEG opinion 10. The following harmonised figures for cleaning of e.g. bait stations per day and professional user (application) are recommended:

* Loose grain, pellets, granules: 16
* Wax block / Paste bait in sachets: 15
* Paste bait in prefilled cartridge: 3

For further details please refer to HEEG opinion 10 (Harmonising the number of manipulations in the assessment of rodenticides; See section 9).

**Table: Rodenticides – some example scenarios**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Load dust or pellet applicator |  |  | Hands. |
| **Application phase** | | | |
| Place loose grain bait  Place pellet or wax bait  Place gassing product (powder, pellet)    Place bait station |  |  | Hands  Hands  Hands, inhaled  None |
| **Post-application phase (includes disposal)** | | | |
| Clean applicator  Collect uneaten bait / dead animal |  |  | Dermal, inhaled  Dermal , Inahaltion |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 13 and is made available here for use if for any application of product type 13 the values/conditions mentioned above are not available or applicable.



Exposure of the user to rodenticides individually packed in LDPP/LDPE sachets is considered in Appendix 1 of this document.

#### Product Type 15 Avicides

There is no other information on patterns of use from the TNsG 2002, or from HEEG opinions.

The user is advised to use values from the Excel spreadsheet bellow (patterns of use database).

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 15 and is made available here for use if for any application of product type 15 the values/conditions mentioned above are not available or applicable.



#### Product Type 16 Molluscicides

There is no other information on patterns of use from the TNsG 2002, or from HEEG opinions.

The user is advised to use values from the Excel spreadsheet bellow (patterns of use database).

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 16 and is made available here for use if for any application of product type 16 the values/conditions mentioned above are not available or applicable.



#### Product Type 17 Piscicides

Within the TNsG 2002, the only information appears to be a TNO review (BIOEXPO, 1997). Avicides appear to be limited to pigeon control. The criteria for non-agricultural, non-water molluscicides are unclear. Piscicides appear to be limited to use in fish farms at the end of a fish harvest, to clear any large fish that would eat newly introduced fry.

There is practically no information on which to base any pattern of use statement. Avicide products are baits or contact poisons. Piscicide products are pellets or pour-in liquids.

**Table: Avicides, Molluscicides & Piscicides**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
|  |  |  |  |
| **Application phase** | | | |
|  |  |  |  |
| **Post-application phase (includes disposal)** | | | |
|  |  |  |  |

The user is advised to use values from the Excel spreadsheet bellow (patterns of use database).

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 17 and is made available here for use if for any application of product type 17 the values/conditions mentioned above are not available or applicable.



#### Product Type 18 Insecticides, acaricides and products to control other arthropods

This product type excludes medicines used for the control of parasites etc. on animals. Insects in wood are addressed as Type 8.02 and in grain store cleaning, Type 4. All other scenarios are covered, including stored product pests, and infestations of commercial and residential property and transport.

|  |
| --- |
| **Recommended Exposure Scenarios** |

The following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1

1. **Professional disinfection of surfaces in stables by brushing (liquid)**
2. **Scattering powder against ants from a hand held flexible duster/hand-held canister by consumers and professionals (powder)**

1. **Spraying models (PT18) for assessing exposure to insecticides for low pressure downward uses**

|  |
| --- |
| **Additional Information** |

**User**

These are professional pest controllers (private companies and local authorities) who use biocidal products during their employment.

**Plant & equipment**

The equipment used in insect control is portable or transportable, and includes the following:

- knapsack and compression sprayers for liquids and dusts  
- dust applicators (blowers, bellows, piston pumps, compression dusters)  
- controlled droplet applicators (CDA) and fogging machines  
- tractor-trailer systems for waste tip spraying  
- pre- and post-construction sub-soil injection apparatus (termite control)  
- fumigant smoke and gas treatments  
- baits (gels applied by caulking, bait stations)  
- lacquers

Fixed installations include remotely operated low-volume misting equipment for warehouse and other "knock-down" space treatments. These are also used for Type 4 products.

Ready-for-use applications include:  
- hand-held pre-pressurised aerosol sprays, for aircraft space treatment on landing  
- adhesive papers and traps (biocidal)

Other applications include building materials (not wood), pre-impregnated with Type 18 biocide, and the professional impregnation of bed-nets for mosquito control (see 18.02).

**Products**

Sprayers use concentrates (liquid, emulsion, wettable powder, micro-encapsulated) diluted for use. Dusting equipment uses ready-for-use (r.f.u.) dusts. Misting and fogging machines use r.f.u. liquids or diluted concentrates. The liquids and dusts are marketed in a variety of containers. Fumigants are smoke generators (pyrotechnic devices, r.f.u.) and volatile liquids vapours applied via evaporator.

**Delivery**

Products are generally ordered at need from a supplier. It is common for user companies to stock a restricted range of products (e.g. one type of pyrethroid, organophosphate, etc. for liquid spray application).

**Process & operations**

The types of treatment are:

- space treatment - to knock down flying insects.  
- nest and harbourage (crack and crevice) treatments  
- blanket treatment - to cover a horizontal and/or vertical surface  
- band treatment - to cover insect access routes along floor-wall junctions etc.  
- injection - to treat sub-soil to protect foundations from termites  
- fumigation - to treat stacked commodities or freight containers

- cracks and crevice

**Mixing and loading** is a process that is often difficult to segregate from application because it is often very short term and does not occur for every application.

**Post-application** tasks such as cleaning out sprayers are not common - the application equipment tends to be dedicated to a range of uses with one type of product.

**Frequency, duration & quantity**

Workers are peripatetic and much time is spent travelling to treatment sites and surveying. Daily use is anticipated. In an HSE survey of pest controllers (1994) it was estimated that the median duration "using pesticides" was 120 minutes, range 40 to 330 minutes. Specific values are:

- professional use daily, several times per day  
- unspecified task - 40 minutes' duration, range 3 to 150 minutes  
- blanket spraying (biting insects) - 32 minutes, range 3 to 105 minutes  
- band spraying and dusting (crawling insects) - 48 minutes, range 10 to 120 minutes  
- wasp nest eradication - 3 minutes  
- aerosol space spraying - 6 second discharge per location, 1 g per second emitted  
- stack fumigation and pyrotechnic treatments - 2 hours (user remote from point of use)  
- termite treatments (surface spray, sub-soil injection at 6 bar) - 4 hours, range 1 to 11.5 hours  
 (Cattani et al, Ann. Occup. Hyg. 2001, 45(4), 299-308)

Suggested values for other activities are:

- waste-tip treatment - 40 minutes  
- CDA and fogging - 40 minutes  
- lacquer application - 20 minutes  
- bait caulking - 10 minutes, in place for 2 weeks (RIVM)  
- soil injection - 4 hours (1 to 11.5 hours)

- scattering powder – 1 hour

**Maintenance, test & clean**

This is limited to unblocking nozzles and replacing seals.

**Removal & disposal**

Products are generally used up. Packaging is returned to the supplier or treated as special waste.

**Controls**

As well as a work uniform and coveralls, operators wear disposable and non-disposable protective gloves. Respiratory protective equipment (RPE) is nearly always available if needed. Washing facilities are often found on pest controllers' vans.

Warning signs should be posted on fumigated containers and on all access routes to treated areas. Fixed installation mist treatments (permit to work rules) must have areas free of people before treatment. Smoke treatments should have the space checked that it is smoke-free before re-entry.

**Table: Insecticides, acaricides and products used by professionals**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Mixing and loading liquids  Loading dusts  Loading remote space treatment |  |  | Hand, forearm  Hand, forearm Dermal, Inhalation |
| **Application phase** | | | |
| Spraying and dusting - surfaces  Space treatment includes smoke and vapour fumigation  Injection  Caulking  Baiting  Lacquers |  |  | Dermal, inhaled  Remote - none. Otherwise none.  Dermal, inhaled  Hand  None  Hand, forearm |
| **Post-application phase (includes disposal)** | | | |
| Re-entry air test (fumigant, smoke) |  |  | Dermal, Inhalation |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 18 and is made available here for use if for any application of product type 18 the values/conditions mentioned above are not available or applicable.



#### Product Type 19 Repellents and attractants

As outlined below for the two subcategories of scenarios for this product type there is very limited information on patterns of use from the TNsG 2002, or from HEEG opinions.

The user is advised to use values from the Excel spreadsheet bellow (patterns of use database).

**Note**: there is no information from the Patterns of use Database for PT 19.

##### i. Repellents applied directly on human or animal skin

There is no other information on patterns of use from the TNsG 2002, or from HEEG opinions.

**Table: Repellents applied directly on human or animal skin**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| - |  |  |  |
| **Application phase** | | | |
| Pour on hand and spread on exposed skin  Direct Application from ready-for-use device |  |  | Skin |
| **Post-application phase (includes disposal)** | | | |
|  |  |  |  |

##### ii.Attractants and repellents not applied directly on human or animal skin

There is very sparse information concerning these products. Impregnated textiles are addressed in Types 9.01 and Type 18.02. Bird repellents are mentioned in Type 15. It is probable that a substance such as tiger dung or orange peel (to repel cats) is out of scope.

**User**

Professionals

**Plant & equipment**

**Products & delivery**

**Process & operations**

Vaporising systems are used to disperse natural oils as insect repellents, e.g. candles, heated blocks. Bone oil is painted on surfaces to repel vermin. Granule packs for scattering are used to repel domestic pests. Pre-formed pheromone traps are used with adhesive boards or insecticides as attractants.

It is uncertain whether substances to deter humans from consuming household products (e.g. BITREX) is within scope.

**Frequency, duration & quantity**

Adults handle articles to set them in operation. Scattering, painting.

**Maintenance, test & clean**

This is not anticipated.

**Removal & disposal**

Disposal in domestic or trade waste.

**Table: Attractants and repellents not applied directly on human or animal skin**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
|  |  |  |  |
| **Application phase** | | | |
| Paint  Vaporiser  Granule scattering |  |  | Inhaled, hand  Inhaled  Hand |
| **Post-application phase (includes disposal)** | | | |
|  |  |  |  |

#### Product Type 20 Control of other vertebrates

Much of this statement repeats that for Type 14. Products will include those for use in emergencies e.g. rabies outbreak. The scope excludes rodents and birds. Typical target species are burrowing animals, squirrels and other creatures classed as vermin.

|  |
| --- |
| **Additional Information** |

**User**

Professional pest controllers (private companies and local authorities)

**Plant & equipment**

Mechanical equipment used by professionals is limited to pellet dispensers.

**Products**

Phosphides are marketed as gassing products and toxic pellets in water-resident packages. Cyanide is available as an encapsulated powder. Other products reported include pyrotechnic fumigants and strychnine (treating worms for mole bait).

**Delivery**

There is no reliable information available. Pellets of phosphide bait are supplied in moisture resistant tubes or canisters.

**Process & operations**

Professional users place bait by pellet dispenser. Outdoor treatments are seasonal. Products relying on body heat loss are of most use in the winter. In general, the highest usage is in the autumn

Mixing is restricted to self-preparation of bait using concentrate. Bait mixing gives the highest potential for exposure, and professionals may undertake mixing on a small or medium scale using mechanical mixers. Pellet dispensers require a reservoir to be filled with pesticide

Application is placing bait in, burrows, etc. Poison gas generators should be used >10 metres away from inhabited buildings and burrow entrances are blocked post-application. Cyanide powders are blown into rabbit warrens.

Post-application tasks include the collection of uneaten baits, and dead animals, to minimise the risks to non-target animals.

**Frequency, duration & quantity**

Workers are peripatetic and much time is spent travelling to treatment sites and surveying. It is expected that rodenticide use is daily

A Danish review (2001) proposed the following:

- sites treated once per week, visiting 8 sites per day (6 to inspect, 2 to treat)  
- private gardens - 30 minute job  
- heavy infestation - 8-hour job  
- loose grain placement - 5 minutes, 6 per site  
- pellet placing - 8 to 16 per site, over 30 minutes - 8 hours (1600 pellets) for large sites  
- bait mixing and application - 5 minutes (apple pieces), 2 applications per site  
- phosphide 0.6 g pellets (56% AlP) - 2 to3 per burrow, 2 burrows per site  
- powders - 10 minutes per application, 2 burrows per site.

This includes rodenticide applications.

**Maintenance, test & clean**

Cleaning of mechanical applicators (with water) takes place outdoors. A Danish review proposed 1 job per day, 5 minutes.

**Removal & disposal**

Collection of uneaten bait, empty packages and dead animals, disposed as controlled waste.

**Controls**

Professionals normally wear a work uniform or coveralls, and protective gloves.

**Table: Control of other vertebrates**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Mix concentrate bait  Load pellet applicator |  |  | Hands - Inhalation  Hands. Outdoors. |
| **Application phase** | | | |
| Place bait  Place gassing product (powder, pellet)  Blow gassing product  Place bait station |  |  | Hands  Hands, inhaled  Dermal, inhaled Inhalation  None |
| **Post-application phase (includes disposal)** | | | |
| Clean applicator  Collect uneaten bait / dead animal |  |  | Dermal, inhaled  Dermal , Inhalation |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 20 and is made available here for use if for any application of product type 20 the values/conditions mentioned above are not available or applicable.

#### Product Type 21 Antifouling products

This statement concerns application to vessels and to nets used in aquaculture. There is no information on application of antifouling products to permanently immersed structures or for stripping expired antifoulant coatings.

**User**

Professionals - sprayers, pot-men and ancillary workers in dockyards and slipways;  
Professionals - chandlers in marinas and on hard-standing  
Professionals - dipping nets in antifoulant (and washing old nets)  
Professionals - installing treated nets at fish farms

|  |
| --- |
| **Recommended Exposure Scenarios** |

The following exposure scenarios (including exposure estimation models) are recommended for this product type. Details are available in Section 3.2.1

1. **Professional spraying**
2. **Professional brushing and combined brush/roller painting**
3. **Professional rolling and combined brush/roller painting**
4. **Professional assistant workers (potmen and ancillary workers)**
5. **Professional paint removal (sand blasting, paint stripping)**
6. **Professional grit fillers**

1. **Cleaning of spray equipment in antifouling use (PT21) (see Section 9, HEAdhoc Recommendation 4)**

|  |
| --- |
| **Additional Information** |

**Plant & equipment**

Professionals use equipment such as high pressure airless sprayers and mobile access platforms. Net dipping requires the use of lifting machinery.

**Products**

Three-quarters of the products in a survey (1994 - HSE) were free-association (the active substance leaches from the coating); one quarter were self-polishing (active ingredient in a copolymer coating which hydrolyses slowly in water - requires reapplication every 5 years). There are no reliable data for the military sector. It is estimated that 30% of the coating active substance remains when coatings are removed (UBA-INFU).

Net dipping is in viscous solvent or waterborne preparations.

**Delivery**

Products for professional use on ships are delivered to the vessel in cans up to 25 litres. Supply in the UK is often via the ship owner, and data sheets are not necessarily transmitted. There is no thinning or dilution.

Products for use in marinas are purchased at need from a chandler, who may offer a service in applying antifoulant to leisure craft.

Products for use on nets are supplied in 200 litre drums.

**Process & operations**

Antifoulant is applied only to areas of vessels intended for immersion. Bare metal surfaces are prepared with sprayed coatings such as corrosion inhibitors. Antifoulant is sprayed using airless spray equipment at or above 100 bar. As a rule, sufficient sprayers are employed to ensure that one full coat is applied in one day. Rarely are more than two coats applied. The pot man attends to mixing and loading the antifoulant to the high-pressure pump reservoir.

Net dipping is the repeated immersion of nets (up to 100 m long) in a reservoir. Nets are packed damp and are still in this state when installed.

Professional sprayers, etc spraying ships:  
- antifoulant reservoir supplying high-pressure pump, operated by pot-man  
- sprayer, often working from a mobile platform,   
- others, e.g. mobile platform operator  
- coating removal by high pressure water or abrasive

Professional chandlers painting boats:  
- coating by brush and roller or (small areas) by hand-held aerosol can  
- coating removal using powered sanding equipment

Professional net-dipping:   
- coating by crane-assisted dipping in a water or solvent dispersion of antifoulant  
- cleaning by pressure washer and large scale washing machine.

Professional net installer:   
- handling freshly coated nets, still damp with antifoulant.

**Frequency, duration & quantity**

Professional antifouling is not seasonal, whereas non-professional application normally takes place in springtime. Much of the time spent by a vessel in dry dock is for refitting and maintenance. Hence, the application of antifoulant is irregular with intervals between exposure. Net deployment is most intensive in the springtime, and net dipping takes place year round.

Professionals spraying antifouling:  
- all workers - 2 to 3 consecutive days per month, duration 180 min, range 40 to 360 min  
- using 240 litres of product (25 to >800 litres) over an area of 1600 m2 (600 to 4000 m2).  
An estimate (UBA-INFU) is for 5 to 45% of antifoulant as overspray.

Professionals and non-professionals - brush and roller application  
- 1 or 2 consecutive days (per year - non-professionals), duration 90 min (62 to 135 min)  
- using 4 litres per session (2 to 5 litres) over an area of 20 m2 (7 to 30 m2)

Professionals coating nets  
- 1 or 2 nets per day, some days a week, 60 minutes’ contact (range 30 to 200 minutes)  
- 8 hours’ drying per net (no contact). Contact - dipping and packing damp nets.

Professionals deploying nets  
- 3 to 7 nets per day, up to 6 persons to deploy one net  
- 80 to 300 minutes per work session per day.

**Maintenance, test & clean**

There is no information on removing residues from reservoirs, pumps or supply lines.

**Removal & disposal**

There is no information on the patterns of use for removing coatings.

**Controls**

Professionals spraying antifouling take care to avoid the products depositing on their skin. Custom in the industry is for operators to coat exposed skin with petroleum jelly. Two sets of coveralls are used, with protective gloves and respiratory protective equipment (preferably air-fed).

Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected.

**Table: Antifouling products**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Load antifoulant reservoir  Prime spraying lines |  |  | Dermal  Dermal |
| **Application phase** | | | |
| Spray  Dip  Paint (brush or roller)  Manoeuvre work platform |  |  | Dermal, inhaled  Dermal  Dermal Dermal, inhaled |
| **Post-application phase (includes disposal)** | | | |
| Clean equipment  Remove expired coatings  Install new net |  |  | Dermal  Dermal, inhaled Dermal |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 21 and is made available here for use if for any application of product type 21 the values/conditions mentioned above are not available or applicable.



#### Product Type 22 Embalming and taxidermist fluids

The type includes cadaver preparation and tissue samples in healthcare, as well as conventional embalming and taxidermy. Preserved animal specimens are conserved in museums and used in education. Products used in cleaning are covered under product type 2(ii).

|  |
| --- |
| **Additional Information** |

**User**

Professionals, principally. There are two main groups:   
- those involved in preserving tissue  
- those involved in using preserved tissue.

Plant & equipment

This is limited to dispensers and pumps connected to trochars for inoculating cadaver arteries and cavities with preservative fluids.

Products and Delivery

Supply is as 10 or 25 litre drums, fitted with taps.

**Process & operations**

Danish and Aberdeen University reviews stated that temporary preservation (embalming) requires 3 to 5 litres of solution pumped at around 1.2 bar, through arteries and (following aspiration) into cavities. Sprays may be used to help preserve skin.

Permanent preservation requires 11 litres, per adult cadaver followed by prolonged immersion in aqueous ethanol to strip out aldehyde preservatives. This process applies also to animal specimens used in education.

Some animal taxidermy preparations are pastes mixed of active substances that are commodity chemicals. There may be links with product type 9.01 - leather preservatives.

Mixing and loading is restricted to diluting concentrate within the pump reservoir, or mixing taxidermy paste. Application of fluid is by injection and of pastes by manual spreading. Post-application tasks are cleaning and (pathology laboratories) tissue sectioning and staining.

Pathological tissue samples are placed in a small vessel into which preservative has been dispensed, and transported to laboratories for examination.

**Frequency, duration & quantity**

Embalming:  
- daily, 2 procedures per day (range 0 to 6)

* peripatetic embalmers who visit many funeral parlours and conduct many more than two corpses per day; more than six may be unrealistic.
* mixing and loading - 10 minutes
* application (excludes aspiration, when no biocide used) - 60 minutes (this values is assumed for formaldehyde application)
* handling and cleaning - 10 minutes

Taxidermy  
- There is no useful information available. Post application - mounting in display cases.

Pathological specimen handling - estimates only  
- frequency - estimate 5 per day by one scrub nurse, 10 per day per pathologist  
- dispensing preservative and adding tissue - 1 minute  
- tissue washing, sectioning, etc - unknown.

**Maintenance, test & clean**

Equipment is cleaned and disinfected after use (Type 2.1)

**Removal & disposal**

Preserved cadavers and tissues are removed for burial or long-term storage.

**Controls**

Embalmers usually wear a cotton theatre suit with wellingtons, apron, protective gloves and forearm protectors, and some head and face protection. Facemasks are medical rather than respiratory protective equipment. There may be exhaust ventilation around the embalming table, and there is general ventilation

**Table: Embalming and taxidermist fluids**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario outline** |  | **Time %** | **Exposure route and controls** |
| **Mixing & loading phase** | | | |
| Decant concentrate  Dilute and mix in pressure vessel  Mix taxidermy paste |  |  | Hands, inhaled  Hands  Hands |
| **Application phase** | | | |
| Connect to artery and inject  Massage cadaver / animal  Connect to cavities and inject  Spray cadaver skin |  |  | Hands  Hands  HandsHands |
| **Post-application phase (includes disposal)** | | | |
| Cleaning  Moving cadaver  Pathology dissection |  |  | Hands  Hands Hands, inhaled |

**Note**: the embedded Excel spreadsheet is the Patterns of use Database for Product Type 22 and is made available here for use if for any application of product type 22 the values/conditions mentioned above are not available or applicable.



### Pattern of Use (Conditions of Use) for non-professional users (Consumers)

For some product types specific exposure scenarios have been elaborated for the primary exposure of non-professional users of biocidal products.

The assessor should consult first the section “Specific Product type exposure scenarios” further below. The Section does not contains exhaustive list of exposure scenarios for these product types and it is recommended that the section on “General sources of information for pattern of use” here below is further consulted too.

#### General sources of information for pattern of use for non-professional users

In order to identify the relevant sources for non-professional uses of biocidal products, the following table provides an overview of a non-exhaustive list of exposure scenarios that can be anticipated per biocidal product type.

|  |  |  |
| --- | --- | --- |
| **Product Type** | **Non-Professional Uses anticipated** | **Exposure Scenario(s) – Task Description** |
| PT01 Human hygiene product | Yes | * residential situations include application to infant skin |
| PT02 Private area/public health area disinfectant | Yes | * residential, disinfecting floors, walls and surfaces, principally in kitchens, bathrooms and lavatories * treat private pools and spa baths * dosing humidifying water sprays with biocide or controlling biological agents in air conditioning condensate sumps * use chemicals in camper van toilets |
| PT03 Veterinary hygiene | Yes | * Fumigation of bird accommodations * Wiping animal accommodations * Spraying transport vehicles for animals * Disinfecting milking machines |
| PT04 Food/feed area disinfectant | Yes | * use in restaurants and other general food premises, home use for disinfection of baby bottles |
| PT05 Drinking water disinfectant | Yes | * treatment water batches during wild camping |
| PT06 In can preservatives | Yes | Detergents:   * Use is in residential activities (home laundry, washing up) * Washing up concentrates for cleaning food contact surfaces * Floor and wall cleaning fluids diluted for use by cloth or mop, or used as concentrate for spot cleaning * Spot and window cleaners supplied in trigger spray ready-for-use (r.f.u.) packs   Other Products:   * Application of paints by brush and roller. * Recreational uses of adhesive, fuelling of vehicles (short-term and intermittent) |
| PT07 Film Preservatives | Yes | * Application of ready for use products (surface coating, wallpaper pastes) for wall coating, sealant replacement sprayer (exterior coatings), with mastic gun, paint brush and roller   Application of surface coatings and pastes is by brush (for more fluid products, rollers maybe used). |
| PT08 Wood Preservative | Yes | * Residential wood preservation (fences, furniture etc) with solvent or water based products |
| PT 09 Fibre, leather, rubber/polymerised materials preservative | No |  |

|  |  |  |
| --- | --- | --- |
| **Product Type** | **Non-Professional Uses anticipated** | **Exposure Scenario(s) – Task Description** |
| PT10 MasonryPreservatives | Yes | * Mould removal in bathrooms and path cleaning to reduce slipping risks with use of ready for use products (water-based concentrates or soluble packs for application by spray and watering can, and ready for use trigger sprayers) * Wash out watering cans |
| PT11 Preservatives for liquid cooling & processing systems | No |  |
| PT12 Slimicides | No |  |
| PT13 Metalworking fluids | No |  |
| PT14 Rodenticides | Yes | * Placing normally ready for use bait stations, often containing grain in a pellet or wax block |
| PT15 Avicides | No |  |

|  |  |  |
| --- | --- | --- |
| PT16 Molluscicides | No |  |
| PT17 Piscicides | No |  |
| PT18 Inscecticides | Yes | * Mixing and Loading of Diluting bed net solution or Loading pump sprayers * Application with ready-for-use products for:   -space treatment - to knock down flying insects. -nest and harbourage (crack and crevice) treatments -broadcast treatment - to cover a horizontal surface -spot and band treatment - to cover insect access routes along floor-wall junctions etc.  Products may also be supplied to impregnate bed nets with insecticide to control mosquito bites. |
| PT19 Repellents & Attractants | Yes | * topically applied insect repellents on skin e.g. as a spray, gel, lotion, cream * plug-in vaporisers * candles * Placing of the biocidal product e.g. in cupboards * application of the biocidal product on the skin of animals e.g. as a spray |
| PT20 Control of other vertebrates | No |  |
| PT21 Antifouling Products | Yes | * Application of paint in leisure craft in marinas and on hard standing -coating by brush and roller -removal by hand-held abrasive |
| PT22 Embalming & taxidermist fluid | No |  |

As this source may not cover all possible non-professional user’s scenarios it is further recommended to consult the ConsExpo Factsheets that contain exposure scenarios either developed for pest control products or for other product types that are however relevant for the creation of exposure scenarios for non-professional users of biocidal products.

**NOTE:**

*For PT06 or other product types, when the addition of the biocidal product or active substance results in a final product that is considered a treated article (e.g. paints), and primary (direct exposure) from its actual use is expected then the the methodology for primary exposure estimation should be followed as in the case of the use of an actual biocidal product.*

The table below provides an overview of the available relevant ConsExpo factsheets that the assessor can look further for the generation of exposure scenarios for non-professional primary exposure assessment.

|  |  |  |
| --- | --- | --- |
| **Source: ConsExpo PestControl FactSheet** | | |
|  |  |  |
| **Description of Product** | **Type of Exposure Scenario** | **Relevance for Biocides Product Types** |
| Any Product for which spraying application is possible | Spray Application: Targeted spot application | **PT06, PT18** |
| Any Product for which spraying application is possible | Spray Application: Crack and crevice application | **PT06, PT18** |
| Any Product for which spraying application is possible | Spray Application: General surface application | **PT06, PT18** |
| Any Product for which spraying application is possible | Spray Application: Air space application | **PT06, PT18** |
| Strips and cassettes | Use of Strips and cassettes in sealed areas | **PT06, PT18** |
|  | Use of Strips and cassettes in living areas | **PT06, PT18** |
| Electrical evaporators | Use of insect repellents indoors | **PT18, PT19** |
| Insect repellents | Use of ready-for-use products to repel insects | **PT19** |
| Baits | Placing baits (against rodents, ants, cockroaches) | **PT06, PT18, PT14** |
| Dusting powders | Use of powders against organisms (outdoor, indoor) | **PT02, PT06, PT14, PT18** |

|  |  |  |
| --- | --- | --- |
| **Source: ConsExpo Disinfectants FactSheet** | | |
| **Type of Products** | **Type of Exposure Scenario** | **Relevance for Biocides Product Types** |
| Algae, green deposit removers | Mixing & Loading, Spraying, Pouring and brushing | **PT02, PT06** |
| Black mould removers | Spraying, Rinsing | **PT02, PT06** |
| Disinfectants for use indoors | Spraying, Wiping | **PT01, PT02, PT06** |
| Swimming pool disinfectants | Use of Liquids, Granules or Tablets | **PT02, PT06** |
| Waterbed conditioners, disinfectants for chemical toilets and rubbish bins | Use of waterbed conditioners at home  Use of disinfectants for chemical toilets and rubbish bins | **PT02, PT06** |
| Veterinary hygiene biocidal products | Fumigation of bird accommodations  Wiping animal accommodations  Spraying transport vehicles for animals  Disinfecting milking machines | **PT03, PT06** |
| Drinking water disinfectant products | Disinfecting drinking water  Disinfectanting water coolers | **PT05** |

|  |  |  |
| --- | --- | --- |
| **Source: ConsExpo Paint Products FactSheet** | | |
| **Type of Product** | **Type of Application** | **Relevance for Biocides Product Types** |
| Paint Products | Brush and roller painting | **PT06, PT07, PT08, PT10** |
| Paint Products | Spray Painting | **PT06, PT07, PT08, PT10** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Source: ConsExpo Cleaning Products FactSheet** | | | | |
| **Type of Product** | | **Type of Application** | | **Relevance for Biocides Product Types** |
| Laundry products: | | *Detergent powders*  *Detergent liquids*  *Fabric conditioners*  *Laundry pre-treatment products*  *Dish washing products*  *Hand dishwashing liquids*  *Machine dishwashing products*  *All-purpose cleaners*  *Liquid cleaners*  *Spray cleaners*  *Wet tissues* | | **PT02, PT03, PT04, PT06** |
| Abrasives | |  | | **PT06** |
| Sanitary products: | | *Bathroom cleaners*  *Toilet cleaners*  *Toilet rim cleaners* | | **PT02, PT06** |
| Floor, carpet and furniture products | |  | | **PT06, PT18** |
| Miscellaneous Cleaning Products: | | *Glass cleaners*  *Oven cleaners*  *Metal cleaners*  *Drain openers*  *Shoe polish products* | | **PT02, PT06** |
| Pressure washers | |  | | **PT06** |
| **Source: ConsExpo Do-It\_Yourself Products FactSheet** | | | | |
| Glues | *Glues from tubes*  *Bottled glue – moderate size surfaces*  *Super glue*  *Two-component glue*  *Wood parquet glue*  *Carpet glue*  *Tile glue*  *Wall paper glue*  *Hot melt adhesives*  *Glue from spray* | | **PT06** | |
| Sealants | *Joint sealants*  *Assembly sealants* | |  | |
| Fillers and putty | *General filler from powder*  *Large hole filler*  *Filler / putty from tubes*  *Two-component filler*  *Putty from spray* | |  | |
| Plasters and equalizers | *Floor equalizer*  *Wall plaster* | | **PT11** | |
| Coatings | *General coatings*  *Gutter coating* | |  | |
| Removers | *Paint remover*  *Glue remover*  *Wall paper remover*  *Sealant / foam remover* | |  | |
| Miscellaneous | *Insulation foams*  *Joint colour* | |  | |

#### Specific product type exposure scenarios:

The following section contains the list of exposure scenarios that have been agreed as suitable for specific product types. The details of the scenario and the exposure estimation method is providing under section 3.2.2 within the table with recommended methods/models for non-professional users.

It is noted that this section covers only a small portion of non-professional uses of biocidal products and the assessor should consider generating the remaining exposure scenarios for this category possibly using the information under the General sources of information.

##### Product type 2

* **Non-Professional pond treatment**
* **Non-professional use of an immersion bath for dipping of equipment (e.g small farmer equipment) in an agricultural environment or medical equipment**

##### Product type 3

* **Non-professional animal house disinfection by spraying**
* **Non-professional use of an immersion bath for dipping of equipment (e.g small farmer equipment) in an agricultural environment or medical equipment**
* **Non-professional use of hoof bath disinfection**
* **Disinfection foot bath for rubber boots**
* **Non-Professional cow teats disinfection by the use of a wiping towel**

##### Product type 4

* **Non-professional use of an immersion bath for dipping of equipment (e.g small farmer equipment) in an agricultural environment or medical equipment**

##### Product type 6

* **Non-professional manual paint spraying (paints, inks, polymer emulsions)**
* **Non-professional use of glues and adhesives and sealants**
* **Non-professional indoor wall plastering**
* **Non-professional use of detergents (worst case for all laundry/washing liquids/detergents applications)**

##### Product Type 14

For rodenticides exposure scenarios for non-professional users can be found within the ConsExpo PestControl Factsheet.

For the number of manipulations the agreed numbers in HEEG Opinion 10 should be used (see section 9, PT14 Harmonising the numbers of manipulations in the assessment of rodenticides).

##### Product type 18

* **Non-professional scattering powder against ants from a flexible duster/hand-held canister by consumers**
* **Non-professional use of insecticide cassettes**

## Exposure Estimation Recommended Models for Primary (direct) Exposure

It is recommended to first consult section 3.2.1 for Professional users and section 3.2.2 for non-professional users that provide the stepwise approach on which elements to consider for the exposure estimation from primary uses. The Section on overview of models is the last step in the process when no other option for exposure estimation is available.

### Professional Users (industrial, trained professional etc)

The Generic Models Algorithms (equations) for all relevant routes of exposure, presented in Section 7 of this document, can be considered either as screening tools to calculate the exposure or when no other suitable model described further in this section is available.

#### Mixing and Loading Professional Users

**Step 1**

The first step in identifying suitable models for mixing and loading applications is to consult the HEEG opinion on “Primary Exposure - Loading of products into vessels/systems industrial scale: available data & models” available in Section 9.

**Step 2**

In case in Step 1 either no adequate models have been identified, or additional ones are needed to cover this task/exposure scenario (mixing & loading) within the recommendations of this opinion, the assessor should consult the following overview table that contains the list of recommended models for professional users.

**NOTE:** *for some mixing and loading tasks, the table of recommended methods under the Application section for professional users includes within one scenario both mixing and loading and application tasks. Therefore it is recommended to check also this table within step 2 as well.*

Depending on the exposure scenario description of tasks and intended uses the assessor should select the realistic worst case exposure modelling approach by selecting the most suitable model.

|  |  |
| --- | --- |
| **Exposure model Name** | **Link** |
| Pouring formulation from container into portable receiving vessel | Available at 6.1 “Mixing and Loading Professional Users” |
| Pouring formulation from container into fixed receiving vessel | Available at 6.1 “Mixing and Loading Professional Users” |
| Pouring liquid agricultural pesticides from various size containers into a receiving vessel | Available at 6.1 “Mixing and Loading Professional Users” |
| Loading antifouling paints into a reservoir for airless spraying | Available at 6.1 “Mixing and Loading Professional Users” |
| Loading of products into vessels or systems in industrial scale:   * + solid (powder) loading/dumping   + liquid manual loading/pouring   + liquid (semi-) automated transfer/pumping | Available at 6.1 “Mixing and Loading Professional Users” |
| Model for Dipping of Hands/forearms in a diluted solution | Available at 6.1 “Mixing and Loading Professional Users” |

**Step 3**

In case in Step 2 either no adequate models have been identified, or additional ones are needed to cover this task/exposure scenario (mixing and loading), the assessor should consult the overview table on generic models and mathematical models available in Section 3.2.3 to identify appropriate models to calculate the exposure from mixing & loading tasks. For a number of these models expertise is required to address applicability of the model for a specific exposure scenario. It is important that the exposure parameters used (conditions of use) are explicitly mentioned within the exposure assessment. In addition, independent of the model used, the default parameters outlined in Section 2 of this document should be used instead of any other defaults available within specific computer based models.

#### Application Professional Users

**Step 1**

In order to estimate the exposure of professional users from tasks regarding application of the biocidal product, the following table (developed by HEAdhoc group within the Recommendation “Methods and models to assess exposure to biocidal products in different product types”; See Section 9”) provides for a number of product types the recommendation on potential scenarios, the conditions of use and the recommended model to estimate the exposure.

The table is non exhaustive and there can be additional scenarios that need to be developed for these product types depending on the intended uses.

The scenarios within the table below are also mentioned within the Patterns of use (conditions of use) section for these product types under section 3.1.1 of this document (Recommended Scenarios per product type where available).

**NOTE:** *for some of the scenarios and models described in the table below, the scenario includes mixing & loading and application phase together.*

**NOTE**: within the table reference is provided indicating the source where the value has been chosen from:

* *In case the reference is TNSG 2002, the assessor can find the relevant detailed model within Section 10 of this document*
* *In case the reference is TNsG 2002 User Guidance Version 1 or TNsG 2007, the assessor can find the available description within Section 6.1 of this document*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PT** | **Exposure scenario** | **state of the product (solid/liquid/aerosol)** | **Proposed exposure model** | **Default settings** | **Remarks on the proposed model** |
| 1 | Hygienic and surgical hand disinfection in health care facilities for professional users by hand rubbing without rinsing | Liquid | Dermal exposure:   1. For volatile compounds: calculation of the evaporation time from skin surface according to the EU Technical Guidance Document (TGD, 2003) ([Part I, App. IF, Evaporation rate, p. 216](http://echa.europa.eu/documents/10162/16960216/tgdpart1_2ed_en.pdf)):   t (s) = (m T R / M ß p A) x K, where:  t = evaporation time (seconds)  m = mass of compound (mg)  R = gas constant (8.314 J K/mol)  T = temperature in Kelvin (303.15 K, equal to 30 ºC)  M = molar mass of compound  ß = coefficient of mass transfer in the vapour phase (8.7 m/h)  p = vapour pressure of compound (Pa)  A = applied area (1950 cm2, surface of both hands and forearms according to HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products)  K = conversion factor (3.6 x 104)   1. Calculation of internal dermal exposure based on dermal flux:   Dermal flux (mg/cm2/hour) / 60 x evaporation time/60) x 25 applications x total skin surface  Inhalatory exposure:  Instant evaporation model (ConsExpo 4.1) for volatile compounds  To calculate internal inhalatory exposure: event concentration x 1.25 m3/hour x total exposure duration (contact time x 25 applications) / 60 kg bw | Dermal exposure:   * Number of applications per shift: 25/day * Contact time: see intended use, otherwise 1 minute * Surface area: 820 cm2 (hands only; hygienic disinfection); 1950 cm2 (hands and forearms, surgical disinfection)   Inhalatory exposure to volatile compounds:  Exposure to vapour, constant release rate (ConsExpo 4.1)   * Exposure duration = contact time * Room volume = 100 m3 * Ventilation rate = 1.5/hour * Respiratory rate 1.25 m3/hour * Amount of product = amount used per one applications (see intended use, usually 3 mL) | For inhalatory exposure, another option could be to consider a total exposure duration of 6 hours and a total amount of the product for 25 applications per day (HEAdhoc Recommendation no.1 - Hand disinfection – PT 1 harmonisation of exposure determinants for professional users).  For non-volatile compounds the calculation of inhalatory exposure is not necessary*1*.  The room volume is given as 100 m2 based on ConsExpo. Harmonised values for a domestic room size are necessary; this of course will be dependent on where the product will be used. |
| 1 | Hygienic and surgical hand disinfection in health care facilities for professional users by hand washing with hand soap | Liquid | Dermal exposure:  ConsExpo 4.1 (Exposure Scenario: Cosmetics\ Bath-shower products\ Soap liquid\Exposure, instant application\uptake diffusion)  Inhalation exposure:  ConsExpo Cleaning and washing Application hand dishwashing liquids, exposure to vapour evaporation | Dermal exposure:  Number of application of hand disinfectant per shift: 10  Usual amount per use: 3 g  Inhalatory exposure to volatile compounds:  Instant evaporation model (ConsExpo)   * Exposure duration = contact time * Room volume - near field= 8 m3 * Ventilation rate = 1.5/hour * Respiratory rate 1.25 m3/hour * Amount of product = amount used per one application | HEAdhoc Recommendation no.1 - Hand disinfection – PT 1 harmonisation of exposure determinants for professional users  A duration of 1 min per task seems to be commonly used by the applicants.  Assessment of Member States:  For dermal exposure different parameters were used:   * 8 tasks per day, 10 tasks per day, 20 tasks * Duration per task: 1 min * Product amount per task: 3 g   Exposed area: 820 cm2 both hands or 1950 cm2 hands and forearms according to HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products  Inhalation exposure:   * 20 applications per day * Exposure time: 1 min per task * Product amount: 3 g * Release area (both hands): 820 cm2 * Room volume: 1 m3 * Ventilation: 2.5/hour |
| 2*2* | Professional hard surfaces disinfection (floors, walls, ceilings) by coarse spraying | Liquid | Spraying Model 1  Spraying Model 1 can be used for spray pressures from 1 to 3 bar.  For volatile compounds the assessment of vapour in addition is necessary. | Indicative dermal exposure   * Hand:   181 mg/min (without protective gloves)  10.7 mg/min (inside gloves)   * Body: 92 mg/min   Indicative inhalation exposure to non-volatile compounds: 104 mg/m3  Exposure duration 6 hours  Area of disinfection is necessary for the assessment of volatile compounds. | For inhalation exposure see *footnote 1*.  For professional use (volume knapsack 15L) time is 6 hours exposure duration. The data originates from a HSE study, UK. The model UK-POEM model, mandatory within European crop pesticide regulation, provides information on the times and volumes used for exposure assessment of knapsack spraying.  181 mg/min = max of range  10.7 mg/min = 75th % value and 104 mg/m3= median (50th % value)  When air concentrations are used to compare to toxicological value choose no median but higher percentiles. However, the use of the 75th percentile (130 mg/m3) is not described in the TNsG 2002 User Guidance - Version 1. |
| 2, 4*3* | Professional hard surfaces disinfection (floors, walls etc.) by wiping/brushing/mopping | Liquid | Dermal exposure:   * Surface disinfection Model 1, TNsG 2002 * Surface disinfection Model 3 in addition to Model 1 for body exposure   Inhalation exposure:   * Surface disinfection Model 1, TNsG 2002 * ConsExpo 4.1: Exposure to vapour, increase release area   For volatile compounds the assessment of vapour in addition is necessary. | Indicative dermal exposure   * Hand:   1030 mg/min (without protective gloves)  10.3 mg/min (inside glove)   * Body (Surface disinfection Model 3): 87.6 mg/min   Inhalation exposure:  Indicative value (Surface disinfection Model 1): 22.9 g/m3  Additional parameters for ConsExpo 4.1:   * Room volume: 80 m3 * Application duration: 15 min * Amount: 1840 g * Mol. Weight matrix: 18 * Mass transfer rate based on Sparks method   Exposure duration: 220 minutes wiping, 110 min mopping (based on indicative value for an isolation room in hospitals, TNsG p. 175, according to HEAdhoc Recommendation no. 2 - Professional Mopping and Wiping Time Used for cleaning Hard Surfaces (PT2) | Assessment of Member States for dermal exposure:  Exposure durations: 240 min per shift for mopping; 30 min, twice per shift, 7 h per shift, Wiping110 min (22 rooms x 10 min); Mopping 110 min (22 rooms x 5 min); 60 min/shift, 360 min/shift, 180 min/shift  In the HEAdhoc Recommendation no. 2 - Professional Mopping and Wiping Time Used for cleaning Hard Surfaces (PT2) 110 min duration for mopping and 220 min per shift for wiping were agreed.  Assessment of Member States for inhalation exposure:  Exposure durations: 30 min, twice per shift, 7 h per shift, 240 min per shift for mopping  For inhalation exposure see *footnote 1* to this table.  There is also a model in the BEAT database (Hospital disinfection).  *BEAT data base model ‘Hospital disinfection’:*  This job consists of two distinct tasks: mopping floors, and wiping surfaces and furniture. Both tasks use disinfectant in its diluted form.  Disposable mop-heads are replaced at the start of each disinfection session. Similarly, cotton cloths are replaced after approximately five minutes of wiping. As inhalation exposure is to chlorine air concentrations, it cannot be expressed in terms of in-use product.  60 % Wiping; 40 % Mopping |
| 2 | Professional surface disinfection by single use wiping tissue  (Cleaning and disinfection of hard surfaces in private areas, public health care facilities, veterinary practices and laboratories) | Wipe with treated tissues | ConsExpo 4.1, default scenario for disinfectants for use indoors, wiping  Detailed information is presented in the Cleaning product Fact Sheet, [RIVM report 320104003](http://www.rivm.nl/bibliotheek/rapporten/320104003.pdf) (2006), “wet tissues”, p. 63. | Dermal exposure:  Exposed area palm: 205 cm2 (HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products).   * Exposure duration: 60 min * Application duration: 2 min   Inhalation exposure to volatile compounds:   * Room size: 20 m3 * Ventilation rate: 0.6/hour (ConsExpo default for a non-specified room) * Constant evaporation rate model (emission duration is equal to exposure duration) * Surface size: 1.71 m2 (Cleaning product Fact Sheet, [RIVM report 320104003](http://www.rivm.nl/bibliotheek/rapporten/320104003.pdf)) |  |
| 2, 3, 4 | Use of an immersion bath for dipping of equipment (e.g small farmer equipment) in an agricultural environment or medical equipment | Liquid | Dermal exposure:   * Dipping Model 1 (TNsG 2002, part 2, p.167) * Dipping Model 4 (TNsG 2002, part 2, p.170)     Inhalation exposure:  Dipping Model 4 (TNsG 2002, part 2, p.170) | Dermal exposure:   * Dipping Model 1   Indicative value hands: 25.7 mg/min  Indicative value body: 178 mg/min   * Dipping Model 4:   Indicative value hands: 16.7 mg/min  Indicative value body: 221 mg/min  Inhalation exposure:   * Dipping Model 4:   Indicative value inhalation: 0.2 mg/m3 | For inhalation exposure:  Duration: 30 min per day  For dermal exposure:  Duration: 30 min per day, 60 min |
| 2, 6 | Professional users exposed to during the mixing and loading operations during manual or automated addition (of the biocidal product to treated articles) | Liquid | Mixing and loading Model 7 for pouring and pumping liquids  *Model used in the EU-CARs.* | Indicative dermal exposure:  101 mg/min (without protective gloves)  1.01 mg/min (inside gloves)  Indicative inhalation exposure:  0.94 mg/m3  (HEEG opinion 1 - Mixing loading model 7 alternatives)  Exposure duration: 10 min | If vapour pressure is < 0.01 Pa, inhalation exposure is not taken into account.*1*  According to the HEEG opinion 1 - Mixing loading model 7 alternatives, the Model 7 should be used with care as it was no longer taken up in TNsG 2007, which might indicate little confidence in the model.  For simple loading (e.g. 1 container per day):  EUROPOEM II database (Professional pouring formulation from a container into a fixed receiving vessel) in TNsG 2002 User Guidance - Version 1 p.24 and TNsG 2007 p.66 should be used.  Alternatively, Mixing and loading Model 4 (UK POEM) in TNsG 2002 User Guidance - Version 1 p. 65 and TNsG 2002 p.138  For repeated loading (several containers per cycle):  Loading DEGBE in BEAT (TNsG 2002) should be used. Alternatively, Loading liquid in RISKOFDERM Dermal model should be utilised, if influence of specific parameters (e.g. contamination, use rate) can be assumed and evaluated.  For smaller quantities (< 1L):  Mixing and loading Model 4 (UK POEM) in TNsG 2002 p.138, TNsG 2002 User Guidance - Version 1 p.24 and TNsG 2002 p.138 or  Mixing and loading Model 2 (HSL 2001) in TNsG 2002 p.136, TNsG 2002 User Guidance - Version 1 p.25 and TNsG 2007 p.66, depending on quantities, can be used.  In case of bulk loading, the occupational first tier model ECETOCTRA for workers can be considered. Refinement can be done by models like ART, RISKOFDERM and STOFFENMANAGER. It is assumed that the truck driver does the connecting of the lines, thus it is occupational exposure to chemicals. In case of large containers (semi-bulk 400-800 L) the truck driver only drops the filled containers and picks up the empty ones, the connecting of lines is been done by the operator (worker), thus the exposure is part of the assessment.  So, differentiation according to used volumes has to be considered. |
| 2, 6 | Professional mixing and loading, manual or (semi)automated addition (of the biocidal product to treated articles). | Solid/Powder | Mixing and loading Model 7 for powders | Indicative dermal exposure:  305 mg/min (without protective gloves)  3.05 mg/min (inside gloves)  Indicative inhalation exposure:  7.2 mg/m3  (HEEG opinion 1 - Mixing loading model 7 alternatives)  Exposure duration: 10 min | Due to possible dust forming, inhalation exposure always needs to be taken into account.  Mixing and loading Model 7 should be used with care as it was no longer taken up in TNsG 2007, which might indicate little confidence in the model (see remarks under no. 8). |
| 3 | Animal house disinfection by spraying | Liquid | Dermal exposure:   * Spraying Model 2, TNsG 2002 * Spraying Models 2 and 3, TNsG 2002 * Spraying Model 7, [TNsG 2002](http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg+human+exposure+2002_en.pdf) * Spraying Model 9, TNsG 2002 * ConsExpo 4.1 Dermal model: Direct dermal contact with product: constant rate   Inhalation exposure:   * Spraying Model 2, TNsG 2002 * Spraying Models 2 and 3, TNsG 2002 * Spraying Model 9, TNsG 2002 * ConsExpo 4.1 | Dermal exposure:   * Indicative values Spraying Model 2: Hands (actual) 7.8 mg/min; hands (potential) 273 mg/min; body 222 mg/min * Indicative values Spraying Model 3: Hands in gloves 2.04 mg/min; body 250 mg/min * Values Spraying Model 7: 75th 100 mg/min * Indicative values Spraying Model 9: Hands 2300 mg/min; body 4900 mg/min * Parameters ConsExpo 4.1: * Exposed area: 1,75 m2 * Contact rate: 540 mg/min * Release duration: 400 min   Inhalation exposure:   * Indicative value Spraying Model 2: 76 mg/m3 * Indicative value Spraying Model 3: 17.3 mg/m3 * Indicative value Spraying Model 9: 3600 mg/m3 | For assessing dermal exposure to an active substance, Spraying Model 7 was chosen which is not reflected in the TNsG User Guidance.  Assessment of inhalation exposure by Member States:  Frequencies and durations:  1 h, 2 h 6 times per year, 126 min once per day, 180 min 12 times per year, 400 min  For most actives, the Spraying Model 2 was chosen to cover inhalation and dermal exposure for the task animal house spraying. This model is based on the task “Mixing and loading liquids in reservoir for powered spray application at 4 to 7 bar pressure as a coarse or medium spray, indoors, overhead and downwards. Scenario - medium pressure spray applications, e.g. for remedial biocides”.  However, there is a great discrepancy in the duration and frequency of the task which might be due to different assumptions on the setting e.g. stable size, treated area, animals etc. An harmonization in this point (if feasible) would be desirable. |
| 3 | Hoof bath disinfection | Liquid | Dermal exposure:  Mixing and loading Model 4 (TNsG 2002 for dermal exposure by mixing and loading and (post)-application)  Inhalation exposure:  ConsExpo 4.1 (for inhalatory exposure by mixing and loading and (post)-application) | Dermal exposure   * Defaults used for mixing and loading and (post)-application by Mixing and loading Model 4: 0.5 mL b.p./loading (based on 20 L container volume and a frequency of 1 loading for mixing and loading and 4 loadings for post-application) * No dermal exposure is expected for application.   Inhalation exposure   * Defaults used for mixing and loading for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): * Application duration: 5 minutes * Ventilation rate: 10/hour * Room volume: 24 m3 * Release area: 100 cm2 * Defaults used for application for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): * Duration: 35 minutes   Ventilation rate: 9.35/hour (“Sächsische Landesanstalt für Landwirtschaft” 900 m3/h per cow (100 cows in 9630 m3, OECD) = 9.35/h) and based on animal welfare)   * Room volume: 9630 m3 * Release area: 3 m2 * Defaults used for post-application for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): * Duration: 10 minutes * Ventilation rate: 9.4/hour * Room volume: 9630 m3 * Release area: 3 m2 | The Approach included mixing and loading of the substance in footbath, walking through of cattle and cleaning and disposal. The approach includes mixing and loading and (post)-application.  Refinement: dermal exposure due to refreshment of the bath could also occur (see <http://www.youtube.com/watch?v=78SD2jPFcmA>) |
| 3 | Professional cow teats disinfection by coarse spraying | Liquid | The constant rate model for the trigger spray in ConsExpo 4.1 is described in the Disinfectant Products Fact Sheet (RIVM report 320005003/2006). The Fact Sheet describes the exposure to spraying of the kitchen working top using a trigger spray. The trigger sprays used by the farmer has the same characteristics as the default trigger spray in the fact sheet.  (see no. 13 for mixing and loading and post-application) | Defaults used for inhalation exposure for application:   * Room size: 168 m3, room height 2.5 m * Ventilation rate: 4 times per hour   Spray and exposure duration: 180 minutes  Mass generation rate 1.5 g spray/sec  (see no. 13 for mixing and loading and post-application)  According to the SCC GmbH (2009) an average parlour milks 100 cows twice per day, 300 days per year. This scenario is based on environmental exposure and not on human exposure. Farmers milk cows every day of the year. Usually cows are milked 300 days a year. Two months before calving, cows do not produce milk.  Therefore, on an average parlour has 100 (cows) 300/365 = 82.2 = 82 milk producing cows per day.  According to the scenario:  The spraying or dipping time per cow per event is 10 seconds. The farmer milks 82 cows twice per day all year through. The cows are treated pre and post milking. The exposure duration is 1.5 hour x 2 = 3 hours per day. The room volume of the parlour is 168 m3. | Due to large droplet size inhalation exposure can be disregarded and/or the vapour pressure of the substance is low. However, if the substance causes local effects in the upper respiratory tract, inhalation exposure needs to be considered.  Trigger spray is meant for teat spraying.  The model in ConsExpo 4.1 is based on:   * RIVM-report 1) Delmaar J.E. and Bremmer H.J. 2009. The ConsExpo Spray Model. Modeling and experimental validation of inhalation exposure of consumers to aerosols from spray cans and trigger sprays. The Netherlands: National Institute for Public Health and the Environment (RIVM). [Report 320104005/2009](http://www.rivm.nl/dsresource?objectid=rivmp:13100&type=org&disposition=inline&ns_nc=1) * RIVM-report 2) Prud'homme de Lodder L.C.H., Bremmer H.J., Pelgrom S.M.G.J., Park M.V.D.Z. and van Engelen J.G.M. 2006. Disinfectant Products Fact Sheet to assess the risks for the consumer. Bilthoven, The Netherlands: National Institute for Public Health and the Environment (RIVM). Report nr. 320005003/2006.   (see no. 13 for mixing and loading and post-application) |
| 3 | Professional cow teats disinfection by the use of dipping cups | Liquid | Approach 1)  Mixing and loading Model 7 for pouring and pumping liquids  Approach 2)   * Mixing and loading:   The TNsG 2007 describes a model for professional pouring liquid agricultural pesticides from various size containers into a receiving vessel.   * Application:   If the active substance is volatile (a volatile substance has vapour pressure > 1 x 10-2 Pa at 20 °C): Consexpo 4.1: evaporation model  Detailed information is presented in the Disinfectant Products Fact Sheet (RIVM report 320005003/2006). | Approach 1)   * Indicative dermal exposure:   101 mg/min (without protective gloves)  1.01 mg/min (inside gloves)   * Indicative inhalation exposure:   0.94 mg/m3  Exposure duration mixing and loading: 10 minutes  Approach 2)   * Mixing and loading: The exposure is limited to the hands and expressed as ml of in-use product per operation. The indicative value of 0.5 g (0.5 ml) for 10 and 20 L containers is used in the calculation of the dermal exposure * Application (worst case scenario): * Surface area of an average teat: 44 cm2 * Room size: 168 m3, room height 2.5 m * Ventilation rate: 4 times per hour   Application and exposure duration: 180 minutes   * Post-application:   The Disinfectant Products Fact Sheet (RIVM report 320005003/2006)describes the exposure during wiping disinfectant indoors for non-professionals. A worst-case estimate of 0.1% of the amount on the surface area (here the teats and a part of the udder) contacts the palm of a hand, where the model as describe in the fact sheet serves as surrogate.  Frequency of teat disinfections: 2 times per cow per day per farmer (pre- and post event and 2 events per day) | Approach 1)  Exposure during the use of dipping cups is considered to be covered by exposure during mixing and loading.  Mixing and loading Model 7 should be used with care as it was no longer taken up in TNsG 2007, which might indicate little confidence in the model (see remarks for no. 8).  Approach 2)  Approach 2 is the preferred one, because mixing and loading, application and post application should be included. |
| 3 | Professional cow teats disinfection by the use of dipping cups | Foam | Dermal exposure:  Approach 1): Spill model  Approach 2):TGD layer thickness and surface area approach  Mixing and loading: The TNsG 2007 describes a model for professional pouring liquid agricultural pesticides from various size containers into a receiving vessel. | Dermal exposure:  Approach 1)  A maximum of 6 mL liquid can adhere to one hand in one hour. If the exposure of two hands is considered, the maximal amount is 12 mL.  Exposure duration mixing and loading: 10 minutes  Mixing and loading: The exposure is limited to the hands and expressed as ml of in-use product per operation. The indicative value of 0.5 g (0.5 mL) for 10 and 20 L containers is used in the calculation of the dermal exposure  Frequency of teat disinfections: 2 times per cow per day per farmer (pre- and post event and 2 events per day) | Based on the construction of the dipping foam cup provided by the applicant dermal exposure during its use is expected to be incidental in nature. No direct contact of the skin with the liquid in the cup is envisaged, so the exposure will occur mostly due to the spilling of the diluted product on hands.  The spilling model is no longer mentioned in TNsG 2007. The RIVM favours the TGD layer thickness and surface area approach (see Guidance for Human Health Risk Assessment - Volume III, Part B, p. 302).  As inhalation exposure is considered to be negligible, it has not been calculated. |
| 3 | Professional cow teats disinfection by the use of a wiping towel | Wiping with a towel | Consexpo 4.1 model for the cleaning and washing with wet tissues | For non volatile active substances the following assumption is valid:  Dermal exposure:  The scenario regards wiping the surface of 2 m2 using a wiping tissue by hand once a day. Based on the total surface area of 2 m2 this is considered to represent a sufficient worst-case scenario for treating ca. 100 cows daily. The exposed surface of the hand is considered to be 205 cm2 (default). It is presumed that by firmly squeezing one tissue 47 mg of the liquid fraction will be transferred to the hand (default ConsExpo 4.1, Cleaning product Fact Sheet, [RIVM report 320104003](http://www.rivm.nl/bibliotheek/rapporten/320104003.pdf) (2006), “wet tissues”, p. 63.  Frequency of teat disinfections: 2 times per cow per day per farmer (pre- and post event and 2 events per day) | To estimate dermal exposure during wiping, the default ConsExpo 4.1 model for the cleaning and washing with wet tissues is considered to be the most suitable. The dermal exposure due to the use of the wiping towel treated with the in-use solution is considered to be comparable with the dermal exposure due the use of wiping tissue.  Note that the current Dutch practice is to refrain from wiping cow teats. From experience, farmers have learned that wiping cow teats is counterproductive for producing high quality milk. By refraining from wiping, the spreading of infectious bacteria between cow udders is decreased. When dirty, the modern farmer wipes udders/teats with “dry” cloth.  As inhalation exposure was considered negligible during loading the inhalation exposure will not be calculated. This is valid for non-volatile active substances. |
| 3 | Professional cow teats disinfection by the use of dipping cups | Drying of teats with a dry paper towel after pre-dipping | Model 2 for Surface disinfection (TNsG 2002, Part 2, p. 174) | Duration: 15 min  Indicative value body: 4.50 mg/min | The model refers to ‘Professional washing and wiping floors using a mop, a bucket and a wringer.’ |
| 3 | Professional cow teats disinfection by the use of dipping cups | Liquid | Dermal and inhalation exposure:  Model 4 for Dipping - net dipping (TNsG 2002, Part 2, p. 170) | Dermal exposure:  Indicative value hands: 16.7 mg/min  Indicative value body: 221 mg/min  Inhalation exposure:  Indicative value inhalation: 0.2 mg/m3  Duration and frequency:  6 seconds/task (i.e. per cow); 6.5 minutes in total for pre-dipping and 11 sec per task for post-dipping, 65 cows, 175 x per year  Product volume: 3 – 10 mL per task | The model is derived from “semiautomatic dipping in open vats (fishing nets)”. This task cannot really be compared to manual disinfection of cow teats with a dipping cup. |
| 3 | Disinfection foot bath for rubber boots | Liquid | Only dermal exposure was assessed:   * EUROPOEM II database (model the exposure (loading /pouring volumes up to 20L)) * Mixing and loading Model 5 (TNsG 2002, Part 2, p.137) | * EUROPOEM 2 database:   Indicative value hands: 8 mg/kg active substance  Indicative value body: 1.95 mg/kg active substance   * Mixing & Loading Model 5 (Liquid):   Indicative value hands: 464 mg/kg active substance  Indicative value body: 48.3 mg/kg active substance | Duration: 30 sec per day, Frequency 104 times per year, Rubber boot foot bath volume: 10 L to 100 L (worst case)  Typically, two footbaths: estimate 20 uses per worker, with hand exposure through scrubbing boots with disinfectant. Footbath volume - 10 L (boots). Footwear disinfection takes place between 6 to 104 days a year (see also TNsG 2002, Part 2, p. 57). |
| 3 | Professional manual loading of buckets or powder to be used on animal beddings (manually or with machine) | Powder | (Dutch) Model 1 of the TNsG 2002 for mixing and loading of powders | Assumption of 1 hour/day for loading | For loading of the buckets or machine, dermal and inhalatory exposure can be calculated using the Dutch Model 1 for mixing and loading of powders. For biocides, the preferred model for loading of powers is TNsG Model 7, however, this model is not used, since this model is considered more suitable for industrial processes. |
| 3 and 4 | Professional surface disinfection by wiping (mop, brush, wet cloth, sponge) | Liquid | Surface Disinfection Model 1 and Surface disinfection Model 3 TNsG 2002 User Guidance - Version 1, p. 28 | Indicative exposure values are 10.3 mg biocidal product/min for the hand exposure inside protective gloves and 87.6 mg biocidal product/min for the body exposure.  The indicative dermal exposure without PPE is calculated using an assessment factor 100 for the use of gloves. The exposure duration is considered to be 79 minutes based on the indicative value for a cleaning of an isolation room in hospitals (TNsG 2002, p.175 and 177).  Because 79 minutes also refer to disinfection in the hospital, the HEAdhoc Recommendation no. 2 - Professional Mopping and Wiping Time Used for cleaning Hard Surfaces (PT2) could be used as well (110 min duration for mopping and 220 min per day for wiping). |  |
| 3 and 4 | Professional surface disinfection by spraying | Liquid | Spraying Model 1 (TNsG 2002 User Guidance - Version 1, p. 31) | Indicative exposure values are 181 mg biocidal product/min for hands outside protective gloves and 10.7 mg biocidal product/min for hands inside protective gloves, 92 mg biocidal product/min for body exposure and 104 mg biocidal product/m3 for inhalatory exposure. The exposure duration is considered to be 6 hours. |  |
| 3 and 4 | Professional surface disinfection by fogging | Liquid | Approach 1)  Fogging and Misting Model 2 (TNsG 2002 User Guidance - Version 1, p. 35)  Approach 2 (Worst case): Spraying Model 1 (TNsG 2002 User Guidance - Version 1, p. 31) | Approach 1)  Indicative exposure values are 0.20 mg biocidal product/min for hands inside protective gloves, 21.8 mg biocidal product/min for body exposure and 70.2 mg biocidal product/m3 for inhalatory exposure. The indicative dermal exposure without PPE is calculated using an assessment factor 100 for the use of gloves. The exposure duration is considered to be 6 hours.  Approach 2)  Indicative exposure values are 181 mg biocidal product/min for hands outside protective gloves and 10.7 mg biocidal product/min for hands inside protective gloves, 92 mg biocidal product/min for body exposure and 104 mg biocidal product/m3 for inhalatory exposure. The exposure duration is considered to be 6 hours. | Approach 2 is the favourite, because the indicative values of fogging are too low compared to spraying. Fogging generates more aerosols.  NL preferred to use both models. |
| 6 | Manual paint spraying by professional and non-professional users (worst-case for paints, inks, polymer emulsions) |  | Non-professional use:  ConsExpo 4.1, painting products, spray painting, pneumatic spraying  Professional use:  Approach 1)  BEAT “masonry preservatives”  Approach 2)  BEAT “designated scenario for PT 7 covers indoor decorative painting” | Professional use:  Spray duration: 6 hours  Non-professional use is covered by professional use. | Inhalation exposure can be disregarded:   * due to large droplet size, * and/or if the vapour pressure of the substance is low.   However, if the substance causes local effects in the upper respiratory tract, inhalation exposure needs to be considered.  Non-professional use:  The TNsG 2007 (p. 63) presents indicative exposure values for pneumatic spray paint (manual spraying: medium/coarse spray). If the flowchart of TNsG 2007 is followed, the indicative values, in case considered valid, should be used. In case considered not valid, the flowchart advices to use ConsExpo fact sheet models (Paint Products Fact Sheet, [RIVM report 320104008/2007](http://users.ugent.be/~pspanogh/ConsExpo%204.1/fact%20sheets/paint%20product%20fact%20sheet.pdf) (2007)).  Professional use:  There is no worked example in BEAT which describes professional spray of painting (in general). The designated scenario for PT 7 in BEAT which covers indoor decorative painting” seems the best suited “worst case” model (compared with Spray application of masonry preservative). |
| 6 | Use of glues and adhesives by professional and non-professional users (worst-case for glues, adhesives, sealants) |  | ConsExpo 4.1  Do-It-Yourself Products Fact Sheet, [RIVM report 320104007/2007](https://rivm.openrepository.com/rivm/bitstream/10029/16399/1/320104007.pdf) (2007), products, glues, carpet glue | Use all default parameters of ConsExpo  Exposure duration: 75 minutes (default ConsExpo 4.1) | It may be necessary to investigate the worst case scenario. It is not clear if both routes (inhalation/dermal) are worst case.  The approach described in the HEEG opinion 14 - An approach to identification of worst-case human exposure scenario for PT6 could be followed for glues. |
| 6 | (Indoor) wall plastering by professional and non-professional users (worst-case for use in construction materials) |  | Professional use:  Approach 1)  RISKODERM  Approach 2)  ConsExpo 4.1  Do-It-Yourself Products Fact Sheet, [RIVM report 320104007/2007](https://rivm.openrepository.com/rivm/bitstream/10029/16399/1/320104007.pdf) (2007), plaster/equalizer, wall plaster  Non-professional use:  ConsExpo 4.1  Do-It-Yourself Products Fact Sheet, [RIVM report 320104007/2007](https://rivm.openrepository.com/rivm/bitstream/10029/16399/1/320104007.pdf) (2007), plaster/equalizer, wall plaster | Professional use:  Approach 2)  Plastering is heavy work, therefore an exposure duration of 8 hours is recommended.  Non-professional use:  Exposed area: 1950 cm2 (hands and forearms, HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products)  Exposure duration: 120 minutes (default ConsExpo 4.1) | Inhalation exposure is not considered by the model ConsExpo default scenario for wall plastering.  For outdoor wall plastering consumers, use the Consumer Brush Painting model 3. |
| 6 | Professional use in textile treatment (worst-case for textile/leather/paper production) |  | Approach 1)  Dipping Model 3  Approach 2)  Timber pre-treatment (water) (from BEAT)  Approach 3)  Washing hospital patients from BEAT  Approach 4)  Car washing from BEAT | Approach 1)  Indicative dermal exposure:   * Hands:   160 mg/min (without protective gloves)  1.6 mg/min (inside gloves)   * Indicative body exposure:   23.8 mg/min  Indicative inhalation exposure: 122 mg/m3  Exposure period 3 hours  Approach 2)   * Potential body exposure: 108 μL/min x 4 * Actual hand exposure: 8.71 μL/min x 4   Approach 3)   * Potential body exposure: 1140 μL/min * Potential hand exposure 388 μL/min   Approach 4)   * Potential body exposure 2070 μL/min * Potential hand exposure 517 μL/min | Approach 1)  The Dipping Model 3 is no longer mentioned in TNsG 2007.  Approach 2)  When frequently touching wet textile, without grabbing, dragging or picking up, the defaults of the BEAT model “Timber pre-treatment (water)” seem to be the best fitting. Dermal exposure in this model occurs primarily through contact with treated timber when it is removed from the vessel. The 75th percentile defaults should be adjusted to account for exposure during timber pre-treatment effectively being limited to the last part of the cycle where the treatment vessel is opened and the timber removed. This accounts for approximately 1/4 of the cycle.  Approach 3)  When frequently handling and picking up wet textile, the defaults of the BEAT model “Washing hospital patients” seem to be the best fitting. At oncology wards of the four hospitals, twenty-six measurements were taken during washing of a patient treated with cyclophosphamide study. The 75th percentile defaults are suggested as appropriate indicative values.  Approach 4)  When frequently handling soaked textile by pick up, dragging and hanging out to dry, the defaults of the BEAT model “Car washing” seem to be the best fitting. Cleaning of cars using a car shampoo dissolved in water and applied using a cloth or sponge dipped into a bucket containing dilute cleaning solution. The 75th percentile defaults are suggested as appropriate indicative values.  Please note that in most situation the Approach 3) will apply as the best option, but the task approach 2) may underestimate the exposure (see 6.1 - Annex I for more information) |
| 8 | Professional automated dipping/immersion of wooden articles | Liquid | Handling Model 1 for dermal exposure  For volatile compounds the assessment of vapour in addition is necessary. | 4 dipping cycles  per day (HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8))  Water-based products:  Hands: 1080 mg/cycle (inside gloves)  Body: 8570 mg/cycle  Solvent-based products:  Hands: 260 mg/cycle (inside gloves)  Body: 158 mg/cycle | According to the HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8) inhalation exposure resulting from aerosol formation should be negligible. |
| 8 | Fully automated dipping | Liquid | Handling Model 1 for dermal exposure  For volatile compounds the assessment of vapour in addition is necessary. | 4 dipping cycles  per day (HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8))  Water-based products:  Hands: 1080 mg/cycle (inside gloves)  Body: 8570 mg/cycle  Solvent-based products:  Hands: 260 mg/cycle (inside gloves)  Body: 158 mg/cycle | According to the HEEG OPINION 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4.  According to the HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8) inhalation exposure resulting from aerosol formation should be negligible. |
| 8 | Professional (double-vacuum treatment of wood) | Liquid | Handling Model 1  For volatile compounds the assessment of vapour in addition is necessary. | 3-6 Cycles  Water-based products:  Hands: 1080 mg/cycle (inside gloves)  Body: 8570 mg/cycle  Inhalation: 1.9 mg/m3  Solvent-based products:  Hands: 260 mg/cycle (inside gloves)  Body: 158 mg/cycle  Inhalation: 0.6 mg/m3  Exposure time (inhalation exposure): 30 min (opening the door, for 3 cycles) | According to TNsG 2002 User Guidance - Version 1:   * vacuum pressure impregnation:   3 cycles   * double vacuum pressure impregnation:   6 cycles |
| 8 | Professional manual dipping of wooden articles (application) | Liquid | Dipping Model 1  For volatile compounds the assessment of vapour in addition is necessary. | Dermal exposure:  Hands: 25.7 mg/min (inside gloves)  Body: 178 mg/min  Inhalation exposure:  Inhalation (non-volatile compounds): <1 mg/m3  Exposure duration 30 min (HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8)) |  |
| 8 | Professional brush treatment | Liquid | For volatile compounds the assessment of vapour in addition is necessary. | Indicative values normalized to  1 % active substance:  Dermal exposure:  Hands: 0.5417 mg/m2  Body: 0.2382 mg/m2  Inhalation exposure:  Inhalation (non-volatile compounds): 0.0016 mg/m2  Exposure duration: 240 min  Application area : 31.6 m2 | Application area calculated (7.6 min/m2) (consumer painting Model 3, median) calculation: 1/7.6\*240  Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006 |
| 8 | Professional spray treatment  Application including Mixing and loading | Liquid | Spraying Model 2  For volatile compounds the assessment of vapour in addition is necessary. | Indicative dermal exposure:   * Hands:   273 mg/min (without protective gloves)  7.8 mg/min (inside gloves)   * Body:   222 mg/min  Indicative inhalation exposure (non-volatile compounds): 76 mg/m3  Exposure duration: 90 min. | The model is appropriate for powered spray application at 4 to 7 bar pressure. |
| 8 | Professional borehole impregnation | Liquid | Mixing and loading Model 4  The application solution is funnelled into boreholes (pressure less pouring).  For volatile compounds the assessment of vapour in addition is necessary. | Number of assumed loadings: 100  Hands: 10 mg/loading |  |
| 8 | Professional borehole pressure impregnation  Application including mixing and loading | Liquid | Subsoil treatment Model 2  The biocidal product is applied to the drills using a wood injector (pressure impregnation).  For volatile compounds the assessment of vapour in addition is necessary. | Indicative dermal exposure:  Hands: 8 mg/min (inside gloves)  Indicative inhalation exposure (non-volatile compounds): 0.57 mg/m3  Exposure duration: 80 min |  |
| 8 | Professional borehole pressure impregnation  Application including Mixing and loading | Solid | For volatile compounds the assessment of vapour in addition is necessary. | Hand exposure:   * Density (product) x layer thickness on skin x contact area x 1000 * Layer thickness on skin: 0.01 cm * Contact area – fingers of both hands: 240 cm2 | Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulations No. 1488/94 on risk assessment for existing substances (Part I, II, III, IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocide products on the market, European Commission 2003 |
| 8 | Professional deluging | Liquid | Dipping Model 1 | Indicative dermal exposure:  Hands: 25.7 mg/min (inside gloves)  Body: 178 mg/min  Indicative inhalation exposure  (non-volatile compounds): <1 mg/m3  Exposure duration 60 min |  |
| 8 | Professional  Mixing with glue and mortar  (only mixing and loading exposure scenario) | Liquid | HEEG opinion 1 - Mixing loading model 7 alternatives | Indicative dermal exposure:  0.92 mg/min (hands, without protective gloves)  Exposure duration: 10 min |  |
| 12 | Prevent bacteria growth in oilfield systems (both off-shore and on-shore) | Liquid | Approach 1)  Mixing and loading Model 7 (corrected) for (semi) automated transfer and pumping.  Approach 2)   * For automated transfer/pumping: Justify that the exposure is negligible compared to other related tasks, or use results from RISKOFDERM Toolkit *Connecting lines* (is not RISKOFDERM)   For semi-automated transfer/pumping: No relevant model in BEAT and TNsG version 2. Estimation can be done with RISKOFDERM Dermal model *Loading liquid, automated or semi-automated*, considering task conditions and use rate. *Mixing and loading Model 7* is not recommended but may be used with caution. | Assumption is valid for non-volatile substances.  Approach 1)  As the calculation includes (de)connection of the dosing device, a default task duration of 3 minutes per day was assumed.  The indicative dermal exposure without PPE is 138 mg/min; this is recalculated from actual exposure inside gloves using a factor 100 for the use of gloves and protective clothing. | Approach 2 is the favourite, because approach 1 is no longer mentioned in TNsG 2007.  The HEEG opinion 1 – On the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale should be followed. |
| 13 | Work with metalworking fluids | Liquid | MWF Model 2 (HEEG 2008) or HEEG Opinion 5 –Human exposure assessment to biocidal products used in metalworking fluids (PT13)  **NOTE: the HEEG opinion 5 has been revised and replaced by the HEAdhoc Recommendation 7** | Indicative dermal exposure:  Hands: 200 mg/min  Body: 92 mg/min  Exposure duration: 4 hours  Indicative inhalation exposure  Inhalation: 0.33 mg/m3  Exposure duration: 8 hours  **NOTE: the HEEG opinion 5 has been revised and replaced by the HEAdhoc Recommendation 7** | According to the HEEG Opinion 5 - Human exposure assessment to biocidal products used in metalworking fluids (PT13):   * 1 hour (for metalworking on turning machine without gloves) * 4 to 7 hours (other tasks in the workshop) for dermal exposure (average 4 hours) and 8 hours for inhalation exposure   **NOTE: the HEEG opinion 5 has been revised and replaced by the HEAdhoc Recommendation 7** |
| 14 | Professional application (loose grain, pellets, granules) | solid | Harmonised exposure assessment of anticoagulants based on the study by Chambers et al. | Mixing and loading (decanting 3 kg loose bait):  Inhalation: 9.62 mg/m³  Dermal: 52.34 mg per manipulation  Application (loading bait boxes):  Dermal: 2.04 mg per manipulation  Inhalation: negligible  Post-application (cleaning up bait boxes):  Dermal: 3.79 mg per manipulation  Agreed number of loadings of bait stations per day and person: 63  Agreed number of cleaning bait stations per day and person: 16 (no cleaning phase in sewage systems) | HEEG opinion 12 - Harmonised approach for the assessment of rodenticides (anticoagulants) |
| 14 | Professional application  (wax block, paste bait in sachets) | Solid, paste-like | Harmonised exposure assessment of anticoagulants based on Chambers et al. | Application (loading bait boxes – placing of 5 blocks into a bait station):  Inhalation: not expected  Dermal: 27.79 mg per manipulation  Post-application (cleaning up bait boxes):  Dermal: 5.70 mg per manipulation  Agreed number of loadings of bait stations per day and person: 60  Agreed number of cleaning bait stations per day and person: 15 (no cleaning phase in sewage systems) | HEEG opinion 12 - Harmonised approach for the assessment of rodenticides (anticoagulants) |
| 14 | Professional application  (paste bait in cartridges) | Paste-like | Application: expert judgement  Post-application: Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulations No. 1488/94 on risk assessment for existing substances (Part I, II, III, IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocide products on the market, European Commission 2003 | Application:  Dermal =  [ x r² x height] x density of product x 14 contacts  Height: length of the strand which gets to skin during each opening/closing considering the viscosity of the biocidal product diameter: diameter of the strand which equals the inner diameter of the nozzle  14 contacts: 7 x opening + 7 x closing, according to the HEEG opinion 10 - Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants)  Post-application:   * Dermal = density of product x layer thickness on skin x contact area * Layer thickness on skin: 0.01 cm * Contact area: 60 cm² (finger tips) |  |
| 14 | Professional application (paste bait in bucket [with spatula]) | Paste-like | Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulations No. 1488/94 on risk assessment for existing substances (Part I, II, III, IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocide products on the market, European Commission 2003 | Application and post-application:   * Dermal = density of product x layer thickness on skin x contact area * Layer thickness on skin: 0.01 cm * Contact area: 60 cm² (finger tips) |  |
| 14 | Professional application (fumigation via application of tablets/pellets) | Solid | Expert judgement | Dermal = surface of tablets x thickness of layer of the product on skin x density of product x amount of tablets/pellets used  Layer thickness on skin: 0.0001 cm |  |
| 14 | Professional application (foaming) | Liquid | ConsExpo 4.1  Do-It-Yourself Products Fact Sheet, [RIVM report 320104007/2007](https://rivm.openrepository.com/rivm/bitstream/10029/16399/1/320104007.pdf) (2007), “Isolation Foam for application”  ConsExpo 4.1  Disinfectant Products Fact Sheet (RIVM report 320005003/2006), “Wiping for post-application” | Application:  Dermal = Content spray can [mg] x 0.03 %  Post-application:  Dermal = [Content spray can [mg] x 0.1 %]/10 | The total amount applied is one can per day. The assumption is that the total amount applied is removed. |
| 18 | Professional control of fly larvae in stables and cages by coarse spraying  Downward spraying | Liquid | HEAdhoc Recommendation no. 3 -  Spraying models for assessing exposure to insecticides for low pressure downward uses |  | If the substance causes local effects in the upper respiratory tract, inhalation exposure needs to be considered. |
| 18 | Professional disinfection of surfaces in stables by brushing | Liquid | Consumer Painting Model 3 | Indicative dermal exposure:  Hands: 5.91 mg/min  Body: 16.9 mg/min  Indicative inhalation exposure:  1.63 mg/m3  Exposure duration: 60 minutes (based on Excel Database human exposure) |  |
| 18 | Scattering powder against ants from a hand held flexible duster/hand-held canister by consumers and professionals | Powder | Approach 1)  Spraying Model 1 for pouring of powder (professionals)  Approach 2)  Hand-held flexible  Duster  (TNsG 2007 p. 63) (consumer)  Approach 3)  ConsExpo 4.1, scenario Pest Control Products, Dusting Powders, Application for dusting of powder (consumers) | Approach 1)  Application duration for pouring is 1 hour (Excel Database human exposure, scenario “gush dilution on surface” for solid substances). A factor 100 is used for the indicative (potential) exposure value (HEEG Opinion on the assessment of potential & actual hand exposure 2008).  Approach 2)  The model from the TNsG 2007 is derived from the following simulated volunteer study: Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 μm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 μm).  Indicative dermal exposure: Hand/forearm: 2.73 mg/min  Legs/feet/face: 2.74 mg/min.  Indicative inhalation exposure:  Inhalation exposure: 2.47 mg/m3  TNsG 2002 Consumer product Spraying and dusting Model 2:  75 μm:   * Hand and forearm: 2.83 mg/min (75th percentile) * Legs/feet/face: 2.15 mg/min (75th percentile)   180 μm:   * Hand and forearm: 2.5 mg/min (maximum value) * Legs/feet/face: 3.2 mg/min (maximum value)   Approach 3)  ConsExpo 4.1, scenario Pest Control Products, Dusting Powders, Application.  (dermal/inhalation defaults consumer = dermal/inhalation defaults professional  Note: For professionals, the defaults for frequency, spray duration and release duration need to be adapted to worker situation. The worker may use the product longer, more frequently and apply larger amounts) | Professional use:  Approach 2 is better because it is based on TNsG 2007, while ConsExpo fact sheet is based on TNsG 2002. In case the application is not performed with hand held flexible duster/hand-held canister, but with a spoon, the inhalation exposure may be assumed negligible compared to the dermal exposure. Dusters are used to generate dust, while spoons are used because they limit dust formation.  The value 2.73 (for hand/foreaem) and 2.74 (for legs/feet/face) is assumed to be the worst case, but there is no other data/model available.  Note: For professionals, the defaults for frequency, spray duration and release duration need to be adapted to worker situation. The worker may use the product longer, more frequently and apply larger amounts  The duration of 1 hour should be used instead of 5 minutes. |
| 21 | Professional spraying | Liquid | Spraying Model 3, TNsG 2002 User Guidance - Version 1 | Indicative dermal exposure:  Hands:  119 mg/min (without protective gloves)  2.04 mg/min (inside gloves)  Body: 250 mg/min  Indicative inhalation exposure (non-volatile compounds): 17.3 mg/m3  Exposure duration:180 min | HEEG opinion 15 - On the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints |
| 21 | Professional brushing and combined brush/roller painting | Liquid | Consumer product painting Model 4 (Recommended for brush or combined brush/roller painting) | Indicative dermal exposure:   * Hands:   76.6 mg/min (without protective gloves)  18.5 mg/min (inside gloves)  Body: 30.7 mg/min  Indicative inhalation exposure (non-volatile compounds): 0.05 mg/m3  Exposure duration:90 min | HEEG opinion 15 - On the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints, modified |
| 21 | Professional rolling and combined brush/roller painting | Liquid | Links et al. study, 2007 (Recommended for roller or combined brush/roller painting) | Indicative dermal exposure:   * Hands:   82.3 mg/min, without protective gloves)  0.014 mg/min (inside gloves)   * Body:   84.2 mg/min (potential value)  0.425 mg/min (actual value)  Indicative inhalation exposure (non-volatile compounds): 0.28 mg/m3  Exposure duration:90 min | HEEG opinion 15 - On the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints |
| 21 | Professional assistant workers (potmen and ancillary workers) | Liquid | Mixing and loading Model 6, TNsG 2002 User Guidance - Version 1 | Indicative dermal exposure:   * Hands:   30 mg/min (without protective gloves)  8.2 mg/min (inside gloves)   * Body: 92 mg/min   Indicative inhalation exposure (non-volatile compounds): 1.9 mg/m3  Exposure duration:180 min | HEEG opinion 15 - On the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints |
| 21 | Professional paint removal (sand blasting, paint stripping) |  | Links et al., 2007 | Values are based on removed old paint equivalents.    Indicative dermal exposure:   * Hands:   23.6 mg/min (without protective gloves)  3.63 mg/min (inside gloves)   * Body:   16.4 mg/min (potential value)  1.31 mg/min (actual value)  Active substance in removed paints contains 90% of the original concentration of active substance in dry paint.  Indicative inhalation exposure (non-volatile compounds): 15.3 mg/m3  Exposure duration:180 min | HEEG opinion 15 - On the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints |
| 21 | Professional grit fillers |  | Links et al., 2007 | Values are based on removed old paint equivalents.  Indicative dermal exposure:   * Hands:   497 mg/h (without protective gloves)  6.49 mg/h (inside gloves)   * Body:   433 mg/h  Active substance in removed paints contains 90% of the original concentration of active substance in dry paint.  Indicative inhalation exposure (non-volatile compounds): 3.87 mg/m3  Exposure duration:180 min | HEEG opinion 15 - On the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints |

**Step 2**

In case in Step 1 either no adequate models have been identified, or additional ones are needed to cover for a specific exposure scenario, the assessor should then look for appropriate model available in the simple database model as outlined in the table below. The table is an overview of the available recommended models for estimating exposure of professional users during application tasks.

Depending on the exposure scenario description of tasks and intended uses the assessor should select the realistic worst case exposure modelling approach by selecting the most suitable model.

|  |  |
| --- | --- |
| **Exposure model Name** | **Link** |
| Intermittent handling of water-wet or solvent-damp wood & associated equipment | Available in Section 6.1 |
| Intermittent handling of treated nets at various stages of dryness | Available in Section 6.1 |
| Carrying out a range of dipping activities involving a variety of articles | Available in Section 6.1 |
| Handling dusty powders packaged in cardboard bags | Available in Section 6.1 |
| Diluting and mixing disinfectant & wiping surfaces with cloth | Available in Section 6.1 |
| Washing and wiping floors | Available in Section 6.1 |
| Treating soil by watering and subsoil by injection | Available in Section 6.1 |
| Spray Application: Mixing & Loading liquids & powders in compression sprayer/dusting applicators and indoor or outdoor spraying in overhead or downward direction | Available in Section 6.1 |
| Spray Application: Mixing & Loading and application of liquids in reservoir for powered spray Application indoors or outdoors in overhead and downward direction | Available in Section 6.1 |
| Spray Application: Spraying viscous solvent-based liquids outdoors in overhead and forward direction | Available in Section 6.1 |
| Spray Application: Disinfection of slaughterhouses and meat processing industry by overhead and downward spraying or foaming | Available in Section 6.1 |
| Spray Application: Application of amenity herbicides at ground level using a controlled droplet wand applicator | Available in Section 6.1 |
| Generic Inhalation/Fogging Application: Application of insecticide at waist level, indoor, using cold (ULV) or thermal foggers | Available in Section 6.1 |
| Generic Inhalation (metal working fluids): Handling mineral oils, semi-synthetic oils and synthetic fluids | Available in Section 6.1 |
| Professional granular bait dispersal by hand | Available in Section 6.1 |
| Inhalation exposure to formaldehyde in human pathologies (PT 22) | Available in Section 6.1 |

The brushing models for non-professional users listed in the table here below are also recommended for professional users:

|  |  |
| --- | --- |
| **Exposure model Name** | **Link** |
| In-situ application of wood preservatives with brush | Available in Section 6.2 |
| Brushing and roller painting of antifouling paint on underside of small boats, outdoor | Available in Section 6.2 |

**Step 3**

In case in Step 2 either no adequate models have been identified, or additional ones are needed to cover for a specific exposure scenario, the assessor should consult the overview table on generic models and mathematical models available in Section 3.2.3 to identify appropriate models to calculate the exposure from mixing & loading tasks. For a number of these models expertise is required to address applicability of the model for a specific exposure scenario. It is important that the exposure parameters used (conditions of use) are explicitly mentioned within the exposure assessment. In addition, independent of the model used, the default parameters outlined in Section 2 of this document should be used instead of any other defaults available within specific computer based models.

#### Post Application Professional Users

**Step 1**

The assessor should consult the following overview table that contains the list recommended models for professional users regarding post application tasks.

Depending on the exposure scenario description of tasks and intended uses the assessor should select the realistic worst case exposure modelling approach by selecting the most suitable model.

|  |  |
| --- | --- |
| **Exposure model Name** | **Link** |
| Cleaning (i.e. washing out) of a brush model | Primary Exposure Paint Model “Washing out of a brush – Section 9 (HEEG opinion) |
| PT14 Post-application - Cleaning of bait boxes”) | PT14 - Professional User Models Section 9 HEEG Opinion |
| PT21 Cleaning of spray equipment in antifouling use | PT21 - Cleaning of spray equipment in antifouling use Section 9 HEAdhoc |
| Model for Dipping of Hands/forearms in a diluted solution | Primary Exposure – Model for dipping of hands/forearms in a diluted solution Section 9 HEEG Opinion |

**Step 2**

In case in Step 1 either no adequate models have been identified, or additional ones are needed to cover for a specific exposure scenario, the assessor should consult the overview table on generic models and mathematical models available in Section 3.2.3 to identify appropriate models to calculate the exposure from mixing & loading tasks. For a number of these models expertise is required to address applicability of the model for a specific exposure scenario. It is important that the exposure parameters used (conditions of use) are explicitly mentioned within the exposure assessment. In addition, independent of the model used, the default parameters outlined in Section 2.1 of this document should be used instead of any other defaults available within specific computer based models.

### Non-Professional Users (Consumers)

#### Mixing and Loading Non-Professional Users

It should be noted that mixing and loading application for non-professional users is a task that is not always applicable for non professional users for ready for use product; in these cases for this task the exposure will be negligible.

The Generic Models Algorithms (equations) for all relevant routes of exposure, presented in Section 7 of this document, can be considered either as screening tools to calculate the exposure or when no other suitable model described further in this section is available.

**Step 1**

The assessor should consult the following overview table that contains the list recommended models for non-professional users regarding mixing and loading tasks.

Depending on the exposure scenario description of tasks and intended uses the assessor should select the realistic worst case exposure modelling approach by selecting the most suitable model.

|  |  |
| --- | --- |
| **Exposure model Name** | **Link** |
| Pouring solvent-based or water-based concentrate from 1lt container into a small bucket | Available in Section 6.2 |
| Model for Dipping of Hands/forearms in a diluted solution | Available in 6.1 “Mixing and Loading Professional Users” |

**Step 2**

In case in Step 1 either no adequate models have been identified, or additional ones are needed to cover for a specific exposure scenario, the assessor should consult the overview table on generic models and mathematical models available in Section 3.2.3 to identify appropriate models to calculate the exposure from mixing & loading tasks.

For the exposure scenarios for non-professional users as indicated in Section 3.1.2, ConsExpo FactSheets provide a good source for the generation of exposure scenarios. In this respect ConsExpo 4.1 can be the first choice for such scenarios when estimating the exposure potential for this task.

For a number of these models expertise is required to address applicability of the model for a specific exposure scenario. It is important that the exposure parameters used (conditions of use) are explicitly mentioned within the exposure assessment. In addition, independent of the model used, the default parameters outlined in Section 2 of this document should be used instead of any other defaults available within specific computer based models.

#### Application Non-professional Users

**Step 1**

In order to estimate the exposure of non-professional users from tasks regarding application of the biocidal product, the following table (developed by HEAdhoc group within the recommendation “Methods and models to assess exposure to biocidal products in different product types” see Section 9) provides for a number of product types the recommendation on potential scenarios, the conditions of use and the recommended model to estimate the exposure.

The table is non-exhaustive and there can be additional scenarios that need to be developed for these product types depending on the intended uses.

The scenarios within the table below are also mentioned in the Patterns of use (conditions of use) section for these product types under section 3.1.2 (Specific product type exposure scenarios) of this document.

**NOTE:** *for some of the scenarios and models described in the table below, the scenario includes mixing & loading and application phase together.*

**NOTE**: within the table reference is provided indicating the source where the value has been chosen from:

* *In case the reference is TNSG 2002, the assessor can find the relevant detailed model within Section 10 of this document*
* *In case the reference is TNsG 2002 User Guidance Version 1 or TNsG 2007, the assessor can find the available description within Section 6.1 of this document*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PT** | **Exposure scenario** | **state of the product (solid/liquid/aerosol)** | **Proposed exposure model** | **Default settings** | **Remarks on the proposed model** |
| 2 | Non-Professional pond treatment | Powder | ConsExpo 4.1, default scenario for mixing and loading of Pest Control Product, powder  It is noted that:   1. Detailed information for the used of this default database is presented in the Pest Control Product Fact Sheet ([RIVM report 320005002/2006](http://users.ugent.be/~pspanogh/ConsExpo%204.1/fact%20sheets/consexpo%20pt18.pdf)). However, no additional information is included on mixing and loading only. 2. This mixing and loading model only consists of dermal exposure data. | Dermal exposure:  Exposed area: 820 cm2 (HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products)  Contact rate of 0.033 mg/min and release duration of 79.8 seconds are defaults of this ConsExpo 4.1 model. |  |
| 3 | Animal house disinfection by spraying | Liquid | Dermal exposure:   * Spraying Model 2, TNsG 2002 * Spraying Models 2 and 3, TNsG 2002 * Spraying Model 7, TNsG 2002 * Spraying Model 9, TNsG 2002 * ConsExpo 4.1 Dermal model: Direct dermal contact with product: constant rate   Inhalation exposure:   * Spraying Model 2, TNsG 2002 * Spraying Models 2 and 3, TNsG 2002 * Spraying Model 9, TNsG 2002 * ConsExpo 4.1 | Dermal exposure:   * Indicative values Spraying Model 2: Hands (actual) 7.8 mg/min; hands (potential) 273 mg/min; body 222 mg/min * Indicative values Spraying Model 3: Hands in gloves 2.04 mg/min; body 250 mg/min * Values Spraying Model 7: 75th 100 mg/min * Indicative values Spraying Model 9: Hands 2300 mg/min; body 4900 mg/min * Parameters ConsExpo 4.1: * Exposed area: 1,75 m2 * Contact rate: 540 mg/min * Release duration: 400 min   Inhalation exposure:   * Indicative value Spraying Model 2: 76 mg/m3 * Indicative value Spraying Model 3: 17.3 mg/m3 * Indicative value Spraying Model 9: 3600 mg/m3 | For assessing dermal exposure to an active substance, Spraying Model 7 was chosen which is not reflected in the TNsG User Guidance.  Assessment of inhalation exposure by Member States:  Frequencies and durations:  1 h, 2 h 6 times per year, 126 min once per day, 180 min 12 times per year, 400 min  For most actives, the Spraying Model 2 was chosen to cover inhalation and dermal exposure for the task animal house spraying. This model is based on the task “Mixing and loading liquids in reservoir for powered spray application at 4 to 7 bar pressure as a coarse or medium spray, indoors, overhead and downwards. Scenario - medium pressure spray applications, e.g. for remedial biocides”.  However, there is a great discrepancy in the duration and frequency of the task which might be due to different assumptions on the setting e.g. stable size, treated area, animals etc. An harmonization in this point (if feasible) would be desirable. |
| 3 | Hoof bath disinfection | Liquid | Dermal exposure:  Mixing and loading Model 4 (TNsG 2002 for dermal exposure by mixing and loading and (post)-application)  Inhalation exposure:  ConsExpo 4.1 (for inhalatory exposure by mixing and loading and (post)-application) | Dermal exposure   * Defaults used for mixing and loading and (post)-application by Mixing and loading Model 4: 0.5 mL b.p./loading (based on 20 L container volume and a frequency of 1 loading for mixing and loading and 4 loadings for post-application) * No dermal exposure is expected for application.   Inhalation exposure   * Defaults used for mixing and loading for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): * Application duration: 5 minutes * Ventilation rate: 10/hour * Room volume: 24 m3 * Release area: 100 cm2 * Defaults used for application for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): * Duration: 35 minutes   Ventilation rate: 9.35/hour (“Sächsische Landesanstalt für Landwirtschaft” 900 m3/h per cow (100 cows in 9630 m3, OECD) = 9.35/h) and based on animal welfare)   * Room volume: 9630 m3 * Release area: 3 m2 * Defaults used for post-application for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): * Duration: 10 minutes * Ventilation rate: 9.4/hour * Room volume: 9630 m3 * Release area: 3 m2 | The Approach included mixing and loading of the substance in footbath, walking through of cattle and cleaning and disposal. The approach includes mixing and loading and (post)-application.  Refinement: dermal exposure due to refreshment of the bath could also occur (see <http://www.youtube.com/watch?v=78SD2jPFcmA>) |
| 3 | Disinfection foot bath for rubber boots | Liquid | Only dermal exposure was assessed:   * EUROPOEM II database (model the exposure (loading /pouring volumes up to 20L))   Mixing and loading Model 5 (TNsG 2002, Part 2, p.137) | * EUROPOEM 2 database:   Indicative value hands: 8 mg/kg active substance  Indicative value body: 1.95 mg/kg active substance   * Mixing & Loading Model 5 (Liquid):   Indicative value hands: 464 mg/kg active substance  Indicative value body: 48.3 mg/kg active substance | Duration: 30 sec per day, Frequency 104 times per year, Rubber boot foot bath volume: 10 L to 100 L (worst case)  Typically, two footbaths: estimate 20 uses per worker, with hand exposure through scrubbing boots with disinfectant. Footbath volume - 10 L (boots). Footwear disinfection takes place between 6 to 104 days a year (see also TNsG 2002, Part 2, p. 57). |
| 6 | Manual paint spraying by professional and non-professional users (worst-case for paints, inks, polymer emulsions) |  | Non-professional use:  ConsExpo 4.1, painting products, spray painting, pneumatic spraying  Professional use:  Approach 1)  BEAT “masonry preservatives”  Approach 2)  BEAT “designated scenario for PT 7 covers indoor decorative painting” | Professional use:  Spray duration: 6 hours  Non-professional use is covered by professional use. | Inhalation exposure can be disregarded:   * due to large droplet size, * and/or if the vapour pressure of the substance is low.   However, if the substance causes local effects in the upper respiratory tract, inhalation exposure needs to be considered.  Non-professional use:  The TNsG 2007 (p. 63) presents indicative exposure values for pneumatic spray paint (manual spraying: medium/coarse spray). If the flowchart of TNsG 2007 is followed, the indicative values, in case considered valid, should be used. In case considered not valid, the flowchart advices to use ConsExpo fact sheet models (Paint Products Fact Sheet, [RIVM report 320104008/2007](http://users.ugent.be/~pspanogh/ConsExpo%204.1/fact%20sheets/paint%20product%20fact%20sheet.pdf) (2007)).  Professional use:  There is no worked example in BEAT which describes professional spray of painting (in general). The designated scenario for PT 7 in BEAT which covers indoor decorative painting” seems the best suited “worst case” model (compared with Spray application of masonry preservative). |
| 6 | Use of glues and adhesives by professional and non-professional users (worst-case for glues, adhesives, sealants) |  | ConsExpo 4.1  Do-It-Yourself Products Fact Sheet, [RIVM report 320104007/2007](https://rivm.openrepository.com/rivm/bitstream/10029/16399/1/320104007.pdf) (2007), products, glues, carpet glue | Use all default parameters of ConsExpo  Exposure duration: 75 minutes (default ConsExpo 4.1) | It may be necessary to investigate the worst case scenario. It is not clear if both routes (inhalation/dermal) are worst case.  The approach described in the HEEG opinion 14 - An approach to identification of worst-case human exposure scenario for PT6 could be followed for glues. |
| 6 | (Indoor) wall plastering by professional and non-professional users (worst-case for use in construction materials) |  | Professional use:  Approach 1)  RISKODERM  Approach 2)  ConsExpo 4.1  Do-It-Yourself Products Fact Sheet, [RIVM report 320104007/2007](https://rivm.openrepository.com/rivm/bitstream/10029/16399/1/320104007.pdf) (2007), plaster/equalizer, wall plaster  Non-professional use:  ConsExpo 4.1  Do-It-Yourself Products Fact Sheet, [RIVM report 320104007/2007](https://rivm.openrepository.com/rivm/bitstream/10029/16399/1/320104007.pdf) (2007), plaster/equalizer, wall plaster | Professional use:  Approach 2)  Plastering is heavy work, therefore an exposure duration of 8 hours is recommended.  Non-professional use:  Exposed area: 1950 cm2 (hands and forearms, HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products)  Exposure duration: 120 minutes (default ConsExpo 4.1) | Inhalation exposure is not considered by the model ConsExpo default scenario for wall plastering.  For outdoor wall plastering consumers, use the Consumer Brush Painting model 3. |
| 6 | Use of detergents by general public (worst-case for all laundry/washing liquids/detergents applications) |  | ConsExpo 4.1, Cleaning and Washing, Dishwashing products, Hand dishwashing liquid, application based on dermal instant application model and evaporation model for inhalatory exposure (Langmuir’ Method) | * The weight fraction compound needs to be recalculated by dividing the concentration of the active substance in the product by factor 714 (due to product dilution in 15 l water in a sink - default ConsExpo 4.1) * Exposed area: 820 cm2 (hands, HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products) * Exposure duration: 15 minutes * Application duration: 15 minutes * Room volume: 15 m3 * Ventilation rate: 2.5/hour   The other parameters remain unchanged. | The inhalation time of 15 min is correct. The instant application model for dermal exposure should be used according the Cleaning product Fact Sheet.  Please note that the dermal instant application model is subject to discussion within the RIVM. This model is not a worst case model due to the fact that information on Kp is rarely available.  (in case the Kp is known, the dermal model diffusion through skin is preferred)  The film thickness on hand has a run-off default of 0.01 cm. In case there is a long contact time, 0.1 cm can be used as a worst case approach. |
| 18 | Scattering powder against ants from a hand held flexible duster/hand-held canister by consumers and professionals | Powder | Approach 1)  Spraying Model 1 for pouring of powder (professionals)  Approach 2)  Hand-held flexible  Duster  (TNsG 2007 p. 63) (consumer)  Approach 3)  ConsExpo 4.1, scenario Pest Control Products, Dusting Powders, Application for dusting of powder (consumers) | Approach 1)  Application duration for pouring is 1 hour (Excel Database human exposure, scenario “gush dilution on surface” for solid substances). A factor 100 is used for the indicative (potential) exposure value (HEEG Opinion on the assessment of potential & actual hand exposure 2008).  Approach 2)  The model from the TNsG 2007 is derived from the following simulated volunteer study: Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 μm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 μm).  Indicative dermal exposure: Hand/forearm: 2.73 mg/min  Legs/feet/face: 2.74 mg/min.  Indicative inhalation exposure:  Inhalation exposure: 2.47 mg/m3  TNsG 2002 Consumer product Spraying and dusting Model 2:  75 μm:   * Hand and forearm: 2.83 mg/min (75th percentile) * Legs/feet/face: 2.15 mg/min (75th percentile)   180 μm:   * Hand and forearm: 2.5 mg/min (maximum value) * Legs/feet/face: 3.2 mg/min (maximum value)   Approach 3)  ConsExpo 4.1, scenario Pest Control Products, Dusting Powders, Application.  (dermal/inhalation defaults consumer = dermal/inhalation defaults professional  Note: For professionals, the defaults for frequency, spray duration and release duration need to be adapted to worker situation. The worker may use the product longer, more frequently and apply larger amounts) | Non-professional use:  Approach 2 is better because it is based on TNsG 2007, while ConsExpo fact sheet is based on TNsG 2002.  In case the application is not performed with hand held flexible duster/hand-held canister, but with a spoon, the inhalation exposure may be assumed negligible compared to the dermal exposure. Dusters are used to generate dust, while spoons are used because they limit dust formation.  The value 2.73 (for hand/foreaem) and 2.74 (for legs/feet/face) is assumed to be the worst case, but there is no other data/model available. |
| 18 | Non-professional use of insecticide cassettes |  | ConsExpo 4.1, constant surface evaporation model   * Langmuir model in case little is known about the product   Thibodeaux’s model for emission on water based liquids. | The following specific default values should be filled in:   * Applied amount: dependent on the product * Emission duration: dependent on the product * Exposure duration: 5 min * Wardrobe volume: 1.5 m3 * Ventilation rate: 0.3/hour | The model should not be used in case the concentration is very low (< 10-8 μg/L). In that case, measurements in the air should be performed.  Langmuir’s and Thibodeaux’s methods are only required in case of the method of release by evaporation and not in the case of constant rate.  See Pest Control Products factsheet ([RIVM report 320005002/2006](http://users.ugent.be/~pspanogh/ConsExpo%204.1/fact%20sheets/consexpo%20pt18.pdf)) for more default values. |

**Step 2**

In case in Step 1 either no adequate models have been identified, or additional ones are needed to cover for a specific exposure scenario, the assessor should then look for appropriate model available in the simple database model as outlined in the table below. The table is an overview of the available recommended models for estimating exposure of non- professional users during application tasks.

For the exposure scenarios for non-professional users as indicated in Section 3.1, ConsExpo FactSheets provide a good source for the generation of exposure scenarios. In this respect ConsExpo 4.1 can be the first choice for such scenarios when estimating the exposure potential for this task.

Depending on the exposure scenario description of tasks and intended uses the assessor should select the realistic worst case exposure modelling approach by selecting the most suitable model.

|  |  |
| --- | --- |
| **Exposure model Name** | **Link** |
| In-situ application of wood preservatives with brush | [Available in Section](#_In-situ_application_of) 6.2 |
| Brushing and roller painting of antifouling paint on underside of small boats, outdoor | [Available in Section](#_In-situ_application_of) 6.2 |
| Spray Application: Spraying liquid (ready for use products) indoors in overhead direction | [Available in Section](#_In-situ_application_of) 6.2 |
| Spray Application: Spraying liquid (ready for use products) outdoors, in forward and downward direction | [Available in Section](#_In-situ_application_of) 6.2 |
| Spray Application: Spraying insecticide indoors on soft furnishings, carpets, skirting board and shelves | [Available in Section](#_In-situ_application_of) 6.2 |
| Spray Application: Spraying incecticide in a small sealed room with trigger sprays, pumped sprayers and aerosol cans | [Available in Section](#_In-situ_application_of) 6.2 |

#### Post Application Non-Professional Users

**Step 1**

The assessor should consult the following overview table that contains the list recommended models for non-professional users regarding post application tasks.

Depending on the exposure scenario description of tasks and intended uses the assessor should select the realistic worst case exposure modelling approach by selecting the most suitable model.

|  |  |
| --- | --- |
| **Exposure model Name** | **Link** |
| Cleaning (i.e. washing out) of a brush model | Primary Exposure Paint Model “Washing out of a brush – Section 9 (HEEG opinion) |
| Model for Dipping of Hands/forearms in a diluted solution | Primary Exposure – Model for dipping of hands/forearms in a diluted solution Section 9 HEEG Opinion |

**Step 2**

In case in Step 1 either no adequate models have been identified, or additional ones are needed to cover for a specific exposure scenario, the assessor should consult the overview table on generic models and mathematical models available in Section 3.2.3 to identify appropriate models to calculate the exposure from post application tasks.

For the exposure scenarios for non-professional users as indicated in Section 3.1.2, ConsExpo FactSheets provide a good source for the generation of exposure scenarios. In this respect ConsExpo 4.1 can be the first choice for such scenarios when estimating the exposure potential for this task.

For a number of these models expertise is required to address applicability of the model for a specific exposure scenario. It is important that the exposure parameters used (conditions of use) are explicitly mentioned within the exposure assessment. In addition, independent of the model used, the default parameters outlined in Section 2 of this document should be used instead of any other defaults available within specific computer based models.

### Overview of Exposure Models

For the estimation of exposure for primary exposure, a number of modelling approaches are available. The principles of these approaches are available within Chapter 3 of the ECHA Guidance for Biocides (Part B, Human Health).

In this section, the following tables provide an overview of available generic models, computer based and mathematical models with an indication of applicability for type of users (professional versus non-professional), certain limitations and applicability for route of exposure.

This overview is non-exhaustive and the assessor should consult further the short description of these models provided in Appendix I (Section 6 of this document) with links to actual sources where the models can be accessed.

In addition, for the actual use of the models expertise is needed especially in the case where the methodology behind the exposure calculations is complex or not directly available for the user.

The models will calculate the exposure estimate and a number of determinants/factors from the exposure scenario (conditions of use) will be needed in most cases as input parameters to the model.

#### Generic Exposure Data Sources / Models

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Route** | | | **Primary Exposure** | | **Comments** | **Limitations** |
| **Exposure Estimation Tools** | **Dermal** | **Inhalation** | **Oral** | **Professional** | **Non-Prof** |  |  |
| Simple Database Models Section 10 (of this document) | x | x |  | x | x |  | Uncertainties for each of the generic models is available in Appendix I, 5.1 (of this document) |
| BEAT | x | x |  | x |  |  |  |
| EMKG-Expo-Tool |  | x |  | x | x | Scientifically conservative tool for tier 1 applications | -Not suited for gases  -Not suited for CMR substance  -Not suited for aerosols of unknown composition |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Route** | | | **Primary Exposure** | | **Comments** | **Limitations** |
| **Exposure Estimation Tools** | **Dermal** | **Inhalation** | **Oral** | **Professional** | **Non-Prof** |  |  |
| Stoffenmanager |  | x |  | x | x |  | -Not suited for gases  -Not suited for fibres  -Not suited for particles from articles  -Not suited for hot work operations |
| RISKOFDERM | x |  |  | x | x | Assessment of potential dermal exposure only | -Not suited for scenarios with use of PPE  -Not suited for very volatile substances (>500Pa) |
| ART |  | x |  | x | x | Suitable for exposure assessment from solids or liquids; expert judjment required for input parameters and use of the tool. | -Not suited for fumes or gases |
| EASE | x | x |  | x | x |  | This model should not be used for dermal exposure assessment (see Opinion on Loading of products into vessels in Appendix V Section 9) |
| AOEM | x | x |  | x | x | Use for typical outdoors scenarios  Mixing& Loading and spraying scenarios included; the model is implemented in the "EFSA Calculator" http://www.efsa.europa.eu/en/efsajournal/pub/3874.htm. |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Route** | | | **Primary** | | **Comments** | **Limitations** |
| Model Name | Dermal | Inhalation | Oral | Professional | Non-Professional |  |  |
| ConsExpo | x | x | x | x (see also Note a) | x |  |  |
| SprayExpo Model | x | x |  | x | x | Inhalative & Dermal exposure from indoor spray applications | -Not suited for long term exposure from emissions of vapours from treated surfaces  -Only for products with non-volatile actives dissolved in solvent with known volatility  -Can underestimate dermal exposure from random spatteringor direct contact |
| SKINPERM | x |  |  |  |  | See Note b |  |
| EUROPOEM | x | x |  | x | x |  |  |
| DEPOSITION | x |  |  | x | x | See Note b |  |
| AIRCHANGE CONCN |  | x |  |  |  | See Note b |  |

#### Mathematical Exposure models

**NOTE a**: *According to a HEEG opinion (see section 9) ConsExpo can be considered for the estimation of exposure for professional users under certain conditions (for more details see Section 9).*

**Note b**: *The SKINPERM, DEPOSITION and AICHANGE CONCN are listed here only for information and originate from the TNsG 2002 version of the Biocides Guidance; there is no experience from their use for the exposure assessment of Biocides and therefore they would not be recommended for use for the time being.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Route** | | | **Primary** | | **Applicability** | **Limitations** |
| Model Name | Dermal | Inhalation | Oral | Professional | Non-Professional |  |  |
| US EPA **E-FAST (CEM)** | x | x |  |  |  | See 6.13.12 | See 6.13.12 |
| US EPA ChemSTEER | x | x |  | x |  | See 6.13.12 | See 6.13.12 |
| US EPA Multi-chamber concentration/exposure mode MCCEM |  | x |  |  |  | See 6.13.12 | See 6.13.12 |
| US EPA Wall Paint Exposure Assessment Model (WPEM) |  | x |  | x | x | See 6.13.12 | See 6.13.12 |
| US EPA Pesticides SOPs (residential exposure) | x | x | x |  |  | See 6.13.12 | See 6.13.12 |
| US EPA PHED | x | x |  | x | x | Agricultural applications; Application of granules | See 6.13.13 |
| US EPA SHEDs | x | x | x | x | x | aggregate exposure | See 6.13.13 |
| US EPA Lifeline | x | x | x |  |  | aggregate exposure | See 6.13.13 |
| US EPA Calendex | x | x | x |  |  | Non dietary exposure assessment | See 6.13.13 |
| US EPA CARES/REx | x | x | x |  |  | aggregate exposure | See 6.13.13 |

***Note:*** *when using models from US sources the user should consided adaptation of the data to align with the principles of exposure assessment used for BPR purposes (e.g. use of 75th or 95th percentiles for BPR exposure assessment versus geometric mean in US exposure assessment tools)*

#### Reverse Reference Scenario

The reverse reference scenario is an option to consider when no suitable modelling approach is available or when some degree of confirmation for the exposure levels estimated is needed. It can be used both for professional and non-professional users’ exposure assessment; however for occupational exposure assessment its use is recommended when only one pathway of exposure is possible (dermal or inhalation exposure). The details on reverse reference scenario, including a worked example, are provided within Chapter 3 (Part B ECHA Biocides Human Health Guidance).

## Refinement Options

If risk is identified for a specific exposure scenario, the assessor should consider refinement options.

For primary (direct) exposure assessment, a number of options are available that either deal with exposure controls, or higher tier methodologies.

It is recommended that when a risk is identified for a specific exposure scenario that the assessor does not attempt to refine only the exposure assessment but also consider the hazard component of the risk assessment (e.g. derivation of reference values AELs, derivation of dermal absorption value).

In addition, refinement elements also include:

* Refinement of conditions of use only if applicable and full justified in a comprehensible way (for example duration, frequency etc)
* Refinement of parameters or models used in case they provide overconservative values.
* Generation of exposure data (measurement studies)

The above should also be seen together with higher tier methodologies (section 3.3.2) aiming at understanding the source of uncertainty behind the exposure estimate.

### Exposure Controls

The Guidance provided in Chapter 3 of Part B (ECHA Biocides Human Health Guidance) regarding exposure controls should be read together with this section.

There are options for exposure controls that assessors can invoke, to abate primary and secondary exposure. In order of priority according to Dir. 98/24/EC, art.6, para.2, the options to consider in Tier 2 exposure assessment are:

* Structure related
* Engineering
* Administrative
* Personal

#### Structure related control of exposure

This applies to residential environments and workplaces alike. Structure related control means the reduction of exposure by inhalation afforded by general ventilation or segregation. For the purposes of biocidal product authorisation:

* general ventilation assumptions will apply in mathematical exposure modelling of primary and secondary exposure (in residential environments) by inhalation;
* general ventilation assumptions will generally not apply to database exposure estimates or to workplace primary inhalation exposure estimates.

However, in some workplaces ventilated refuges will be provided to establish segregation between the worker and the biocidal product.. Such issues may be factored into estimates of primary exposure by inhalation, but good data on the pattern of use and the degree of protection will be required.

#### Engineering control of exposure

This applies to workplaces only. The listing provided here is non-exhaustive.

Engineering control in industrial processes means the abatement of exposure by local exhaust ventilation at the point of emission, or by containment in pipework or other systems from which minor emissions only are anticipated. For the purposes of biocidal product authorisation:

* local exhaust ventilation can be assumed to reduce inhalation exposure to some degree*. It is recommended that when LEV is specified as control of exposure justification on the reduction factor is provided. The table below from Fransman et al (2008) provides a list of average efficacy values for risk management measures including LEV. This table can be consulted as default reduction factor of inhalation exposure with the implementation of such measures. Before applying a default value from this table, it should be checked that LEV is not already taken into account in the model or study used for exposure assessment. Within exposure models recommended in this document, specific LEV reduction factor is provided and can be used when the specific model is applied for estimation of exposure for a specific task.*)
* containment is assumed to reduce inhalation exposure by a factor of 100;

containment is assumed to eliminate dermal (bare hand) exposure, except for loading (connnecting lines), sampling and maintenance operations.

The table below presents the estimated efficacy values (with a random effect of sampling ID) associated with each RMM category and the 95% confidence intervals.

*The table is taken from: Development and Evaluation of an Exposure Control Efficacy Library (ECEL); WOUTER FRANSMAN\*, JODY SCHINKEL, TIM MEIJSTER, JOOP VAN HEMMEN, ERIK TIELEMANS, HENK GOEDE; Ann. Occup. Hyg., Vol. 52, No. 7, pp. 567–575, 2008*

Additional details on the estimation of the presented values can be found in the original paper.

These values can be considered for use where relevant using expert judgment.,

**Table:** Estimated average efficacy values and 95% confidence intervals for individual RMMs. Sampling ID was included as random effect in the mixed-effect models

|  |  |  |  |
| --- | --- | --- | --- |
| **RMM** | **na** | **Estimated**  **efficacyb**  **(%)** | **95% confidence**  **interval (%)** |
| **Enclosure** | 14 | 50 | 4 to 74 |
| Complete | 3 | 86 | 30 to 97 |
| Partial | 6 | 23 | -103 to 70 |
| **LEV** | 280 | 82 | 78 to 84 |
| Exterior | 65 | 81 | 75 to 86 |
| LEV + enclosure | 9 | 86 | 69 to 94 |
| Integrated | 133 | 87 | 84 to 90 |
| Mobile | 4 | 61 | -28 to 88 |
| Vapour collection | 19 | 64 | 23 to 83 |
| **Specialised ventilation** | 14 | 87 | 73 to 94 |
| Specialised booth | 1 | 94 | 37 to 99 |
| Clean-zone worker | 6 | 86 | 64 to 95 |
| Miscellaneous | 7 | 85 | 47 to 96 |
| **General ventilation** | 42 | 43 | 17 to 61 |
| Natural | 9 | 31 | -56 to 70 |
| Mechanical | 31 | 46 | 17 to 65 |
| **Suppression techniques** | 69 | 83 | 77 to 88 |
| Wet suppression | 32 | 84 | 75 to 89 |
| Capture sprays | 25 | 88 | 80 to 93 |
| Stabilization | 12 | 58 | -3 to 83 |
| **Separation of workers** | 14 | 87 | 71 to 94 |
| Complete | 9 | 90 | 75 to 96 |
| Partial | 5 | 71 | -31 to 94 |

a In case the RMM subcategory was not clearly described in the published paper, no RMM subcategory was recorded.

b Back-transformed regression coefficient.

#### Administrative control of exposure

This applies to residential environments and workplaces in different ways.

Residential administrative control means the exclusion of residents from treated spaces until aerosols have dispersed and surfaces are dry. All subsequent exposure is secondary.

Workplace administrative control has several levels:

* proper supervision and training of workers could lead to the selection of a percentile from databases other than the realistic worst case; for the correct selection of exposure percentiles more information can be found within Appendix 3-2 of Chapter 3 (Volume B, Human Health) of the Guidance for Biocides
* procedural plans, event planning (such as accidental spill procedures) and permits to work for operations such as fumigation and maintenance should lead to less precautionary assumptions being taken in deterministic estimates

"Safe systems of work", "emergency procedures" and “permits to work” mean that hazardous biocides can used with minimum risk. For example, the risk is likely to be high in operations such as maintenance, and a Permit to Work is needed. The permit sets out the steps to assure that situations are made safe before work starts, remains safe, and includes standby rescue and recommissioning procedures. Another example would be the use of a toxic fumigant to disinfect a Biological Agent Containment Level 3 facility.

#### Personal protective equipment

Personal protective equipment (PPE) means the abatement of primary exposure by the user taking specific steps to limit inhalation and skin exposure. PPE is relevant to primary exposure only. It is noted that in principle Personal exposure controls (e.g. personal protective equipment) should not be assumed even in Tier II refinement step for non-professional users (consumers). An exception to this can be the use of antifouling paints for amateur use. It has been decided by the biocides CAs that in Tier II refinement, non-professional uses of products containing antifouling biocides are allowed if the products are sold with suitable gloves that decrease the risk to an acceptable level.

**Residential environment**

While residents may wear coveralls, gardening or kitchen gloves, or even a dust mask, such usage cannot be assured and must not be assumed in exposure estimation. For example, amateur users wearing sandals and shorts when applying antifoulants to leisure craft is the rule rather than the exception in warm weather. At the most, a user may be expected to wear a long shirt, long trousers and footwear, irrespective of any label stipulation.

For inhalation exposure, no exposure reduction should be assumed.

For dermal exposure, actual dermal exposure is assumed as 100% of potential dermal exposure because the typical minimal clothing worn by non-professionals should be shorts and short-sleeve shirts, shoes, and socks. The use of long sleeved shirt and trousers can only be a risk mitigation measure and the applicability should be discussed on a case by case basis, also taking into account the product type (see further details within Table B of this section relevant default values and corresponding recommendation of HEAdhoc “consumer use of biocidal product and protection from typical clothing”

**Workplaces**

Workers may use PPE at work. PPE includes respirators, gloves, footwear and work clothing. Many of these are subject to EN design and performance criteria, though assessors need to take great care in interpreting data such as protection factors and permeation / breakthrough data.

##### Respiratory protective equipment

Our current knowledge for estimating reduction factors through the wearing of adequate PPE/RPE, in an appropriate way, is incomplete. Agreeing the meaning of the terms ‘adequate’ and ‘appropriate’ is also a long way off. A paper by Gerritsen-Ebben et al. (2007)[[1]](#footnote-1) investigated current views and facts on the use of default values for the estimation of the effectiveness of PPE in exposure reduction in the registration processes for biocides; this paper is commended to the reader. Whilst we can acknowledge there are difficult issues, a way forward, to ensure a consistent and transparent approach to the selection of protection factors, is required.

Tables A and B below pull together current thoughts on default values that should be used in exposure calculations.

Assigned Protection Factors (APF) for different designs of RPE are well documented and have been introduced, with general acceptance, to quantify effectiveness of RPE. In Table 1 the bold typed numbers are the default values to be used. When no bold number is indicated for a specific type of RPE within the table, it is recommended to use the respective lowest indicated APF.

The derived exposure value has to be divided by the corresponding APF (for the specific exposure scenario where a specific RPE is used) to get the reduced figure that will be used as actual inhalation exposure estimate.

**Table A:** Overview of ‘Assigned Protection Factors’ for filtering devices

(British standard, American standard and German standard)

| **Mask type** | **Filter type** | **BS 4275** | **ANSI Z88.2** | | **BGR 190** |
| --- | --- | --- | --- | --- | --- |
| Filtering half masks | FFP1 | 4 |  | | 4 |
| FFP2 | 10 |  | | 10 |
| FFP3 | 20 | **10** | | 30 |
| Half or quarter mask and filter | P1 | 4 |  | | 4 |
| P2 | 10 |  | | 10 |
| Gas | 10 | 10 | | 30 |
| GasXP3 | 10 | 10 | | 30 |
| P3 | 20 | **10** | | 30 |
| Filtering half masks without inhalation valves | FMP1 | 4 |  | |  |
| FMP2 | 10 |  | |  |
| FMGasX | 10 | 10 | |  |
| FMGasXP3 | 10 |  | |  |
| FMP3 | 20 | **10** | |  |
| Valved filtering half masks | FFGasXP1 | 4 |  | |  |
| FFGasX | 10 | 10 | |  |
| FFGasXP2 | 10 |  | |  |
| FFGasXP3 | 10 | 10 | |  |
| Full face masks and filter | P1 | 4 |  | | 4 |
| P2 | 10 |  | | 15 |
| Gas | **20** | 100 | | 400 |
| GasXP3 | 20 |  | |  |
| P3 | **40** | 100 | | 400 |
| Powered filtering devices  incorporating helmets or hoods | TH1 all types | **10** | 100 | | 5 |
| TH2 all types | **20** | 100 | | 20 |
| TH3 (semi)hood/ blouse | **40** | 1000 | | 100 |
| Power assisted filtering devices incorporating full, half or quarter masks | TM1 (all types) | **10** | 50 (Half face) | 100 (full face) | 10 |
| TM2 (all types) | **20** | 50 (Half face) | 100 (full face) | 100 |
| TM3 (half face) particle, gas or combined filters | **20** | 50 | |  |
| TM 3 (full face) gas or combined filters | **40** | 1000 | | 500 |

##### Protective clothing – Dermal Protection

Compared to respiratory protection, determination of APFs for protective clothing and gloves is much more complex. This is in part due to the multi-compartment origin of dermal contamination and the effect of workers’ behaviour. The assessment of protective properties for PPE (including gloves) relies on laboratory test data on penetration, permeation rates and break-through times. Hand exposure inside protective gloves is common. The mechanisms for this are:

* permeation through the glove fabric;
* penetration of the glove (drips, flaws, worn gloves); and
* human factors (taking gloves off, contaminating the hands, then putting the gloves back on).

*Exposure to hands when wearing gloves*

HSE data (Garrod et al., Ann. Occ. Hyg., 45(1):55-60, 2001) show that protective gloves do have the capacity to reduce exposure to the hands but are nonetheless fallible. The distribution of in-glove exposure to hands is independent of substance or task and relates more to the age of the glove and the number of times the glove is removed and replaced during a work operation. In this sense, quality procedures which require operators to remove gloves frequently to record information may play a significant role in increasing the potential for exposure.

**Table B** Default protection factors

|  |  |  |  |
| --- | --- | --- | --- |
| **Description** | **Default Protection Factor (%)** | **Source/Reference** | **Notes** |
| **No PPE, gloves or clothing which could afford protection** | 0 | TNsG, January 2008, p. 27 | The TNsG informs that Tier 1 human exposure assessments ‘must not take account of exposure reduction measures such as personal protective equipment’. |
| Double coveralls | 99 | TNsG 2002, Part 3, p. 60 | Usually this is for the professional spraying of antifoulants where the spraymen often wear two sets of coveralls, one over the other. In practice this is a long-sleeve, long-leg cotton coverall with a second coverall with a hood worn over the cotton coverall. With exposure to wet paint, spray mist or solvents, this outer coverall should be chemically resistant. |
| Impermeable coveralls | 95 | TNsG 2007, Table 2, p. 19  TNsG 2002, Part 2, p. 36  TNsG 2002, Part 3, p. 60 | The actual penetration figure is 4 % (TNsG 2002, Part 3, p. 60).  The protection is 95 % where a challenge is "considerable" (i.e. at or above 200 mg in-use product/minute) on the whole of the body - not including the hands (TNsG 2002, Part 2, p. 36).  ’Impermeable’ coveralls should provide a high degree of protection against heavy contamination by being relatively resistant to the penetration of the biocide through the material of which the coverall is made. |
| Coated coveralls  (coveralls designed to protect against spray contamination such as chemical protection clothing of type 6) | 90 | TNsG 2002, Part 2, p. 36  User Guidance, version 1, 2002, p. 42 | This value was used in a worked example for vacuum-pressure/double vacuum impregnation of a wood preservative.  A 90 % protection factor has been generally used for wood preservatives where the main challenge is from contact with preservative wet wood.  Body exposure occurs mostly through the coverall material. This is usually so for PT 8, post-application exposure, but this is not necessarily the case for other PTs. |
| 80 | TNsG 2002, Part 2, p. 36  For insecticide assessment: TNsG 2002, Part 3, p. 71 | The protection is 80 % where a challenge is "light" (i.e. less than 200 mg in-use product/minute) on the whole of the body - not including the hands (TNsG 2002, Part 2, p. 36).  An 80 % default protection factor has been generally used for insecticides where they are applied by spray.  Body exposure occurs through the coverall material, but may occur also through seams and at the wrist and neck. This is usually so for PT 18, exposure during application, but other scenarios are possible for other PTs. |
| Uncoated cotton coveralls (dry) | 75 | TNsG 2007, Table 2, p. 19 | Only for dry substances. Cotton coveralls may offer little or no protection from wet substances and may lead to increased rather than reduced dermal exposure if the challenge is from a wet substance by absorbing the liquid challenge and holding it next to the skin. |
| Protective gloves: For use of protective gloves, it is assumed that the worker has a good occupational hygiene approach in his/her behaviour and uses, where appropriate, gloves with long sleeves to prevent exposure via the openings around the wrists. It is also assumed that gloves are taken off carefully, without touching the outside of the contaminated gloves with bare hands. | | | |
| **Description** | **Default Protection Factor (%)** | **Source/Reference** | **Notes** |
| Protective gloves | 90  for challenges by a liquid | TNsG 2007, Table 2, p. 19  HEEG opinion agreed at TM I 2008 | 1) When **potential hand exposure data** are available, a factor of 10(90 % reduction of exposure by gloves manufactured from appropriate material) can be used as a reasonable and conservative default value to convert the potential to actual hand exposure when using appropriate gloves.  2) When only **actual hand exposure data** are available, it should not be attempted to convert it to potential hand exposure. The data for actual hand exposure can be used for the exposure assessment with the provision that the users will have to wear gloves. This approach needs to be followed in the case of products that cause skin irritation and/or sensitisation and warrant the wearing of gloves.  If there is a justified need to convert actual hand exposure data to potential hand exposure (e.g. when the same scenario needs to be used for assessing a less toxic substance or no gloves can be used) a multiplication factor of **100** should be used for the conversion of actual to potential hand exposure. This multiplication factor of 100 is conservative in order to take into account uncertainties over the nature of the gloves to be worn, e.g. permeability of the glove material and glove design. In cases where there are data available in the model with respect to the use of new gloves, a lower percentile and the data on new gloves may be used. This will be a case-by-case decision. |
| Protective gloves | 95  for challenges by a solid | Draft EFSA Guidance |  |
| Protective gloves – new gloves for each work shift | 95 | TNsG 2002, Part 2, p. 194  Annals of Occupational Hygiene 45 (1): 55-60, 2001 (Table 1, p. 59) | Using new gloves reduces hand-in-glove exposure to approximately half (arithmetic mean factor of 0.52).  Therefore, for professional users where new gloves are changed at the beginning of each work shift, the default protection factor of 95 % can be used for the gloves. |
| Non-professionals wearing long-sleeved shirt and trousers or skirt with shoes – no gloves worn | 50 | TNsG 2007, Table 2, p. 19  TNsG 2002, Part 2, p. 34 – Options for exposure reduction and personal protective equipment (PPE) and quoted on p. 71 of Part 3 | According to recommendation of HEAdhoc the use of long sleeved shirt and trousers can only be a risk mitigation measure. This protection factor can be used for non-professionals applying a dry substance. This protection value can also be used for challenge by a liquid formulation where contamination is judged to be relatively light (e.g. from using an aerosol canister or application by a trigger spray). Wearing long-sleeved shirt and trousers reduces dermal body exposure without hands; therefore dermal exposure values have to be given for hands and body separately. |
| Non-professionals wearing working gloves |  |  | There is currently no agreed protection factor. In analogy with wearing long-sleeved shirts and trousers or skirt with shoes, the wearing of working gloves might be considered as a risk mitigation measure too with the use of an appropriate protection factor. |

**Prevention of accidents, Safe systems of work and “Permit to Work” stipulations**

For applications, where an increased risk of a severe accident could exist for the user or for others, suitable measures for prevention of these accidents should be considered. These measures may involve, e.g., information requirements, posting of warning signs, setting up of a danger area or access restrictions. In this respect, it is important to note that national regulations may be in place for some applications (e.g., for fumigations or pest control).

The fact of hazard of a biocide active substance can be countered through safe use - Safe Systems of Work, and for potential high-risk situations, Permit to Work procedures. The Safe System of Work is a procedure laid down for conducting a continuing operation at minimum risk. Where that minimum remains unacceptably high, most often in individual operations such as maintenance, a Permit to Work procedure is needed. This permit sets out the steps to assure that situations are made safe before work starts, remains safe, and includes recommissioning. The Permit specifies the site and process specific actions necessary to achieve the required degree of safety. An example would be the use of a highly toxic fumigant to disinfect a Biological Agent Containment Level 3 facility. These stipulations are relevant only for professional users.

Measures found adequate für accident prevention or for control of risks in Tier 2 assessment should be stipulated as requirements in the product authorisation.

### Higher Tier Methodologies

Higher tier methodologies are described in Chapter 3 of ECHA Biocides Human Health Guidance document. These methodologies aim to address uncertainty with more qualitative terms and should be further explored together with other refinement options.

# Secondary (indirect) Exposure

## Exposure Scenarios for Secondary (Indirect) Exposure Assessment

Secondary (indirect) exposure can occur from the use of biocidal products within residential environment or from the use of articles treated with biocides.

The populations that need to be considered within this part of the exposure assessment include:

* General Public (residents and/or bystanders with subcategorization to adults and children)
* Professional or non-professional users (when the exposure is not from the actual use of the product but as a result of a task where the users is exposed to the biocide substance as consequence e.g. sanding wood that has been treated with wood preservative)

It is important that the conditions under which the secondary exposure occurs are clearly indicating the duration of the exposure under realistic worst cases. This enables the identification of acute, short term or long term exposure conditions where the exposure estimate will be compared with the corresponding reference value (AEL).

### Identification of Secondary Exposure Scenarios

In this section a number of resources and recommendations on the types of secondary exposure scenarios are provided.

For some product types specific secondary exposure scenarios have been developed and are listed in Section 4.1.3. For these scenarios the exposure estimation is further described within Section 4.2.1.

The assessor should consult both sections 4.1.1 and 4.1.3 in order to decide which scenarios are expected to lead to realistic worst case secondary exposure.

Further to the essential information needed for primary exposure assessment (see Section 3) the following elements are required for the generation of the secondary exposure scenarios:

|  |  |  |
| --- | --- | --- |
| **Data requirement Priority Comment** | | |
| Secondary exposure | | |
| - population (acute phase) | Essential | include mode and likelihood of exposure |
| - population (chronic phase) | Essential | include mode and likelihood of exposure |
| - removal of product | Desirable | include mode of exposure |

For all relevant populations the four routes of exposure need to be taken into account for each Product type secondary exposure scenario (oral, inhalation, dermal, eye).

Secondary exposure can occur via:

* **Residential Environment (Treated area and/or surfaces)**
* **Treated articles**
* **Dietary sources**

For the dietary component of secondary exposure see section 4.1.5.

The table below provides a general overview of the types of scenario that need to be considered for **each population** and product type in relation to exposure from residential environment (treated area/surfaces) and treated articles.

|  |  |  |  |
| --- | --- | --- | --- |
| **Route** | **Scenario Type** | **Residential Exposure** | **Treated Articles** |
| **Oral** | *Mouthing* | x | x |
|  | *Direct Ingestion* | x | x |
|  | *Hand to mouth contact* | x | x |
| **Inhalation** | *Release from solid* | x | x |
|  | *Release from liquid* | x | x |
|  | *Exposure during/after fumigation* | x |  |
| **Dermal** | *Rubbing off/Leaching from solid product* | x | x |
|  | *Direct skin contact during application* | x | ? |
| **Eye** | *Leaching from solid product* | x | x |
|  | *Application of semi-solid product* | x | x |
|  | *Evaporation from solid product* | x | x |
|  | *Hand-eye contact* | x | x |

Within section 4.1.4 guidance on how to distinguish between a biocidal product and a treated article is provided, as well as some additional considerations for the secondary exposure from treated articles. The whole life-cycle of a biocidal product including service-life of a treated article should be taken into account.

However the principles of exposure assessment both for residential and treated articles are the same and presented together in this section.

The table below provides an overview of possible secondary exposure scenarios that might be considered when doing risk assessments for specific biocidal products in view of their uses within a certain Product Type.

The list is by no means exhaustive nor does it contain the possible pattern (duration and frequency) of exposure, nor contains a possible approach for assessing the exposure levels.

The table should be consulted together with the table in section 4.1.2 (Overview of RIVM reports and Factsheets for Secondary Exposure Scenarios). The overall scenarios mentioned there would also include the default parameters to be used in the exposure estimation.

It is suggested to use these scenarios to cover the most relevant secondary exposure that may occur using products per Product Type.

**Table:** Possible (non-exhaustive) list of secondary scenarios per Product Type (only positive relations are indicated: †).

| **Product type** | **Secondary scenario** | **Route(s) of exposure** | **Exposed population(s)** | | |
| --- | --- | --- | --- | --- | --- |
|  | | | Professionals | Non-professionals | |
|  | Adults | Children |
| ***Disinfectants & general biocidal products*** | | | | | |
| **1**: Human hygiene products  skin disinfectants | Residues in Air | Inhalation | **†** | **†** | **†** |
| **2**: Private area and public area disinfectant  private area  private cleaning  professional cleaning  medical equipment  swimming pools  air conditioning  chemical toilets  laundries  waste | Swimming in swimming pool/fountain water  Contact with treated surfaces, equipment or materials  Re-entry | Dermal, Oral, Inhalation  Dermal, Inhalation  Dermal, Inhalation | **†**  **†**  **†** | **†**  **†** | **†**  **†** |
| **3**: Veterinary hygiene products  domestic animals (feet, udder)  animal housing  milking equipment | Re-entry | Dermal, Inhalation | **†** |  |  |
| **4**: Food and feed area disinfectants  agriculture  food-processing industry  food retail shops | Residues in food  Touching/mouthing treated surfaces  Re-entry | Oral  Dermal, Oral  Dermal, Inhalation | **†**  **†** | **†**  **†** | **†**  **†** |
| **5**: Drinking water disinfectants  waterworks  private use | Residues in drinking water | Oral, Dermal, Inhalation (showering) |  | **†** | **†** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Preservatives*** | | | | | |
| **6**: In can preservative  detergents (laundry, surface, dishwash)  water based paint, dyes, ink  polishes, lubricants | Paint trays and application equipment (brushes, rollers) left in room where product is being applied ; Person entering and staying in room that has just been painted  Person comes into contact with wet treated material  Food is placed directly onto surface that has just been cleaned and is still wet  Mouthing of treated paper and paint chips | Dermal, Inhalation  Dermal  Dermal  Ingestion |  | **†**  **†**  **†**  **†** | **†**  **†**  **†**  **†** |
| **7**: Film preservatives  paints  plastics  sealants, fillers & other products | Person entering and staying in room that has just been painted  Person comes into contact with wet adhesive/sealant (not commonly used)  Mouthing of treated objects | Inhalation, Dermal  Dermal  Ingestion |  | **†**  **†** | **†**  **†**  **†** |
| **8**: Wood preservative  industrial processes  surface treatment | Sawing/sanding of treated wood  Mouthing of treated woods (chips)  Playing on treated wood structures | Inhalation, Dermal  Ingestion  Dermal | **†** | **†** | **†**  **†** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 9: Fibre, leather & polymerised materials  textiles  leather  paper  rubber and polymerised materials | Wearer of sport/outdoor clothing, which has been treated    Cleaning of tanks used to house hides before tanning process  Worker is exposed during restoration work to a property that has cavity wall insulation  Library archivist working with books that have been treated for storage under moist conditions  Mouthing of treated materials  Touching of treated materials (wine labels, all types of polymers which contain plasticisers=require preservation)  Hand to mouth contact | Dermal  Dermal  Inhalation  Dermal  Oral  Dermal  Oral | †  †  †  †  † | †  †  † | †  †  †  † |
| 10: Masonry preservative | Maintenance worker is undertaking remedial work to building that has recently been treated with preservative  (skin) contact with treated surfaces and inhalation of residues from treated areas | Dermal  Dermal, Oral, Inhalation | † | †  † | † |
| 11: Liquid cooling and processing systems  once-trough systems  recirculating systems | Biocide is added to wet cooling system, passer by is exposed to biocide due to windage  Contact with treated water (decorative fountains) | Inhalation  Dermal, Oral, Inhalation | † | †  † | †  † |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 12: Slimicides  wood and paper pulp  oil extraction / fuel storage | | Cleaning out tanks that have been used to store pulp  Mouthing of treated paper/carton (chips) | | Dermal  Oral | | | † | |  | | † |
| 13: Working or cutting fluid preservatives | | Transfer of machined metal from lathe to storage area  Handling petrol or car motor oil | | Dermal  Dermal | | | † | | † | |  |
| ***Pest control products*** | | | | | | | | | | | |
| 14: Rodenticides | | Collecting/contact with (old) bait  Collecting/contact with dead rodents | | | Dermal, Inhalation  Dermal  Oral | **†**  **†**  **†** | | **†**  **†**  **†** | | **†**  **†**  **†** | |
| **15**: Avicides | | Taking treated grain | | | Oral |  | |  | | **†** | |
| 16: Molluscicides | | Contact with treated surface  Picking grains | | | Oral, Dermal |  | | **†** | | **†**  **†** | |
| 17: Piscicides | | Swimming in water treated with piscicides | | | Dermal, Oral |  | | **†** | | **†** | |
| 18: Insecticides, acaricides and products to control other anthropods   * sprays * gases * flypaper * paints * decoy boxes * powders | | Collecting strips/cassettes, impregnated mats, -papers, -stickers  Re-entry of treated spaces  Crawling on treated surfaces | | | Dermal, (Inhalation)  Inhalation  Dermal, Oral | **†**  **†** | | **†**  **†** | | **†**  **†**  **†** | |
| 19: Repellents and attractants   * on skin * not directly on skin | | Mouthing of repellents  Re-entry treated spaces  Touching treated surfaces | | | Oral  Inhalation, Dermal  Dermal | **†**  **†** | | **†**  **†** | | **†**  **†**  **†** | |
| ***Other biocidal products*** | | | | | | | | | | | |
| 20:Control of vertebrates/vermin | Pickup and removal of contaminated animal carcasses  Taking treated grain | | Dermal  Oral | | | † | | † | | †  † | |
| 21: Antifouling products   * vessels * nets and cages | Abrasion/removal of paint  Contact with treated surfaces | | Inhalation, Dermal  Dermal | | | †  † | | †  † | | † | |
| 22:Embalming and taxidermist fluids | Handling treated corpses, body parts/organs | | Dermal, Inhalation | | | † | | † | |  | |

### Default Parameters for Secondary Exposure Assessment

For each exposure scenario a set of parameters are necessary for the estimation of exposure. The default parameters for human factors as described in Section 2 of this document should be used.

The relevant ConsExpo Factsheets as well as the RIVM report 320005001 / 2004 (Non-food products: How to assess children’s exposure) contain a variety of exposure scenarios with the parameters required for the exposure estimation and should be consulted. The table below provides recommendations regarding which Factsheet or report is relevant for the secondary exposure scenarios from RIVM. The listing is non-exhaustive.

**Table:** Overview of RIVM reports and Factsheets for Secondary Exposure Scenarios

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Biocidal Product Type** | **Scenario** | **ConsExpo Factsheet** | **Adults** | **Children** |
| All product types | Secondary Exposure Scenarios for adults & children | Children Exposure RIVM Report | x | x |
| PT01, PT02, PT06 | Secondary Exposure Scenarios for swimming pool disinfectants | Disinfectants FactSheet | x | x |
| PT05 | Secondary Exposure Scenarios for drinking water disinfectants | Disinfectants FactSheet | x | x |
| PT06, PT18 | Secondary scenarios from Evaporation from strips and cassettes | PestControl FactSheet | x | x |
| PT18, PT19 | Secondary scenarios from Electrical evaporators | PestControl FactSheet | x | x |
| PT19 | Secondary scenarios from Insect repellents | PestControl FactSheet | x | x |
| PT06, PT14, PT18 | Secondary scenarios from Baits | PestControl FactSheet | x | x |
| PT02, PT06, PT14, PT18 | Secondary scenarios from Dusting powders | PestControl FactSheet | x | x |
| PT06, PT07, PT09 | Secondary Exposure for children playing with treated toys, treated materials | Toys FactSheet |  | x |
| Various PTs might be applicable | Secondary exposure from application of cleaning products | Cleaning Products FactSheet | x | x |

In addition within **the Children Exposure RIVM Report** (RIVM report 320005001 / 2004 (Non-food products: How to assess children’s exposure) Tables 2 and 3 provide overview of exposure aspects during age-specific activities and Exposure routes and models in ConsExpo 4.0 respectively. These can be consulted and used where relevant for the generation of exposure scenarios (including the use of default parameters if not available already in Section 2 of this document).

For exposure scenarios where the source of exposure is a treated surface or treated article the following table gives a preliminary list of transfer coefficients that can be used in the exposure estimation for specific exposure scenarios.

**Table:** Transfer coefficients – Dislodgeable residues

|  |  |  |  |
| --- | --- | --- | --- |
| **Substrate** | **Residue** | **Transfer efficiency** | **Reference no.** |
| Painted wood (MDF) | Dried fluid | 3 % | 1 |
| Short pile tufted nylon carpet | Dried fluid | 6 % | 1 |
| Carpet | Powder | <1 % | 4 |
| Nylon carpet | Powder | 1 to 3 % | 5 |
| Carpet | Dried fluid | 9 % averaged | 6 |
| Carpet | Powder | 9 %, 3 % if trodden-in | 8 |
| Rough sawn wood | Dried fluid | 2 % | 1 |
| White smooth glazed tile | Dried fluid | 55 % | 1 |
| Brown rough glazed tile | Dried fluid | 60 % | 1 |
| Non-slip vinyl flooring | Dried fluid | 15 % | 1 |
| Vinyl | Powder | 50 % | 8 |
| Various types of surface | Dried fluids | 8 to 18 % | 2 |
| Smooth surface | Powder | 2 to 6 % | 3 |
| Cotton, knitwear, plastic, wood | Dried fluid | 20 % - dry hand | 7 |
| Cotton, knitwear, plastic, wood | Dried fluid | 30 % - wet hand | 7 |
| Stainless steel | Powder | 70 % - dry hand | 8 |

**References:**

1.Roff and Wheeler, HSL reports IR/ECO/00/11 and IR/ECO/01/02  
2.Houghton, thesis 1997, UK  
3.Brouwer et al., Appl. Occ. Env. Hyg. 14:231-239, 1999  
4.Lu & Fenske, Env. Health Perspect. 107(6):463-467, 1999  
5.Ross et al., Chemosphere 22(9-10):975-984, 1991  
6.Jazzercise data - Ross et al., Chemosphere 20(3-4):349-360, 1990  
7.Fogh et al., Riso-R-1075, Riso Lab, Roskilde, Denmark, 1999  
8.Rodes et al., JEA & E, 11:123-139 (2001)

**Release of active substance from treated article matrix**

The release rate may be constant, or change over time. This depends on the function of the article and the properties of the substance and the article matrix in which it is contained.

For screening purposes, simple worst-case assumptions may be sufficient. The producer/importer of articles that contain substances intended to be released should have more detailed, relevant information on estimating the release rate and the total amount released from their articles.

Two main possibilities are distinguished:

* The release is controlled by the user of the article (e.g., release of ink from a pen) and therefore dependent on use frequency and use time per event. The release is constant over the time of use to ensure its function.
* The release is controlled by the matrix of the article, e.g. scented objects. The release is declining over time because the total amount of substance in the object declines over time (usually approximated by first-order release kinetics).

The release rate of a substance from an article can be expressed on a weight basis (mg.kg-1.d-1) or on a surface basis (mg.m-2.d-1), depending on the type of substance and use characteristics of the object. Release rates can be

* Based on worst-case assumptions, e.g. all substance contained in the article is released (almost) instantaneously, or released over a period of time representing the service-life, etc. This can be useful for screening purposes.
* Modelled using appropriate software.
* Measured under the relevant conditions.

For some classes of articles, release rates are given in relevant OECD emission scenario documents (e.g., on plastic additives; OECD 2004).

For articles that may be taken into the mouth or sucked on (mouthing) as part of reasonable foreseeable misuse, substances can migrate into saliva or (through it) to skin. This could be limited to a few classes of articles.

In addition, it is recommended to consider where relevant the information on impregnated materials available with the US EPA Residentials SOPs.

The document is available at:

http://www.epa.gov/opp00001/science/residential-exposure-sop.html

where the Residential SOPs (Section 9 on Impregnated materials) can be found.

### Specific Product Type Secondary exposure scenarios

The following exposure scenarios have been developed to address specific cases within a product type and/or population specific behaviours:

* **Exposure of a child to residues in clothes (see section 4.2.2)**
* **Child touching treated surfaces and hand to mouth transfer (see section 4.2.2)**
* **Toddler secondary exposure assessment from non-professional use of antifouling paints (see section 4.2.2)**
* **PT06 An approach to identification of worst case human exposure scenarios for PT06 (see Section 9)**

### Treated Articles

Articles treated with or incorporating biocidal products can lead to general public and environmental exposure if chemical components of the biocidal active substance(s) are released from the article. The exposure from treated articles during service life of the article can constitute a significant exposure to the biocidal active substance. Due to the variety of uses/applications of treated articles by consumers the exposure situation can be complex and should take into account combined exposure from multiple routes of exposure (aggregated exposure from the use of multiple articles at the same time).

The applicant seeking authorisation of a biocidal product or an active substance that is intended to be used within treated articles must identify possible worst case exposure scenarios and submit exposure assessments including use in treated articles. For some PTs, use in treated articles is more likely than for others, for instance material preservatives, because the materials are eventually manufactured into treated articles. The table further down helps to identify PTs where use in treated articles is to be expected.

The definition of treated articles and other frequently asked questions on this topic are further elaborated within the Biocides CA document entitled “Frequently asked questions on treated articles” (CA-Sept13-Doc.5.1.e; Revision 1, December 2014) available on CIRCABC.

#### Assessment elements for treated articles

The assessment of exposure from treated articles, like in case of other situations within secondary exposure assessment, can be performed using model calculations with well supported default and/or measured values or with the use of measured data for the specific treated article.

It is noted that for liquid treated articles that are actually used by a person for a specific task (e.g. falling under preservative type such as in can preservatives), the exposure assessment should be conducted as for other product types (primary exposure for professional and/or non-professional user and secondary residential exposure similar to residential section). In addition, the service-life phase of the treated article has to be taken into account if the expected exposure is significant compared to exposure from the use-phase

For other types of treated articles where the use-phase does not play a significant role for exposure of consumers/bystanders, the exposure is of secondary nature only, i.e. the service life has to be taken into account.

It is recommended that the exposure estimate from a single article is calculated assuming first-time use (i.e. the highest migration rate of active substance from treated article) compared to long term AEL value to account for remaining uncertainty (resulting from the likelihood of having long term exposure to an active substance by overlapping and/or continuous use of multiple treated articles).

#### Identification of treated articles and exposure potential

For the purpose of identification if for a specific product type the exposure assessment should also cover the situation of exposure via treated articles the following table can be consulted as indicative about the possibility of intentional or unintentional presence of a biocidal active substance in a biocidal product and/or a treated article (developed within the Biocides CA document (CA-Sept13-Doc.5.1.e; Revision 1, December 2014).

|  |  |
| --- | --- |
| **PT1** (human hygiene disinfectants) | Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect. |
| **PT2** (disinfectants)  **PT3** (veterinary hygiene products)  **PT4** (food and feed area disinfectants) | Chemical substances or mixture containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.  The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles. |
| **PT5** (drinking water disinfectants) | Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect. |
| **PT6** (preservatives for products during storage) | Biocidal products of PT6 are widely used to preserve products during storage. If the preserved good (a chemical substance, a mixture or an article) itself is placed on the market, it qualifies as a treated article.  An exceptional case are biocidal products (examples given in BPR, Annex V are rodenticides, insecticides, other baits, but in principle applicable to all BPs), preserved with PT6 preservatives, which qualify as biocidal products due to the presence of other biocidal active substances.  Chemical substances and mixtures containing an in-can preservative may however be further used as ingredients in the manufacturing process of other finished goods. In these cases, when such in-can preservative has no further intended biocidal function later in the finished good, the residual presence of preservatives stemming from preserved ingredients should not qualify the finished good as a treated article.  Also solid components used in the manufacture of a complex finished article may incorporate a PT6 preservative. In such cases it needs to be considered whether the preservation is relevant only during storage of this component (and not later in the finished article), or whether the preservation is also beneficial during the storage and possibly use of the finished article. In the first case, the finished article does not qualify as a treated article. In the latter case, the finished article would have to be considered a treated article. |
| **PT7** (film preservatives) | The incorporation of biocidal products of this PT in a chemical substance or mixture or an article generally indicates an intended effect in the final good and such articles would qualify as treated articles. |
| **PT8** (wood preservatives) | Biocidal products of PT8 (wood preservatives) will usually be used with the intention to provide long-term preservation of the wood, which would continue to be effective in the finished good, which would thus qualify as a treated article.  Exceptions to this may be PT8 biocidal products used at saw-mill stage or during initial storage, which only serve to protect the wood at this stage from harmful organisms (e.g. short-term preservation of freshly cut wood with fungicides to prevent the discoloration caused by blue stain forming fungi until further processing), or curative treatments of wood before being manufactured into a finished good. Articles made at a later stage from wood that has undergone such treatments should not be considered treated articles. |
| **PT9** (fibre, leather, rubber and polymerised materials preservative)  **PT10** (construction material preservatives) | The incorporation of biocidal products of this PT in a chemical substance or mixture or an article generally indicates an intended effect in the final good and such articles would qualify as treated articles. |
| **PT11** (preservatives for liquid-cooling and processing systems) | Biocidal products of PT 11 are likely to be used mainly in closed systems. Any traces of such preservatives in finished goods produced in the facility using these biocidal products should be considered unintentional and thus do not qualify the good as a treated article.  However, preserved cooling or processing liquids as well as systems containing them, have to be considered treated articles when they are placed on the market. |
| **PT12** (slimicides) | Biocidal products of PT12 are used in industrial processes to control slime growth at certain stages. Any traces of the AS in a finished good should be considered unintentional and thus do not qualify the good as a treated article. However, any liquids, fluids etc. containing slimicides, when placed themselves on the market, have to be considered treated articles. |
| **PT13** (working or cutting fluid preservatives) | Cutting or working fluids are used at certain stages of the production process. Any traces of such preservatives in finished goods produced in the facility using these biocidal products, should be considered unintentional and thus do not qualify the good as a treated article. However, any working or cutting fluids containing preservatives, when placed on the market, have to be considered treated articles. |
| **PT14-17, 20** (vertebrate pest control) | Any chemical substance, mixture or article containing AS that fall into these PTs are likely to be classified as biocidal products due to their use and the nature of the biocidal effect. |
| **PT18** (insecticides)    **PT19** (repellents and attractants)    **PT21** (antifouling products)  **PT22** (embalming and taxidermist fluids) | Chemical substances or mixture containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.  The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles. |

In addition Appendix I of the CA document on “frequently asked questions on treated articles” provides examples (see table below) that are indicative and refer to the typical categorisation of a listed product group. The assessment of whether any individual product is a treated article, a biocidal product or neither of the two must be made on a case-by-case basis, taking into account all its characteristics.

|  |  |  |
| --- | --- | --- |
| **Biocidal product** | **Treated article** | **Not a treated article** |
| **Disinfecting wipe** | Article in which a disinfectant was incorporated to generate an antimicrobial surface (e.g. chopping board or equipment in the production of foodstuff) | Components or intermediate forms which were disinfected (which are not themselves placed on the EU market) |
|  | An article which has been disinfected (in the form as it is placed on the EU market) to render it sterile or reduce contamination |  |
|  | Wooden article, or wooden components of a complex article, impregnated with an insecticidal wood preservative in order to protect it from becoming infested | Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation |
|  | Wooden article treated with an insecticide (e.g. by fumigation) in order to remove a present infestation |  |
|  | Speciality paper incorporating a preservative in order to protect the finished article during use such as anti-mould treated papers | Paper made of paper pulp (cellulose) incorporating a preservative in order to protect the pulp (an aqueous mixture) during storage before use in the manufacturing of paper; equally incorporation of a preservative in other intermediates such as starch, pigments, coatings or fillers during storage |
|  |  | Paper resulting from a production process where slimicides were used in order to avoid slime development in the paper machine and in the process water system |
|  | Mixtures like paints, glues, inks, detergents, etc. containing an in-can preservative | Complex articles containing e.g. glues, inks, paints which had in-can preservatives added in order to protect them during storage, where these preservatives have no further function in the finished good |
|  |  | Paint, detergents, etc. containing an additive, and that additive had an in-can preservative added in order to protect its during storage, where this preservative has no further preserving function in the final product |
| **Paints and coatings containing a fungicide to fight existing mould infestations (anti-mould paint)** | Paints and coatings containing a preservative that extends the durability of the applied layer |  |

|  |  |  |
| --- | --- | --- |
| **Biocidal product** | **Treated article** | **Not a treated article** |
| **Paints and coatings intended to prevent microbial settlement and growth in order to provide a germ-free environment e.g. in hospitals** |  |  |
|  | Complex articles containing e.g. paints, adhesives which contain a film preservative in order to protect the paint/glue layer during use of the article |  |
|  | Leather goods (shoes, seats) treated with a fungicide protecting the leather from decay |  |
|  | Textiles, or textile components of complex articles, treated with a preservative in order to increase durability of the fabric (also when used in multi-component articles) |  |
| **Mosquito net treated with an insecticide or insect repellent** | Textiles, or textile components of complex articles, treated with an insecticide in order to protect the fabric from destruction by insects |  |
| **Insect-repelling bracelets** | Clothes treated with an insect repellent |  |
|  | Clothes treated with a biocidal product in order to control odour-forming bacteria (also when used in multi-component articles) |  |
|  | Kitchen sponge treated to inhibit microbial growth during use |  |
|  | Plastic articles, or plastic components of complex articles, incorporating a preservative that protects them against harmful organisms and increases durability of the material | Plastic articles or plastic components of complex articles, made of ingredients (monomers, polymerisation aids, etc.) which contained preservatives in order to protect them during storage and manufacture, where these preservatives have no further function in the finished good |
| **Antifouling paints** | Fishing or aquaculture equipment and boats treated with antifouling products |  |
| **Embalming and taxidermist fluids** | Stuffed animals, which have been impregnated with taxidermist fluids containing (e.g. insecticides or preservatives) |  |

### Dietary Exposure and Human Exposure via the Environment

Methodology Guidance is currently under development including for livestock exposure assessment.

## Exposure Estimation

### Specific Product Type Secondary exposure Scenarios

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PT** | **Exposure scenario** | **Aggregation state of the product (solid/liquid/aerosol)** | **Proposed exposure model** | **Default settings** | **Remarks on the proposed model** |
| 6 | Child touching treated surfaces and hand to mouth transfer |  | [HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4](http://echa.europa.eu/documents/10162/19680902/heeg_opinion_7_choice_parameters_pt_2_3_4_en.pdf) | * Exposed area: 234 cm2 ([HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4](http://echa.europa.eu/documents/10162/19680902/heeg_opinion_7_choice_parameters_pt_2_3_4_en.pdf)) * Film thickness on a surface: 0.01 cm * Paint density: 1000 mg/cm3 * Transfer coefficient of dried liquid from different types of surfaces: 18% ([TNsG 2002](http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg+human+exposure+2002_en.pdf), p. 204) * Percent of hand contamination: 100% * Child weight (default 10.5 months): 8 kg ([HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4](http://echa.europa.eu/documents/10162/19680902/heeg_opinion_7_choice_parameters_pt_2_3_4_en.pdf) and [HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products](http://echa.europa.eu/documents/10162/19680902/heeg_opinion_17_default_human_factor_values_en.pdf)) | [HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4](http://echa.europa.eu/documents/10162/19680902/heeg_opinion_7_choice_parameters_pt_2_3_4_en.pdf)  This opinion may be useful although it does not refer to PT6. In this opinion is described that for hand-to-mouth transfer, it is assumed that 50% of the product that ends up on the hands is taken orally. As the hands form about 20% of the total uncovered skin, this means that, via hand-mouth contact, 10% of the calculated external dermal exposure is ingested. |
| 6 | Exposure of a child to residues in clothes |  | The exposure is calculated based on the considerations of [HERA, Guidance Document Methodology (2005)](http://www.heraproject.com/files/hera%20tgd%20february%202005.pdf).  For 5 kg laundry, 150 g of product and 15 L of water are required ([TGD on Risk Assessment, Part I, p. 239](http://echa.europa.eu/documents/10162/16960216/tgdpart1_2ed_en.pdf)).  According to the [HERA, Guidance Document Methodology (2005)](http://www.heraproject.com/files/hera%20tgd%20february%202005.pdf):   * the residues deposited on the clothes are 5 %; * the fabric density is assumed at 20 mg/cm2; * the weight fraction transferred from the fabric to the skin is 1 %. | * Product used for 5 kg laundry: 150 g * Product deposit on clothes from laundry :5% * Pullover weight (20 mg/cm2 fabric density): 70800 mg * Surface area (arms and trunk): 4646 cm2 ([HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products](http://echa.europa.eu/documents/10162/19680902/heeg_opinion_17_default_human_factor_values_en.pdf)) * Product transfer from pullover to skin: 1% | The approach is based on [HERA, Guidance Document Methodology (2005)](http://www.heraproject.com/files/hera%20tgd%20february%202005.pdf). Also the Cleaning Products Fact Sheet (p. 36) describes residues on clothing. According to the fact sheet there is 6 g detergent/kg fabric. The fact sheet assumes 1 kg fabric is worn and that there is a skin factor of 0.8.  The [AISE react tool](http://www.aise.eu/our-activities/product-safety-and-innovation/reach/consumer-safety-exposure-assessment.aspx) may be more realistic. A justification for the use of additional defaults is necessary. |
| 21 | Toddler secondary exposure assessment from non-professional use of antifouling paints |  | See  [Section 9](#_PT21_–_Toddler) |  |  |

### Recommended models for Secondary Exposure Assessment

When no specific product type exposure scenario is available in section 4.2.1, a stepwise approach can be followed using first worst case estimates (Step 1) and in case of risk identified to proceed to modelling approach of higher tiers (Step 2).

**Step 1**

The Generic Models Algorithms (equations) for all relevant routes of exposure, presented in Section 7 of this document, can be considered either as screening tools to calculate the exposure or when no other suitable model described further in this section is available. These can aslo apply for treated articles Tier I assessment with the assumption that the full amount of the substance contained in the article becomes bioavailable.

In addition the two opinions on “Secondary Exposure - Contact with Treated Surfaces” and the one on “Secondary Exposure - Assessment of Inhalation Exposure of Volatilised Biocidal Active Substances” (see Section 9) should be consulted at this step (for secondary residential and treated articles mediated exposure).

**Step 2**

**Models available within ConsExpo 4.1**:

The following section provides an overview of the available models and sub-models of ConsExpo:

**Inhalation Route**

**Evaporation model, for volatilised product**

This model describes a scenario in which a compound evaporates from a surface into the room air, for example, from a painted wall, or a can of product. Depending on what product details are available, different sub-models can be selected, describing various ways in which a substance is released: instantaneously (first tier), at a constant rate or via evaporation over time.

**Liquid aerosols model, for generated liquid aerosols from sprays or shower**

An important parameter in this model is the respirable fraction. This parameter defines which fraction of the inhaled particles descends in the lungs, which depends on the particle size. For example, particles larger than 20 μm are all non-respirable and particles smaller than 5 μm are respirable for about 35% (Reference: European Committee for Standardization (CEN): EN 481 Workplace atmospheres - Size fraction definitions for measurements of airborne particles. Brussels 1993, Beuth Verlag, Berlin 1993 quoted from DFG (2001): List of MAK- and BAT-Values 2001, Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Report No. 37, page 165). The remainder, deposited in nose, throat or upper bronchial tract, can be swallowed and is assumed to cause oral exposure.

**Dermal Route**

**Direct contact with the skin**

* instant application,
* constant rate
* rubbing off
* migration
* diffusion model

**Oral Route**

**Oral ingestion of the product containing the substance**

* direct oral intake
* intake with a constant rate
* migration of a substance from a product to the saliva in the mouth

**Exposure through migration of the substance from packaging material**

Examples of different oral exposure scenarios for children are:

• Ingestion of dislodged dust and deposits (direct oral intake or constant rate model);

• Mouth treated articles (direct oral intake, constant rate or migration model);

• Ingest food contaminated with direct or dislodged deposits (direct oral intake or migration from packaging material model).

If no suitable model is identified it is recommended to identify suitable models available within the table in Section 4.2.3 below.

### Overview of Exposure Models for Secondary Exposure

In order to calculate the exposure for each exposure scenario per biocidal product type, a number of modelling approaches are available.

It is recommended that in a first step the assessor consults Section 4.2.2 to identify existing scenarios and models as developed by the HEEG/Ad-hoc group.

If not suitable models exist, it is recommended first to identify the suitable model described in Section 4.2.3.

The overview table below provides additional models available also from US EPA; however these models should be used with care.

**Table: Models for Secondary Exposure Assessment**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Route** | | | **Secondary Exposure** | | **Comments** |
| **Exposure Estimation Tools** | **Dermal** | **Inhalation** | **Oral** | **Users** | **General Public (residents, bystander)** |  |
| ConsExpo | x | x | x | x | x |  |
| Emission Tool |  | x |  | x | x | Estimation of exposure to substances from solid materials.  This exposure is via indoor air into the lungs |
| EUROPOEM | x | x |  | x | x |  |
| US EPA **E-FAST (CEM)** | x | x |  | x | x |  |
| US EPA Multi-chamber concentration/exposure mode MCCEM |  | x |  | x | x |  |
| US EPA Wall Paint Exposure Assessment Model (WPEM) |  | x |  | x | x |  |
| US EPA Pesticides SOPs (residential exposure) | x | x | x | x | x |  |
| US EPA Calendex | x | x | x | x | x |  |

***Note:*** *when using models from US sources the user should consider adaptation of the data to align with the principles of exposure assessment used for BPR purposes (e.g. use of 75th or 95th percentiles for BPR exposure assessment versus geometric mean in US exposure assessment tools)*

### Refinement Options

In the case risk is identified for a specific exposure scenario when the exposure estimate is compared to the most relevant reference value (AEL), refinement of the exposure assessment should be attempted.

However it is noted that the assessor should at the same time consider refinement of the hazard components of the assessment, since over- or underestimation of the risk may be due to elements from the calculation of the reference value (AELs).

Refinement options for the secondary (indirect) exposure assessment can include the following:

1. Refinement of parameters used in the exposure scenario (duration, frequency)
2. Refinement of parameters used in the exposure estimation

In any of the above two options the refinement should be performed within realistic worst case scenarios and not with an attempt to bring the risk to acceptable levels by only reducing the numbers used.

1. **Measured data**

When no option of refinement within the exposure scenario as such is possible, it is recommended to consider the need for generation of exposure measured data.

This is particular important in the case of treated articles. Specifically for treated articles, the exposure estimations can be refined with data obtained in leaching tests. Such tests must be conducted in appropriate media (for example artificial sweat, saliva etc.). The tests should also be specific for the intendeed material (e.g. type of polymer), conditions of use (e.g. mouthing, skin exposure potential), article form (hard, smooth, and porous) and duration of exposure. Leaching rates can vary during the service life of an article, with many articles giving high levels of exposure during the first period of use which diminishes after repeated uses.

Testing methods are available to determine the release from the article into water, saliva or gastric fluid (physiology-based extraction test). These tests assume that the object is either put in the mouth or is ingested. The most refined method is a simulation of the gastro-intestinal digestion by an in vitro digestion model (e.g., Oomen et al., 2003).

Van Engelen et al. (2006) list and discuss the different methods for testing of release rates and bioavailability of substances in toys that are either put in the mouth or ingested.

(Van Engelen et al. (2006). *Chemicals in toys. A general methodology for assessment of chemical safety of toys with a focus on elements. RIVM/SIR advisory report 0010278A02*).

1. **Exposure Controls**

For secondary assessment scenarios exposure controls are difficult to determine as specific as in the case of primary exposure. However sometimes exposure can be reduced by following the specific product labelling instructions.

1. **Higher Tier Methodologies**

Higher tier methodologies are described in Chapter 3 of ECHA Biocides Human Health Guidance document. These methodologies aim to address uncertainty with more qualitative terms and should be further explored together with the refinement options (1 and 2) above.

# Combined Exposures

The principles of combined exposures and combined scenarios can be found in Chapter 3 and Chapter 4 of the ECHA Biocides Human Health Guidance.

The following table provides an overview of available models that can be considered when assessing combined exposures to single chemicals from different sources or multiple chemicals from one or multiple sources, regarding residential uses of biocidal products; however these models have been built using US population data and therefore their use for EU based assessments should be considered carefully taken into account applicability for EU populations.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Route** | | | **Combined Exposures** | | **Comments** |
| **Exposure Estimation Tools** | **Dermal** | **Inhalation** | **Oral** | **Users** | **General Public** |  |
| **SHEDS**  The Stochastic Human Exposure and Dose Simulation model for pesticides  (see further at Section 6.3.13) | x | x | x | x | x | Residential exposure   * to characterise variability and uncertainty in population estimates; * to quantify infants and children’s aggregate and cumulative exposure and dose to pesticides; * to identify significant media, routes, pathways and exposure factors; |
| **Lifeline**  (see further at Section 6.3.13) | x | x | x | x | x | Exposures to pesticides from   * dietary residues * residential uses * contamination of tap water that occur on each day of an individual’s life |
| **Calendex**  (see further at Section 6.3.13) | x | x | x | x | x | Estimation of aggregate exposure due to   * residues in the diet and drinking water * residues from residential uses of pesticides |
| **CARES/REx**  Cumulative and Aggregate Risk Evaluation System  (see further at Section 6.3.13) | x | x | x | x | x | Exposure and associated risk from residential use(s) of pesticides:   * post application whole-body dermal transfer coefficients * and/or unitless bodypart- specific transfer factors) |

# Primary Exposure Generic and Computer Based Exposure Models

## Professional-Users **Generic Simple Database Models (TNsG 2002&2007)**

### Mixing and Loading Professional Users

#### Pouring formulation from container into portable receiving vessel

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional pouring formulation from a container into a portable receiving vessel e.g. knapsack sprayer. The models are derived from data relating to mixing and loading of agricultural pesticides and cover relatively large volumes. The exposures are expressed as mg a.s./kg a.s. per operation and dermal exposure is limited to the hands.  *1EUROPOEM II database*  *2Lundehn et al., Mitteilungen aus der Biologischen Bundesanstalt für Land-  und Forstwirtschaft, Heft 277, Berlin, Germany*  *2Mixing and Loading model 5 TNsG part 2, p 137* | Granule2 | Hands 171 mg/kg a.s.  Inhalation 0.036 mg/kg a.s. | Uncertainty for hands is *high –* indicative value based on highest of 8 data.  Inhalation uncertainty is *moderate;* 90 % C.I. for 75th 0.02-0.06.  Uncertainty is *moderate.* 90 % C.I. for 75th 0.9-2.3 mg/kg a.s. |
| Powder2 | Inhalation 1.5 mg/kg a.s. |
| Liquid1 | Hands 464 mg/kg a.s.  Body 48.3 mg/kg a.s.  Inhalation 0.021 mg/kg a.s. | Uncertainty is *moderate.* 90 % C.I. for the 75th 278-775 (hands); 21-112 (body); 0.014-0.034 (inhalation). |

#### Pouring formulation from container into fixed receiving vessel

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional pouring formulation from a container into a fixed receiving vessel e.g. reservoir tank on tractor. The models are derived from data relating to loading of agricultural pesticides and cover relatively large volumes. The exposures are expressed as mg a.s /kg a.s. per operation and dermal exposure is limited to the hands only.  *1EUROPOEM II database*  *2Lundehn et al., Mitteilungen aus der Biologischen Bundesanstalt für Land-  und Forstwirtschaft, Heft 277, Berlin, Germany*  *2*Mixing and loading model 5 TNsG part 2, p 137 | Granule2 | Hands 3.3 mg/kg a.s.  Inhalation 0.24 mg/kg a.s. | Hand exposure uncertainty is *moderate.* 90 % C.I. for 75th 2.1-5.4. Inhalation uncertainty is *high*, Indicative value is highest of 13 data.  Hand exposure uncertainty is *moderate.* 90 % C.I. for 75th percentiles 5.5-18.7. Inhalation uncertainty is *high*, Indicative value is highest of 8 data. |
| Powder2 | Hands 10.2 mg/kg a.s.  Inhalation 0.66 mg/kg a.s. |
| Liquid1 | Hands 8.0 mg/kg a.s.  Body 1.95 mg/kg a.s.  Inhalation 0.003 mg/kg a.s. | Uncertainty is *moderate.* 90 % C.I. for the 75th percentiles are 4.9-13.0 (hands); 1.4-2.6 (body); 0.002-0.004 (inhalation). |

#### Pouring liquid agricultural pesticides from various size containers into a receiving vessel

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional pouring liquid agricultural pesticides from various size containers into a receiving vessel. Exposure is limited to the hands and expressed as ml of in-use product per operation.  *UK POEM, Guidance 1992, PSD, York, UK* | Liquid  1 litre  5 litre  10&20 litre | 0.01 ml (hands)  0.2 ml (hands)  0.5 ml (hands) | Indicative values currently based upon 75th. |

#### Loading antifouling paints into a reservoir for airless spraying

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional “potmen” loading antifouling paints into a reservoir for airless spraying. The model covers a wide range of antifouling applications, from small through to very large vessels. Hand exposure is actual exposure inside gloves. The exposures are expressed as mg/min and mg/m3 in-use product.  *Mixing and loading model 6 TNsG part 2, p 138* | Paint | Hands actual 8.2 mg/min  Hands potential 30 mg/min  Body 92 mg/min  Inhalation 1.9 mg/m3 | Uncertainty for actual hand exposures is *considerable*. 95th taken as indicative value.  Potential hand exposure uncertainty is *high*. Indicative exposure based upon highest of 4 data.  Uncertainty for body exposures is *moderate*. 90% C.I. for 75th 50-168  Inhalation uncertainty is *considerable*. 75th percentile of non-zero data taken as indicative value (≈84th overall) |

#### Loading of products into vessels or systems in industrial scale

See Section 9, Opinion on “Primary Exposure - Loading of products into vessels/systems industrial scale: available data & models”

#### Model for Dipping of Hands/forearms in a diluted solution

See Section 9 Opinion on “Primary Exposure - Model for dipping of hands/forearms in a diluted solution”

### Application Professional Users

#### Intermittent handling of water-wet or solvent-damp wood & associated equipment

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional intermittently handling water-wet or solvent-damp wood and associated equipment. The models are derived from data relating to industrial timber treatment using vacuum pressure plants and water-based (WB) or solvent –based (SB) liquid formulations. Hand exposure is actual exposure inside gloves. Exposure is expressed as mg/cycle and mg/m3 in-use product.  *Handling model 1 TNsG part 2, p 160* | Vacuum pressure plant (timber) | WB  Hands 1080 mg/cycle  Body 8570 mg/cycle  Inhalation 1.9 mg/m3  SB  Hands 260 mg/cycle  Body 158 mg/cycle  Inhalation 0.6 mg/m3 | WB uncertainty is *moderate*. 90% C.I. for 75th; 946-1233 (hands), 6299-11660 (body), 1.4-2.6 (inhalation).  SB 90% C.I. for 75th: hands 27-295 (95th used as indicative value); body 113-221 (75th used as indicative value).  19 out of 24 inhalation non-detected, indicative value median measured value (≈ 90th overall). |

#### Intermittent handling of treated nets at various stages of dryness

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional net deployment activity – an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated handling of the nets during the process of reconstructing the cages around fish farms. Hand exposure is actual exposure inside gloves.  *Handling model 2 TNsG part 2, p 163* | Handling of contaminated objects | Hands 0.21 mg/min  Body 7.55 mg/min | Uncertainty is *moderate*. 90% C.I. for 75 percentiles: 0.15-0.30 (hands), 4.6-12.4 (body). |

#### Carrying out a range of dipping activities involving a variety of articles

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional carrying out a range of dipping activities (including mixing/diluting formulations, handling wet articles, machine minding and loading/unloading) involving a variety of articles. The models are reflective of conditions where operatives may contact treatment fluids and wet objects and the exposures are expressed as mg/min or mg/m3 in-use product. Hand exposure is actual exposure inside gloves.  *1Dipping model 1 TNsG part 2, p 167*  *2Dipping model 2 TNsG part 2, p 168*  *3Dipping model 3 TNsG part 2, p 169*  *4 Dipping model 4 TNsG part 2, p 170* | Manual dipping in open tanks (wooden articles)1 | Hands 25.7 mg/min  Body 178 mg/min  Inhalation <1 mg/m3 | Uncertainty is *high.* Models 1-3 contain only 5 data each, whilst model 4 contains 9 data. Indicative exposures are based upon maximum values. |
| Manual dipping in enclosed vessels (leather)2 | Hands 39.9 mg/min  Body 178 mg/min |
| Semi-automatic dipping in open vats (fishing nets)4 | Hands 16.7 mg/min  Body 221 mg/min |
| Automated dipping (textiles)3 | Hands 1.6 mg/min  Body 23.8 mg/min  Inhalation 122 mg/m3 |

***Note:*** *For the dipping model 1 of TNsG 2002, part 2, p 167 the inhalation exposure should be as listed in the table above <1 mg/m3 and not as indicated in the TNsG 2002 section*,

#### Handling dusty powders packaged in cardboard bags

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional handling dusty powders packaged in cardboard bags of approximately 25 kg. The exposures are expressed as mg/min in-use product. The model relates to manual handling of bags containing calcium carbonate in paint factories and is appropriate for other similar powder handling situations.  *TNO report V96.064 (Lansink et al., 1996)*  *Dust and soil adhesion model 3 TNsG part 2, p 181*  *Sub models describing exposures resulting from the different tasks can also be found in part 2 p 181* | Weighing/scooping powder.  Handling, emptying and disposal of bags. | Hands 347 mg/min | Uncertainty is *moderate*. 90 % C.I. for 75th percentile is 271-441 mg/min. |

#### Diluting and mixing disinfectant & wiping surfaces with cloth

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional operator diluting and mixing disinfectant and wiping surfaces using a cloth. The exposure to the hands inside protective gloves is expressed as mg/min in-use product.  *1Schipper et al., 1996. TNO report V96.314*  *2 Fenske & Elkner, Tox. Indust. Health 6 :349-371(1990)*  *1Surface disinfection model 1 TNsG part 2, p 173*  *2Surface disinfection model 3 TNsG part 2, p 175* | Dipping of cloth and wiping of surfaces with rung cloth | Hands1 10.3 mg/min  Body2 87.6 mg/min  Inhalation1 22.9 mg/m3 | Model 1: uncertainty is *moderate*; 90 % C.I for 75th of hand exposures 5.4-19.6. Indicative inhalation exposure is 50th of non-zero values – approximately 80th overall.  Model 3: uncertainty is *high*. Indicative body exposure based upon highest of 8 data. |

#### Washing and wiping floors

| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| --- | --- | --- | --- |
| Professional washing and wiping floors using a mop, bucket and wringer, e.g. hospitals and schools. Mixing and loading is not included and the task durations are between 10-40 mins. Exposure data is for the body (no hand data) and is expressed as mg/min in-use product.  *Popendorf & Selim, Am Ind Hyg Assoc J 56: 1111-1120 (1995)*  *Surface disinfection model 2 TNsG part2, p 174* | Mopping | 4.50 mg/min (body) | Uncertainty is *high*. Indicative exposure is maximum of 6 data. |

#### Treating soil by watering and subsoil by injection

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| These two models relate to professional treating soil by watering-can and subsoil by injection. The tasks include mixing and loading and the exposure is expressed as mg/min and mg/m3 in-use product. Hand exposure is actual exposure inside gloves.  *Cattani et al., Ann. Occ. Hyg. 45(4):299-308, 2001. Full data set at* [*www.pesticide**-research.curtin.edu.au*](http://www.pesticide-research.curtin.edu.au)  *Subsoil treatment model 2 TNsG part 2, p 177* | Watering-can | Hands 48.8 mg/min  Body 38.2 mg/min  Inhalation 4.15 mg/m3 | Uncertainty is *high.* Indicative exposures based upon the highest of 4 data. |
| Sub-soil injection | Hands 8 mg/min  Body 25.8 mg/min  Inhalation 0.57 mg/m3 | Uncertainty is *moderate.* 90 % C.I. for 75th: 5.1-12.6 (hands), 18-37(body), 0.4-0.8 (inhalation). |

#### Spray Application: Mixing & Loading liquids & powders in compression sprayer/dusting applicators and indoor or outdoor spraying in overhead or downward direction

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Model** | **Application**  **Method** | **Indicative Exposures** | **Uncertainty** |
| Professional mixing and loading liquids and powders in compression sprayers or dusting applicators, and applying indoors and outdoors in overhead or downward direction. This model relates to insecticide application to various surfaces and articles in domestic and public (e.g. schools, nursing homes, restaurants, hospitals) areas. The model may also apply to other operations involving application via hand-held compression sprayers. Hand exposure is actual exposure inside gloves.  *Spraying model 1 TNsG part 2, p 143*  *Another model (model 10) describing exposures resulting from low pressure spraying of insecticides can be found in part 2 p 156* | Hand-held low pressure (1-3 bar) spraying  Medium/coarse spray  Spot, crack and crevice and broadcast applications | Hands 10.7 mg/min  Hands (potential) 181 mg/min  Body 92 mg/min  Inhalation 104 mg/m3 | Uncertainty is *moderate*. 90% C.I. for 75th: 5.8-19.8 (hands), 64-132 (body). Indicative exposure for inhalation based upon 50th of non-zero data (≈ 85th overall)  Uncertainty for potential hand exposures is *high.* Indicative exposure based upon maximum of 5 data. |

#### Spray Application: Mixing & Loading and application of liquids in reservoir for powered spray Application indoors or outdoors in overhead and downward direction

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Model** | **Application**  **Method** | **Indicative Exposures** | **Uncertainty** |
| Professional mixing, loading and applicating liquids in reservoir for powered spray application indoors and outdoors, in overhead and downward direction. This model relates to application of remedial biocides to structural timbers and masonry in industrial, recreational and residential settings. The model will also apply to other operations involving application using a pump-pressurised sprayer. Hand exposure is actual exposure inside gloves.  *Spraying model 2 TNsG part 2, p 146* | Hand-held medium pressure (4-7 bar) spraying  Medium/coarse spray  Broadcast application | Hands 7.8 mg/min  Hands (potential) 273 mg/min  Body 222 mg/min  Inhalation 76 mg/m3 | Uncertainty is *moderate*. 90% C.I. for 75th: 4.3-14.3 (hands), 134-368 (body), Indicative inhalation exposure is 75th of non-zero values (≈ 80th overall) 90% C.I. 45-128.  Uncertainty for potential hand exposures is *high.* Indicative exposure based upon maximum of 6 data. |

#### Spray Application: Spraying viscous solvent-based liquids outdoors in overhead and forward direction

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Model** | **Application**  **Method** | **Indicative Exposures** | **Uncertainty** |
| Professional spraying viscous solvent-based liquids outdoors, in overhead and forward direction. This model relates to high-pressure spraying of antifouling paints to ships. The model is equally applicable to many high-pressure paint-spraying operations. Hand exposure is actual exposure inside gloves.  *Spraying model 3 TNsG part 2, p 149*  [These generic indicative exposure values are for the in-use product (antifouling paint) and are based on antifouling paints of densities varying from 1.25 to 2 g/ml]. | Hand-held high pressure (>100 bar) airless spraying  Medium/coarse spray  Broadcast application | Hands 2.04 mg/min  Body 250 mg/min  Inhalation 17.3 mg/m3 | Uncertainty is *moderate*. 90% C.I. for 75th: 0.86-4.97 (hands), 152-410 (body), 7.5-40 (inhalation). |

#### Spray Application: Disinfection of slaughterhouses and meat processing industry by overhead and downward spraying or foaming

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Model** | **Application**  **Method** | **Indicative Exposures** | **Uncertainty** |
| Professional disinfection of slaughterhouses and meat processing industry by overhead and downward spraying or foaming. Exposures include mixing and loading, as well as application. The mixing and loading was done manually or by using automated dosing systems.  *Spraying model 9 TNsG part 2, p 159* | Various techniques | Hands 2300 mg/min  Body 4900 mg/min  Inhalation 3600 mg/m3 | Inhalation uncertainty is considerable; indicative exposure is based upon the 95th percentile.  Uncertainty for hand exposures is *high.* Indicative value is based upon the highest of 9 exposures.  Uncertainty for body exposures is *moderate*. 90% C.I. for 75th percentile is 2650-9070. |

#### Spray Application: Application of amenity herbicides at ground level using a controlled droplet wand applicator

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Model** | **Application**  **Method** | **Indicative Exposures** | **Uncertainty** |
| Professional application of amenity herbicides at ground level using a controlled droplet wand applicator. Hand exposures are actual exposures inside gloves.  *Fogging and misting model 1 TNsG part 2, p 183* | Controlled droplet applicator | Hands 0.12 mg/min  Body 13.8 mg/min  Inhalation 0.26 mg/m3 | Uncertainty for hand exposures is *moderate,* 90% C.I for hand exposures 0.06-0.25.  Uncertainty for body and inhalation exposures is *high*. Indicative values based upon highest of 12 data. |

#### Fogging Application: Application of insecticide at waist level, indoor, using cold (ULV) or thermal foggers

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Professional applying insecticide at waist level, indoor, using cold (ULV) or thermal foggers. The models are based on simulation studies using professional operators in realistic building settings. Hand exposure is actual exposure inside gloves.  *1Fogging and misting model 2 TNsG part 2, p 185*  *2Fogging and misting model 3 TNsG part 2, p 186* | Cold (ULV) fogging1 | Hands 0.20 mg/min  Body 21.8 mg/min  Inhalation 70.2 mg/m3 | Uncertainty is *moderate.* 90% C.I. for 75th are 0.03-0.05 (hands), 11-43 (body), 49-102 (inhalation). |
| Thermal Fogging2 | Hands 0.33 mg/min  Body 1.13 mg/min  Inhalation negligible | Uncertainty is *high.* Indicative exposures based upon maximum of 4 data. |

#### Generic Inhalation (metal working fluids): Handling mineral oils, semi-synthetic oils and synthetic fluids

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Model** | **Process** | **Indicative exposures** | **Uncertainty** |
| Professionals at companies ranging from multinationals to small independent engineering workshops handling mineral oils, semi-synthetic oils and synthetic fluids.  *Metal working fluids model 2 TNsG part 2, p 188* | Tool making and other metalworking operations. | Oil-based  Inhalation 2.18 mg/m3  Water-based  Inhalation 0.33 mg/m3 | Uncertainty is *moderate.* Data set contains over 300 personal samples. Indicative exposure values represent 75th. |

#### Professional granular bait dispersal by hand

Exposure Data from PHED (Pesticide Handler Exposure Database); NOTE: The US EPA PHED use central tendency value for deterministic exposure assessment; this differs from the European approach that uses the 75th or 95th percentile; therefore the values from this model will lead to underestimation of the exposure for the purposes of the BPR. The following model is not recommended for use.

| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| --- | --- | --- | --- |
| Scenario 17 of the PHED (Pesticide Handler Exposure Database)  “Granular bait dispersed by hand” presents indicative exposure data for inhalation and dermal exposure.  The data presented are summaries of the worker exposure outputs generated by PHED. These estimates are derived from actual field studies and are based on the physical factors of a handler scenario (e.g. the type of protective clothing worn, method of application, formulation type, etc.)  Reference: EPA, PHED Surrogate Exposure Guide; Estimates of Worker Exposure from The Pesticide Handler exposure Database Version 1.1., August 1998. | Granular bait dispersed by hand: No clothing scenario | Inhalation exposure: 1034  µg/kg a.i. handled  Head and neck exposure: 12.47 mg/kg a.i. handled  Upper and lower arm, chest, back, thigh and lower leg exposure: 157.96 mg/kg a.i. handled  Hand exposure: no data | Uncertainty for dermal exposure is high due to lack of no glove replicates for this scenario.  Uncertainty for inhalation exposure is medium  (number of data: 16) |
| Granular bait dispersed by hand: Single layer, No gloves scenario | Inhalation exposure: 1034  µg/kg a.i. handled  Head and neck exposure: 12.47 mg/kg a.i. handled  Upper and lower arm, chest, back, thigh and lower leg exposure: 136.4 mg/lb a.i. handled  Hand exposure: no data | Uncertainty is high due to lack of no glove replicates for this scenario.  Uncertainty for inhalation exposure is medium  (number of data: 16) |
| Granular bait dispersed by hand: Single layer, Gloves scenario | Inhalation exposure: 1034  µg/kg a.i. handled  Head and neck exposure: 12.47 mg/kg a.i. handled  Upper and lower arm, chest, back, thigh and lower leg exposure: 136.4 mg/kg a.i. handled  Hand exposure: 7.94 mg/kg a.i. handled | Uncertainty is medium  Uncertainty for inhalation exposure is medium  (number of data: 16 and 15 replicates for hand exposure (all non detect (LOQ = 41 µg)) |

#### Inhalation exposure to formaldehyde in human pathologies (PT 22)

Exposure Data from MEGA. These data are not generic, because they cover inhalation to a volatile compound.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Indicative data to assess inhalation exposure to formaldehyde in  human pathologies (e.g. product type 22). The dataset is determined by technical measurement services of the Institution for Statutory Accident Insurance and Prevention in Health and Welfare (BGW) in Germany.  *The detailed report can be downloaded (www.bgw-online.de)!*  The following activities in pathology are covered by the data:  1. Filling of sample vessels with water based formaldehyde solution (4 % w/w). 50-460 vessels up are filled in pathology labs using up to 2 L formaldehyde solution (4 % w/w).  Workplace: separate room without LEV. Duration per shift: 7-57 minutes.  2. Cutting of tissue samples onto a cutting board. Formaldehyde (4 % w/w) is present as fixing agent in the vessel, on tissue sample and cutting board.  Workplace: Cutting room with under-table extraction. Duration per shift: 11-178 minutes.  3. Disposal of preservatives (tissue samples). The preservatives is formaldehyde saturated (max. 4 % w/w). Workplace: separate room without LEV. Duration per shift: 7-120 minutes. | 1. Filling of sample vessels | Inhalation exposure to formaldehyde 0.76 mg/m3 | Uncertainty is *moderate.*  90 % C.I. for 75th: 1.19 – 1.53 .  (inhalation, number of data: 42) |
| 2. Cutting of tissue samples | Inhalation exposure to formaldehyde 0.72 mg/m3 | Uncertainty is *moderate.*  90 % C.I. for 75th: 1.01 – 1.14.  (inhalation, number of data: 191). |
| 3. Disposal of preservatives | Inhalation exposure to formaldehyde 1.43 mg/m3 | Uncertainty is *moderate.*  90 % C.I. for 75th:2.07 – 2.58.  (inhalation, number of data: 89). |

### Post Application Professional Users

#### Cleaning (i.e. washing out) of a brush model

See Section 9 “Primary Exposure Paint Model “Washing out of a brush”

#### Model for Dipping of Hands/forearms in a diluted solution

See Section 9 “Primary Exposure - Model for dipping of hands/forearms in a diluted solution

## Non-Professional Users **Generic Simple Database Models (TNsG 2002&2007)**

### Mixing and Loading Non-Professional Users

#### Pouring solvent-based or water-based concentrate from 1lt container into a small bucket

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Non-professional pouring a solvent-based (SB) or water-based (WB) concentrate from a 1 litre container into a small bucket. Exposure is limited to the hands and forearms and expressed as mg in-use product per operation.  *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*  *Mixing and loading model 2 TNsG part 2, p 134* | Liquid | SB  Hand/forearm 1.7 mg/event  WB  *Hand/forearm 3.2 mg /event*  For the case of single event - skin exposure worst case:  SB  Hand/forearm 6.7 mg/event  WB  Hand/forearm 12.8 mg /event | Uncertainty is *high.* Indicative exposure values based upon worst case. |

### Application Non-professional Users

#### In-situ application of wood preservatives with brush

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| In-situ application of wood preservatives with brush. These models relates to a Non-professional painting:  1. Rough wooden joists and the underside of floor boards, overhead indoors, with water based product (includes decanting).  *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*  Consumer product painting model 1 TNsG part 2, p200  2. Brushing sheds and fences, outdoor (direct from can).  *Ann. Occup. Hyg. 44: 421-426 (2000); ACP – SC 11000 – Consumer exposure to non-agricultural pesticide products*  Consumer product painting model 3 TNsG part 2, p202 | 1. Brushing | Hands/forearms 150 mg/min  Legs/feet/face 35.7 mg/min  Inhalation 3.1 mg/m3 | Uncertainty is *moderate.* 90 % C.I. for 75th: 116-193 (hands), 21-60 (legs), 1.9-5.1 (inhalation). |
| 2. Brushing | Hands 5.91 mg/min  Body 16.9 mg/min  Inhalation 1.63 mg/m3 | Uncertainty is *moderate.* 90 % C.I. for 75th: 3.7-9.4 (hands), 7.3-39.2 (body).  Indicative exposure based upon 50th of non-zero values (80th overall, 9 zero inhalation exposures out of 15). |

#### Brushing and roller painting of antifouling paint on underside of small boats, outdoor

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Non-professionals brushing and roller painting antifouling paint on underside of small boats, outdoor (direct from can or paint tray). Hand exposure is actual exposure inside gloves or on gloves.  These generic indicative values are for in-use product (i.e. antifouling paint) and  are based on antifouling paints of densities ranging from 1.25 to 2 g/ml  *Ann. Occup. Hyg. 44: 421-426 (2000); ACP – SC 11000 – Consumer exposure to non-agricultural pesticide products*  Consumer product painting model 4 TNsG part2, p 203 | Brushing and roller | Gloved hands 76.6 mg/min  Protected hands 18.5 mg/min  Body 30.7 mg/min  Inhalation 0.05 mg/m3 | Uncertainty for hand exposures is *high.* Indicative exposure is highest value out of 9 data for protected hands and out of 2 data for gloved hands.  Uncertainty for body and inhalation exposures is *moderate.* 90 % C.I. for 75th: 28-91 (body), 0.035-0.07 (inhalation). |

#### Spray Application: Spraying liquid (ready for use products) indoors in overhead direction

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Non-professional spraying liquid ready for use product indoors, in overhead direction. This model relates to powered application of wood preservatives to joists and underside of floorboards. The model may apply to other pump-pressurised operations in an overhead direction.  *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*  *Consumer spraying and dusting model 3 TNsG part 2, p 197* | Hand-held medium pressure spraying  Medium/coarse spray | Hands/forearms 176 mg/min  Legs, feet & face120 mg/min  Inhalation 115 mg/m3 | Uncertainty is *moderate.* 90 % C.I for 75th are 117-265 (hands), 85-170 (legs), 79-168 (inhalation). |

#### Spray Application: Spraying liquid (ready for use products) outdoors, in forward and downward direction

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Non-professional spraying liquid ready for use product outdoors, in forward and downward direction. This model relates to powered application of wood preservative to solid and lattice fences.  *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*  *Consumer spraying and dusting model 3 TNsG part 2, p 197* | Hand-held medium pressure spraying | Hands/forearms 144 mg/min  Legs, feet & face 84 mg/min  Inhalation 6.5 mg/m3 | Uncertainty is *high.* Indicative exposures based upon maximum of 6 data. |

#### Spray Application: Spraying insecticide indoors on soft furnishings, carpets, skirting board and shelves

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Non-professional surface spraying insecticide, indoors, on soft furnishings, carpets, skirting boards and shelves with dust applicators trigger sprays and aerosol cans. The models are derived from the following simulated volunteer studies:   1. Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 microm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 microm). 2. Crack and crevice insecticide treatment (skirting, shelves, horizontal/vertical laminate surfaces) using a ready for use liquid spray. 3. Broadcast treatment of small room (sofa, skirting dining chairs and carpet) using liquid spray.   *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*  *Consumer spraying and dusting model 2 TNsG part 2, p 197* | 1.Hand-held flexible duster | Hand/forearm 2.73 mg/min  Legs/feet/face 2.74 mg/min  Inhalation 2.47 mg/m3 | Uncertainty is *moderate.* 90 % C.I. for 75th are 1.9-3.9 (hands), 1.7-4.4 (legs), 1.5-4.2 (inhalation). |
| 2.Hand-held trigger spray | Hand/forearm 36.1 mg/min  Legs/feet/face 9.7 mg/min  Inhalation 10.5 mg/m3 | Uncertainty is *moderate.* 90 % C.I. for 75th are 26-50 (hands), 7.6-12.4 (legs), 9.0-12.2 (inhalation). |
| 3. Pre-pressurised aerosol spray can | Hand/forearm 64.7 mg/min  Legs/feet/face 45.2 mg/min Inhalation 35.9 mg/m3 | For hands and inhalation uncertainty is *moderate.* 90 % C.I. for 75th are 37-114 (hands), 31-43 (inhalation). Uncertainty for legs is *high –* highest exposure out of 6 used. |

#### Spray Application: Spraying insecticide in a small sealed room with trigger sprays, pumped sprayers and aerosol cans

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Exposure Model** | **Application Method** | **Indicative Exposures** | **Uncertainty** |
| Non-professional space spraying insecticide in a small sealed room with trigger sprays, pumped sprayers and aerosol cans. The models are derived from simulated volunteer studies involving the discharge of the sprayer into the air on four consecutive occasions. Each discharge took six seconds and the user remained in the room for the next 30 seconds before exiting  Liquid. It is important to note that application and dwell times are critical determinants of exposure in such scenarios and the data presented in these models are a reflection of the specific scenarios used in the experiments.  *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*  *Consumer spraying and dusting model 1 TNsG part 2, p 194* | Hand-held trigger sprayer | Hand/forearm 136 mg/min  Legs/feet/face 42.4 mg/min  Inhalation 90.2 mg/m3 | Uncertainty is *moderate.* 90% C.I. for 75th are 95-194 (hands), 22-82 (legs), 69-118 (inhalation). |
| Hand-held pumped spray | Hand/forearm 98.4 mg/min  Legs/feet/face 22.7 mg/min  Inhalation 76.3 mg/m3 | Uncertainty is *moderate.* 90 % C.I. for 75th are 36-271 (hands), 19-28 (legs), 65-90 (inhalation). |
| Aerosol can | Hand/forearm 156 mg/min  Legs/feet/face113 mg/min  Inhalation 234 mg/m3 | Uncertainty is *moderate.* 90 % C.I. for 75th are 114-214 (hands), 83-153 (legs), 175-312 (inhalation). |

### Post Application Non-professional Users

#### Cleaning (i.e. washing out) of a brush model

See Section 9 “Primary Exposure Paint Model “Washing out of a brush”

#### Model for Dipping of Hands/forearms in a diluted solution

See Section 9 “Primary Exposure - Model for dipping of hands/forearms in a diluted solution

## **Computer based & Mathematical data models**

### Bayesian Exposure Assessment Toolkit (BEAT model)

The computerised version of BEAT is available from <http://xnet.hsl.gov.uk/download/> (copy this in your browser). An installation password is required to install BEAT. You receive this password when registering your software download by sending an email to [beat@hsl.gsi.gov.uk](mailto:beat@hsl.gsi.gov.uk) with the subject registration.

For installation of BEAT on computers with Windows 7 the following steps need to be followed once you receive the password:

1. Install Microsoft Access
2. Install BEAT
3. Install the Matlab Module
4. Activate macros in Microsoft Access
5. Within Microsoft windows, give the user the right to modify the BEAT file
6. Within Microsoft windows, check that in the regional parameters the dot "." is use for decimal separation and not comma ","

The available version of BEAT covers dermal exposure.

The use of BEAT might be limited in certain cases due to the fact that:

- worked examples are not state of the art since they were prepared before the agreed HEEG/HEAdhoc recommendation were established,

- protection factors for PPE don't fit to the HEEG opinion 9 and should be changed manually in the output file,

- not all aplication methods are available in the database,

- results generated using BEAT differ from those found in the TNsG 2002 (sometimes in an order of magnitude) even if the same data base is used

- the worked examples are only examples and not recommended exposure assessments

**BEAT Worked Examples Database**

The professional users worked examples database consists of a number of integrated databases, search algorithms and statistical routines designed to assist exposure assessments for professional use scenarios. Components of the system include the following elements.

* A database of fully worked examples of exposure assessments for professional use scenarios for all 23 product types. Each example contains a full description of the scenario, details of tasks performed, pattern of use, PPE, suitable indicative exposure values for relevant routes of exposure and all other quantitative data required to calculate total internal dose. Users can add their own new scenarios to this database.
* An export facility to an Excel exposure calculator that presents a calculation of internal dose in an approved standard format for each worked example.
* A database of measured exposure data (inhalation and dermal) for a wide range of occupational exposure scenarios relevant to biocides. Data are presented generically in terms of in-use formulation as rates of dermal exposure per minute and as air concentrations (low volatility formulations only). This database contains full contextual information on every measurement.
* Task-based search algorithms that search the measurement database on the basis of information provided in a worked example (e.g. formulation properties, tasks performed, method of application, environment and control measures) and return the most appropriate generic data sets. The search algorithm ranks these data sets according to their strength of analogy with the user provided information. It should be cautioned that these algorithms have only been designed to assess analogy between dermal exposure scenarios.
* Automated statistical analysis providing summary statistics and recommended indicative exposure values for each dataset. A second version of this system incorporates a Bayesian pooled analysis of all selected generic exposure data sets, weighting each data set by its strength of analogy to the assessment scenario.

A user of this system can thus create new worked examples for their own exposure scenarios, search for appropriate generic data and suitable indicative exposure values, calculate internal doses to the active substance and present these calculations in a preferred format suitable for inclusion in a product dossier. Users are not restricted to using exposure values extracted from the measurement database and can instead insert other suitable values taken from elsewhere (including product specific exposure data or predictions from mathematical models). It is envisaged that this system will develop further with time via the incorporation of additional measured exposure data and expansion of the catalogue of worked examples of exposure assessments.

In the computerised database a series of worked examples for workers has been collected, as indicated by title in the following table:

Table: Overview of Worked Examples of Primary Professional Use Scenarios

|  |  |  |
| --- | --- | --- |
| **Product type** | **Use scenario** | **Formulation type** |
| PT 1: Human hygiene products | Sprayed on the hands and rubbed in for disinfection purposes | Liquid |
| PT 2: Private area and public health area disinfectant, etc. | Disinfection of floors, walls, furniture by using a cloth or a mop | Tablet |
| PT 3: Veterinary hygiene products | Disinfection of feet and hoofs of animals | Liquid |
| PT 4: Food and feed area disinfectants | Disinfect equipment, materials, walls and floors by spraying | Liquid |
| PT 5: Drinking water disinfectants | Disinfection of water (drinking-, pipes, wells) by adding product type to the water | Liquid |
| PT 6: In-can preservatives | Cleaning of cars using a car shampoo and hand held cloth | Liquid |
| PT 7: Film preservatives | Indoor decorative painting use a brush | Liquid |
| PT 8: Wood preservatives | Water-based vacuum timber pre-treatment | Liquid |
| Solvent-based double vacuum timber pre-treatment | Liquid |
| Application of curative paste using a trowel (reverse-reference approach) | Paste |
| Brush application of curative paste | Liquid |
| PT 9: Fibre, leather, rubber and polymerised materials preservatives | Mixing and loading of biocide for an automated dipping process | Liquid |
| PT 10: Masonry preservatives | Spray application of masonry preservative | Liquid |
| PT 11: Preservatives for liquid-cooling and processing systems | Loading of biocide into a closed system | Liquid |
| PT 12: Slimicides | Loading of biocide into a closed system | Liquid |
| PT 13: Metal working fluids | Machining of metal parts | Liquid |
| PT 14: Rodenticides | Filling and placing boxes with bait | Granular bait |
| PT 15: Avicides | Spreading/ scattering pellets by hand | Pellets |
| PT 16: Molluscicides | Spreading/scattering bait by hand | Pellets |
| PT 17: Piscicides | Pour directly from the container (package) into the water | Ready for use liquid |
| PT 18: Insecticides, acaricides, etc. | Low pressure spraying | Liquid |
| PT 19: Repellents and attractants | Filling and placing boxes with bait | Granular Bait |
| PT 20: Control of other vertebrates | Professional ground-man placing bait | Solid |
| PT 21: Antifouling products | Use of antifouling paints in all phases: Task of a pot-man (mixing & loading),  ancillary worker (lineman) and sprayer. | Liquid |
| PT 22: Embalming and taxidermist fluids | Use of formaldehyde in human pathologies during filling of sample vessels, cutting of tissue and disposal work | Liquid |

### ConsExpo

ConsExpo 4, successor to ConsExpo 3.0, is a computer program that was developed to assist in the exposure assessment of compounds in non-food consumer products. The wide range of available consumer products is associated with an even wider variation in consumers and product use. Measured data on exposure to compounds in products is not always available. In the absence of these data, ConsExpo 4 can be used to estimate the exposure for different exposure scenarios. The program offers a number of generally applicable exposure models and a database with data on exposure factors for a broad set of consumer products. Together, database and models provide the tools to assess exposure for a wide range of consumer products, whereby only basic additional information on product composition and the physicochemical properties of the compound of interest are needed.

ConsExpo 4 implements a wide range of generally applicable mathematical models describing the exposure processes via inhalation, dermal contact and oral ingestion. The program contains algorithms which have also been included in the EU revised Technical Guidance Document on Risk Assessments (ECB, 2003). For all routes of exposure, ConsExpo 4 offers models of increasing complexity, from simple, rough estimate models to more detailed mechanistic models. The exposure assessment can be carried out using a tiered approach, starting with simple first order models that can be used to estimate the upper level of exposure, and working down to more detailed and complex models when the exposure estimation needs to be refined. For more guidance please see the ConsExpo manual (ref. Delmaar 2005, [www.consexpo.nl](http://www.consexpo.nl)).

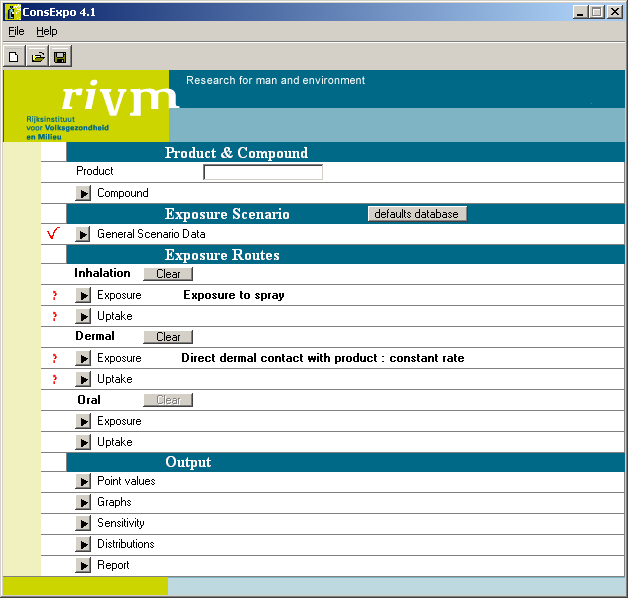
The justification of data in the database is given in the so-called ‘factsheets’.

A number of factsheets have been published, that compile relevant exposure information for a main category of consumer products, such as cosmetics, cleaning products, disinfectants, children’s toys, pest control products, do-it-yourself products and paint products (available via [*www.consexpo.nl*](http://www.consexpo.nl)). A separate factsheet called the ’General Fact Sheet’ gives general information about the factsheets, and deals with subjects that are important for several main categories. It gives, for instance, information on anthropometric data and on housing: data that are needed in all product factsheets. In the factsheets, information about exposure to chemical substances from consumer products is collected into certain product categories. These categories are chosen so that products with similar exposures are grouped. For each of the product categories relevant ConsExpo models are described, for a given scenario default parameters are provided and the derivation of the parameters is justified.

The default parameters are available via a database, which is an integral part of ConsExpo 4.

When selecting a sample product, the database provides default scenarios and parameter values for the models. When using the database, the user should always consult the corresponding fact sheet, in order to be aware of the limitations and the basis for the selected parameter values. The defaults can serve as a starting point for exposure estimation and should be used in the absence of accurate scenario data only. Whenever more detailed information for the product is available, these data should be used instead.

The ConsExpo model can be retrieved via [www.consexpo.nl](http://www.consexpo.nl), including the associated database.



Worked example:

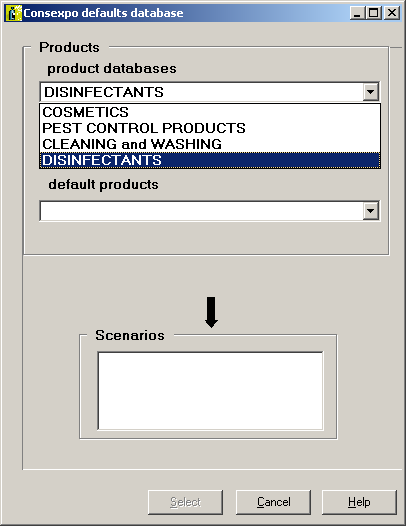
In fact the database provides worked examples. Below, all steps that have to be taken to assess the exposure to (as an example) black mould remover are described.

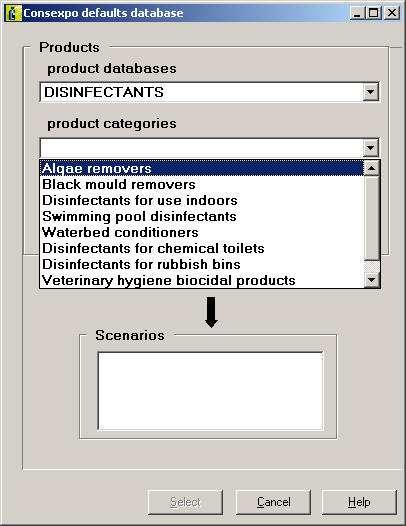
Black mould remover:

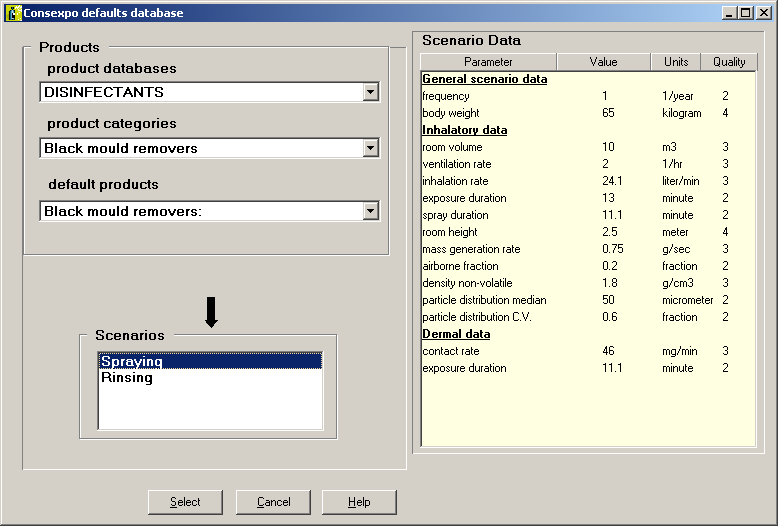
In the defaults database (see button on ConsExpo screen), first a product type has to be chosen. In this example disinfectants, choose the product category black mould remover, then default products: black mould removers. One has then to choose a scenario, in this case spraying or rinsing. By selecting spraying and press ‘select’, the relevant default parameters are automatically fed into the model. Compound specific data are not part of the default set and have to be filled in manually, using information from the product under study. Also product specific data like weight fraction should be filled in manually.

The default parameters that are proposed for the black mould remover (and disinfectants in general) are described in the factsheet ‘Disinfectants’ (see [www.consexpo.nl](http://www.consexpo.nl)). It is strongly recommended to carefully compare the data in the database (and their derivation as reported in the factsheet) and the assumptions in the exposure scenario (also reported in the factsheet) with the actual situation that has to be assessed.

Deviations should be reported, and the choice for alternative input parameters has to be motivated.







### Emission Tool (RIVM)

Information on the Emission tool is available at:

http://www.rivm.nl/dsresource?objectid=rivmp:24644&type=org&disposition=inline

whereas the softoware is available at:

http://www.rivm.nl/en/Documents\_and\_publications/Scientific/Models/Download\_page\_for\_ConsExpo\_software

### Stoffenmanager Tool

The “Stoffenmanager” (Dutch for “substance manager”) tool was originally a web-based risk prioritizing tool for small and medium sized enterprises (www.stoffenmanager.nl). The version 4.010 includes a quantitative model for estimating inhalation exposure to vapours, aerosols of low volatility liquids and inhalable dusts (including comminuting activities such as grinding and sawing). The model is also available in English. The web-based tool now has a specific REACH section and a section for exposure calculations in which e.g. full shift time weighted averages can be calculated. An exposure database containing around 1000 measurements with all relevant Stoffenmanager parameters is used to further underpin and validate the model. The database is still growing to allow future further validations and updates of the model. The Dutch Labour Inspectorate accepts Stoffenmanager 4.0 results as an alternative to measurements.

The Stoffenmanager 4.0 exposure model tool is currently somewhere between first Tier and higher Tier models. The rationale of the underlying exposure algorithm is based on work of Cherrie and Schneider (1999) but is adapted in several ways. The model uses process information, physicochemical characteristics, and mass balance to assess exposure situations. It needs more information than Tier 1 tools, but its flexibility is higher and the results are expected to be more accurate (and therefore in many instances probably less conservative). The model is easy to use. Stoffenmanager estimates task based exposure levels in mg/m3. A time-weighted average can be calculated for one or several combined tasks with duration of less than 8 hours. This is however only possible in the ‘exposure calculation’ section.

The following text gives a short evaluation of the Stoffenmanager 4.0 tool.

*Strengths*

* Clear and user friendly structure; easy to understand and use
* Based on handling categories that largely resemble the “technical process in which the substance is used” that is required in the short title of the exposure scenarios under REACH.
* Several choices for Operational Conditions and Risk Management Measures enable more specific estimates of exposure compared to simpler models.
* The output is based on statistical analyses of the relation between deterministic scores and around 1000 real exposure measurements.
* Results of assessments can be saved for later use or modification.
* The variation in the model is included in the exposure assessment output, which enables the use of different percentiles of the exposure distribution. The estimated exposure distribution is also visualized in a graph.
* Based on the outcome of the model, several control strategies (with different RMMs) can be selected and the effect of these strategies on the exposure estimate can be calculated.

*Limitations*

* Stoffenmanager 4.0 cannot (yet) be used to assess exposure to 1) gases, 2) fibres, 3) solid objects (= articles in REACH) other than wood or stone, or 4) “hot work techniques” like welding or waste burning.
* Handling categories are not directly linked to use descriptors (PROCs)
* Choice of dustiness category is not always obvious.
* No direct quantitative influence of parameters such as use rate or ventilation rate.
* No probabilistic use of input parameters possible yet.
* Changes in the calibration in the tool over time are not visible to the user
* Some parameters used to determine exposure are difficult to apply in the context of REACH. (e.g. room volumes)

*Ways to compensate for limitations*

* PROCs can be transposed to Stoffenmanager handling categories.
* Use the most conservative option of the dustiness category that is possibly relevant.
* Run the model with several combinations of input parameters, if the conditions are variable, and select a conservative but reasonable outcome from the resulting values, i.e. the most conservative option from the handling categories that are possibly relevant (expert assessor work).

*Applicability*

The tool cannot be used for gases, fibres, particles from articles and hot work operations.

*Status of validation*

The tool is based on a published scientific conceptual model of exposure (Marquart 2007, Tielemans 2007a). Extensive comparison with measured data sets has been carried and published (Marquart 2007, Tielemans 2007a). Stoffenmanager is regularly validated by comparison with independent measurement data. After validation, where relevant, the calibration is updated and the validity domain is expanded (Schinkel 2009).

### RISKOFDERM TOOL

The model is not currently available on the public domain. The link will be provided once the model is placed on the web.

The RISKOFDERM dermal model is the result of a European 5th framework programme project focused solely on dermal exposures in industrial and professional settings (Warren 2006). On the basis of measured data, approaches were developed to assess dermal exposure for six different so-called Dermal Exposure Operation units (DEO units). It assesses potential dermal exposure, i.e.

exposure on the skin and on the layers (of clothing or e.g. gloves) covering the skin. It therefore does not take into account any protective effect of clothing or gloves.

An Excel spreadsheet version of and a guidance document for the model can be downloaded from the TNO website11. A web-based version, with extended functionalities, is under development.

The basic estimate made by RISKOFDERM is the potential exposure per minute (for hands and/or remainder of the body). Total exposure over a longer period is calculated by entering the duration of the activity leading to exposure.

The following text gives a short evaluation of the tool.

*Strengths*

* Clear and user-friendly structure
* Model takes into account the influence of handling type/process through different algorithms for six Dermal Exposure Operation units (DEO Units)12
* The model is task-based
* Potential exposure of the hands and of the body are estimated separately (for some of the DEO Units)
* Several OCs and RMMs can be included
* Duration of exposure is taken into account
* Use rate of product is taken into account
* Algorithms are based on statistical analyses of a large set of measured potential dermal exposure data
* Choice of percentile of the output distribution can be based on the relative conservatism of the inputs
* The model provides warnings for input values outside of the ranges used for building the model
* The model also provides warnings if exposures are estimated that are expected to be unreasonably high compared to the level of contamination that the skin can contain.

*Limitations*

* The basis for the algorithms for handling of powders is relatively limited
* Information that is needed may not always be available to the assessor (e.g. use rate, direction of airflow)
* Only hands or body can be chosen as the exposed area, no further differentiation is possible
* Model does not take into account protective effect of clothing or gloves
* Algorithms for potential exposure of hands or body are not available for all DEO Units. Also, within DEO Units, not all possible situations were covered by the measured data underpinning the model13
* The dermal exposure data set supporting the algorithms may be heterogeneous
* The Choice of percentile of the output distribution is not always obvious
* Probabilistic assessments are not possible in the spreadsheet version
* The model does not combine estimates for separate tasks to full shift estimates.

*Ways to compensate for limitations*

* Conservative inputs can be chosen for parameters for which the assessor has limited real information available
* A few “what if” analyses can be done to study the influence of uncertain inputs
* A known or assumed effect of (protective) clothing or gloves can be taken into account separately from the model
* When conservative values are used for all inputs, the 75th percentile of the output distribution can be used as a reasonable worst case estimator; when less conservative input values are used, the use of the 90th percentile of the output distribution is recommended.

*Applicability*

Due to a lack of data on dermal exposure to volatile substances the model is not optimally suitable for very volatile substances (e.g. > 500 Pa vapour pressure). Use with input values outside those found in the measured data sets should also be done very carefully. These boundaries are provided in the Guidance document with the spreadsheet version that can be downloaded from the TNO website.

*Status of validation*

The validity of the model has not been established with independent data. A benchmark study after a first draft version showed that in general the model appeared to be quite reasonable. The validity and adequacy of the model is relatively well-known for situations resembling those measured in the data set that was the basis for the model (Warren 2006).

### ART (Advanced REACH Tool)

The ART approach makes use of mechanistically modelled estimates of exposure and any relevant measurements of exposure. The tool provides estimates of the whole distribution of exposure variability and uncertainty, allowing the user to produce a variety of realistic and reasonable worst-case exposure estimates, dependent upon the requirements of the particular risk assessment. The approach facilitates the inclusion of any new data that become available in the future or during the risk assessment process. The tool is suitable for expert assessors.

Since the tool allows the use of analogous exposure data from comparable scenarios, exposure assessments will not automatically require scenario-specific exposure data (Tielemans 2007b). However, the tool will provide an incentive for uniform exposure data collection and facilitate the sharing of exposure data up and down the supply chain. The tool incorporates both a mechanistic model and an empirical part with information from an exposure database. Both parts will be combined using a Bayesian statistical process in order to produce exposure estimates for specific scenarios relevant to the REACH process.

ART is a web-tool that is free to use following registration. Registration can be easily done via the website http://www.advancedreachtool.com.

*Strengths*

* Easy to use well structured web-tool
* The model takes into account several operational conditions and risk management measures throughout the whole exposure pathway from source to worker
* The effect of determinants is based on a combination of published effects and expert judgement
* The model was calibrated with extensive measured data
* It provides the choice of several percentiles of the resulting exposure distribution
* It provides an indication of the uncertainty of the mechanistic model result
* There is the possibility to estimate exposure during a number of consecutive activities
* It combines mechanistic model results with measured data in a Bayesian statistical process

*Limitations*

* High information requirements compared to Tier 1 models
* Expert judgement is often required in the selection of input parameters
* The tool does not predict dermal exposures
* Changes in the data set are not easily detected by the user
* The present version of ART cannot estimate exposure to fumes or gases
* It is difficult to convert the factors driving the exposure estimate in ART into operational conditions and risk management measures to be assessed and communicated under REACH

*Ways to compensate for limitations*

* Defaults for many inputs could be established, e.g. by registrants or consortia in an internal process or (preferably) in a wider stakeholder process
* Such defaults could be dependent on the industry sector or substance category
* Defaults could be included in Generic Exposure Scenarios based on ART, which could also include integration of available measured data
* Full shift exposure levels for short term activities can be calculated within the tool.

*Applicability*

ART can be used when exposure needs to be assessed for liquids and solids that are used in processes (either manual or non-manual). It can also be used for liquids and solids that are formed during processes such as fracturing of solid objects, abrasive blasting, impaction on, and handling of contaminated objects. It is, however, not suitable for use in scenarios where substances are formed through reaction processes (e.g. exhaust fumes, rubber fumes) or for scenarios where gases or fibres are used.

*Status of validation*

An evaluation of the tool predictions against an independent set of modelled data has not been published yet.

### EMKG-Expo Tool

The exposure prediction model of the German EMKG-Expo-Tool9 “Easy-to-use workplace control scheme for hazardous substances” is a generic tool that can be used to derive a Tier 1 inhalation exposure value for the workplace (EMKG, BAuA 2008). The tool was developed to help small and medium sized companies to comply with the Chemical Agents Directive. The EMKG-Expo-Tool is based on the banding approach of the COSHH Essentials originally developed by HSE (HSE 1999). While COSHH Essentials is seen as a qualitative approach to guide the assessment and management of workplace risks, the EMKG-Expo-Tool can also be used as a generic tool for assessing and comparing the level of exposure with limit values (OEL, DNEL). Hence the EMKG-Expo-Tool should be seen as an approach for filtering the non-risky workplace situations from those requiring detailed attention. The exposure assessment part is based on the banding approach of COSHH Essentials originally developed by HSE (HSE 1999). The tool only functions for inhalation exposure. The English version of the EMKG-Expo-tool is available on the BAuA website: (www.baua.de), http://www.reach-helpdesk.de/en/Exposure/Exposure.html.

The EMKG-Expo-Tool uses three input parameters: volatility or dustiness, amount of substance used, and control strategy. For solids, the dustiness of the substance is the principal physical property to be considered for the exposure potential. For liquids, ‘volatility’ is the key determinant. The amount used per batch or operation (small (g/ml), medium (kg/l) or large (tonnes/m3)) is regarded to be the most important condition to be considered, as it impacts how the material is packaged, transported and used.

The control strategy is defined with factors that aim at exposure reduction (general ventilation, local exhaust ventilation, containment). These general control solutions are underpinned by a series of Control Guidance Sheets (CGS) which provide practical examples of control approach for common industrial unit operations such as weighing mixing and filling. Often these unit operations can be linked to a process category of the use descriptor system.

The tool predicts a lower and an upper value for the exposure range (in mg/m3 for solids and ppm for vapours). In order to arrive at a conservative estimate the upper value of the exposure range should be used for the risk characterisation, i.e. the comparison with the DNEL-value.

*Strengths*

* Clear and user friendly structure
* Influence of amount of product is taken into account
* Iteration is possible by considering short term exposure, scale of use, control strategy
* Provides control strategies for a range of common tasks, e.g. mixing, filling etc.
* Control guidance sheets are available on the Internet, thus the use of the tool in connection with a use descriptor may lead to the identification of relatively detailed risk control guidance.

*Limitations*

* Can only derive inhalation estimates.
* The exposure assessment parts are not visible to the user.
* The number of choices regarding the input values is relative limited, thus iteration is limited as well. E.g., the substance concentration (in products) is assumed to be 100%. The duration of exposure is assumed to be the shift length. If the activity is carried out for less than 15 minutes a day the next lower exposure range can be used.
* Not suited for gases (handled or released)
* Should not be used for tasks where aerosols of unknown composition are formed (e.g. fumes, dusts are formed through abrasive techniques)
* Not suitable for CMR substances.

*Status of validation*

The exposure prediction model of COSHH Essentials was evaluated by comparison of predicted exposure ranges presented in Table R.14-15 with measured data, and by extensive peer review of the logic and content by experts (Maidment 1998). However, it was very difficult to find quality data for comparisons.

The German BAuA conducted the first and most complete evaluation of its exposure predictive model to date, based on 958 independent measurement data points (Tischer 2003 a, b). The primary empirical basis for the analysis was measurement data collected within several BAuA field studies. Some data were also provided by the chemical industry. It was found that for solids (powders) and medium-scale use of liquids, measured exposures were lower or within the predicted range. For the wide dispersive use of small quantities (millilitres) of solvent-based products (such as paint or adhesive), measured exposures sometimes exceeded the range of EMKG-Expo-Tool assessment.

Testing the COSHH Essentials model for three volatile organic chemicals at a small printing plant suggests that the tool works reasonably well both for short-term task-based and full-shift exposure measurements (Lee et al. 2009). Evaluation of the model with exposure measurements from 12 petroleum company workplaces in Japan found that the model tends to provide safe-sided judgements (Hashimoto et al. 2007).

Overall the conclusion, on the basis of the available evidence, is that the EMKG-Expo-tool is sufficiently conservative for a Tier 1 tool and can thus be used as such.

### EASE (model implemented in EUSES) (inhalation)

The EASE model (Estimation and Assessment of Substance Exposure) is a rule-based expert system that has been in use for several years to estimate personal exposure to hazardous substances in the workplace. It was developed by the UK Health and Safety Executive (HSE) to enable exposure to be assessed for European regulatory risks assessments of new and existing substances. The system uses a number of rules to predict a range of likely exposures or an “end-point” for a given work situation. The end-point ranges were derived from an analysis of data contained in the HSE’s National Exposure Database. For inhalation exposure the rules incorporated into EASE encompass the physico-chemical properties of the substance (physical state, vapour pressure, type of dust) and the way in which it is used (source of substance, pattern of use, type of control measures used). Exposure is estimated as contaminant concentration in air for the identified task (as mg/m3), rather than 8-hour time-weighted average. For dermal exposure EASE only estimates the rate of contamination (as g/cm2/day) of the hands and forearms of the worker.

**NOTE: this model is not recommended for the assessment of dermal exposure for biocidal products**

In 1999, the Institute of Occupational Medicine in Edinburgh (IOM) conducted a series of validation studies. These studies involved over 4,000 inhalation exposure measurements covering fifty-three EASE end-points. The data included measurements of solvent vapours, non-fibrous dusts and fibres, both asbestos and synthetic fibres. In 56% of the end-points the EASE prediction was mostly greater than the exposure measurements and in one third of the end-points the EASE estimates were comparable with the measurements. The predictions were generally more reliable for solid aerosols compared with gases and vapours. Similar studies involving dermal exposure assessment suggest that EASE also tends to overestimate the dermal exposure by about one order of magnitude, although the average measured exposure levels appear to increase in line with the predictions from EASE.

The output ranges for exposure by inhalation are considered acceptable for exposure assessment. However, as currently implemented, the dermal routines of EASE are not recommended for use unless the hands and forearms are the only locations for skin contamination.

EASE is available from the Health and Safety Executive and is free.

### AOEM

The AOEM (Agricultural Operator Exposure Model) is a predictive model for the estimation of agricultural operator exposure from the application of pesticides outdoors. It has been developed on the basis of exposure data from more than 30 unpublished GLP exposure studies conducted between 1994 and 2009 mainly for the purpose of plant protection product authorisation. The statistical analysis of the data resulted in six validated models for typical scenarios of pesticide mixing/loading, and application outdoors including downwards and upwards spraying with vehicle-mounted/-trailed or hand-held equipment. As a major factor contributing to the exposure of operators, the amount of active substance used per day was identified. Other parameters such as formulation type, droplet size, presence of a cabin or density of the canopy were selected as factors for particular sub-scenarios. However, in the case of knapsack mixing/loading, and hand-held application directed downwards, the number of data was too small for identifying reliable exposure factors; instead the relevant percentiles of the exposure distribution were used. Exposure predictions are generally made for the 75th percentile to account for medium term exposure and also for the 95th percentile to account for acute exposure. The model represents current application techniques and practices in Europe and allows for a tiered approach considering personal protective equipment if necessary. The model and the corresponding EFSA calculator is part of the EFSA guidance on the assessment of non-dietary exposure to plant protection products and is used for national authorisation and for registration procedures of plant protection products in the EU.

### SprayExpo model

*Theoretical background and model features*

The Fraunhofer Institute for Toxicology and Aerosol Research has developed a deterministic model for predicting aerosol exposure during spraying [Koch et al., 2004]. The resulting software product, “SprayExpo” in the current version 2.0, is available as a worksheet for MS Excel on the BAuA homepage (http://www.baua.de/dok/3053520).

It is suitable for all different types of applications that involve large-area indoor spraying or nebulizing of biocidal products, including surface disinfection in hospitals, canteen kitchens and animal husbandry.

The model calculates the time-dependent airborne concentration of the respirable, thoracic and inhalable size fraction of aerosols generated from the spraying of liquid products in indoor environments. In addition, the dermal exposure of the sprayer is modelled.

The model is suitable to calculate short-term exposure originating from the release process during spraying scenarios. Long-term exposure due to the emissions of vapours from walls and other surfaces are not included in the model. One prerequisite for the model is that the biocidal product is composed of a non-volatile active substance dissolved in a solvent with known volatility. This prerequisite applies to most of the biocidal products.

The main input parameters are: the released droplet spectrum, the release rate, the concentration of the active substance, the spatial and temporal pattern of the release process (surface spraying against floor, ceiling, wall; room spraying, etc), the vapour pressure of the liquid, the size of the room and the ventilation rate. The path of the sprayer can be explicitly included into the model.

To support the user, standard scenarios have been included in the worksheet and droplet spectra of several often-used spraying devices are provided. The modelled rooms and spray patterns are graphically visualized. In addition, a detailed guidance including a description of the theoretical background is included within the worksheet.

*Validation*

An advantage of SprayExpo is that it was validated against real situations. This validation was performed for various scenarios and is based on a comparison of calculated model estimations with actual measurements. The results of the validation have been published [Koch et al., 2012] and are available at: <http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/SprayExpo.html;jsessionid=1CB61000FB45A429C44C96FDF3753CEF.1_cid380>

They demonstrate that SprayExpo generates good estimates of the inhalative exposure from indoor spray applications. Dermal exposure gives good results, particularly for room spraying. However, the dermal burden is often underestimated when random spattering or direct contact occurs.

***References***

W. Koch, E.Berger-Preiß, A. Boehncke, G. Könnecker, I. Mangelsdorf, Arbeitsplatzbelastungen bei der Verwendung von Biozid-Produkten, Teil 1: Inhalative und dermale Expositionsdaten für das Versprühen von flüssigen Biozid-Produkten, Forschungsprojekt F1702 der BAuA, Dortmund 2004.

W. Koch, W. Behnke., E. Berger-Preiß, H. Kock, S. Gerling, S. Hahn, K. Schröder, Validation of an EDP-assisted model for assessing inhalation exposure and dermal exposure during spraying processes. Forschungsbericht F 2137, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin Dortmund/ Berlin/ Dresden, 2012.

M. Tischer, U. Poppek, SprayExpo – Softwaretool zur Bewertung der inhalativen und dermalen Exposition bei Sprühprozessen, Sicherheitsingenieur 2/2013, pp. 8-13.

### EUROPOEM

The European Predictive Operator Exposure Model Database Project (EUROPOEM)

EUROPOEM I constructed a generic database of monitored operator exposure studies on plant protection products in Europe. EUROPOEM II now expands that objective, also covering bystanders and re-entry workers, and examines mitigation measures.

* **Exposure data on a range of techniques including:**
  + boom sprayers
  + knapsack sprayers
  + airblast sprayers
* **Dermal and inhalation exposures included**
  + Measured by
    - patch techniques
    - whole body dosimetry
    - personal air pumps
    - fixed site air collectors
  + Allows
    - scenario subsetting
    - statistical analysis
    - exposure summaries
  + Useful for
    - designing exposure studies
    - predicting exposures
    - model validation
    - risk analysis
    - comparing application techniques
    - product authorisation
    - defining need for protective clothing

*Availability* EUROPOEM is available through <http://www.ctgb.nl/en/plant-protection/assessment-framework-plant-protection-products/drr>

http://www.ctb.agro.nl/

### Models of the US-EPA Office for Pollution Prevention and Toxics

The Office for Pollution Prevention and Toxics of the US-EPA (EPA-OPPT) maintains a series of models for exposure assessment. The main use of these models is for assessments of new and existing chemicals. The consumer and worker exposure models are also useful for exposure assessment of biocides, if the expected exposure scenario matches the scenario assumed in the model.

The OPPT explicitly recognises screening tier and higher tier models. Relevant models in the screening tier are E-Fast and ChemSTEER. E-Fast contains consumer and environmental release models, ChemSTEER contains industrial and worker exposure models, and environmental release models. Relevant models in the higher tiers are MCCEM and WPEM. MCCEM models release and indoor distribution of volatile substances, WPEM models exposure to volatile substances from paint.

**1 Screening tier models**

#### US EPA E-FAST2014

*Features* Provides screening-level estimates of the concentrations of chemicals released to air, surface water, landfills, and from consumer products. Estimates provided are potential inhalation, dermal and ingestion dose rates resulting from these releases. Modelled estimates of concentrations and doses are designed to reasonably overestimate exposures, for use in screening level assessment. E-Fast contains the Consumer Exposure Module (CEM) that includes and updates the former **FLUSH, DERMAL, and SCIES tools.** This means that instead of running the individual cluster of DOS-Based tools, a user now only needs to run the E-FAST model.

* E-FAST calculates appropriate human potential dose rates for a wide variety of chemical exposure routes and estimates the number of days per year that an aquatic ecotoxicological concern concentration will be exceeded for organisms in the water column.
* To execute the E-FAST model in order to assess general population exposure and aquatic environmental exposure and risk resulting from industrial releases, you will need to enter: amount of chemical releases; media of release; days per year of release; certain chemical properties; where possible, detailed release location data; if no detailed location data is available, generic industry codes can be applied. To execute the consumer exposure assessment modules in E-FAST, the user will need to enter: the type of product; weight fraction; vapour pressure; and molecular weight.

*Theoretical* The Consumer Exposure Module (CEM) is an interactive model within E-FAST which calculates conservative estimates of potential inhalation exposure and potential and absorbed dermal exposure to chemicals in certain types of consumer products. The scenarios covered with relevance to consumer biocide use are:

- liquid cleaners (Types 2.01 and 6.02);  
- latex paints (Type 6.02);  
- laundry detergents (Type 6.01)  
- air fresheners (vapour dispersion, Types 18.02 and 19.02);  
- bar soap (Type 1)  
- custom.

CEM allows for screening-level estimates of acute potential dose rates, and average and lifetime average daily dose rates. Because the model incorporates either a combination of upper percentile and mean input values or all upper percentile input values for various exposure factors in the calculation of potential exposures/doses, the exposure/dose estimates are considered "high end" to "bounding" estimates. Consumer inhalation exposures modelled in CEM use the same approach and calculations as the Multi-Chamber Concentration and Exposure Model (MCCEM) (Versar, 1997b), as well as scenarios depicted in the Screening -Level Consumer Inhalation Exposure Software (SCIES) (Versar, 1994). Dermal exposures are modelled using the same approach and equations as the DERMAL Exposure Model (Versar, 1995).

*Availability* E-Fast is available from the web site of US-EPA OPPT:

<http://www.epa.gov/oppt/exposure/pubs/efast.htm>

#### US EPA ChemSTEER

The Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) is a computer-based software program that can be used to estimate workplace exposures and environmental releases for chemicals manufactured and used in industrial/commercial settings.

*Features* The tool provides screening tier exposure estimates for

• Occupational inhalation and dermal exposure to a chemical during industrial and commercial manufacturing, processing, and use operations involving the chemical.   
• Releases of a chemical to air, water, and land that are associated with industrial and commercial manufacturing, processing, and use of the chemical.

The first set of estimation methods is useful to identify exposure to biocides

ChemSTEER allows users to select predefined industry-specific or chemical functional use-specific profiles or user-defined manufacturing, processing and use operations. Using these operations and several chemical-specific and case-specific parameters and general models, the ChemSTEER computer program estimates releases and occupational exposures. The methods in ChemSTEER were developed by the EPA Office of Pollution Prevention and Toxics (OPPT); Economics, Exposure, and Technology Division; Chemical Engineering Branch.

ChemSTEER is available from the web site of US-EPA OPPT <http://www.epa.gov/oppt/exposure/pubs/chemsteer.htm>

#### US EPA Pesticides Inert Risk Assessment Tool (PIRAT)

Provides screening level estimates of exposure and risk to pesticide inert ingredients that are used in a residential setting. This includes assessing both indoor and outdoor residential uses of pesticide products. PIRAT will assess acute and chronic risks and will be able to assess adults and children separately.

PIRAT calculates human dose rate and Margin of Exposure (MOE) for a wide variety of chemical exposure routes. The model is organized by the type of pesticide product, for example liquid ready-to-use or granular products, as well as by application technique, such as spray can or drop-type spreader.

In order to run the PIRAT model, the user must have the following information: the formulation type of the pesticide product (liquid ready to use, powder, etc.); the function of the inert ingredient in question (wetting agent, solvent, dye, etc.); an appropriate toxicity endpoint (typically a No Observed Adverse Effect Level - NOAEL); an understanding on how the pesticide product is used; the equipment used to apply the pesticide product; and an application rate.

PIRAT is available from the website of US EPA OPPT: <http://www.epa.gov/oppt/exposure/pubs/pirat.htm>

#### US EPA ADL Polymer Migration Estimation Model (AMEM)

The ADL Polymer Migration Estimation Model (AMEM) estimates the fraction of a chemical additive that migrates from polymeric materials to air, water, and solids. There are "default" coefficients for six different polymers: silicone rubber, natural rubber, LDPE (Low Density Polyethylene), HDPE (High Density Polyethylene), polystyrene, and unplasiticized PVC (Polyvinylchloride).

The model assumes:

* The chemical is homogeneously distributed throughout the polymer and is not initially present in the phase external to the polymer,
* Migration of the chemical is not affected by the migration of any other chemical or by the penetration into the polymer of any component of the external phase,
* The migration is isothermal,
* and Fick's law of diffusion and convective mass transfer theory applies.

In order to use the model the following determinants are needed:

* Polymer category (i.e., Silicone Rubber, Natural Rubber, LDPE, HDPE, Polystyrene, or unplasiticized PVC) or diffusion coefficient of the polymer.
* Molecular weight of additive.
* Total polymer sheet thickness (cm) External phase (i.e., air, water, or solid)
* One or two sided migration Time frame of interest

AMEM is available from the website of US EPA OPPT: <http://www.epa.gov/oppt/exposure/pubs/amem.htm>

#### US-EPA Multi-Chamber Concentration and Exposure Model (MCCEM), Version 1.2

*Features* The Multi-Chamber Concentration and Exposure Model (MCCEM) was developed for the U.S. EPA Office of Pollution Prevention and Toxics to estimate indoor concentrations for chemicals released in residences (GEOMET, 1995). The feature of MCCEM is as follows:

1. MCCEM need time-varying emission rates for a chemical in each zone of the residence and outdoor concentrations. The emission rates of pollutants can be entered into the model either as numbers or as formulas.
2. Inhalation exposure levels are calculated from the estimated concentration if the user specified the zone where an individual is located in a spreadsheet environment.
3. MCCEM has data sets containing infiltration and interzonal airflow rates for different types of residences in various geographic areas. The user can select from the data sets, or can input zone descriptions, volumes and airflow rates.
4. Concentrations can be modelled in as many as four zones (chambers) of a residence.
5. The program is capable of performing Monte Carlo simulation on several input parameters (i.e., infiltration rate, emission rate, decay rate, and outdoor concentration) for developing a range of estimates for zone-specific concentrations or inhalation exposure.
6. The program has an option to conduct sensitivity of the model results to a change in one or more of the input parameters.
7. The percentage of cases for which modelled contaminant concentrations are at or above a user-specified level of possible concern or interest is determined.

*Theoretical* This multi-chamber mass-balance model has been developed by using air infiltration rates and corresponding interzonal air flows for a user-selected residence or a user-defined residence. This model provides a spreadsheet environment to the user for entering time-service data for emission rates in one or more zones, the zone of exposure, and concentration values of the contaminant outdoors.

Information assembled by Brookhaven National Laboratory concerning measured infiltration/exfiltration airflow, interzonal airflow, and the volume and description of each zone for different types of structures in various geographic areas has been incorporated in the software for access by users. Two generic houses represent average volume (408 m3) and flow information in summer or fall/spring that has been complied from a large number of residences. One generic house has a bedroom and the remainder, while the other has a kitchen and the remainder.

*Remarks* The user's guideline listing good examples enable risk assessors to handle easily the full items within MCCEM. In addition, MCCEM contains a database of various default house data that are needed to complete each calculation such as air-exchange rates, geographically based inter-room air flows, and house/room volumes. However, so many data might confuse risk assessors who aim to evaluate the risk tendency of pesticides for a typical population at the first tier approach. Therefore, it seems reasonable that the user’s guide suggests that a two-storey residence will be chosen by defaults, and that US EPA(1997) recommends a fixed storey using the above generic house in summer to estimate a high-end assessment.

*Availability* MCCEM is available as version 1.2 from the web site of US-EPA OPPT as a beta version: http://www.epa.gov/opptintr/exposure/

*References*

GEOMET Technologies, Inc., *USER’S GUIDE; Multi-Chamber Concentration and Exposure Model,* Maryland, 1995.

Residential Exposure Assessment Work Group, (1997) *Standard Operating Procedures (SOPs) for Residential Exposure Assessments,* Contract No. 68-W6-0030, Work Assignment No. 3385. 102.

U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, *Series 875 - Occupational and Residential Exposure Test Guidelines, Group B - Post application exposure monitoring test guidelines,* Version 5.3, 1997.

#### US-EPA Wall Paint Exposure Assessment Model (WPEM)

*Features* The Wall Paints Exposure Assessment Model (WPEM) estimates the potential exposure of consumers and workers to the chemicals emitted from wall paint which is applied using a roller or a brush. WPEM is a user-friendly, flexible software product that uses mathematical models developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. This is then combined with detailed use, workload and occupancy data (e.g., amount of time spent in the painted room, etc,) to estimate exposure. The output of WPEM was evaluated in a home used by EPA for testing purposes and, in general, the results were within a factor of 2. The WPEM provides exposure estimates such as Lifetime and Average Daily Doses, Lifetime and Average Daily Concentrations, and peak concentrations.

*Remarks* WPEM uses US units (feet and gallons) instead of SI-units. User input and interpretation of results is hampered for those not used to these units. It should also be noted that some US units are not the same as the UK’s imperial weights and measures, e.g. gallons.

*Availability* WPEM Version 3.2 was developed under a contract by Geomet Technologies, a subsidiary of Versar, Inc. for the EPA's Office of Pollution Prevention and Toxics, Economics, Exposure, and Technology Division, Exposure Assessment Branch. This project was accomplished in co-ordination and co-operation with the National Paint and Coatings Association (NPCA), in addition to paint manufacturers and chemical suppliers. WPEM is available as version 3.2 from the web site of US-EPA OPPT: http://www.epa.gov/opptintr/exposure/

#### US-EPA SOP Residential Pesticide Pesticide Exposure Assessment

The Residential Exposure Assessment Work Group developed Standard Operating Procedures for Residential Exposure Assessments for the US-EPA Office of Pesticide Programs.

The Standard Operating Procedures for Residential Pesticide Exposure Assessment (Residential SOPs) are instructions for estimating exposure resulting from the most common non-occupational pesticide uses including lawn and garden care, foggers, and pet treatments.

They provide:

* guidance for exposure assessors who are responsible for the residential non-dietary component of the risk assessment process,
* a description of the methods used to evaluate chemicals in a straightforward and user-friendly fashion, and
* a framework for future research directed at improvements in the residential assessment process for pesticides.

The objective of the SOPs is to provide standard default methods for developing residential exposure assessments for both application and post-application exposures when applicable monitoring data are limited or not available. The SOPs cover calculation algorithms for estimating dermal, inhalation, and/or incidental ingestion doses for a total of 13 major residential exposure scenarios: (a) lawns; (b) garden plants; (c) trees; (d) swimming pools; (e) painting with preservatives; (f) fogging; (g) crack and crevice treatments; (h) pet treatments; (i) detergent; (j) impregnated materials; (k) termiticides; (l) inhalation of residues from indoor treatments; and (m) rodenticides. Default values for the underlying exposure factors, such as amount used or dermal transfer factors, are specified. These defaults represent (reasonable) worst case values.

Theory The SOPs aim at screening tier residential exposure assessment. Each SOP provides (1) a description of the exposure scenario; (2) recommended algorithms and default values for parameters for quantifying exposures; (3) example calculations; (4) a discussions of limitations and uncertainties; and (5) references.

The calculations are build around the general equation PDR = C x CR, where PDR = potential dose rate (mg/day); C = contaminant concentration in the media of interest (mg/cm2; mg/m3, mg/g); and CR = contact rate with that media (cm2/day; m3/day; day). Each product category and exposure route may differ with respect to the specification of the contact rate CR. The contaminant concentration C may be expressed as an in use concentration or a unit exposureThe current version of the Residential SOPs (referred to as the 2012 Residential SOPs) can be downloaded from <http://www.epa.gov/opp00001/science/residential-exposure-sop.html>

### US Aggregate exposure models

Newly emerging exposure models are set up to accommodate aggregated residential exposure scenarios, containing multiple sources of a chemical. These models are mostly initiated in response to the demands of the Food Quality Protection Act (FQPA) in the United States. The FQPA forces legislators to account for aggregated and cumulative exposures of pesticides.

Four sets of models are available to comply with the demands of the FQPA: SHED, Lifeline, Calendex and CARES/REx. A common approach in these models is that they estimate exposure from the probability to contact a source of exposure (e.g. a product or a food item) and the exposure resulting from that contact. The incorporation of the probability of contact is new in comparison with the other models. It is included because the FQPA-initiated models sum exposures from all potential sources of the active ingredient (treatments, products and food-items). The assumption that the probability of contact is one, i.e. a single person experiences all contacts, would result in an overestimation of exposure. All other models take a single contact, e.g. a single product use, as their basis and may therefore neglect the probability of exposure. The European Union biocides directive focuses on single products and the risks of their use. Therefore, product-based models are appropriate instead of the FQPA-initiated models.

For information, and as sources of information, the FQPA-initiated models are described below.

##### US EPA SHEDS

*Features* The Stochastic Human Exposure and Dose Simulation model for pesticides (SHEDS-pesticides) is developed by the US-EPA, Office of Research and Development, National Exposure Research Laboratory in Cupertino with ManTech Environmental Technology Inc. Overall goals of SHEDS are

* to characterise variability and uncertainty in population estimates;
* to quantify infants and children’s aggregate and cumulative exposure and dose to pesticides;
* to identify significant media, routes, pathways and exposure factors;
* to provide a framework for prioritising measurement needs under FQPA.

Exposure estimates are based on the inhalation, dermal and oral route of exposure, application and post-application exposures, for users and the entire population. SHEDS calculates a longitudinal 1-year exposure profile with averaging time periods of 1 day, 7 days, and 30 days and a seasonal and annual average.

*Theory* The basic unit of the SHEDS model is the exposure profile of an individual during a 1-year time period. Total exposure is a summation from residential and dietary exposures. From a simulated personal activity pattern and the application times of pesticides over the year, route specific exposure profiles are calculated. Activities of a person are based on the simulation of a 1-year diary, differentiating the four seasons and differentiating weekdays from weekends. Population estimates are generated by simulating many persons by Monte Carlo sampling.

Residential exposure estimation is largely based on the Residential Exposure SOPs (US-EPA, 1997). Refinements include

* variability within a day;
* dermal hand and dermal non-hand body parts separately;
* bathing and hand washing adjust dermal profiles;
* non-dietary ingestion via both hand-mouth and object-mouth;
* hand-mouth ingestion linked to dermal hand exposure.

Calculation includes uptake of the active ingredient, distribution in the body and elimination by urine of the substance and its metabolites.

*Availability* SHEDS is available from the US-EPA. Contacts are V. Zartarian and H. Özkaynak (US-EPA, Office of Research and Development, NERL).

*References*

US EPA. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. US-EPA, Draft.

##### Lifeline

*Features*. The LifeLine™ model is developed by the Lifeline group (Price et al., 2001). It defines the exposures to pesticides from dietary residues, residential uses, and contamination of tap water that occur on each day of an individual’s life. These exposures determine the doses that result from the exposures, which are in turn summed to give an estimate of the total or aggregate dose.

The model determines the individual's exposures by modelling where people are born, how individuals grow and age, how they move from home to home and region to region of the US, how they use or do not use pesticides, and their daily activity and dietary patterns. Using chemical-specific information on the fraction of the dermal, oral, and inhalation exposures that are absorbed, the LifeLine™ model calculates the total absorbed dose received from the oral, dermal, and inhalation routes for each day of the individual’s life. These estimates of absorbed dose can be summed to give the total systemic (aggregate) dose that can provide the basis for assessing aggregate risk.

*Residential exposures* Estimates of exposure from residential uses of a pesticide are based on data on pest pressure collected in the National Home and Garden Survey (US EPA, 1992b). This survey determined the frequency with which specific pests required treatment in different residential microenvironments. These data are used to determine the probability and frequency of using each pesticide in the residence. User-supplied data on pesticide product’s characteristics are then used to predict the residues on surfaces and in the air of the residences that result from the use of the pesticide.

LifeLine™ contains information on the US housing stock, including information on room sizes, air exchange rates and other factors. Using these data and the exposure equations described in US EPA SOPs for residential exposure assessments (US EPA, 1997) the model estimates the exposures that occur by the oral, dermal, and inhalation routes. These data are used to estimate the absorbed doses for each route and the aggregate dose. These exposures include both the application-related exposure and the post-application exposures. The post application exposures considered by LifeLine™ include exposures that happen on the day of application and on subsequent days.

*Availability* Lifeline is available from the Lifeline group, 129 Oakhurst Road, Cape Elizabeth ME 04107 USA, e-mail: psprice@pipeline.com.

*References*

Price P.S., Young J.S. and Chaisson C.F. 2001. Assessing Aggregate and Cumulative Pesticide Risks Using a Probabilistic Model. Annals of Occupational Hygiene 45: 131-142.

US Environmental Protection Agency, 1992b. *National Home and Garden Pesticide Use Survey*. Prepared by the Research Triangle Institute for the Office of Pesticides and Toxic Substances, Biological and Economic Analysis Branch.

US EPA (U.S. Environmental Protection Agency). 1997. Exposure Factors Handbook. EPA/600/P-95/002F(a-c), Washington, DC.

US EPA. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. US-EPA, Draft.

##### Calendex

*Features* Calendex™ has been developed to provide a flexible, but powerful, tool to use in estimating consumer and occupational exposure to chemicals. FQPA specifically requires estimation of aggregate exposure due to residues in the diet and drinking water as well as those encountered due to residential uses of pesticides. The Calendex™ software provides a vehicle for managing the various scenarios and data sources in complex analyses of aggregate and cumulative exposure and providing full documentation that is suitable for regulatory situations. Detailed objectives and uses of Calendex™ currently include the following:

* Calendex™ provides estimates of exposure that are statistically representative of the US population as well as a wide range of user-specified subpopulations.
* Calendex™ permits the estimation of exposure to single or multiple compounds for a wide variety of time periods (daily/acute, short-term, intermediate-term, and chronic (up to one year) time periods).
* Exposure to chemicals can result from residues in food, residues in or around the residence, and/or residues from occupational uses of the chemical. The route of exposure can result from oral, dermal, or inhalation, or a combination of these routes.
* Calendex™ is designed to permit the inclusion of the temporal aspects of exposure in each assessment.
* Calendex™ is designed to permit the inclusion of the spatial aspects of exposure in each assessment. For example, the types of pests encountered in a home in Florida may be very different than those found in a home in northern Maine.
* Calendex™ is designed to permit the user to conduct simple exposure estimates based on point estimates or probabilistic estimates based on distributions and Monte Carlo analysis techniques.

*Theory* The goal of non-dietary exposure assessments is to characterise the exposure of the population of concern (e.g., adults, toddlers, etc.) and to identify the variability associated with that exposure. Typically, the primary objectives are to estimate the level of exposure via ingestion, inhalation, or dermal absorption of the substance and to identify the sources of both variability and uncertainty in the estimate. In addition, the exposure assessment can also be useful in identifying the potential importance of a specific route relative to other pathways of exposure.

The general exposure model is of the form *Contact x Residue = Exposure.* To assess the total aggregate or cumulative exposure, three types of data for each product or use are required:

* use pattern information of products of interest, frequency of application and amount of product applied;
* environmental concentration data on days before, during and after treatment (residue factors); and
* exposure factors such as body weight, breathing rate, and activity patterns (contact factors).

Calendex™ currently uses the calendar day as the basic unit of time for calculating human exposure to one or more chemicals. All reporting periods longer than a day are built up from sequential daily exposures to an individual, summed, and averaged over the number of days included in the reporting period to provide an average daily exposure for that individual over the time duration specified in the analysis. The calendar model:

* Uses the probability that individual exposures occurs around specific dates
* Calculates exposure for individual chemical uses and exposure routes
* Combines the exposure-probability distributions for individual uses using Monte Carlo sampling techniques

*Availability* Calendex is available from Novigen Sciences Inc., 1730 Rhode Island Avenue NW Ste. 1100, Washington, DC 20036 UNITED STATES, info@novigensci.com or Novigen Sciences Inc. 75 Graham Road Malvern, Worcs, WR14 2HR UNITED KINGDOM, info@novigensci.co.uk.

##### CARES/REx

*Features*. CARES stands for Cumulative and Aggregate Risk Evaluation System. It contains a part that models dietary exposure to pesticides and a part that models residential exposures to pesticides, the REx model. REx is a **R**esidential **Ex**posure Model which automates the calculations required to estimate exposure and associated risk from residential use(s) of pesticides. REx provides a multi-pathway, multi-route modelling approach and includes multiple assessment methods (e.g., post application whole-body dermal transfer coefficients and/or unitless bodypart- specific transfer factors). It allows the risk assessor to examine exposure values for selected applicator or post-application scenarios and considers inhalation, dermal, and incidental ingestion routes. Multiple subpopulations are addressed simultaneously. Exposure factors associated with these subpopulations can be customised by the user. Further, the default scenarios and algorithms currently specified in the EPA Standard Operating Procedures for Residential Exposure Assessment are included as optional selections in REx.

*Theory* The product use scenarios in REx are those based on EPA's Residential SOPs draft document (US-EPA, 1997). One or more (up to six) scenarios can be aggregated to estimate exposure and dose to receptors of interest.

*Availability* REx is available though http://www.infoscientific.com/ where the spreadsheet can be downloaded.

*References*

US EPA. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. US-EPA, Draft.

# Generic Models Algorithms for Primary & Secondary Exposure Assessment

In this appendix simple algorithms are given that are useful for calculating the exposure via inhalation or the dermal or the oral route. These model approaches were described in the TGD for new and existing chemicals [1], Chapter 2, Appendix II.

The considered approaches wwere also published in the *TNsG Huaman Exposure to Biocidal Products* (2007) in Appendix4: Human Exposure to Rodenticides (Protuct Type 14). Since the generic models can be used for different product types the generic models are described here without the reference to rodenticides application.

Note that the algorithms that are presented in the following have been also implemented in ConsExpo [1, 2].

## Inhalation exposure

A substance that is released as a gas, vapour or airborne particulate into a room (e.g. a component of an aerosol insecticide, a solvent in a formulation, a powder detergent).

Exposure concentration in air is higher in confined spaces such as indoor rooms. Therefore, and in agreement with worst case and realistic worst case concepts, the scenario covers indoor use. Both professionals and non-professionals are expected to be exposed under such conditions.

An equation for volatile substances and airborne particles was developed. It is assumed that the substance is released as vapour, gas, or airborne particles, and the room is filled immediately and homogeneously with the substance. Ventilation of the room is assumed to be absent. When the inhalable and/or respirable fraction is known, it should be taken into account. It should be remembered that the non-respirable-fraction can be swallowed and oral exposure may also need to be considered.

The concentration in the inhaled air (*Cinh*) after using an amount *Qprod* of the product is then:

|  |  |
| --- | --- |
|  | *Equation 1* |

|  |  |  |  |
| --- | --- | --- | --- |
| *Cinh* | Average concentration in inhaled air | mg/m3 |  |
| *Qprod* | Amount of undiluted product used | mg |  |
| *Fcprod* | Weight fraction of active substance in the product |  |  |
| *Vroom* | Volume of the room (living room) | m3 |  |

For indoor use, for example the default living room size is 50 m3. It should be noted that for short-term local exposure the volume of the room could be reduced (e.g. to 2 m3) to represent the volume of air immediately surrounding the user.

The resulting inhalation intake of the active substance might be calculated as:

|  |  |
| --- | --- |
|  | *Equation 2* |

|  |  |  |  |
| --- | --- | --- | --- |
| *Ainh* | Amount of active substance inhaled/respired |  | mg/kg BW/d |
| *Fresp* | Inhalable or respirable fraction of product |  | (Default : 1) |
| *Cinh* | Average concentration in inhaled air |  | mg/m3 |
| *Qinh* | Ventilation rate of adult |  | m3/hour  (Default: 0.021 m3/min; 1.25 m3/h) |
| *Tcontact* | Duration of exposure |  | hours |
| *Nevent* | Number of events |  | (usually per day) |
| *BW* | Body weight | Kg |  |

## Dermal exposure to a non-volatile active substance

A non-volatile active substance (e.g. vapour pressure < 10 mPa[[2]](#footnote-2)) contained in a medium. The concentration in the product as it is used can be calculated from the following equation:

|  |  |
| --- | --- |
|  | *Equation 3* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Cder* | Average concentration of active substance in product on skin | mg/cm3 |  | |
| *Cprod* | Average concentration of substance in undiluted product | mg/cm3 |  | |
| *D* | Dilution factor. If dilution results in a 1 % dilution, then *D* is the reciprocal: *D* = 1/0.01 = 100 | (Default : 1) | |  |
| *Qprod* | Amount of undiluted product used | mg |  | |
| *Fcprod* | Weight fraction of active substance in the product |  |  | |
| *Vprod* | Volume of undiluted product | cm3 |  | |

Dermal exposure is possible as a result of direct contact without gloves or insufficient covering of the skin during application of dusty formulations. Liquids and dusty formulations have the ability to spread/wander during handling, and the exposure of hands and forearms are used in the scenario.

The total amount to which the skin is exposed estimated by the following equation:

 *Equation 4*

|  |  |  |  |
| --- | --- | --- | --- |
| *Ader* | Amount of active substance on skin | mg or | mg/event, mg/d, mg/kg |
| *Cder* | Average concentration of substance in product on skin | mg/cm3 |  |
|  |  |  |  |
| *THder* | Thickness of layer of product in contact with skin | cm | (Default: 0.01 cm) |
| *AREAder* | Surface area of exposed skin | cm2 |  |

Assuming that 400 g with 0.01 % a.s. and density 0.5 g/cm3 gets into contact with hands and forearms (2000 cm2) then:

Ader = (400000 × 0.0001 / (400 / 0.5) × 1) × 0.01 × 2000 = 1.0 mg.

## Dermal exposure to a volatile active substance

A volatile substance could e.g. be a substance with a vapour pressure above 10 mPa contained in a medium.

As a worst case approach, the evaporation of the compound is neglected and the algorithms presented for dermal exposure by non-volatile substances are to be used. At the risk characterisation stage, the area of skin involved and the known or derived dermal absorption of the product/substance will be taken into account. The balance between evaporation and skin permeation (dermal absorption) will determine the dermal exposure.

## Evaporation time

For the purpose of determining the evaporation rate of a substance, an equation can be used which was derived within the framework of a research project. This project was aimed at calculating airborne concentrations of substances when emitted from liquid mixtures taking into account the evaporation and the spreading of the substance at the workplace. To calculate the evaporation times of substances, an equation was derived based on the mass transfer at the interface between the liquid and the vapour (two-film-theory). Mass transfer during evaporation occurs until the equilibrium state is achieved. The main influence on evaporation is the transfer through the interface.

For pure substances, the following equation is used:

 *Equation 5*

Explanation of symbols

: time [s]

: mass, EASE estimate, [mg]

: gas constant: 8.314 [J.K-1.mol-1]

: skin temperature [K]

: molar mass [g/mol]

*:* coefficient of mass transfer in the vapour phase [m h-1], for calculation: β = 8.7 m/h

: vapour pressure of the pure substance [Pa]

: area, EASE: 1 cm2

: conversion factor: 3.6\*104

According to Technical Guidance Document on Risk Assessment for new notified substances and for existing substances, EU, 2003 (Appendix IF, Evaporation rate)

## Oral exposure

Oral exposure may take place if after handling biocide product a person is not aware of dermal contamination of, for example, the hands. If the hands are not properly washed before e.g. eating, drinking or smoking, the person may directly or indirectly transfer the substance to the mouth. These considerations should be known to the professionals and to a lesser extent to non-professionals. However, studies have shown that both groups may forget these elementary rules of hygiene.

The average concentration of active substance in the product swallowed is calculated from:

|  |  |
| --- | --- |
|  | *Equation 6* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Coral* | Average concentration of active substance in product | mg/cm3 |  | |
| *Cprod* | Average concentration of substance in undiluted product | mg/cm3 |  | |
| *D* | Dilution factor. If dilution results in a 1 % dilution, then *D* is the reciprocal: *D* = 1/0.01 = 100 | (Default : 1) | |  |
| *Qprod* | Amount of undiluted product used | mg |  | |
| *Fcprod* | Weight fraction of active substance in the product |  |  | |
| *Vprod* | Volume of undiluted product | cm3 |  | |

If an undiluted product is ingested or dilution unknown, the default dilution (*D*) is 1.

The oral intake is then given by:

|  |  |
| --- | --- |
|  | *Equation 7* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Aoral* | Amount of active substance ingested | mg/kg BW/d |  | |
| *Vappl* | Volume of product in contact with mouth | cm3 |  | |
| *Foral* | Fraction of *Vappl* that is ingested |  |  | |
| *Coral* | Average concentration in product | mg/cm3 |  | |
| *Nevent* | Number of events | (usually per day) | |  |
| *BW* | Body weight | kg |  | |

**References:**

[1] Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulations No. 1488/94 on risk assessment for existing substances (Part I, II, III, IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocide products on the market. European Commission 2003

[2] Bremmer HJ, van Veen MP (2001). Factsheet toys. National Institute of Public Health and Environmental Protection (RIVM)

# Background on Pattern of Use Excel Spreadsheet Database

**Background Information on the Pattern of Use Database (Excel spreasheets per product type further below).**

This section of the document introduces the patterns of use database. The purpose of the database was to establish generic use patterns for all different biocide product types. The database can be used only in cases where no other information is available for the product type regarding conditions of use; this is due to the fact that there is no clear background information on how the defaults presented in the database have been derived and often its use has resulted in over- or under-estimation of exposure estimates.

The pattern of use database provides defaults for duration and frequency of the different tasks for each biocidal product type for different formulation types. These defaults are set up based on currently readily available information and generic assessments. The defaults are limited for professional use only. For non-professional users (consumers) the ConsExpo factsheets should be used.

*Information sources for the pattern of use database*

The pattern of use database was developed by using all relevant information gathered from the contact points for biocides of the Commission Services, members of EBPF (European Biocidal Product Forum) and Competent Authorities of the USA (EPA), California (Cal-Department of Pesticide Regulation) and Canada (Health Canada Pesticide Management Regulation Agency), as well as the Biocides Taskforce of the American Chemistry Council (ACC). In addition to this, available information from branch/sector organisations and single firms was used. Also databases of the competent authorities (CTB in NL, the Biocide/Pesticide Approval Systems in UK, BVL in Germany) were searched for relevant information. The University of Ulster (TEIC Innovation Centre) in Northern Ireland, UK, which also provides the so-called Biocide Information Services (BIS) provided requested information through structured telephone interviews with a large series of companies that are leading and relevant for all product types. Also the literature was searched with relevant descriptors and gathered information was used to set up the pattern of use database. After setting up the database based on all the information gathered, the industry (mainly through the EBPF) was allowed to check the information on accuracy and completeness before the final version was developed.

*When to use the pattern of use database*

The defaults presented are based on reasonable worst case values and are meant to be used for the exposure estimation. Whenever more detailed information for the product is available, these data should be used instead. However the use of other data should be fully justified, with underlying documents and/or information.

The database is not comprehensive but covers about 90% of all possible patterns of use. If a use pattern is, however, not contained in the database, the registrant should provide their own defaults with underlying documentation and/or information.

*Defaults for duration and frequency*

For frequency and duration standardised values are presented. Presenting standardised values prevents a large number of different durations being used in practice. The values are based on reasonable worst case assumptions. For the duration the minimum value is 10 minutes and the maximum is >8 hours. This means that if a specific task lasts for about 2 minutes the nearest default (in this case 10 minutes) is presented in the database. If the duration of a task is about 20 minutes the nearest default is 30 minutes and therefore presented.

*Framework pattern of use database and used terminology*

The database consists of a number of tables for each product type and for each formulation type. The tables consist of the following columns (see also Figure 5):

1. **Formulation:** In this column the type of formulation is presented.
2. **“Other” formulation:** In this column the specific description of the “other” formulation is filled in (if you find no good choice).
3. **Mixing and loading phase:** In this column the mixing and loading phase, i.e. the task(s) a professional user has to do before application is presented (e.g. preparing the biocidal solution or filling spray equipment with the biocidal product). The following types of different mixing/ loading scenarios are listed:
   * closed transfer: refers to the biocidal product that is transferred through a closed system (e.g. wood preservatives that are added automatically to a vacuum treatment vessel);
   * pour and dilute: refers to the biocidal product that has to be poured into a receiving vessel/ container/ equipment device and than diluted;
   * fill undiluted: refers to the biocidal product being poured into a receiving vessel/ container/ equipment device without dilution;
   * other and dilute: refers to other formulations e.g. tablets that are put into a receiving vessel/ container/ equipment device and than diluted; and
   * no mixing and loading required: refers to the biocidal product that can be directly used without any mixing and loading required (e.g. most ready for use products but for example also products used for application on the skin directly from a pump device onto the hands).
4. **Total duration mixing and loading per day (default):** This column refers to the duration a specific phase will take during any particular day. This means that the total duration can consist of repeated tasks. The total duration refers to the duration of the mixing and loading and not to the contact duration of the professional user with the biocidal product.
5. **Exposure frequency (default):** this column refers to how often an exposure will take place (daily, weekly, monthly) Daily means every day during a workweek (e.g. 5 times a week). The frequency may indicate whether the exposure is acute, semi-chronic or chronic.
6. **Application phase (category):** in this column a specific application group (task) can be chosen. The task “handling” is unspecified meaning that the professional is handling the biocide and performs different subtasks with it (e.g. sprayed on hands and rubbing it in or adding a biocidal product to a system volume) The others tasks mopping, wiping, scrubbing etc. are self-explanatory and are taken from the RISKOFDERM[[3]](#footnote-3) project.
7. **Description of phase:** In this column a short description of the application phase (task performed) is presented.
8. **Total duration application per day (default):** this column refers to the duration a specific phase will take during an exposure day. This means that the total duration can consist of repeated tasks. The total duration refers to the duration of the application and not to the contact duration of the professional user with the biocidal product.
9. **Exposure frequency (default):** this column refers to how often an exposure day will take place (daily, weekly, monthly, etc.) Daily means every day during a workweek (e.g. 5 times a week). The frequency indicates if the exposure is acute, semi-chronic or chronic.
10. **Comments:** In this column specific comments on the use pattern are presented if applicable.

**Figure: Example patterns of use database table (first rows only)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Formulation**  *(column 1)* | **If formulation is “other” then define**  *(column 2)* | **Mixing and loading phase**  *(column 3)* | **Total duration mixing and loading per day (default)**  *(column 4)* | **Exposure frequency (default)**  *(column 5)* | **Application phase (category)**  *(column 6)* | **Description of phase**  *(column 7)* | **Total duration application per day (default)**  *(column 8)* | **Exposure frequency (default)**  *(column 9)* | **Comments**  *(column 10)* |
| Liquids | | | | | | | | | |
| Liquid |  | No mixing and loading required |  |  | Handling | Sprayed on hands and rubbed in | 30 minutes | Daily | about 20 times a day for about 1 minute |
| Liquid |  | No mixing and loading required |  |  | Handling | Wash hands | 30 minutes | Daily | about 20 times a day for about 1 minute |

# List of HEEG & Ad-Hoc Expert Group Opinions

**Background**

Member states identified several issues in exposure assessment for human health which need to be discussed and further elaborated. In the context of the biocidal product directive 98/8/EC the **Human Exposure Expert Group (HEEG)** was established. The HEEG prepared opinions in order to provide guidelines towards a harmonised approach to biocide exposure assessment for industry and competent authorities.

The HEEG opinions listed below can still be used in the framework of the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012), notwithstanding the references to the BPD and without prejudice to the scientific content.

Under the BPR the **Ad hoc Working Group on Human Exposure (HEAdhoc)** was established. The Ad hoc Working Group on Human Exposure supports the Biocidal Products Committee and its Working Groups (especially the Working Group on Human Health) with issues related to human exposure to biocides, including among others:

* Technical or scientific matters as well as generic or specific methodological issues
* Harmonisation of the approach for assessing human exposure to biocides
* Implementation of the strategies of biocides exposure assessment
* Identification of the needs to revise the existing guidance documents on human exposure to biocidal products and contribution to the revision, where appropriate.

This group prepares recommendations. Since the work of HEAdhoc is ongoing it is recommended to follow the following ECHA homepage on a regular basis to find further guidance:

<http://echa.europa.eu/web/guest/view-article/-/journal_content/title/recommendations-of-the-ad-hoc-working-group-on-human-exposure>

### (HEEG No.17) Default human factor values for use in exposure assessments for biocidal products

### (HEEG No.9) Exposure Controls “PPE”: Default protection factors for protective clothing and gloves

### (HEAdhoc No.1) PT01 - Hand disinfection (Harmonisation of exposure determinants for professional users)

### (HEAdhoc No.2) PT02 - Professional Mopping and Wiping Time Used for cleaning Hard Surfaces

### (HEEG No.14) PT06 - An approach to identification of worst-case human exposure scenario for PT6

### (HEEG No.18) PT08 - Industrial treatment of wood by fully automated dipping by professional users

### (HEEG No.08) PT08 - Dipping Processes “Defaults and appropriate models to assess human exposure”

### (HEEG No.05) PT 13 Human exposure assessment to biocidal products used in metalworking fluids (PT13)

### (HEAdhoc No.7) PT 13 Professional Exposure Assessment to biocidal products used in metalworking fluids (PT13)

### (HEEG No.10) PT14 - Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants)

**(HEEG No.12) PT14 – Harmonised approach for the assessment of rodenticides; professional users models**

### (HEAdhoc No.3) PT18 - Spraying models for assessing exposure to insecticides for low pressure downward uses

### (HEAdhoc No.4) PT21 - Cleaning of spray equipment in antifouling use

### PT21 - Technical agreements – Human Health

**(TM I 2013)**

During TM I 2013 (Under Agenda point 3.m. Consolidated Technical Agreements for PT21) UK mentioned comments received by IND concerning human health that remains to be covered for a later MOTA revision. On the basis of the Table received by CEPE working group AFWG "*Recent TM decisions with regard to Human Health and Environmental Risk Assessment in PT21"* COM made a search through the document to see what has already been covered in MOTA v.5, and therefore suitable for the new revision of MOTA. UK checked the results and confirmed the screening results.

The following 5 decisions were considered not covered by the MOTA v.5 and considered suitable for MOTA v.6. inclusion.

**1. Use of PPE by non-professionals:** Several discussions were conducted on the issue at the previous TMs (TM I 2011 and TM III 2011) and some documents provided (i.e. TMI 2011: Agenda point 3a. *"Feasibility for non-professional users of antifouling to wear gloves"*). TMIII 2011 agreed that all PT21 CARs having non-professional applications should include two exposure/risk assessments; one assessment where no gloves are worn and the other assessment where gloves are worn. At the CA level a note with the title: [*"Authorisation of skin sensitizer biocidal products requiring PPE for non-professional users"*](https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal:_idcl=FormPrincipal:_id3&FormPrincipal_SUBMIT=1&id=d5dc2776-eba2-473c-9dba-d8d47cfc90f9&javax.faces.ViewState=rO0ABXVyABNbTGphdmEubGFuZy5PYmplY3Q7kM5YnxBzKWwCAAB4cAAAAAN0AAE2cHQAKy9qc3AvZXh0ZW5zaW9uL3dhaS9uYXZpZ2F0aW9uL2NvbnRhaW5lci5qc3A=) was endorsed by the 53 CA meeting. There are also on-going discussions in the PA&MRFG.

**2. By-stander scenario:** TMIII 2011 (agenda item 4. Substances in PT 21) agreed that where afps are applied by professionals, it was a requirement that the product label carried the statement *‘Unprotected persons should be kept out of treatment areas’*. TM agreed that access to the boatyards would be controlled and so by-standers in the vicinity of the painting could be warned to keep away from treatment areas. Thus for this professional-use a scenario was not necessary for ‘bystander’ exposure/risk assessments to be included in the CAR.

**3. Dermal penetration, exclusion of tape strip data:** TM III 2011 agreed that newer available guidance from EFSA should take into account. MS agreed to take account of EFSA guidance (ignore first two tape strips only), but MOTA guidance, which allows more flexibility, depending on available data, may still be used.

**4. Professional application - exposure duration:** TM III 2011 agreed (item 4.b.2. in the final Minutes) that the medium-term AEL and time duration of 180 minutes should be used for professional spray application of antifouling paint.

**5. Professional application - choice of threshold value:** See above, TM III 2011 agreed that the Medium term AEL should be used.

### (HEEG No.4) PT21 - Antifouling painting model non-professional users (Ammendment of TNsG on Human exposure to biocidal products – Antifouling painting model)

### (HEEG No.15) PT21 - Occupational exposure during application and removal of antifouling paints

### (HEAdhoc No.5) PT21 – Toddler Secondary Exposure Assessment from non-professional uses of antifouling paints

### (HEEG No.01) Primary Exposure - Loading of products into vessels/systems industrial scale: available data & models

### (HEEG No.02) Primary Exposure - Assessment of Potential & Actual Hand Exposure

### (HEEG No.16) Primary Exposure - Model for dipping of hands/forearms in a diluted solution

### (HEEG No.03) Primary Exposure - Use of ConsExpo in the exposure assessment for professional users

### (HEEG No.11) Primary Exposure Paint Model “Washing out of a brush”

### (HEEG No.7) Secondary Exposure – Contant with treated surfaces; Choice of secondary exposure parameters for PTs 2, 3 and 4

### (HEEG No.13) Secondary Exposure - Assessment of Inhalation Exposure of Volatilised Biocide Active Substance

### (HEAdhoc No.6) Methods and models to assess exposure to biocidal products in different product types

### (HEEG No.6) Harmonising the use of new and old versions of the TNsG on human exposure and BEAT

# TNsG2002 Database Detailed Models

**NOTE:** This Section is copied from the TNsG 2002 Part 2, Section 3.3); a number of the models here are referred in the main sections of the Methodology document; some additional models are further provided in this section, however it is not recommended to use them unless they are specified in the main sections of the Methodology document.

This section reports those models that are considered adequate for human exposure assessment and gives references. It is notable that:

- many database models relate to workplace situations and few to home use;  
- some are valid for specific scenarios only;   
- the models relate to exposure by inhalation and skin contact.

Database models - advantages and drawbacks

The advantages include:

- the data set is clearly linked with a scenario or task;  
- the inputs and outputs can be simply documented;  
- they are self-validated, provided the underlying studies are well enough reported.

But the disadvantages include:

- many - if not most - scenarios have not been monitored or measured  
- there is reliance on critical factors such as the pattern of use or clothing penetration;  
- the underlying studies may have been closely controlled;  
- the data ranges can be very wide and data sets very sparsely populated.

Model reference

The models in this section are allocated a reference name - the index is on the next page. As state-of-the-art at the end of 2001, the models reported are or are not recommended for use in the tiered approach to exposure assessment. In the latter case, they are only acknowledged.

The ‘probability’ term in the descriptions that follow indicate just the distribution of detectable and non-detectable amounts in the respective underlying studies.

Great care needs to be taken in modelling reasonable worst cases where there are a number of scenarios undertaken per day - in such situations, probabilistic routines are preferred. None of the models addresses aggregated exposure (that is, exposure resulting from the full range of sources where an active substance might be used), nor exposure through dietary intake. That is also best approached through probabilistic modelling, the detailed description of which is beyond the scope of this report.

Simple database models

Mixing and loading

Spray application

Handling

Dipping

Surface disinfection (manual)

Sub-soil treatment

Dust and soil adhesion

Fogging and misting

Metalworking fluid

Pyrotechnic aerosol settlement

PPE penetration and deposition

Consumer product spraying and dusting

Consumer product painting

Dislodgeable residues - transfer coefficients

Household products - secondary exposure

BSG Indicative exposures meta-model

## MIXING AND LOADING

### Mixing and loading Model 1

User: Professionals at work   
Task: Loading quantities around 50 kg  
Data source: Dutch model, Agricultural pesticide database  
Reference: van Golstein Brouwers et al., Assessment of occupational exposure to pesticides in agriculture Part IV, TNO Report V96, Zeist, NL.

Exposure to the hands is expressed as in-use product being transferred, handling around 50 kg   
(liquid density = 1.0 g/ml)

|  |  |  |
| --- | --- | --- |
| Potential dermal exposure, liquid | 90th % value | 300 mg / hour |
| Exposure by inhalation, liquid | 90th % value | 0.02 mg / hour |
| Potential dermal exposure, powder | 90th % value | 2000 mg / hour |
| Exposure by inhalation, powder | 90th % value | 15 mg / hour |

The model is based on data extracted from the open literature. Better databases for liquid formulations are now available for estimation of exposure during mixing/loading of agricultural pesticides, such as EUROPOEM (model 3).

### Mixing and loading Model 2

User: Non-professionals / anyone  
Task: Diluting concentrate from 1 litre can with water in bucket (200 ml to 2.5 litres)  
Data source: HSL 2001  
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure (hands and forearms) expressed as mg concentrate  
density assumed at 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Water-based fluid concentrate**, no foaming | | **Solvent-based viscous concentrate**, foaming | |
| Dispensing and dilution, skin exposure averaged over 4 events for bare hands and forearms | | | |
| Probability | 80% | Probability | 70% |
| Range | 0.33 to 3.2 mg / event | Range | 0.3 to 1.7 mg / event |
| 50th % value | 1.1 mg / event | 50th % value | 0.8 mg / event |
| Worst case | 3.2 mg / event | Worst case | 1.7 mg / event |
| Dispensing and dilution, skin exposure worst case single event for bare hands and forearms | | | |
| Probability | 33% | Probability | 26% |
| Worst case | 12.8 mg / event | Worst case | 6.7 mg / event |

(Subsequent uses of a container increase the probability of container contamination, hence hand contamination).

### Mixing and loading Model 3

User: Professionals at work   
Task: Loading agricultural pesticides

Data source: EUROPOEM  
Reference: BIBRA TNO, Carshalton, UK, 1996.

Exposure expressed as mg a.s./kg a.s. per operation (75th percentile).  
(portable equipment and machine reservoir)

|  |  |  |  |
| --- | --- | --- | --- |
| **Liquid concentrate loading** | | **Portable reservoir** | **Machine reservoir** |
| Potential dermal exposure | 75th % value | 230 mg/kg a.s. | 20 mg/kg a.s. |
| Exposure by inhalation | 75th % value | 0.1 mg/kg a.s. (95th %) | 0.005 mg/kg a.s. |

The model is developed for the loading of agricultural pesticides and covers relatively large amounts.

### Mixing and loading Model 4

User: Professionals at work   
Task: Pouring fluid from container into receiving vessel  
Data source: UK POEM model  
Reference: Guide 1992, PSD, York, UK

Exposure expressed as ml of in-use product per operation as 75th % value

|  |  |  |  |
| --- | --- | --- | --- |
| **Container of unspecified design** | | **Wide-necked container** | |
| Container volume | Contamination | Container | Contamination |
| 1 litre | 0.01 ml | 1 litre, D = all | 0.01 ml |
| 5 litre | 0.2 ml | 2 litre, D = all | 0.01 ml |
| 10 litre | 0.5 ml | 5 litre, D = 45 / 63 mm | 0.01 ml |
| 20 litre | 0.5 ml | 10 litre, D = 45 mm 10 litre, D = 63 mm | 0.10 ml  0.05 ml |
|  | | D = neck diameter | |

The model is developed for the loading of agricultural pesticides and covers relatively large amounts.

### Mixing and loading Model 5

User: Professionals at work   
Task: Pouring from container into receiving vessel  
Data source: German model  
Reference: Lundehn et al., Mitteilungen aus der Biologischen Bundesanstalt für Land-  
 und Forstwirtschaft, Heft 277, Berlin, Germany

Exposure expressed as mg a.s./kg a.s. per operation   
(portable equipment and machine reservoir)

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Portable reservoir** | **Machine reservoir** |
| Potential dermal exposure, liquid | 50th % value | 205 mg/kg a.s | 2.4 mg/kg a.s. |
| 90th % value | 1195 mg/kg a.s | 50 mg/kg a.s. |
| Exposure by inhalation, liquid | 50th % value | 0.05 mg/kg a.s. | 0.001 mg/kg a.s. |
| 90th % value | 0.10 mg/kg a.s. | 0.005 mg/kg a.s. |
|  |  |  |  |
| Potential dermal exposure, powder | 50th % value | 50 mg/kg a.s. (nominal) | 6 mg/kg a.s. |
| 95th % value | - | 14.3 mg/kg a.s. |
| Exposure by inhalation, powder | 50th % value | 0.8 mg/kg a.s. | 0.07 mg/kg a.s. |
| 95th % value | 2.4 mg/kg a.s. | 0.55 mg/kg a.s. |
|  |  |  |  |
| Potential dermal exposure -granule | 50th % value | 21 mg/kg a.s. | 2 mg/kg a.s. |
| 95th % value | 122 mg/kg a.s. | 5.6 mg/kg a.s. |
| Exposure by inhalation, granule | 50th % value | 0.02 mg/kg a.s. | 0.008 mg/kg a.s. |
| 95th % value | 0.06 mg/kg a.s. | 0.24 mg/kg a.s. |

The model is developed for the loading of agricultural pesticides and covers relatively large amounts. Only exposure to the hands is involved.

A better model for liquid formulations is now available (EUROPOEM, model 3).

**Note:** *The German Model is based on old data and will be replaced by the AOEM next year for plant protection product authorisation.*

### Mixing and loading Model 6

User: Professionals at work   
Task: loading liquid antifoulant into reservoir for airless spray application  
Data source: HSE surveys 1995-6, IOM study on PPE, 1996  
Reference: EH74/3 (excludes data for other ancillary workers)

Exposure expressed as mg/min in-use product, and *estimate mg a.s. / kg a.s.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 23 data, 0 data = zero |
| Range of non-zero values | | 0.27 to 252 mg/min | *0.96 to 351 mg/kg a.s.* |
|  | 50th % value | 43 mg/min | *13 mg/kg a.s.* |
|  | 75th % value | 92 mg/min | *71 mg/kg a.s.* |
|  | 95th % value | 222 mg/min | *292 mg/kg a.s.* |
| Probability of clothing penetration | | 59% | 17 data, 7 data =-zero |
| Range of non-zero values | | 1% to 28% | - |
|  | 50th % value | 3% | - |
| **Probability of hand exposure inside gloves** | | 100% | 17 data, 0 data = zero |
| Range of non-zero values | | 0.003 to 10.8 mg/min | - |
|  | 50th % value | 0.6 mg/min | - |
|  | 75th % value | 2.7 mg/min | - |
|  | 95th % value | 8.2 mg/min | - |
| Deposition on outside of protective gloves | | 100% | 4 data, 0 data =-zero |
| Range of non-zero values | | 7.6 to 30 mg/min | - |
|  | 50th % value | 25 mg/min | - |

Exposure by inhalation, exposure as mg/m3 in-use product, *estimate* *mg/m3 a.s.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 100% | 20 data, 7 data = zero |
| Range of non-zero values | | 0.04 to 42\* mg/m3 | *0.01 to 2.1 mg a.s./m3* |
|  | 50th % value | 0.8 mg/m3 | *0.2 mg a.s./m3* |
|  | 75th % value | 1.9 mg/m3 | *0.4 mg a.s./m3* |
|  | 95th % value | 17 mg/min | *1.4 mg a.s./m3* |

**Context of model**

**Inhalation exposure**

For the anti-fouling pot-men, exposure to spray aerosol is intermittent and unusual. Results indicate that the normal range (18 of 19 results) is between 0.2 and 4.0 mg/m3 of product. One exceptional result (the highest recorded) has been recalculated at 24 mg/m3 (previously 42 mg/m3, but closer inspection of the proportion of active material in the paint has caused abatement of this particular result). However, it is considered to be unlikely that even a result of this magnitude would be a true reflection of the personal exposure of a pot-man to aerosol. The individual result showed no elevated potential dermal exposure and associated inhalation of the sprayer was below the level recorded for the pot-man. HSE has judged that, when considered in the context of the other samples taken at the same time, that datum resulted from a minor splash of product depositing on the sampling filter, and should be discounted as an outlier.

**Potential dermal exposure**

The model is based on assumed concentrations of active substance (usually copper) at the bottom end of the published range. This leads to worst case estimates of deposition rates.

The data have been collected using a seven patch methodology and the results calculated by applying a factor of two to take account of the unexposed areas of clothing where patches are not normally worn. This approach has been proposed as a result of independent research by the Institute of Occupational Medicine.

The model is considered to provide a fairly accurate representation of typical rates of contamination that may be found in a wide range of anti-fouling applications, from small through to very large vessels.

### Mixing and loading Model 7

User: Professionals at work   
Task: Pouring and pumping liquid, and dumping solids into systems  
Reference: Popendorf et al., Am. Ind. Hyg. Ass. J. 56:993-1001, 1995.

Exposure expressed as mg/min and mg/m3 concentrate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | **Task** | |
| **Potential dermal exposure** | | | **Pour liquid** | **Pump liquid** |
| Probability of exposure | | | 100% (15 data) | 93% (14 data, 1 = zero) |
|  | Range | | 0.002 to 10.4 mg/min | 0.001 to 1.76 mg/min |
|  | 50th % value | | 0.04 mg/min | 0.12 mg/min |
|  | 75th % value | | 0.10 mg/min | 0.60 mg/min |
| **Probability of exposure by inhalation** | | | 27% (15 data, 11 = zero) | 21% (14 data, 11 = zero) |
|  | | Range | 0.09 to 0.94 mg/m3 | 1.1 to 22 mg/m3 |
|  | | 50th % value | 0.29 mg/m3 | 3.9 mg/m3 |
|  | | |  |  |
| **Potential dermal exposure** | | | **Weigh / dump solid** | **Place solid** |
| Probability of exposure | | | 91% (11 data, 1 = zero) | 100% (3 data) |
|  | | Range | 0.008 to 3.05 a mg/min | 0.02 to 1.35 mg/min |
|  | | 50th % value | 0.27 mg/min | 0.08 mg/min |
|  | | 75th % value | 1.15 mg/min | - |
| **Probability of exposure by inhalation** | | | 18% (11 data, 9 = zero) | 33% (3 data, 2 = zero) |
|  | Range | | 2.6, 7.2 mg/m3 | - mg/m3 |
|  | 50th % value | | 5.0 mg/m3 | 1.0 mg/m3 |

a. highest value for weighing / dumping at 56.5 mg/min is an outlier.

Note, these data include an element for hand exposure inside gloves. It is not possible to tease these data out of the data set as presented. Consequently , this model will over-predict.

Task information (potential dermal exposure per task):

Pour: range 0.01 to 73.1, 50th % at 0.65 75th % at 1.74 mg/cycle  
 Duration range 1 to 78 min, 50th % at 12, 75th % at 22 min/cycle

Pump: range 0.04 to 30, 50th % at 2.45 75th % at 8.60 mg/cycle  
 Duration range 3 to 51 min, 50th % at 18, 75th % at 32 min/cycle

Dump : range 0.05 to 833, 50th % at 2.55 75th % at 6.7 mg/cycle  
 Duration range 2 to 70 min, 50th % at 13, 75th % at 33 min/cycle

Place: range 0.0.04 to 9.0, 50th % at 0.68 mg/cycle  
 Duration range 0.5 to 12 min, 50th % at 2 min/cycle

The same data set can be re-expressed in terms of biocidal product type (next page)**Model 7 (re-expressed)**

Exposure expressed as mg/min and mg/m3concentrate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | **Product type** | |
| **Potential dermal exposure** | | | **In-can preservative** | **Wood, paper & pulp** |
| Probability of exposure | | | 87% (15 data, 2 = zero) | 100% (7 data) |
|  | Range | | 0.008 to 3.05 a mg/min | 0.001 to 1.38 mg/min |
|  | 50th % value | | 0.10 mg/min | 0.17 mg/min |
|  | 75th % value | | 0.43 mg/min | 0.37 mg/min |
| **Probability of exposure by inhalation** | | | 13% (15 data, 13 = zero) | 29% (7 data, 5 = zero) |
|  | | Range | 2.6, 7.2 mg/m3 | 1.1, 3.9 mg/m3 |
|  | | 50th % value | 5.0 mg/m3 | 2.5 mg/m3 |
|  | | |  |  |
| **Potential dermal exposure** | | | **Cooling water** | **Metalworking fluid** |
| Probability of exposure | | | 91% (11 data, 1 = zero) | 100% (10 data) |
|  | | Range | 0.03 to 10.5 mg/min | 0.002 to 1.35 mg/min |
|  | | 50th % value | 0.11 mg/min | 0.04 mg/min |
|  | | 75th % value | 0.74 mg/min | 0.10 mg/min |
| **Probability of exposure by inhalation** | | | 27% (11 data, 8 = zero) | 30% (10 data, 7 = zero) |
|  | Range | | 0.16 to 0.94 b mg/m3 | 0.09 to 1.0 mg/m3 |
|  | 50th % value | | 0.94 mg/m3 | 0.42 mg/m3 |

a. highest value at 56.5 mg/min b. highest value at 22. (Outliers)

The present paper describes a series of measurements for pouring and pumping liquid and solid (powder or flakes) biocidal products. The data have been recalculated by HSE from the data described in the paper. There is a large variation in the packages and scenario’s involved and the amounts handled.

The data indicated above should just guide the exposure assessor. The most relevant data for the scenario under consideration should be taken from the paper. It must be emphasised that the exposures should only be used as indicative values in view of the small database.

## SPRAYING MODELS

### Spraying Model 1

User: Professionals, principally  
Task: Mixing and loading liquids and powders in compression sprayers or dusting  
 applicators, and applying at 1 to 3 bar pressure as a coarse or medium spray,  
 indoors and outdoors, overhead and downwards. Scenario: low-pressure   
 insecticide application.  
Data source: HSE surveys 1992-3, IOM study on PPE, 1996  
Reference: EH74/3

Exposure expressed as mg/min in-use product, and *estimate* *mg a.s. / kg a.s.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 84% | 102 data, 18 data = zero |
| Range of non-zero values | | 0.63 to 692 mg/min | *9.4 to 12500 mg/kg a.s.* |
|  | 50th % value | 24.5 mg/min | *164 mg/kg a.s.* |
|  | 75th % value | 92 mg/min | *462 mg/kg a.s.* |
|  | 95th % value | 251 mg/min | *3280 mg/kg a.s.* |
| Probability of clothing penetration | | 41% | 61 data, 36 data =-zero |
| Range of non-zero values | | 2% to 78% | - |
|  | 50th % value | 44% | - |
| **Probability of hand exposure inside gloves** | | 50% | 71 data, 35 data = zero |
| Range of non-zero values | | 0.08 to 120 mg/min | - |
|  | 50th % value | 1.3 mg/min | - |
|  | 75th % value | 10.7 | - |
|  | 95th % value | 39.4 | - |
| Deposition on outside of protective gloves | | 100% | 5 data, 0 data =-zero |
| Range of non-zero values | | 12 to 181 mg/min | - |
|  | 50th % value | 31 mg/min | - |

Exposure by inhalation, exposure as mg/m3 in-use product, *estimate mg/m3 a.s.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 28% | 97 data, 70 data = zero |
| Range of non-zero values | | 0.2 to 631 mg/m3 | *0.01 to 2.1 mg a.s./m3* |
|  | 50th % value | 104 mg/m3 | *0.2 mg a.s./m3* |
|  | 75th % value | 130 mg/m3 | *0.4 mg a.s./m3* |
|  | worst case value | 405 mg/m3 | *1.4 mg a.s./m3* |

(Professionals often use disposable gloves for public hygiene insecticide applications).

**Context of model**

The above model relates in particular to products applied in public hygiene areas (e.g. schools, restaurants, swimming pools, hospitals, nursing homes). In the domestic setting they are used on insect nests, both indoors and out, on indoor surfaces, in cracks and crevices, on soft furnishings, as space sprays, and in clothing storage. Uses in work environments include food factories and on waste tips. Products are mostly used in a dispersive manner to knock down insects, or leave residual active substance to eradicate populations of insects or prevent reinfestation. Fumigation is a separate and specialised activity.

The work is peripatetic, with lone working most common. Typically, less than two hours a day is spent using pesticides, with some applications being seasonal (e.g. wasps in midsummer) and some year-round (e.g. bakeries).

The tasks for which HSE hold data are mixing and loading of liquids and powders, and spraying by compression sprayer (i.e. at 1-3 bar). HSE also holds data for application of powders. There is detailed information about the particular exposure scenario, but very often the data sets are too sparse to draw satisfactory conclusions about specific tasks, e.g. differentiating between the exposure at blanket, band and pin-stream spraying.

The quantities used per treatment for liquid insecticide spraying ranged from 1 to 20 litres, with a median quantity of 5 litres of fluid. Concentrations of active substance ranged from 0.03 to 1% w/w, usually using water as the solvent or dispersing liquid (71 data). For insecticidal dusting, operators used between 60 - 2200g of dusting powders at nominal in-use concentrations between 0.5 - 1.0% active substance (15 data).

The model represents the data arising from 100 separate studies of pest control operators using public hygiene insecticides. The jobs are mainly application through the use of fine sprays emanating from low pressure compression sprayers. Other results relate to application of dusts. Public hygiene insecticide application is often of short duration (a matter of minutes) and the use of any one particular product or active substance may also be infrequent.

Two HSE projects (permethrin and bendiocarb *technical development surveys , TDS*) and part of a contract project (validation of surface sampling techniques) by the Institute of Occupational Medicine, contributed to the data-set. The data cover similar ranges when translated to a rate of contamination (mg diluted formulation per minute of application).

The results apply to both dusting and spraying, indoors and outdoors, whether in an overhead or downward direction, and include a contribution to exposure from mixing and loading operations which ensure the spraying aspect of the model over-predicts deposition to a marginal degree.

This public hygiene insecticide model may also be termed a low-pressure spraying model as it may apply to many operations where the emission profile is similar to that during application of dilute non-agricultural pesticide products. For instance, it could be applied to any operation involving a hand-held compression sprayer or even an industrial process where there is a low-level fine spray emission.

There may be some uncertainty over the in-use concentrations used to establish this model but the calculations have been made on the basis of operators applying products at preferred concentrations and according to prescribed conditions of use.

### Spraying Model 2

User: Professionals, principally  
Task: Mixing and loading liquids in reservoir for powered spray application at  
 4 to 7 bar pressure as a coarse or medium spray, indoors, overhead and  
 downwards. Scenario - medium pressure spray applications, e.g. for remedial  
 biocides.  
Data source: HSE survey 1988, BPCA 1990, ECoS 1996, IOM study on PPE, 1996  
Reference: EH74/3 and Ann. Occ. Hyg. 42(3):159-165, 1998

Exposure expressed as mg/min in-use product, and *estimate* *mg a.s. / kg a.s.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 55 data, 0 data = zero |
| Range of non-zero values | | 2.3 to 36300 mg/min | *0.6 to 2360 mg/kg a.s.* |
|  | 50th % value | 45 mg/min | *63 mg/kg a.s.* |
|  | 75th % value | 222 mg/min | *278 mg/kg a.s.* |
|  | 95th % value | 2100 mg/min | *2090 mg/kg a.s.* |
| Probability of clothing penetration | | 71% | 51 data, 15 data =-zero |
| Range of non-zero values | | 1% to 85% | - |
|  | 50th % value | 6% | - |
| **Probability of hand exposure inside gloves** | | 90% | 50 data, 5 data = zero |
| Range of non-zero values | | 0.11 to 358 mg/min | - |
|  | 50th % value | 2.4 mg/min | - |
|  | 75th % value | 7.8 mg/min | - |
|  | 95th % value | 191 mg/min | - |
| Deposition on outside of protective gloves | | 100% | 6 data, 0 data =-zero |
| Range of non-zero values | | 13.9 to 273 mg/min | - |
|  | 50th % value | 35 mg/min | - |
| **Probability of feet exposure inside shoes** | | 94% | 17 data, 1 data = zero |
| Range of non-zero values | | 0.15 to 260 mg/min | - |
|  | 50th % value | 2.04 mg/min | - |
|  | 75th % value | 5.4 mg/min | - |

Exposure by inhalation, exposure expressed as mg/m3 in-use product, *estimate mg/m3 a.s.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 84% | 61 data, 10 data = zero |
| Range of non-zero values | | 0.98 to 813 mg/m3 | *0.01 to 21 mg a.s./m3* |
|  | 50th % value | 20 mg/m3 | *0.08 mg a.s./m3* |
|  | 75th % value | 76 mg/m3 | *0.25 mg a.s./m3* |
|  | 95th % value | 198 mg/m3 \* | *5.4 mg a.s./ m3* |

\* 95th % inhaled omits two highest data at >10x higher than next highest data point

**Context of model**

Application of remedial biocides in the range of industrial, recreational, and residential settings, and in the remediation of old buildings prior to their conversion to domestic premises, form the basis for this model. These products are applied to interior and exterior structural timber, masonry and surfaces, to wooden articles (fences, sheds, seating) and to exterior monuments, pathways and stairways.

Products may be applied by spraying, as a surface wash using a brush, or by a variety of manual methods. Pastes, for instance, may be applied by brush, trowel, caulking tool, palette knife, or by gloved hand. Monument, exterior brickwork and path cleaners are either sprayed or washed, with vigorous agitation using a scrubbing brush or stiff broom.

Although products may be applied using a wide range of techniques, the HSE work has concentrated on those areas where exposure has been subjectively assessed to be highest, i.e. during spray application. Other data have been collected which address some of the other methods of application, such as application of timber treatment fluids by brushing, but these data are not represented here within this model.

Four studies contributed to the data set - an early HSE study, a sponsored study by Tilt *et al* (both on remedial timber treatment), a contract study (surface biocide and remedial timber) by ECoS Environmental and a contract project (validation of surface sampling techniques) by IOM. The data are reasonably coherent - they cover similar ranges when transformed as a contamination rate *(mg diluted formulation per minute application).*

Some data for gloves have been omitted because the experiment determined what fell on the outside of gloves, not what had penetrated. The early HSE study data for surface deposition was omitted because it reported only what had penetrated.

The findings from over 50 separate investigations of operator exposure during the application of remedial treatment fluids are used. Most in-use solutions were water based and studies investigated treatment of timber and masonry. Concentrations of concentrate and in-use fluid were provided through chemical analysis. Typically, the work entailed much initial preparation to clear areas prior to treatment and to expose masonry and timbers - it was estimated that this phase could account for 50-90% of the time on site. Mixing, loading, and application are done as a single scenario. Solvent or water-based treatment products are applied, through an electrical- or fuel-driven pump-pressurised sprayer, supplied from a reservoir.

The top end of the model represents contamination rates arising from use of high pressure hosing of large areas and the operators became visibly drenched over a period of time. It is difficult to imagine higher rates of contamination arising from other processes.

### Spraying Model 3

User: Professionals   
Task: Airless spraying viscous solvent-based liquids at >100 bar pressure, overhead  
 and forwards. Scenario - high-pressure spraying of antifoulants.  
Data source: HSE surveys 1993, 1996, IOM study on PPE, 1996  
Reference: EH74/3

Exposure expressed as mg/min in-use product, and *estimate* *mg a.s. / kg a.s.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 27 data, 0 data = zero |
| Range of non-zero values | | 0.88 to 1240 mg/min | *0.63 to 1140 mg/kg a.s.* |
|  | 50th % value | 103 mg/min | *87 mg/kg a.s.* |
|  | 75th % value | 250 mg/min | *177 mg/kg a.s.* |
|  | 95th % value | 745 mg/min | *984 mg/kg a.s.* |
| Probability of clothing penetration | | 93% | 14 data, 1data =-zero |
| Range of non-zero values | | 1% to 41% | - |
|  | 50th % value | 5% | - |
| **Probability of hand exposure inside gloves** | | 100% | 19 data, 0 data = zero |
| Range of non-zero values | | 0.003 to 4.22 mg/min | - |
|  | 50th % value | 1.0 mg/min | - |
|  | 75th % value | 2.04 mg/min | - |
|  | 95th % value | 3.95 mg/min | - |
| Deposition on outside of protective gloves | | 100% | 6 data, 0 data =-zero |
| Range of non-zero values | | 21.7 to 119 mg/min | - |
|  | 50th % value | 76 mg/min | - |

Exposure by inhalation, exposure expressed as mg/m3 in-use product, *estimate mg/m3 a.s.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 91% | 21 data, 2 data = zero |
| Range of non-zero values | | 0.04 to 79.4 mg/m3 | *0.01 to 16.2 mg a.s./m3* |
|  | 50th % value | 6.6 mg/m3 | *0.92 mg a.s./m3* |
|  | 75th % value | 17.3 mg/m3 | *2.8 mg a.s./m3* |
|  | 95th % value | 64.6 mg/m3 \* | *6.2 mg a.s./m3* |

**Context of model**

High pressure airless spraying of paints has been studied to assist with the assessment of exposure at operations such as application of antifouling paints to ships. The data are equally applicable to many high-pressure paint spraying operations. The limited available data have arisen from three main sources. 40 exposure data were provided by 9 surveys in a 1994 HSE study. 20 exposure data were provided by 5 surveys in a 1996 HSE study and 10 exposure data were produced from 4 surveys in a 1996 IOM study investigating the validity of surface sampling techniques.

Painting tasks usually involve a sprayer and ancillary workers who may tend the paint reservoir and others who may assist by managing the trailing paint lines and moving the platform from which the painter operates. All groups of workers can expect exposure and it has been possible to differentiate the distributions for each category. Two sets of data are presented, one for spray painting and the second related to all ancillary tasks other than paint spraying.

***Antifouling paint application***

Professionals apply antifoulant paint to vessels by airless spraying, by roller and brush. Application of antifoulants is usually only one part of a general overhaul and refitting of a vessel. Professional painters work year-round but applying antifouling is intermittent. Once dry-docked, the vessel is cleaned, usually through the use of high-pressure water-jets (for self-polishing coatings) or with abrasive grit (for erodable coatings). Bare metal surfaces are prepared with other coatings such as corrosion inhibitor before application of an antifouling topcoat. The antifouling is applied `using airless spray techniques at up to 100 bar.

The frequency of exposure to any particular ingredient is very important - painters rarely apply antifouling coatings more often than one or two days in a month - and even then the active substances may not be the same in each case.

During application of antifoulant HSE studies have indicated paint usage to range from 25 to over 800 litres during a spray session. The vessel surface areas ranged between 600 to 4000m2. The duration of the work ranged from 40 to 360 minutes (median about 180 minutes).

Most of the contamination arises from impingement of the paint aerosol with the operator, but a contribution from contact with painted surfaces will almost always occur. Environmental conditions, such as wind speed and turbulence around the vessel being painted are important variables affecting exposure. Other factors which impact on the measured levels of contamination are the proximity to the coated surface and the confinement of the job. Exposures will always be maximised if the painter has to work in a confined area such as in a well beneath the bottom of a vessel.

### Spraying Model 4

User: Professionals   
Task: Airless spraying viscous solvent-based liquids at >100 bar pressure both  
 inside and outside a container.  
Reference: Brouwer et al., Ann Occ. Hyg. 44(7):543-549, 2000

Exposure expressed as Uvitex at 39 to 109 mg/litre, mean 64.8 mg/litre (mass concentration 0.0074% mg Uvitex OB/kg paint)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Duration 4 to 21 min | | | **Spray activity** | |
| Potential dermal exposure(coverall/body) | | | **Spray inside** | **Spray outside** |
| Probability of exposure | | | 100% (5 data) | 100% (21 data) |
| Arithmetic mean |  | | 0.558 mg | 0.144 mg |
| Standard deviation |  | | 0.294 mg | 0.127 mg |
| Actual dermal exposure (uncovered/ hands and face) | | |  |  |
| Arithmetic mean | |  | 0.011 mg | 0.007 mg |
| Standard deviation | |  | 0.012 mg | 0.013 mg |

Percentile estimates as in-use spray, assuming 65 mg/litre:

**Spray inside** 50th % at 7540 mg/min, 75th % at 10600 mg/min, 95th % at 17500 mg/min  
**Spray outside** 50th % at 1690 mg/min, 75th % at 2770 mg/min, 95th % at 5540 mg/minPenetration: no data available

Deposition pattern:  
Head - 2% Arms - 9% Torso - 13% Legs - 72% (Hands - 4%)

For comments see after model 5.

### Spraying Model 5

Airless pressure spraying model

User: Professionals   
Task: Airless spraying viscous solvent-based liquids at >100 bar.  
Reference: Brouwer et al., Ann Occ. Hyg. 45(1):15-23, 2001

This model is available as an Excel spreadsheet "spray paint model"

Models 4 and 5 Potential dermal exposure during airless spray painting

Context of the models

The data for these models were generated in a field study during airless spraying a large container. All conditions were similar to field practice, however the paint was colourless to enable detection of a fluorescent tracer that was added to the paint at a concentration of appr. 65 mg/L. Model 4 consists of a dataset shops of 21 datapoints collected in three different paint and includes two repeated measurements for10 spray painters and one single data point for one spray painter) for airless spraying the outside of the container, and 5 datapoints during spraying the inside of the container. All data reflect exposure (mg tracer) resulting from actual spraying, *i.e.* a single spray task, where the duration of exposure is similar to the actual duration of the emission of paint from the spray gun.

The amount of tracer (Uvitex OB) that was deposited onto a Tyvek coverall or the uncovered skin (hands and face) was quantified by a image acquisition and processing technique (VITAE).

Model 5 predicts potential whole body dermal exposure (mg) of non-volatile substances in paint during actual spraying. It is a structured approach of the mass transport processes that are involved in the processes of generating aerosols through the deposition of aerosols onto the spray painters body. The model uses several defaults for key parameters, *e.g.* immission and spray deposition efficiency, and assigned vales for factors which are considered to modify deposition, *e.g.* object structure or size, ventilation etc.

The model predicts potential whole body exposure based on actual data of the concentration of non-volatile substances in the paint, but does not generate a distribution of the exposure over the body.

The model has not been validated, however the output of the model for airless spray painting has been compared with the data set of model 4. The predicted exposure correlated reasonably well with the measured exposure (RSP = 0.82). This was remarkably better compared to the correlation between one single parameter of the model (amount of paint sprayed) and measured exposure (RSP = 0.15).

Both the dataset ‘model 4’ (for airless spray painting) and model 5 (all kinds of spray painting) can be used as a first Tier exposure assessment of potential body exposure of non-volatile substances. The percentage of non-volatile substances in the paint for extrapolations (‘model 4’), since the date are based on a concentration of 0.0074% tracer in paint. For use of model 5 the spray rate should be known, in addition to the percentage of non-volatile substances in the paint, and the assigned values for all other parameters can be kept 1. If more information on these parameters is available the estimate may be improved, as indicated by the improved correlation between measured and predicted exposure.

The advantages of model/dataset 4 and 5 the relatively easiness of use and the limited information that is needed for a first tier exposure assessment. The application of both ‘models ‘ is limited to estimate dermal exposure to non-volatile substances that were generated as part of mixed-phase aerosols and were deposited on the painters body during actual spraying. Other mass transport processes that may result in additional exposure, *e.g.* transfer from contaminated surfaces or direct contact with paint, are not included. Model 5 is not validated.

Models 4 and 5 predict deposition of non volatile substances of paint onto paint sprayers body, face and hands during actual spraying. Since the data generated by model 4 are based on very low mass concentrations of a tracer in paint (<0.01%) very large extrapolation factors, resulting in inaccurate estimates of predicted exposure to biocides. Model 5 has not been validated.

### Spraying Model 6

User: Professionals  
Task: Disinfection by spraying surfaces at 140 bar – animal husbandry (pig and  
 poultry units). Duration 3 to 126 min (median at 9 min).  
 No mixing or loading.  
Reference: Popendorf and Selim, Am. Ind. Hyg. Ass. J. 56:1111-1120, 1995

Expressed as mg/cycle and mg/cycle in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 10 data, 0 = zero |
| Range of non-zero values | | 4.28 to 317 mg/min |  |
|  | 50th % value | 21.4 mg/min |  |
|  | 75th % value | 90 mg/min |  |
|  | | **Task-based data** | |
| Range of non-zero values | | 120 to 1800 mg/task |  |
|  | 50th % value | 442 mg/task |  |
|  | 75th % value | 1100 mg/task |  |

No data for hand exposure.

The present paper describes a series of measurements for high-pressure spraying of ceilings, walls and floors of empty livestock production buildings for swine or poultry. The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry of the buildings in the USA and Europe.

### Spraying Model 7

User: Professionals  
Task: Disinfection by spraying surfaces at up to 14 bar or with hand-held   
 compression sprayer (up to 3 bar) – carpets, walls, ceiling voids.  
 Duration 17 to 141 min (median at 47 min). No mixing or loading.  
 Reference: Popendorf and Selim, Am. Ind. Hyg. Ass. J. 56:1111-1120, 1995

Expressed as mg/cycle and mg/task in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 8 data, 0 = zero |
| Range of non-zero values | | 4.63 to 200 mg/min |  |
|  | 50th % value | 48.0 mg/min |  |
|  | 75th % value | 100 mg/min |  |
|  | | **Task-based data** | |
| Range of non-zero values | | 80 to 23000 mg/task |  |
|  | 50th % value | 2150 mg/task |  |
|  | 75th % value | 9500 mg/task |  |

No data for hand exposure.

The present paper describes a series of measurements for low-pressure spraying of carpets, walls and the area above ceiling tiles, in institutional, commercial and residential settings. The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry of the buildings in the USA and Europe.

### Spraying Model 8

User: Professionals  
Task: Using aerosol spray can for disinfecting dental chairs, plumbing fixtures,  
 walls. Duration 1 to 43 min (median at 17 min). No mixing or loading.  
Reference: Popendorf and Selim, Am. Ind. Hyg. Ass. J. 56:1111-1120, 1995

Expressed as mg/cycle and mg/task in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 63% | 8 data, 3 = zero |
| Range of non-zero values | | 3.43 to 40.6 mg/min |  |
|  | 50th % value | 5.55 mg/min |  |
|  | 75th % value | 6.33 mg/min |  |
|  | | **Task-based data** | |
| Range of non-zero values | | 7 to 780 mg/task |  |
|  | 50th % value | 12 mg/task |  |
|  | 75th % value | 90 mg/task |  |

No data for hand exposure.

The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry of the buildings in the USA and Europe.

### Spraying Model 9

User: Professionals

Task: Disinfection of slaughterhouses and meat processing industry by spraying or foaming.

Reference: Preller and Schipper, respiratory and dermal exposure to disinfectants: a study in slaughterhouses and the meat producing industry, TNO Report V98.1306, Zeist, Netherlands.

The authors have measured exposures during mixing and loading, as well as application. The mixing and loading was done manually or by using automated dosing systems. The compound measured was alkyldimethyl-benzylammonium chloride. The total duration of the mixing, loading and applications was between 14 and 108 minutes, with a median of 32 minutes. The treated area (up- and downward spraying) varied between 125 and 3650 m3. The median was 375 m3. The study involved 15 workers in 10 companies.

The range of inhalation exposure was 11.4-424 µg/m3, with a GM of 53.6 µg/m3.

The potential body exposure was expressed in various units, considering with and without hands, as well as measurements underneath gloves.

For modelling purposes, the authors suggest a 90th percentile. For inhalation exposure this amounts to 2 ml spray/m3. The potential dermal exposure amounts to 800 ml spray/hr (including hands).

The data can be used in a first tier exposure assessment. The used techniques are not differentiated in the above numbers and may therefore be used for a mixture of mixing/loading and spraying techniques.

### Spraying Model 10

User: Professionals

Task: Low-pressure spraying by pest control operators

Reference: De Cock and Van Drooge, Field study on occupational exposure during spraying of biocidal products by pest control operators using deltamethrin and cyfluthrin, TNO Report V3806, 2001, Zeist, Netherlands.

The spraying techniques used were manual spraying (< 3 bar) and spray can, with the inclusion of the preparation part (mixing/loading). Both techniques were used for up- and downward spraying and used indoors and outdoors. A total of sixteen workers was considered in this study.

The authors propose to use the 90th-percentile of their exposure data for risk assessment purposes. The total duration varied between 30 and 159 minutes, with an average of 81 minutes.

For inhalation exposure, the spread in the data was from 0.3-342 µg/m3, with a 90th-percentile of 65 µg/m3.

The potential dermal exposure to the body alone varied from 50-5900 mg/kg a.s., with a 90th-percentile of 1200 mg/kg a.s. The potential hand exposure varied from 21-10100 mg/kg a.s., with a 90th-percentile of 4700 mg/kg.

### Spraying Model 11 (compound-specific)

User: Professionals  
Task: Disinfection by foam coating surfaces - food production.   
 No mixing or loading.  
Reference: Hygiene et Securite de Travail 1999 term 3, 176, 5-9

Estimated **exposures by inhalation**:

Chlorine:  
Range 0 to 1.33 mg/m3, 50th % at 0.1 mg/m3, 75th % at 0.16 mg/m3, 95th % at 0.65 mg/m3

Nitrogen trichloride  
Range 0 to 1.96 mg/m3, 50th % at 0.06 mg/m3, 75th % at 0.15 mg/m3, 95th % at 0.80 mg/m3

Formaldehyde:  
Range 0.06 to 0.62 mg/m3, 50th % at 0.3 mg/m3, 75th % at 0.4mg/m3

Glutaraldehyde;  
Range 0.01 to 0.25 mg/m3, 50th % at 0.05 mg/m3, 75th % at 0.10 mg/m3

The applied foam contained only a small %-age of active substance. The exposure is linked to spray model 2 (medium pressure, 4-7 bar coarse spraying droplets).

## HANDLIND MODELS

### Handling Model 1

User: Professionals  
Task: Industrial wood preservation - intermittent manual handling of water-wet or  
 solvent-damp wood and associated equipment.  
Data source: HSE surveys 1989, 1993, 1996, AEAT survey 1997-8  
Reference: EH74/3, and Ann. Occ. Hyg. (43):543-555, 1999

Expressed as mg/cycle in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| Process | | **Water-based** | **Solvent-based** |
| **Probability of potential dermal exposure** | | 100% (45 data) | 89% (19 data, 2 = zero) |
| Range of non-zero values | | 63.6 to 132000 mg/cycle | 7 to 450 mg/cycle |
|  | 50th % value | 3990 mg/cycle | 95 mg/cycle |
|  | 75th % value | 8570 mg/cycle | 158 mg/cycle |
|  | 95th % value | 32200 mg/cycle | 450 mg/cycle |
| Probability of clothing penetration | | 98% (43 data, 1 = zero) | 60% (15 data, 6 =-zero |
| Range of non-zero values | | 1% to 100% | 1% to 100% |
|  | 50th % value | 12% | 21% |
| **Probability of hand exposure inside gloves** | | 100% (43 data) | 91% (23 data, 2 = zero) |
| Range of non-zero values | | 42 to 7570 mg/cycle | 0.5 to 1330 mg/cycle- |
|  | 50th % value | 783 mg/cycle | 11.6 mg/cycle |
|  | 75th % value | 1080 mg/cycle | 88.8 mg/cycle |
|  | 95th % value | 2410 mg/cycle | 260 mg/cycle |
| Probability of hand exposure - new gloves | | 100% (29 data) | 64% (14 data, 5 = zero) |
| Range of non-zero values | | 10.2 to 2330 mg/cycle | 0.5 to 106 mg/cycle |
|  | 50th % value | 135 mg/cycle | 23.6 mg/cycle |
| **Probability of feet exposure inside shoes** | | 88% (43 data, 6 = zero) | 38% (23 data, 15 = zero) |
| Range of non-zero values | | 7.3 to 2670 mg/cycle | 1.01 to 18.7 mg/cycle |
|  | 50th % value | 125 mg/cycle | 2.7 mg/cycle |
|  | 75th % value | 501 mg/cycle | 2.9 mg/cycle |

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 73% (49 data, 17 = zero) | 21% (24 data,19 = zero) |
| Range of non-zero values | | 0.02 to 7.96 mg/m3 | 0.25 to 0.75 mg/m3 |
|  | 50th % value | 1.0 mg/m3 | 0.6 mg/m3 |
|  | 75th % value | 1.9 mg/m3 | - |
|  | 95th % value | 5.5 mg/m3 \* | - |

(vacuum-pressure - water based products - typical cycle time 180 min:  
double-vacuum process - solvent or water based products - typical cycle time 60 min)

(continued)

The above values can be re-expressed through the metric "mg/min" as follows:

**Water-based vacuum pressure process** (27 data)

Range 50th % GM GSD  
Potential dermal exposure: 6.52 to 99.4 mg/min, 25.7 26 2.06  
Hands inside gloves 0.11 to 15.3 mg/min 2.76 2.19 3.06  
Feet inside shoes 0.05 to 6.54 mg/min 0.51 0.53 3.88

**Water-based double vacuum process** (7 data)

Potential dermal exposure: 0.67 to 117 mg/min 46.9 16.7 7.69  
Hands inside gloves 0.24 to 80.2 mg/min 3.24 3.29 10.2  
Feet inside shoes 0.19 mg/min

**Solvent-based double vacuum process** (11 data)

Potential dermal exposure: 0.06 to 6.41 mg/min 2.14 0.88 5.69  
Hands inside gloves 0.003 to 8.0 mg/min 0.19 0.18 8.37  
Feet inside shoes 0.02 to 0.04 mg/min 0.03

**Context of the models**

In all cases samples of the in-use fluid were analysed to allow for derivation of the associated rates of contamination.

Timber is treated industrially to protect it against insect and fungal attack when in use. Typically timber will be treated with either water- or solvent-based formulations. Standard methods are used, typically complying with British Standards, BS 4072, BS 5268 part 5, BS 5589, and BS 5707. Usually timber is treated in sealed treatment vessels and the job entails a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination occurs through direct contact with the surface of treated timber and through contact with ancillary equipment and contaminated process plant. Dermal exposure may also arise from the spread of contamination into areas such as control rooms and from secondary sources such as previously contaminated overalls and gloves.

Traditionally, the water-based formulations have been mixtures of copper, chromium and arsenic compounds (commonly referred to as CCA), sometimes with the addition of organic chemicals to provide a degree of early protection against sap stain fungi. In recent years some water-based formulations have foresaken CCA and incorporated synthetic organic biocidal substances as the main active ingredient. There are a variety of modes of action and ways in which substances migrate through, and leach out of, the timber. Water-based processes usually tend to enhance penetration of the timber by application of pressure (10 to 14 Bar) in the treatment vessel. The treatment cycle, which may take several hours, inevitably results in the treated timber being removed from the vessel in a wet state, sometimes with small pools of treatment fluid being evident.

Solvent-based processes appear similar to water-based processes to the casual observer. After loading and sealing of the treatment vessel, the process involves the application of vacuum to the timber, addition of the treatment fluid for a pre-set time at around atmospheric pressure, followed by draining of the fluid and final application of vacuum to remove much of the available solvent from surfaces. The vessel is reopened, timber removed and placed in a suitable covered store. The timber tends be touch dry but there may be small pools of liquid. The timber slowly releases residual solvent to atmosphere during the period of storage.

As may be seen from the data sets illustrated below the profiles of exposure resulting from the two processes are rather different. In both cases primary exposure to timber preservatives in industrial pre-treatment is through dislodging residues from contaminated surfaces, with a small contribution to exposure from inhalation. HSE data have been gathered from 4 separate studies involving 56 timber treatment sites around the UK between spring 1996 and spring 1998.

***Water-based timber treatment***

CCA timber treatment operators may carry out 2-3 cycles of treatment in any day. The workload is variable, being seasonal and demand driven. Results may be presented as ***rates of contamination per cycle*** or as ***rates of contamination per minute*** to allow comparison with other models.

Rates of contamination per cycle have been used to present the results. Water-based treatments average around 3 hours, but some accelerated fixation methods may take longer - indicating fewer treatments per day. The exposure may be best described as intermittent contact with wet objects. Exposure appears to be a function of wetness.

The values for *penetration of gloves* need to be interpreted with caution when used in risk assessment. Hand exposure is dependent on a number of contributory elements. Highest exposures will be seen when inappropriate gloves are used in an inappropriate way, where the barrier (if there is any) has been compromised and when exchange for new ones is infrequent. Much of the exposure may result from pre-existing contamination. Proportionately much lower levels of exposure are seen where new gloves are used and careful hygiene practices are followed. The timber treatment data provide some insight into the way gloves may act as a potential source of exposure.

### Handling Model 2

User: Professionals  
Task: installing fish cages using lifting equipment and handling,  
 nets damp with sticky product.  
Data source: HSE survey 2000  
Reference: JS2002033, HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 9 data, 0 data = zero |
| Range of non-zero values | | 3.34 to 56.9 mg/min |  |
|  | 50th % value | 6.43 mg/min |  |
|  | 75th % value | 7.55 mg/min |  |
| **Probability of hand exposure inside gloves** | | 89% | 9 data, 1 data = zero |
| Range of non-zero values | | 0.08 to 0.50 mg/min | - |
|  | 50th % value | 0.19 mg/min | - |
|  | 75th % value | 0.21 mg/min | - |
| **Probability of feet exposure inside shoes** | | 50% | 6 data, 3 data = zero |
| Range of non-zero values | | 0.002 to 0.03 mg/min | - |
|  | 50th % value | 0.01 |  |

Context of model

The data, from which the above model derive, were collected as part of a HSE sponsored survey of the major treaters and users of nets in the UK. The results reflect the true nature of the net deployment activity – an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated handling of the nets during the process of reconstructing the cages around fish farms. The model is very specific to that activity and thought to be a reasonable predictor of rates of contamination during the task.

In all cases the in-use concentration of fluids were evaluated through chemical analysis.

### Handling Model 3

User: Professionals  
Task: Handling wood - gluing with phenol-formaldehyde resin  
Reference: Mäkinen et al., Int. Arch. Occ. Environ. Health (72):309-314, 1999

Expressed as mg/min in-use product at assumed density = 1.0 g/ml and 0.3% free phenol

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% |  |
|  | Range | 1.71 to 14.8 mg/min |  |
|  | mean value | 5.67 mg/min |  |
| **Probability of hand exposure inside gloves** | | 100% |  |
| Range of non-zero values | | up to 0.71 mg/min |  |
|  | mean value | 0.23 mg/min |  |

The occupational hygiene data are limited with only a few measurements. Standard deviation is very high. These single cases are difficult to generalise. The model is suitable only in limited cases for very similar agents (biocides with same viscosity) and the same kind of processes. For these particular processes studied, the measurements performed are representative, no other applications could be found.

### Handling Model 4

User: Professionals  
Task: Handling synthetic mineral fibre filament spray coated with size,  
 and handling winding reels  
Reference: Mäittälä et al., Int Arch Occ. Environ. Health (72):539-545, 1999

Expressed as 3-gycidoxypropyltrimethylsilane active substance

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Forming** | **Winding** |
| **Probability of potential dermal exposure** | | 69% (5 data = zero) | 86% (1 data = zero) |
|  | Range | 5.33 to 176 mg/min | 7.67 to 19 mg/min |
|  | 50th % value | 40.3 mg/min | 13.3 mg/min |
|  | 75th % value | 41.3 mg/min | 15.3 mg/min |
| **Probability of hand exposure inside gloves** | | 100% (8 data) | 100% (6 data) |
| Range of non-zero values | | 10.2 to 38.5 mg/min | 18.8 to 44.8 mg/min |
|  | 50th % value | 24.2 mg/min | 28.3 mg/min |
|  | 75th % value | 29.7 mg/min | 38.8 mg/min |

There is no data as to the quantity of size on the coated filament (bulk analysis).

The occupational hygiene data are limited with only a few measurements. Standard deviation is very high. These single cases are difficult to generalise. The model is suitable only in limited cases for very similar agents (biocides with same viscosity) and the same kind of processes. For these particular processes studied, the measurements performed are representative, no other applications could be found.

### Handling Model 5

User: Professionals  
Task: Embalming  
Reference: University of Aberdeen report and  
 Bennett et al., Am. Ind. Hyg. Ass. J. (57):599-609, 1996

Expressed as inhaled formaldehyde

Duration 50 to 92 min, median 65 min.  
Exposure by inhalation: Range 0.37 to 3.02 ppm formaldehyde, 50th % at 1.37 ppm  
University of Aberdeen

TWA formaldehyde, 60-100 minute procedure with all exposure in second half:  
Exposure 50th % at 2.3 ppm, 75th % at 3.9 ppm, 95th % at 5.5 ppm.

This ‘model’ can only be used for estimation of exposure to formaldehyde.

## DIPPING MODELS

### Dipping Model 1

User: Professionals  
Task: Dipping wooden articles (fences, window frames) in tanks  
 and coating with fluid by pouring and scrubbing.  
Data source: HSE survey 1999  
Reference: 3830 / R51.169 HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 5 data, 0 data = zero |
| Range of non-zero values | | 6.26 to 178 a mg/min |  |
|  | 50th % value | 16.7 mg/min |  |
|  | 75th % value | 178 mg/min |  |
| **Probability of hand exposure inside gloves** | | 80% | 5 data, 1 data = zero |
| Range of non-zero values | | 1.12 to 25.7 mg/min | - |
|  | 50th % value | 7.56 mg/min | - |
|  | 75th % value | 12.7 mg/min | - |
| **Probability of feet exposure inside shoes** | | 80% | 5 data, 1 data = zero |
| Range of non-zero values | | 0.10 to 25.8 mg/min | - |
|  | 50th % value | 2.57 mg/min | - |
|  | 75th % value | 4.87 mg/min | - |

a. highest data point at 2780 is an outlier.

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |
| --- | --- | --- |
| **Probability of exposure by inhalation** | 0% | 5 data, 5 data = zero |
| Range of non-zero values | - |  |

**Context of model**

The data for this model were generated during a survey of dipping activities. The methods for determining deposition on clothing utilised a seven patch technique and rates of contamination have been calculated using findings from an earlier IOM study on comparisons between patch and whole garment sampling. The model (though of very few data points) is thought to be reflective of conditions at a range of dipping tasks where operators may contact treatment fluids and certainly falls within the expected ranges.

In all cases the in-use concentration of fluids were evaluated through chemical analysis.

### Dipping Model 2

User: Professionals  
Task: Fellmongers and tanners, mixing and diluting, and loading,  
 and unloading treatment vessels.  
Data source: HSE survey 1999  
Reference: 3830 / R51.169 HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 5 data, 0 data = zero |
| Range of non-zero values | | 0.19 to 178 a mg/min |  |
|  | 50th % value | 15.0 mg/min |  |
|  | 75th % value | 168 mg/min |  |
| **Probability of hand exposure inside gloves** | | 80% | 5 data, 1 data = zero |
| Range of non-zero values | | 0.05 to 39.9 mg/min | - |
|  | 50th % value | 0.20 mg/min | - |
|  | 75th % value | 0.22 mg/min | - |
| **Probability of feet exposure inside shoes** | | 20% | 5 data, 4 data = zero |
| Range of non-zero values | | 0.05 mg/min | - |
|  | 50th % value | - | - |

a. . highest data point at 3050 is an outlier.

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 20% | 5 data, 4 data = zero |
| Range of non-zero values | | 424 mg/m3 | *(SPLASH)* |
|  | 50th % value | - |  |

**Context of model**

The data for this model were generated during a survey of dipping activities. The methods for determining deposition on clothing utilised a seven patch technique and rates of contamination have been calculated using findings from an earlier IOM study on comparisons between patch and whole garment sampling. The model (though of very few data points) is thought to be reflective of conditions at a range of dipping tasks where operators may contact wet objects and treatment fluids and certainly falls within the expected ranges.

The in-use concentrations of fluids were evaluated through chemical analysis.

### Dipping Model 3

User: Professionals  
Task: Textile treatment - mixing, diluting and machine minding.  
Data source: HSE survey 1999  
Reference: 3830 / R51.169 HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 5 data, 0 data = zero |
| Range of non-zero values | | 0.02 to 23.8 mg/min |  |
|  | 50th % value | 1.37 mg/min |  |
|  | 75th % value | 7.49 mg/min |  |
| **Probability of hand exposure inside gloves** | | 80% | 5 data, 1 data = zero |
| Range of non-zero values | | 0.07 to 1.60 mg/min | - |
|  | 50th % value | 0.25 mg/min | - |
|  | 75th % value | 0.34 mg/min | - |
| **Probability of feet exposure inside shoes** | | 80% | 4 data, 3 data = zero |
| Range of non-zero values | | 0.32 mg/min | - |
|  | 50th % value | - | - |

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 91% | 6 data, 4 data = zero |
| Range of non-zero values | | 80, 122 mg/m3 | *splash ?* |
|  | 50th % value | 101 mg/m3 |  |

**Context of model**

The data for this model were generated during a survey of dipping activities. The methods for determining deposition on clothing utilised a seven patch technique and rates of contamination have been calculated using findings from an earlier IOM study on comparisons between patch and whole garment sampling. The model (though of very few data points) is thought to be reflective of conditions at automated dipping activities where there is little scope for operator contact with treated materials.

The in-use concentration of fluids were evaluated through chemical analysis.

### Dipping Model 4

User: Professionals  
Task: Aquaculture - net dipping, dispensing to pit from IBC, stirring and crane-  
 assisted dipping, solvent-based and water-based products.  
Data source: HSE survey 1999  
Reference: 3830 / R51.169 HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 8 data, 0 data = zero |
| Range of non-zero values | | 0.67 to 221 a mg/min |  |
|  | 50th % value | 11.9 mg/min |  |
|  | 75th % value | 19.3 mg/min |  |
| **Probability of hand exposure inside gloves** | | 100% | 9 data, 0 data = zero |
| Range of non-zero values | | 0.11 to 16.7 mg/min | - |
|  | 50th % value | 1.02 mg/min | - |
|  | 75th % value | 2.98 mg/min | - |
| **Probability of feet exposure inside shoes** | | 100% | 9 data, 0 data = zero |
| Range of non-zero values | | 0.04 to 5.66 mg/min | - |
|  | 50th % value | 0.92 |  |
|  | 75th % value | 2.18 | - |

a. highest data point at 5620 is an outlier.

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 100% | 9 data, 0 data = zero |
| Range of non-zero values | | 0.05 to 0.20 mg/m3 |  |
|  | 50th % value | 0.07 mg/m3 |  |
|  | 75th % value | 0.11 mg/m3 |  |

**Context of model**

The data from which the above model derive were collected as part of a HSE sponsored survey of the major treaters of nets in the UK – there are only four companies carrying out this work. The results reflect the true nature of the net dipping activity – an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated immersion of the nets in large vats of fluid and similar retrieval at the conclusion of the process. This work is then followed by the preparation of the nets and wrapping prior to transportation to the ultimate customer.

In all cases the in-use concentration of fluids were evaluated through chemical analysis. This model could be used for a number of operations involving intermittent, but close, handling of immersed objects.

### Dipping Model 5

User: Professionals (Hospitals and healthcare)  
Task: Disinfection of articles in trough or ventilated cabinet / auto-disinfector  
Reference: Pisaniello et al., Appl. Occ. Environ. Hyg. 12(3):171-177, 1997

Glutaraldehyde vapour.

No LEV GM 0.034 ppm GSD 2.7  
LEV GM 0.014 ppm GSD 2.4

These map to percentiles:

No LEV 50th % at 0.04 ppm, 75th % at 0.06 ppm, 95th % at 0.18 ppm  
LEV 50th % at 0.02 ppm, 75th % at 0.03 ppm, 95th % at 0.06 ppm

This ‘model’ can only be used for glutaraldehyde.

## SURFACE DISINFECTION MODELS

### Surface disinfection (manual) Model 1

User: Professionals  
Task: Dilution and mixing of disinfectant and cleaning surfaces with a   
 wrung cloth or mop and wringer bucket  
Reference: Schipper et al., 1996, TNO Report V96.314

Exposure inside protective gloves, expressed as mg/min in-use product  
at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of hand exposure inside gloves** | | 100% | 16 data, 0 data = zero |
| Range of non-zero values | | 1.08 to 15.5 mg/min | - |
|  | 50th % value | 3.96 mg/min |  |
|  | 75th % value | 10.3 mg/min |  |
| Deposition on bare hands | | 100% | 2 data, 0 data =-zero |
| Non-zero values | | 1.7 and 70.2 mg/min | - |
|  | Average | 36 mg/min |  |

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 39% | 18 data, 11 data = zero |
| Range of non-zero values | | 5 to 55.6 mg/m3 | - |
|  | 50th % value | 22.2 mg/m3 | - |
|  | 75th % value | 28.9 mg/m3 | - |

The duration of the work considered per shift was on average 22 minutes for an operation room and 79 minutes for an isolation room in hospitals.

The authors have calculated 90th-percentile values, which they consider relevant for registration purposes. For the preparation of a solution this amounts to 500 mg/kg; for the actual washing/cleaning and mopping/wiping this amounts to 2000 mg/kg for potential dermal exposure.

### Surface disinfection (manual) Model 2

User: Professionals  
Task: Washing and wiping floors with mob, bucket and wringer (e.g. hospitals,  
 schools). Duration 8 to 39 min (median at 15 min). No mixing or loading.  
Reference: Popendorf and Selim, Am. Ind. Hyg. Assoc. J. (56):1111-1120, 1995

Expressed as mg/cycle and mg/task in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 6 data, 0 = zero |
| Range of non-zero values | | 0.45 to 4.50 a mg/min |  |
|  | 50th % value | 2.97 mg/min |  |
|  | 75th % value | 4.11 mg/min |  |
|  | | **Task-based data** | |
| Range of non-zero values | | 11 to 786 mg/task |  |
|  | 50th % value | 32.5 mg/task |  |
|  | 75th % value | 91.5 mg/task |  |

a. outlier at 68.7 mg/min

No data for exposure of hands.

The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry in the USA and Europe.

### Surface disinfection (manual) Model 3

User: Professionals  
Task: Wiping plumbing fixtures and surfaces with rag washed in bucket.  
 Duration 8 to 78 min (median at 15 min). No mixing or loading.  
Reference: Popendorf and Selim, Am. Ind. Hyg. Assoc. J. (56):1111-1120, 1995

Expressed as mg/cycle and mg/task in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 88% | 8 data, 1 = zero |
| Range of non-zero values | | 8.62 to 87.6 mg/min |  |
|  | 50th % value | 23.8 mg/min |  |
|  | 75th % value | 56.6 mg/min |  |
|  | | **Task-based data** | |
| Range of non-zero values | | 87 to 3900 mg/task |  |
|  | 50th % value | 886 mg/task |  |
|  | 75th % value | 1550 mg/task |  |

No data for exposure of hands.

The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry of the buildings in the USA and Europe.

## SUBSOIL TREATMENT

### Sub-soil treatment

User: Professionals  
Task: treating subsoil against termites by injection, spraying foundations and  
 sub-building crawl spaces  
Reference: Fenske & Elkner, Tox. Indust. Health 6(3-4):349-371, 1990

This study is interesting, since it covers a typical application. The compound was applied by sub-slab and soil injection to houses. This included in some cases crawl space application.

Exposure was measured on a few outer patches and a few inner patches, as well as by biological monitoring (chlorpyrifos).

From the data no potential dermal exposure data for the whole body can be estimated.

Inhalation exposure over the whole work time varied between 1.8 and 35.4 µg/m3, with a median of 10.1 µg/m3 active substance. This amounts to 12.6 to 247.8 µg/m3 and 70.7 µg/m3 in-use product.

### Sub-soil treatment Model 2

User: Professionals  
Task: Mixing and loading, and treating soil by watering and subsoil by injection,  
 spraying foundations and sub-building crawl spaces  
Reference: Cattani et al., Ann. Occ. Hyg. 45(4):299-308, 2001. Full data set will be at  
 [www.pesticide-research.curtin.edu.au](http://www.pesticide-research.curtin.edu.au) and revision will be needed.

Expressed as mg/min in-use product at assumed density = 1.0 g/ml, in-use concentration 1%

|  |  |  |  |
| --- | --- | --- | --- |
| **Task** | | **Ground spraying pre-construction** | |
| **Probability of potential dermal exposure** | | 100%, 3 data | 3.3 to 38.2 mg/min |
|  | 50th % value | 20 mg/min |  |
|  | 75th % value | 29.2 mg/min |  |
| **Probability of hand exposure inside gloves** | | 100%, 4 data | 3.17 to 48.8 mg/min |
|  | 50th % value | 3.50 mg/min | - |
|  | 75th % value | 15.0 mg/min | - |
| **Probability of exposure by inhalation** | | 100%, 4 data | 0.58 to 4.15 mg/m3 |
|  | 50th % value | 2.16 mg/m3 |  |
|  | 75th % value | 3.81 mg/m3 |  |
| **Task** | | **Post-construction injection** | |
| **Probability of potential dermal exposure** | | 94%, (18 data, 1 = zero) | 0.3 to 69.8 mg/min |
|  | 50th % value | 14.7 mg/min |  |
|  | 75th % value | 25.8 mg/min |  |
| **Probability of hand exposure inside gloves** | | 94% (17 data, 1 = zero) | 0.20 to 144 mg/min |
|  | 50th % value | 4.0 mg/min | - |
|  | 75th % value | 8.0 mg/min | - |
| **Probability of exposure by inhalation** | | 100%, 17 data | 0.07 to 5.83 mg/m3 |
|  | 50th % value | 0.33 mg/m3 |  |
|  | 75th % value | 0.57 mg/m3 |  |
| **Task** | | **Under-floor spraying, post-construction** | |
| **Probability of potential dermal exposure** | | 100%, 6 data | 5.3 to 54.6 mg/min |
|  | 50th % value | 32.2 mg/min |  |
|  | 75th % value | 42.2 mg/min |  |
| **Probability of hand exposure inside gloves** | | 100%, 6 data | 1.83 to 77.8 mg/min |
|  | 50th % value | 13.3 mg/min | - |
|  | 75th % value | 19.0 mg/min | - |
| **Probability of exposure by inhalation** | | 100%, 5 data | 1.70 to 21.9 mg/m3 |
|  | 50th % value | 4.0 mg/m3 |  |
|  | 75th % value | 20.6 mg/m3 |  |

## DUST AND SOIL ADHESION

### Dust and soil adhesion Model 1

Finley et al., Risk Analysis (14):555-569, 1994

The authors propose source terms for use in probabilistic modelling:

Adult mean 0.49 mg soil / cm2 skin 95th % 1.6 mg soil / cm2 skin  
Child mean 0.63 mg soil / cm2 skin 95th % 2.4 mg soil / cm2 skin

All log-normal distributions, arithmetic mean = 0.52, SD 0.9 mg/ soil / cm2 skin  
 50th % = 0.52 mg soil / cm2 skin

### Dust and soil adhesion Model 2

User: Professionals  
Task: Bagging treated seed (active substance 0.01 to 5.05% of dust generated,  
 50th % = 0.06%)  
Reference: HSL report, work in progress on Phase 2 - cleaning.

Expressed as mg/min dust, calculated from related inhalation results. The final concentration of dressing on the treated seed is not known, but it lays mostly on the seed coat).

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Dust** | **Concentrate** |
| **Probability of potential dermal exposure** | | 100%, 17 data | 100%, 22 data |
| Range of non-zero values | | 0.37 to 84.9 a mg/min | 0.006 to 0.75 mg/min |
|  | 50th % value | 11.4 mg/min | 0.15 mg/min |
|  | 75th % value | 33.6 mg/min | 0.38 mg/min |
| **Probability of hand exposure inside gloves** | | 100%, 16 data | 100%, 20 data |
| Range of non-zero values | | 0.3 to 44.9 b mg/min | 0.002 to 0.26 mg/min |
|  | 50th % value | 4.68 mg/min | 0.04 mg/min |
|  | 75th % value | 25.3 mg/min | 0.09 mg/min |

a. two outlier data discarded - highest value 6910 mg/min  
b. outlier at 383 mg/min.

Exposure by inhalation, exposure expressed as mg/m3 dust or concentrate

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Dust** | **Concentrate** |
| **Probability of exposure by inhalation** | | 100%, 21 data | 86% (22 data,3 = zero) |
| Range of non-zero values | | 0.61 to 19.4 mg/m3 | 0.001 to 0.34 mg/m3 |
|  | 50th % value | 1.79 mg/m3 | 0.006 mg/m3 |
|  | 75th % value | 2.7 mg/m3 | 0.02 mg/m3 |
|  | 95th % value | 10.6 mg/m3 \* | - |

### Dust and soil adhesion Model 3

User: Professionals  
Task: mixing and loading dusty bags, weighing and bag crushing  
Reference: TNO report V96.064 (Lansink et al., 1996)

Expressed as mg/min in-use product, assumed from stated data ranges

|  |  |  |  |
| --- | --- | --- | --- |
| **Task** | | **Transporting bags** | |
| **Dust on gloves** | 50th % value | 135 mg/min |  |
|  | 75th % value | 205 mg/min |  |
|  | 95th % value | 363 mg/min |  |
| **Task** | | **Manual scooping and weighing** | |
| **Dust on gloves** | 50th % value | 221 mg/min | - |
|  | 75th % value | 373 mg/min |  |
|  | 95th % value | 647 mg/min | - |
| **Task** | | **Dumping into vessel** | |
| **Dust on gloves** | 50th % value | 117 mg/min |  |
|  | 75th % value | 224 mg/min |  |
|  | 95th % value | 552 mg/min |  |
| **Task** | | **Bag collection and crushing** | |
| **Dust on gloves** | 50th % value | 142 mg/min |  |
|  | 75th % value | 228 mg/min |  |
|  | 95th % value | 496 mg/min |  |

**Context of the model**

The data for this model were gathered in a survey of several types of handling of calcium carbonate used from bags in 10 different paint factories. Sampling was done using cotton gloves only over the period that the activity actually took place. The method of analysis was specific to calcium carbonate. Results are applicable to manual handling of dusty powders packaged in cardboard bags of approximately 25 kg. Particle sizes of calcium carbonate varied from < 0.1 µm to a median diameter of 30 µm for different varieties of calcium carbonate. Manual weighing was generally done with local exhaust ventilation of questionable effectiveness. Dumping in vessels was done with local exhaust ventilation of reasonable to very good effectiveness. Duration of measured tasks was between 1 and 15 minutes. Each measurement regarded activities for only one batch of paint. The model is considered appropriate for transporting bags, dumping into vessel and bag collection and crushing. The number of measurements for manual scooping and weighing is small (n=6) and the model for this activity is only indicative. The model can be used for estimating exposure if up to 25 bags (or 1000 kg) of dusty powder are handled. Extrapolation to substantially longer duration of tasks, more batches, higher numbers of bags or larger amounts of powder should be done very cautiously, due to the expectation that the adherence of powder to either skin or cotton slopes to a maximum. The model cannot be used for very coarse or non-dusty powders (e.g. median diameter > 100 µm), granules or flakes. It can also not be used for handling of powders in containers (drums) with inner lining. It may provide only indicative results for handling of polymer bags that are substantially more “dust-tight” than cardboard bags, especially for the transporting of bags.

## FOGGING AND MISTING

### Fogging and misting

Misting Model 1

User: Professionals  
Task: misting at low level using CDA wand (CDA low level sprayer).   
 No mixing or loading.  
Data source: HSE survey 1999  
Reference: Ann. Occ. Hyg. (to be published), ACP paper 70 (283/01).

Expressed as mg/cycle in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 12 data, 0 data = zero |
| Range of non-zero values | | 0.05 to 13.8 mg/min |  |
|  | 50th % value | 2.21 mg/min |  |
|  | 75th % value | 8.08 mg/min |  |
| **Probability of hand exposure inside gloves** | | 100% | 12 data, 0 data = zero |
| Range of non-zero values | | 0.003 to 0.98 mg/min | - |
|  | 50th % value | 0.06 mg/min | - |
|  | 75th % value | 0.12 mg/min | - |
| **Probability of feet exposure inside shoes** | | 100% | 12 data, 0 data = zero |
| Range of non-zero values | | 0.002 to 0.76 mg/min | - |
|  | 50th % value | 0.02 mg/min |  |
|  | 75th % value | 0.05 mg/min | - |

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 33% | 12 data, 8 data = zero |
| Range of non-zero values | | 22 and 26 mg/m3 | *2 data very high outliers* |
|  | 50th % value | 24 mg/m3 |  |

6 data relate to ready for use product and 6 for diluted concentrate

*Deposition pattern - head - 0.3%; arms - 1.3%; torso - 13.7%; legs - 84.7%*

Context of model

Data collected from a survey of application of amenity herbicides by controlled droplet application. The data are specific to this type of activity. In-use concentrations of product were established through chemical analysis.

### Misting Model 2

User: Professionals  
Task: misting at waist level using CDA (ULV) mist blower.   
 No mixing or loading.  
Data source: HSE survey 2000  
Reference: HSL report in press

Expressed as mg/cycle in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 8 data, 0 data = zero |
| Range of non-zero values | | 6.11 to 35.5 mg/min |  |
|  | 50th % value | 13.8 mg/min |  |
|  | 75th % value | 21.8 mg/min |  |
| **Probability of hand exposure inside gloves** | | 100% | 8 data, 0 data = zero |
| Range of non-zero values | | 0.02 to 0.20 mg/min | - |
|  | 50th % value | 0.03 mg/min | - |
|  | 75th % value | 0.04 mg/min | - |
| **Probability of feet exposure inside shoes** | | 25% | 8 data, 6 data = zero |
| Range of non-zero values | | 0.03 and 0.04 mg/min | - |
|  | 50th % value | 0.04 mg/min |  |

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 100% | 8 data, 0 data = zero |
| Range of non-zero values | | 31.0 to 79.5 mg/m3 |  |
|  | 50th % value | 47.7 mg/m3 |  |
|  | 75th % value | 70.2 mg/m3 |  |

**Context of model**

Simulation of misting activity but using services of professional operator in a realistic building. In-use concentrations determined by chemical analysis. Data specific to mode of application.

### Fogging Model 3

User: Professionals  
Task: Fogging at mid level using fogging machine. No mixing or loading.  
Data source: HSE survey 2000  
Reference: HSL report in press

Expressed as mg/cycle in-use product at assumed density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| Probability of potential dermal exposure | | 100% | 4 data, 0 data = zero |
| Range of non-zero values | | 0.60 to 1.13 mg/min |  |
|  | 50th % value | 0.74 mg/min |  |
|  | 75th % value | 0.79 mg/min |  |

Exposure inside protective gloves, expressed as mg/min in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| Probability of hand exposure inside gloves | | 100% | 4 data, 0 data = zero |
| Range of non-zero values | | 0.03 to 0.33 mg/min | - |
|  | 50th % value | 0.16 mg/min | - |
|  | 75th % value | 0.29 mg/min | - |

Exposure inside shoes, expressed as mg/min in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| Probability of feet exposure inside shoes | | 100% | 4 data, 0 data = zero |
| Range of non-zero values | | 0.003 to 0.009mg/min | - |
|  | 50th % value | 0.006 mg/min |  |
|  | 75th % value | 0.009 mg/min | - |

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |
| --- | --- | --- |
| Probability of exposure by inhalation | 0% | 4 data, 4 data = zero |
| Range of non-zero values | - |  |

**Context of model**

Simulation of fogging activity but using services of professional operator in a realistic building. In-use concentrations determined by chemical analysis. Data specific to mode of application.

## METALWORKING FLUIDS

### MWF Model 1

User: Professionals  
Task: Mounting and demounting hard metal saw blades in a sharpening machine  
 using lubricant fluid   
Reference: Linnainmaa and Kiilunen, Int. Arch. Occ. Env. Health (69):193-200, 1997

The report quotes hand-wash data for cobalt on workers' hands following hard metal working. Protective gloves were not worn.

In-use fluid 1.2 to 5100 mg / litre cobalt, mean 696 mg / litre  
 density unknown, assumed 0.9 to 1.1 g / ml

Hand washes wash 1 0.39 to 6.5 mg cobalt removed  
 wash 2, 3 no data, reported "exponential decline"  
 wash 4 0.022 to 0.212 mg

The ranges for washes 2 and 3 were interpolated from a simple plot of wash number against log10 (mg cobalt).

All washes were assumed as uniform distributions between the ranges.  
Wash 2 was 0.75 correlated with wash 1, etc. until wash 4 was correlated 0.75 with wash 3.  
The in-use fluid was assumed as a triangular distribution, most likely value at 696 mg / l. The concentration was a uniform distribution.

A Crystal Ball probabilistic estimate for **fluid on the hands**:

50th % 2.8ml  
 75th % 5.1 ml  
 95th % 13.1 ml

The 95th % value is very similar to the default 6 ml spill model which assumes 6 ml of fluid adhering to a bare hand.

The occupational hygiene data are limited with only a few measurements. Standard deviation is very high. These single cases are difficult to generalise. The model is suitable only in limited cases for very similar agents (biocides with same viscosity) and the same kind of processes. For these particular processes studied, the measurements performed are representative, no other applications could be found, except probably spilling or splashing of liquids to hands.

### MWF Model 2

User: Professionals  
Task: using water and oil based metal working fluids (MWF)  
Reference: HSE report EH74/4

Expressed as mg/m3 in-use oil or water based MWF

|  |  |  |  |
| --- | --- | --- | --- |
| **Exposure by inhalation** | | **Oil based MWF** | **Water-based MWF** |
| Range of values | | 0.03 to 3.7 mg/m3 | 0.01 to 13.0 mg/m3 |
|  | 50th % value | 0.78 mg/m3 | 0.12 mg/m3 |
|  | 75th % value | 2.18 mg/m3 | 0.33 mg/m3 |
|  | 95th % value | 3.35 mg/m3 | 1.58 mg/m3 |
|  | | **Total inhalable particulate** | |
| Range of non-zero values | | 0.05 to 4.4 mg/m3 | 0.02 to 23mg/m3 |
|  | 50th % value | 0.55 mg/m3 | 0.32 mg/m3 |
|  | 75th % value | 1.84mg/m3 | 0.65 mg/m3 |
|  | 95th % value | 3.26 mg/m3 | 1.91 mg/m3 |

The oil or water mist particle sizes were not determined.

**Context**

A study of 31 companies ranging from multinationals to small independent engineering workshops handling mineral oils, semi-synthetic oils and synthetic fluids. In excess of 300 personal samples were collected.

### MWF Model 3

User: Professionals  
Task: Using cutting fluids in case and valve making, and assembly   
Reference: Abrams et al., Appl. Occ. Environ. Hyg. 15(16):492-502, 2000

Expressed as mg/m3 MWF

Case-making GM 0.54 mg/m3 GSD 1.58  
Valve-making GM 0.30 mg/m3 GSD 1.61  
Assembly GM 0.12 mg/m3 GSD 1.40

Percentile estimates:

Case-making 50th % at 0.55 mg/m3, 75th % at 0.75 mg/m3, 95th % at 1.09 mg/m3  
Valve-making 50th % at 0.31 mg/m3, 75th % at 0.41 mg/m3, 95th % at 0.63 mg/m3  
Assembly 50th % at 0.01 mg/m3, 75th % at 0.06 mg/m3, 95th % at 0.49 mg/m3

These data should not be read as a model; it just indicated levels of exposure to metal working fluids observed by inhalation.

## PYROTECHNIC AEROSOL SETTLEMENT

### Pyrotechnic Aerosol Settlement

User: Professionals  
Task: Settlement of aerosols (vacated space - fumigation with biocide smoke)   
Data source: HSL 2001  
Reference: ACP 23/2 (284/01)

|  |  |  |  |
| --- | --- | --- | --- |
| **Test** | **Air changes per hour** | **Maximum airborne concentration, mg/m3** | **Settled surface concentration, mg/m2** |
| Phase 1 dicloran - test 1 | 0.4 | 31 | 17 |
| Phase 1 dicloran - test 6 | 0 | 37 | 295 |
| Phase 1 permethrin - test 2 | 0 | 8 | 5 |
| Phase 1 permethrin - test 4 | 0 | 10 | 7 |
| Phase 1 red smoke - test 7 | 0 | 48 | 18 |
| Phase 2 dicloran - test 9 | 0.4 | 92 | 135 |
| Phase 3 dicloran - test 1 | 3.2 | 47 | 19.5 |
| Phase 3 dicloran - test 2 | 0.3 | 90 | 59.6 |
| Phase 3 dicloran - test 3 | 0 | 78 | 63.1 |
| Phase 3 dicloran - test 5 | 0.3 | 133 | 96.5 |

(omits failed tests)

**Deposit from a given airborne aerosol concentration (particle size 2 microns and below**

Other than the outlier (Phase 1 dicloran - test 6), the data follow a straight line with a formula

**mg/m2 = 0.073 x mg/m3**

Further formulae link the **quantity** used, the **deposit** and the **maximum concentration**:

* The maximum concentration of airborne biocide aerosol = 65 mg/m3 per 100 mg of biocide in the unburned smoke generator per m3 of enclosure. (That is, 100 mg of biocide in a smoke generator, fired in a 10 m3 enclosure, would produce a maximum airborne concentration of 6.5 mg/m3). In default of any other data, a worst case value in any space is 15 mg/m3 at 4-hours post-firing.

- The maximum deposit of aerosol on upward-facing surfaces = 13.3 micrograms  
 per cm2, per gram of biocide in the unburned smoke generator, per square metre of  
 surface. (That is, 100 mg of biocide in a smoke generator, fired in an enclosure with  
 10 m2 horizontal area would produce a maximum deposit of 0.13 micrograms  
 per cm2). In default of any other data, a worst case value in any space is   
 14 micrograms per cm2.

## PPE penetration and deposition

User: Professionals  
Task: all.  
Data source: HSE surveys 1991-2000  
Reference: EH74/3 and Ann. Occ. Hyg. 45(1):55-60, 2001

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of clothing penetration** | | 62% | 231 data,  (87 data = zero) |
| Range of non-zero values | | 1 to 100% |  |
|  | 50th % value | 11% |  |
|  | 75th % value | 42% |  |
| **Probability, hand exposure inside new gloves** | | 95%% | 47 data |
| **Probability, hand exposure inside old gloves** | | 95% | 190 data |
|  | 50th % value | 1.36 mg/min |  |
|  | 75th % value | 4.21 mg/min |  |
|  | 95th % value | 71.9 mg/min |  |
| **Probability of feet exposure inside shoes** | | Assume 100% |  |
| Range of non-zero values | | 0.05 to 14.8 mg/min | 68 data |
|  | 50th % value | 0.28 |  |
|  | 75th % value | 1.44 | - |
|  | 95th % value | 4.57 mg/min |  |

**Non-professionals**: assume 20% clothing penetration (light clothing)  
50% or 100% penetration (minimal clothing)

New gloves reduce hand-in-glove exposure by a factor of 0.6.

Creely & Cherrie (Ann Occup Hyg 2001 45(2) 137-143)

Probability of exposure of hands inside gloves = 83%  
Protection factor versus the challenge to the outside of gloves > 220.

Deposition pattern (next page)

**Deposition patterns**

The following data are taken from workplace surveys only (omits data for hands)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Survey** | **% head** | **% arms** | **% trunk** | **% legs** |
| Industrial preservation - water | 1 | 5 | 8 | 86 |
| Industrial preservation - solvent | 1 | 3 | 4 | 93 |
| Remedial spray - much overhead work | 2 | 11 | 12 | 75 |
| Brush wood preservative | 4 | 19 | 29 | 48 |
| Brush / roller antifoulant - some overhead | 19 | 12 | 26 | 43 |
| High pressure airless spray - some overhead | 9 | 18 | 40 | 33 |
| Mixing and loading antifoulant | 3 | 12 | 21 | 64 |
| Insecticide spraying - downwards | 4 | 10 | 21 | 65 |
| Insecticide spraying - around and overhead | 9 | 13 | 34 | 44 |
| Orchard - tractor spraying - overhead | 4 | 9 | 36 | 52 |
| Dipping - immersing articles | 3 | 7 | 18 | 73 |
| Sheep dipping - immersing | - | 12 | 23 | 65 |
| Sheep dipping - handling | - | 8 | 17 | 75 |
| *Normalised 50th % value* | *4* | *11* | *21* | *65* |
| *Whole body - areas for comparison* | *7* | *11* | *46* | *36* |

## Consumer product spraying and dusting

### Spraying - air space spraying Model 1

User: Non-professionals  
Task: air space spraying with pre-pressurised aerosol cans, trigger sprays  
 and pumped sprayers  
Data source: HSL 2001  
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of forearms and hands / legs, feet and face, as mg/min in-can product  
at nominal density = 1.0 g/ml; Inhaled as mg/m3 in-can product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Pre-pressurised aerosol spray cans  Task  Intermittent discharge of a hand-held aerosol can into the air of a small sealed room, a sum of four events. The subjects remained in the room for 30 seconds after each event before exiting. The aerosol continuous discharge rate was 2.3 g/sec.  Exposure assessment note  The predicted inhalation exposure is highly sensitive on the dwell time within the area sprayed and careful judgement is required in the interpretation of both the measured airborne concentrations and the dermal exposure values. In practice the dermal exposure probably occurs mainly during the period of aerosol release. The value of the inhalation component results from a 36 second exposure (6 second release + 30 second dwell time).  *Dermal deposition rates* relate to actual dermal exposure.  *Results* all based on strontium washings, actual dermal exposure to in-use product,   sum of 4 spraying events | | | | |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% | 100% | 100% |
|  | | 10 data | 10 data | 10 data |
| Range of non-zero values | | 21.6 to 432 mg/min | 24.5 to 233 mg/min | 64 to 374 mg/m3 |
|  | 50th % value | 108 mg/min | 79.2 mg/min | 167 mg/m3 |
|  | 75th % value | 156 mg/min | 113 mg/min | 234 mg/m3 |
|  | | | | |
| Hand-held trigger spray  Task  Discharge of a hand-held trigger spray into the air of a small sealed room, a sum of four events. The subjects remained in the room for 30 seconds after each event before exiting. The sprayer discharged up to 1.1 g of product per trigger pull.  (Note, hand muscles experience rapid fatigue after very few minutes’ use of these devices)  *Results*  all based on strontium washings, actual dermal exposure to in-use product,   4 spraying events (adjusted for blanks) | | | | |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% | 100% | 90% |
|  | | 10 data | 10 data | 10 data (1 = zero) |
| Range of non-zero values | | 47.5 to 173 mg/min | 8.5 to 90.8 mg/min | 27 to 129 mg/m3 |
|  | 50th % value | 89.5 mg/min | 19.7 mg/min | 66.2 mg/m3 |
|  | 75th % value | 136 mg/min | 42.4 mg/min | 90.2 mg/m3 |
|  | | | | |
| Hand-held pumped sprayer (averaged over 4 events)  Task  Discharge of a hand-held pump sprayer into the air of a small sealed room, a sum of four events. The subjects remained in the room for 30 seconds after each event before exiting. The sprayer was pre-loaded and given to the subject, who paused to re-pressurise the device every few seconds.  *Results*  all based on strontium washings, actual dermal exposure to in-use product,   4 spraying events (adjusted for blanks) | | | | |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% | 100% | 100% |
|  | | 10 data | 10 data | 10 data |
| Range of non-zero values | | 17 to 189 mg/min | 7.1 to 39.3 mg/min | 19.1 to 110 mg/m3 |
|  | 50th % value | 30 mg/min | 18 mg/min | 63.3 mg/m3 |
|  | 75th % value | 98.4 mg/min | 22.7 mg/min | 76.3 mg/m3 |

Median 9% of the legs etc. deposit was on the face

The use of consumer deposition and exposure models demands a full explanation of the proposed in-use scenario and will vary from product to product. The conditions of the simulation exercises may not be a true representation of the way a product is meant to be used. The selection of application period, followed by dwell period is the key determinant of predicted deposition and dose through inhalation. The data presented in these models are a reflection of the specific scenarios used in the experiments.

### Consumer product spraying and dusting Model 2

User: Non-professionals  
Task: surface spraying (soft furnishings, skirting boards, shelves) with   
 pre-pressurised aerosol cans, trigger sprays and dust applicator packs;   
 also vacuum cleaning dust deposits.  
Data source: HSL 2001  
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of forearms and hands / legs, feet and face, as mg/min in-can product  
at nominal density = 1.0 g/ml; Inhaled as mg/m3 in-can product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Pre-pressurised aerosol spray can  1995 study: spraying a small room including a sofa, 6 metres of skirting board, 2 dining chairs and 6 m2 of carpet. Hand and forearm dermal measurements only were taken.  1998 study: spraying a living room containing a 3-piece suite, 6 m2 of carpet and a pet bed. | | | | |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% | 100% | 93% |
|  | | 15 data | 6 data | 15 data (1 = zero) |
| Range of non-zero values | | 1.7 to 156 mg/min | 17 to 45.2 mg/min | 0.33 to 49.5 mg/m3 |
|  | 50th % value | 33.4 mg/min | 28.4 mg/min | 30.5 mg/m3 |
|  | 75th % value | 64.7 mg/min | 35.7 mg/min | 35.9 mg/m3 |
|  | | | | |
| Hand-held trigger spray  Hand-held trigger spraying 13 m skirtings, 2 m2 of shelves and 8 m2 of horizontal and vertical laminate surfaces. The sprayer discharged up to 1.1 g of product per trigger pull.  (Note, hand muscles experience rapid fatigue after very few minutes’ use of these devices)  *Results*  all based on strontium washings, actual dermal exposure to in-use product | | | | |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% | 100% | 100% |
|  | | 11 data | 11 data | 11 data |
| Range of non-zero values | | 3 to 68.2 mg/min | 1.9 to 12.4 mg/min | 2.6 to 19.5 mg/m3 |
|  | 50th % value | 24 mg/min | 7.2 mg/min | 8.7 mg/m3 |
|  | 75th % value | 36.1 mg/min | 9.7 mg/min | 10.5 mg/m3 |
|  | | | | |
| Hand-held dusting applicator pack for crack and crevice  Task  A Crack and crevice powders for fleas and ants, indoor and outdoor use  The products were found to be particles of inert filler such as fine talc or chalk (median, 45% of dust less than 75 µm) in a flexible canister with a single dispense hole, diameter 2 to 2.5 mm. This is the group on the left of the illustration. A synthetic mixture reproduced the finest grade of powder found from six different products, with 5% Tinopal and 1% strontium.  Volunteers wearing minimal clothing applied dust in a simulated ant treatment in a kitchen, including 13 m of skirtings, 2 m2 of shelves and 3 m2 of horizontal laminate surfaces.  B Broadcast powders for fleas, indoor carpet / furnishings use.  Products specified for use on soft furnishings were fine powders as (a), above. Other products, exclusively for use on carpets, were found to be coarse granules (median, >95% of granules greater than 180 µm) in a hard container with either one large or several small dispense holes, diameter up to 4.8 mm. The likelihood and level of contamination was considered to be higher for the finer dusts and the same synthetic mixture and dispenser were used as for (a).  Volunteers wearing minimal clothing applied the powder in a simulated flea treatment of a living room, then removed it with an inefficient (i.e. not cyclone) vacuum cleaner. | | | | |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% | 100% | 100% |
|  | | 10 data | 10 data | 10 data |
| Range of non-zero values | | 0.4 to 4.18 mg/min | 0.22 to 6.56 mg/min | 0.21 to 8.01 mg/m3 |
|  | 50th % value | 2.39 mg/min | 1.34 mg/min | 1.42 mg/m3 |
|  | 75th % value | 2.83 mg/min | 2.15 mg/min | 1.78 mg/m3 |
|  | | | | |
| Hand-held dusting applicator pack, broadcast powder (3 data only) | | | | |
| Range of non-zero values | | 0.8 to 2.5 mg/min | 2.4 to 3.2 mg/min | 0.8 to 1.9 mg/m3 |
|  | | | | |
| Vacuuming after dusting application, non-cyclone vacuum cleaner (3 data only) | | | | |
| Range of non-zero values | | 0.6 to 1.0 mg/min | 1.0 to 3.2 mg/min | 0.6 to 0.8 mg/m3 |

Median 5% of the legs etc. deposit was on the face

### Consumer product spraying and dusting Model 3

User: Non-professionals  
Task: Surface spraying (underside of joists indoors with hand-held pressurised   
 sprayer; fence outdoors with electric powered sprayer),  
 i.e. refillable pressure spray equipment.  
Data source: HSL 2001  
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of forearms and hands / legs, feet and face, as mg/min in-use product  
at nominal density = 1.0 g/ml; Inhaled as mg/m3 in-can product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Hand-held pressurised 3-litre garden sprayer, spraying 16 m2 joists overhead**  **Task**  Spraying 16 m2 of rough wooden joists and the undersides of floorboards, overhead indoors, with water-based product using a hand-held pumped pressurised 3-litre garden sprayer (includes loading). | | | | |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% (10 data) | 100% (10 data) | 100% (10 data) |
| Range of non-zero values | | 19.2 to 219 mg/min | 6.9 to 138 mg/min | 7.8 to 160 mg/m3 |
|  | 50th % value | 109 mg/min | 79.7 mg/min | 73.8 mg/m3 |
|  | 75th % value | 176 mg/min | 120 mg/min | 115 mg/m3 |
|  | | | | |
| **Electric powered sprayer outdoors - all types of fence** | | | | |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% (6 data) | 100% (6 data) | 100% (6 data) |
| Range of non-zero values | | 32.4 to 144 mg/min | 13.4 to 84 mg/min | 1.1 to 6.5 mg/m3 |
|  | 50th % value | 52.8 mg/min | 36.3 mg/min | 2.0 mg/m3 |
|  | 75th % value | 72.6 mg/min | 39.9 mg/min | 3.3 mg/m3 |

Median 7% of the legs etc. deposit was on the face   
Skin deposit - spraying lattice fences 50th% = 120 mg/min, solid fences 50th% = 70 mg/min

## Consumer product painting

### Brush painting Model 1

User: Non-professionals  
Task: Brush painting 16 m2 of rough wooden joists and the undersides of floorboards, overhead indoors, with water-based product (includes decanting).

Data source: HSL 2001  
Reference:: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of forearms and hands / legs, feet and face, as mg/min in-use product  
at nominal density = 1.0 g/ml; Inhaled as mg/m3 in-can product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | **Hand and forearm** | **Legs, feet & face** | **Inhaled** |
| Probability of exposure | | 100% (11 data) | 100% (11 data) | 100% (11 data) |
| Range of non-zero values | | 43.2 to 239 mg/min | 8.0 to 54.6 mg/min | 0.6 to 11.4 mg/m3 |
|  | 50th % value | 110 mg/min | 18.8 mg/min | 1.7 mg/m3 |
|  | 75th % value | 150 mg/min | 35.7 mg/min | 3.1 mg/m3 |

Median 18% of the legs etc. deposit was on the face

### Consumer product painting Model 2

User: Non-professionals  
Task: brush painting sheds and fences   
Data source: Ann. Occ. Hyg. 41(3):97-312, 1997  
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of hands and whole body minus hands, as mg/min in-use product  
at nominal density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| Laboratory studies - lattice fence painting, water-based product | | | |
|  | | **Hands** | **Body (less hands)** |
| Probability of exposure | | 100% (12 data) | 92% (8 data) |
| Range of non-zero values | | 0.05 to 17 mg/min | 1.18 to 28.1 mg/min |
|  | 50th % value | 2.54 mg/min | 5.61 mg/min |
|  | 75th % value | 6.32 mg/min | 13.8 mg/min |
|  | | | |
| Laboratory studies - lattice fence painting, solvent-based product | | | |
|  | | **Hands** | **Body (less hands)** |
| Probability of exposure | | 100% (12 data) | 100% (7 data) |
| Range of non-zero values | | 0.03 to 87.3 mg/min | 3.83 to 133 mg/min |
|  | 50th % value | 6.18 mg/min | 24.6 mg/min |
|  | 75th % value | 19.5 mg/min | 30.2 mg/min |

### Consumer product painting Model 3

User: Non-professionals  
Task: Brush painting sheds and fences using household gloves or no gloves  
Data source: Ann. Occ. Hyg. 44(6):421-426, 2000  
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure as mg/min in-use product at nominal density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 15 data, 0 data = zero |
| Range of non-zero values | | 0.06 to 63.3 mg/min |  |
|  | 50th % value | 5.06 mg/min |  |
|  | 75th % value | 16.9 mg/min |  |
| **Probability of hand exposure inside gloves** | | 83% | 6 data, 1 data = zero |
| Range of non-zero values | | 0.01 to 3.24 mg/min | - |
|  | 50th % value | 0.02 mg/min | - |
|  | 75th % value | 0.3 mg/min | - |
| **Deposition on bare hands** | | 100% | 9 data, 0 data =-zero |
| Range of non-zero values | | 0.11 to 56.3 mg/min | - |
|  | 50th % value | 3.47 mg/min | - |
|  | 75th % value | 5.91 mg/min | - |
| **Probability of feet exposure inside shoes** | | 53% | 15 data, 7 data = zero |
| Range of non-zero values | | 0.01 to 0.24 mg/min | - |
|  | 50th % value | 0.02 mg/min | - |
|  | 75th % value | 0.05 mg/min | - |

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 40% | 15 data, 9 data = zero |
| Range of non-zero values | | 0.5 to 8.03 mg/m3 |  |
|  | 50th % value | 1.63 mg/m3 |  |
|  | 75th % value | 4.15 mg/m3 |  |

### Consumer product painting Model 4

User: Non-professionals  
Task: brush and roller painting antifoulant on the underside of small boats  
 (leisure craft) using household gloves. Field survey data. The product was mixed and applied by brush direct from the can, or poured to a paint tray and applied by roller. The task was mostly done outdoors in a cramped position, with the single-hull boat (one double-hull) on a sling, cradle or trailer.

Data source: Ann.. Occ. Hyg. 44(6):421-426, 2000  
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure as mg/min in-use product at nominal density = 1.0 g/ml

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of potential dermal exposure** | | 100% | 11 data, 0 data = zero |
| Range of non-zero values | | 3.53 to 108 mg/min |  |
|  | 50th % value | 15.7 mg/min |  |
|  | 75th % value | 50.8 mg/min |  |
| **Probability of hand exposure inside gloves** | | 89% | 9 data, 1 data = zero |
| Range of non-zero values | | 0.07 to 18.5 mg/min | - |
|  | 50th % value | 0.74 mg/min | - |
|  | 75th % value | 3.77 mg/min | - |
| **Deposition on outside of protective gloves** | | 100% | 2 data, 0 data =-zero |
| Range of non-zero values | | 70 and 76.6 mg/min | - |
|  | 50th % value | 73.3 mg/min | - |
| **Probability of feet exposure inside shoes** | | 100% | 2 data, 0 data = zero |
| Range of non-zero values | | 0.1 and 0.11 mg/min |  |
|  | 50th % value | 0.1 mg/min | - |

Exposure by inhalation, exposure expressed as mg/m3 in-use product

|  |  |  |  |
| --- | --- | --- | --- |
| **Probability of exposure by inhalation** | | 40% | 11 data, 7 data = zero |
| Range of non-zero values | | 0.03 to 0.11 mg/m3 |  |
|  | 50th % value | 0.04 mg/m3 |  |
|  | 75th % value | 0.05 mg/m3 |  |

Transfer coefficients – dislodgeable residues

|  |  |  |  |
| --- | --- | --- | --- |
| **Substrate** | **Residue** | **Transfer efficiency** | **Reference no.** |
| Painted wood (MDF) | Dried fluid | 3% | 1 |
| Short pile tufted nylon carpet | Dried fluid | 6% | 1 |
| Carpet | Powder | <1% | 4 |
| Nylon carpet | Powder | 1 to 3% | 5 |
| Carpet | Dried fluid | 9% averaged | 6 |
| Carpet | Powder | 9%, 3% if trodden-in | 8 |
| Rough sawn wood | Dried fluid | 2% | 1 |
| White smooth glazed tile | Dried fluid | 55% | 1 |
| Brown rough glazed tile | Dried fluid | 60% | 1 |
| Non-slip vinyl flooring | Dried fluid | 15% | 1 |
| Vinyl | Powder | 50% | 8 |
| Various types of surface | Dried fluids | 8 to 18% | 2 |
| Smooth surface | Powder | 2 to 6% | 3 |
| Cotton, knitwear, plastic, wood | Dried fluid | 20% - dry hand | 7 |
| Cotton, knitwear, plastic, wood | Dried fluid | 30% - wet hand | 7 |
| Stainless steel | Powder | 70% - dry hand | 8 |

References:

1 Hand press data: Roff (in press) – HSL reports IR/ECO/00/11 and IR/ECO/01/02  
2 Houghton, thesis 1997  
3 Brouwer et al., Appl. Occ. Env. Hyg. 14:231-239, 1999  
4 Lu & Fenske, Env. Health Perspect. 107(6):463-467, 1999  
5 Ross et al., Chemosphere 22(9-10):975-984, 1991  
6 Jazzercise data - Ross et al., Chemosphere 20(3-4):349-360, 1990  
7 Fogh et al., Riso Lab, Roskilde, Denmark 1999  
8 Rodes et al., JEA & E, in press  
9 Coldwell and Corns, 2001, HSL report OMS/2001/14

## Household products - secondary exposure

The following data appear in the identified publications.

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance** | **Matrix** | **Conc. max** | **Reference no.** |
| Bendiocarb | Air | 0.05 µg/m3 | 3 |
|  | Air | 2 µg/m3 | 6 |
|  | Dust | 0.9 µg/g | 9 |
| Carbaryl | Air | 0.03 µg/m3 | 3 |
| Chlorothalonil | Air | 0.001 µg/m3 | 3 |
| Chlorpyrifos | Air | 0.5 µg/m3 | 1 |
|  | Air | 0.13 µg/m3 | 3 |
|  | Air | 4 µg/m3 | 6 |
|  | Air | 1.6 µg/m3 | 8 |
|  | Dust | 22 µg/g | 1 |
|  | Dust | 3.1 µg/g | 4 |
|  | Dust | 119 µg/g | 5 |
|  | Dust | 15 µg/g | 8 |
| Deltamethrin | Air | 0.005 µg/m3 | 2 |
|  | Dust | 50 µg/g | 2 |
| DDT | Dust | data | 9 |
| Diazinon | Air | 0.02µg/m3 | 1 |
|  | Air | 0.32 µg/m3 | 3 |
|  | Air | 35 µg/m3 | 6 |
|  | Dust | 0.4 µg/g | 1 |
|  | Dust | 66 µg/g | 5 |
|  | Dust | 5.8 µg/g | 8 |
| Dichlofluanid | Air | 0.14 µg/m3 | 1 |
| Dichlorvos | Air | 0.15 µg/m3 | 3 |
|  | Dust | 1.7 µg/g | 8 |
| Glyphosate | Dust | 3.5 µg/g | 9 |
| Lindane | Air | 0.02 µg/m3 | 3 |
|  | Dust | 9.4 µg/g | 9 |
| Malathion | Air | 0.01 µg/m3 | 3 |
| Pentachlorophenol | Dust | 3.3 µg/g | 4 |
| Permethrin | Air | 0.02 µg/m3 | 1 |
|  | Air | 0.1 µg/m3 | 2 |
|  | Dust | 320 µg/g | 1 |
|  | Dust | 800 µg/g | 2 |
|  | Dust | 284 µg/g | 9 |
| Permethrin (vacuuming) | Air | 0.10 µg/m3 | 1 |
| o-Phenyl phenol | Dust | 0.8 µg/g | 8 |
| Piperonyl butoxide (pyrethroid synergist) | Dust | 111 µg/g | 9 |
| Propoxur | Air | 0.04 µg/m3 | 1 |
|  | Air | 0.32 µg/m3 | 3 |
|  | Air | 10 µg/m3 | 7 |
|  | Dust | 0.6 µg/g | 1 |
|  | Dust | 1.6 µg/g | 8 |
| Tetramethrin | Air | 10 µg/m3 | 8 |
| Transfluthrin (thermal vaporiser) | Air | 20 µg/m3 | 7 |
| In cupboard vaporiser | Air | 71 µg/m3 | 7 |

References:

1 Schenk et al., Indoor Air 7:135-142, 1997  
2 Berger-Preiss et al., Indoor Air 7:35-142, 1997  
3 Whitmore et al., Arch. Env. Cont. Tox. 26:47-59, 1994  
4 Lewis et al., Arch. Env. Cont. Tox. 26:37-46, 1994  
5 Gordon et al., J. Exp. Anal. Env. Epidemiol. 9:456-470, 1999  
6 Currie et al., Am. Ind. Hyg. Ass. J. 57(1):23-27, 1990 (*all high values*)  
7 Pauluhn, personal communications, also Appl. Occ. Env. Hyg. 13(6):469-478, 1998  
8 IEH review, 1999  
9 HSL report (in press) Coldwell et al., 2001

It has been stated (Ref. 7) that for pyrethroids, there is no correlation between airborne concentrations and concentrations in house dust

Ref 9 found none of the following in 28 samples of house dust taken from non-professional users’ houses:

Chlorpyrifos, dichlorvos, dimethoate, fenitrothion, bioallethrin, tetramethrin, phenothrin, deltamethrin, bioresmethrin, bifenthrin, 2.4-D, 2,4-DB, 2,4,5-T, 2,4,5-TP, dichlorprop, mecoprop, MPCA, dicamba, dinoseb.

## BSG Indicative exposures meta-model

The DG XI Biocides Steering Group developed a conceptual model for potential dermal exposure in 1998. This has become a founding concept for the “HSL MODEL” cross-reference. The matrix appears below

Using indicative exposures according to task

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Median deposit, mg.min-1** | | **Percentile** | **“Low”  4 mg.min-1** | **“Medium” 20 mg.min-1** | **“High”  100 mg.min-1** | **“Top”  500 mg.min-1** |
| Profile 1 | Narrow (GSD 2.45) | 50% 75% 95% | 4  7  18 | 20  37  87 | 100  180  440 | 500  920  2200 |
| Profile  2 | Intermediate (GSD 3.36) | 50% 75% 95% | 4  8  29 | 20  45 150 | 100  230  730 | 500  1100  3700 |
| Profile 3 | Wide (GSD 6.04) | 50% 75% 95% | 4  14  77 | 20  67 390 | 100  340  1900 | 500  1700  9700 |

(Percentile values at 50%, 75%, and 95% are commonly used in the regulation of pesticide products.)

It is possible to map tasks onto the matrix as set out below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **“Low”  4 mg.min-1** | **“Medium” 20 mg.min-1** | **“High”  100 mg.min-1** | **“Top”  500 mg.min-1** |
| Profile 1 | \* Timber pre-treatment (solvent)  \* Cda spraying  \*Trigger spray | \* Anti-foul mix and load  \* Flea dusting  \* Brushing overhead | \* Spraying overhead  \* Aerosol space spray |  |
| Profile  2 |  | \* Low pressure spray  \* Timber pre-treatment (aqueous)  \* Anti-fouling brushing | \* Anti-fouling spray |  |
| Profile 3 | \* Fence brushing |  | \* Medium pressure spray  \* Dipping | \* Sheep dipping |

The model can be used in two ways:

- to identify an application which is similar to that for which there are no data and use the corresponding indicative data, or for precautionary estimates, the data set one cell below or one cell to the right  
- to conduct a few studies to establish a mean value, and select an indicative data cell based on the emerging pattern.

It is clear that the indicative distribution matrix provides a useful tool for assessing exposure where little is currently known about the application in mind. The matrix is used only to predict rates of contamination related to potential dermal exposure, but does not include contamination to the hands (or feet). Separate models exist to help predict hand exposure and empirical models have been derived for exposures inside gloves, (Garrod et al., Ann. Occ. Hyg., 45(1):55-60, 2001).

The rates of contamination are often most usefully converted into mg/hour to give a clearer representation of the level of exposure that is occurring. For instance at the 95th percentile the 100 mg/min wide profile cell equates to a deposition of almost 120 ml per hour.

The assessor should attempt to place the expected level of contamination in this context. On many occasions it will be possible to make an assessment on the basis of a cell to the right (five times higher) or below (up to three times higher) the cell within which the assessor believes the contamination rate to reside. With this added level of confidence it may prove possible to complete a screening tier risk assessment using calculations based on these very worst case predictions.

Bayesian logic techniques may provide a method to further refine the assessment and provide the necessary level of reassurance required by the assessor, whilst at the same time reducing to a minimum the quantity of new data that is required to be generated.

*Exposure to hands when wearing gloves*

HSE data (Garrod et al., Ann. Occ. Hyg., 45(1):55-60, 2001) show that protective gloves do have the capacity to reduce exposure to the hands but are nonetheless fallible. The distribution of in-glove exposure to hands is independent of substance or task and relates more to the age of the glove and the number of times the glove is removed and replaced during a work operation. In this sense, quality procedures which require operators to remove gloves frequently to record information may play a significant role in increasing the potential for exposure.

A median value for all non-zero data was indicated at 1.36 mg of in-use product per minute, a 75th percentile at 4.21 mg per minute and a 95th percentile at 71.9 mg per minute, assuming product densities of 1.0 g ml-1.

Full details are to be found in the original paper.

# Appendix

# Exposure of the user to rodenticides individually packed in LDPP/LDPE sachets

# Background and description of topic

In rodenticides risk assessment, all characteristics of the products (*e.g.* types of product, packaging, user category) have to be considered carefully, especially considering that the AELs of the AVK active substances in these products are very low and that any variations in the exposure can have a significant impact on the risk assessment.

This consultation deals with PT14 products in the form of paste, grain or block which are wrapped individually in sachet in low density polyethylene (LDPE) or polypropylene (LDPP). Therefore, rodenticide products with active substances under the form of gas are not considered in this consultation.

FR considers that dermal exposure is not expected for the user (professional and non-professional) during the handling of the rodenticide product when the product is wrapped individually in low density polyethylene (LDPE) or polypropylene (LDPP) sachets as long as the sachet is not open. This is only for the application phase and so it does not cover the clean-up and the disposal phase. This topic was already raised at the WG-IV-2017 where FR presented a draft document on the “Exposure assessment issues for harmonization in PT 14 products” and it was agreed that FR would propose a position paper. Considering the comments received in the frame of recent mutual recognitions and the on-going and future renewal dossiers, FR prepared this document to support further this approach.

First, the information available in the stability studies of rodenticides dossiers and their physico-chemical properties have been taken into consideration. Then, data on the plastic properties and information on the different fields of use of PE and PP plastics have been analyzed.

The purpose of this document is to justify why no dermal exposure is expected for the user during the handling of the product individually wrapped in LDPE or LDPP sachets in order to reach an agreement with the other MSs for future authorization’s renewals.

**A- Review of stability studies data**

Among the product’s stability data available in a biocidal dossier, the endpoint concerning the compatibility of the product with the packaging allows for relevant indications regarding the integrity and/or the permeability of the sachet (*i.e.* presence or not of some product inside or outside the sachet).

Therefore, all stability studies available in rodenticides dossiers submitted for renewal in France have been collected and information concerning the compatibility of the product with the individual sachet (paper tea bag, paper, LDPE and LDPP sachets) and the overall packaging has been reviewed. Information is reported in Annex I.

Based on all the reliable data collected, which are valid under normal conditions of use as reported in the SPC of each product, it has been observed that:

* For pasta product, LDPE or LDPP individual sachets are always in sound condition and clean outside. Grease is observed on the internal wall of the sachet but, when the information is available, the packaging (such as cardboard box, bucket in which individual sachets are packed) is clean and without any spot or grease.

On the contrary, for pasta in paper tea sachets, some of the product leaks through the paper and ends up soiling the packaging. The presence of grease or fat is generally observed inside the packaging.

* For grain or block in individual LDPE or LDPP sachets, some dust is observed inside the individual LDPE or LDPP sachets but the packaging (such as cardboard box, bucket in which individual sachets are packed) is clean and without dust on the internal wall.

On the contrary, for grain or block not individually packed, dust is generally observed inside the packaging (cardboard box, bucket, big bag…).

Another parameter for the compatibility of the product with the packaging is required in stability studies: the variation of weight of the packaging between the beginning and the end of the stability study. It has to be measured on the sachet only in order to check the penetration of the product through the sachet.

The weight variation between the beginning and the end of the stability study is difficult to consider in this case because it is not significant due to the low weight of these sachets. Therefore, this parameter has not been deemed relevant for the discussed subject.

**B- Properties of LDPE and LDPP materials**

Polypropylene (PP) and polyethylene (PE) are formed through the polymerization of propylene and ethylene monomer units respectively, only one carbon unit differentiating the monomers. Polypropylene is therefore more rigid, less translucent and has a higher melting point than polyethylene [1]. Otherwise, there is no major difference between both materials.

Regarding the physico-chemical properties of a packaging material, three mechanisms may be possible to check the barrier properties of a material, in addition to the sealing of the packaging:

- **Permeability to gas or vapour** which is defined as the quantification of permeate transmission, gas or vapour, through a resisting material by diffusion [2];

- **Migration / diffusion** of fatty co-formulants (for example fatty acids, mineral oil ...) which is the ability of a material to facilitate the migration or penetration of fatty co-formulants through the sheet [3];

- **Porosity** which is the measure of spaces or holes in a material through which particles may pass.

B.1- Permeability to gas or vapour of the LDPE and LDPP materials

These materials (LDPE or LDPP) are permeable at different degrees to small molecules [2] such as gases, water vapour, organic vapour and to other low molecular weight compounds like aromas, flavour, and additives with high vapour pressure. For example, see Table 1 below for water vapour, dioxygen (O2) and carbon dioxide (CO2). [4] [5].

**Table 1: Physical and chemical properties of water, dioxygen and carbon dioxide**

|  |  |  |
| --- | --- | --- |
| **Constituents** | **Molecular weight**  **(g/mol) [3]** | **Vapour pressure**  **(Pa) [4]** |
| Water | 18.02 | 2.3 kPa at 20°C |
| Dioxygen | 32.00 | > 4.2 MPa[[4]](#footnote-4) at 20°C |
| Carbon dioxide | 44.01 | 6.0 MPa at 22°C |

Due to their physical properties, once through the membrane, these molecules disperse directly into the air and do not stay in contact with the material.

The active substances in rodenticide products are large non-volatile molecules, which prevents them to pass through the barrier by diffusion if there are not driven by other co-formulants.

In Table 2 below, the molecular weight and the vapour pressure of rodenticide active substances are presented.

**Table 2: Summary of physical and chemical properties of rodenticides active substances[[5]](#footnote-5)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Active substance** | **CAS Number** | **Molecular weight**  **(g/mol)** | **Vapour pressure**  **(Pa)** | **Partition coefficient octanol/water**  **(Log Kow)** |
| Alphachloralose | 15879-93-3 | 309.54 | 8.83x10-3 at 25°C | 0.85 |
| Brodifacoum | 56073-10-0 | 523.4 | 2.6x10-22 at 20°C | 6.12 |
| Bromadiolone | 28772-56-7 | 527.4 | 2.13x10-8 at 25°C | 6.8 |
| Chlorophacinone | 3691-35-8 | 374.82 | 4.46x10-4 at 23°C | 2.42 (at pH7) |
| Cholecalciferol | 67-97-0 | 384.64 | 4 x10-5 at 20°C | > 5 (at pH6.7-7.0) |
| Coumatetralyl | 5836-29-3 | 292.3 | < 1x10-3 at 20°C | - |
| Difenacoum | 56073-07-5 | 444.5 | 6.7x10-9 – 5.4x10-14 at 20°C | 4.78 (at pH7) |
| Difethialone | 104653-34-1 | 539.495 | < 1.33x10-5 at 22.6°C | >5 |
| Flocoumafen | 90035-08-8 | 542.6 | < 1x10-3 at 20°C | >4 |
| Warfarin | 81-81-2 | 308.25 | 3.47x10-3 at 20°C | - |
| Chlorophacinone | 3691-35-8 | 374.82 | 4.46x10-4 at 23°C | 2.42 (at pH7) |

There is another active substance (powdered corn cob) used in rodenticide products that can also be wrapped in sachet. This substance doesn’t appear in the table above as it is a naturally occurring composite material under solid form.

B.2 Migration / diffusion of fatty co-formulants through LDPE and LDPP materials

Regarding the chemical compatibility between LDPE and LDPP materials and product formulation, interaction is possible between plastic and fatty co-formulants. Indeed, fatty co-formulants can penetrate in the structure of the plastic material leading to a softening of the plastic film and a weakening of the packaging. [6]

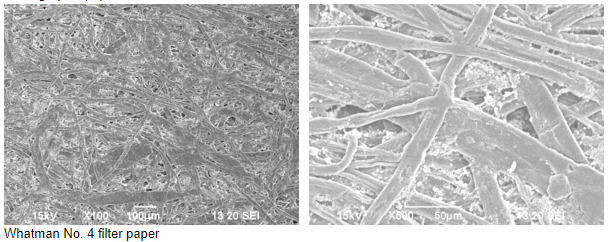
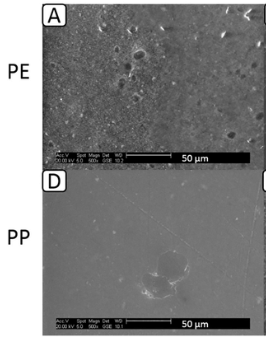
This migration of fatty co-formulants is dependent of different parameters (such as packaging material, composition of the product, temperature). It corresponds to a long-term process and is expressed in time.

Since it is product dependent (especially composition and shelf-life), it is not possible to extrapolate the result from one product to another and this has to be checked every time.

This mechanism is important for rodenticide products as the majority of rodenticide active substances are molecules which have a strong affinity with fatty co-formulants (identified by a high (above 4.5) partition coefficient octanol/water) (see Table 2) and some products (*i.e.* paste and some block formulations) contain fatty acids. Therefore, rodenticides active substances can migrate along with the fatty co-formulants outside the sachet. However, this migration through the membrane can take a long time and has to be verified on a case-by-case basis. It is noted that among all the stability studies reviewed, no deformation of the LDPE or LDPP sachet or leakage has been observed throughout the shelf life of the products.

B.3 Porosity of LDPE and LDPP material

LDPE and LDPP are not considered as porous material in contrary to paper and the size of the holes is small enough not to let solid particles pass through the holes. Indeed, paper is a tangle of cellulose fibers, whereas plastic material is obtained by chemical synthesis. In Figure 1, scanning electron microscope (SEM) images of PE and PP plastics (image A) [7] and filter paper (image B) [8] are presented. The difference of porosity between the materials can be observed under the same magnification (x500).



**A.**

**B.**

**Figure 1: Scanning electron microscope (SEM) images of PE and PP fresh plastic waste (A) and Whatman No. 4 filter paper (B) under 500x magnification (A) and x100 and x500 magnification (B).**

B.4 Sealing of the sachets

The properties of the sealing of the sachets have also been considered as it can be seen as a weak point in the packaging. When available in the description, the LDPE and LDPP sachets are indicated as thermo-sealed and are not supposed to be opened. It leaves the material completely undamaged and unweakened and close the sachets hermetically, eliminating the possibility of leakage through sewing holes, which is one of the alternative closure method [9].

**C- Exposure assessment in dossier**

Usually, the biocidal product is considered stable and compatible with its packaging (used for the product’s preservation) during its shelf-life based on the data reported in the stability studies and as stated in the SPC. No deformation, leakage, ballooning or degradation of the packaging is acceptable, and the shelf-life is established considering these results. If alteration of the packaging is observed during the long-term stability study, the packaging material is not authorized.

For PT14 products or products individually wrapped, the sachet is not used for the preservation of the biocidal product. Therefore, if deformation, leakage or ballooning of the sachet is observed, there won’t be any impact on the acceptability of the packaging, but it will have an impact on the exposure. However, if there is degradation of the packaging in which the sachets are contained (cardboard box, bucket, big bag…), the packaging material will not be authorized.

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**D- Use of PE and PP plastics in other fields**

There are multiple other fields where flexible PE and PP plastics are used because of their reliability to protect and preserve the integrity of the product within. The main one is the food industry [12]. This packaging protects food from outside contamination, prevents the food itself (grease, chocolate, crusts, etc.) from leaking and spoiling outside areas and avoids consumer exposure. They are mostly used for fruits and vegetables (fresh and frozen), meat, poultry and fish products, but also cereals, bread and bakery products.

PP plastic is the most common type of plastic used for cosmetic containers [13]. PP plastic is also used for various other types of products, such as stretch film, poly bags, rubbish bags, bottles and containers [14].

**E- Conclusion**

No dermal exposure of the users (professional and non-professional) is expected during the application of PT14 solid dry products, block or grain formulations without fatty co-formulant, wrapped in closed LDPE or LDPP sachets.

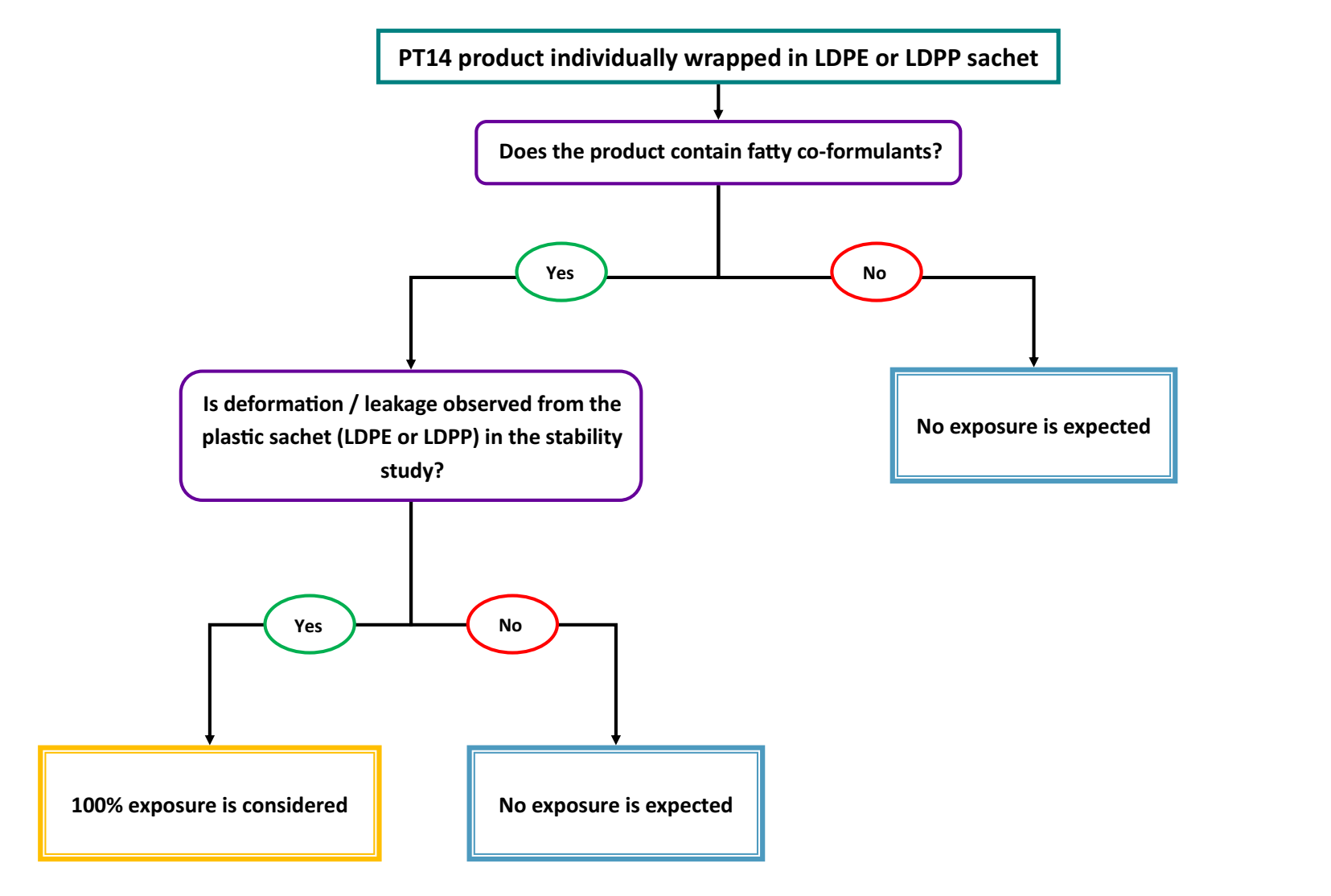
This has been concluded considering the physico-chemical properties of the PT14 active substances (i.e. molecular weight > 250 g/mol and vapour pressure < 10-3 Pa) and the properties of the LDPE or LDPP material (permeability to small molecules with low molecular weight and high vapour pressure, migration of fatty co-formulants and very low porosity).

Moreover, it has been demonstrated in the stability studies provided in the dossiers that when a PT 14 solid dry product (grain and block formulations without fatty co-formulant) is wrapped in LDPP or LDPE sachet, no leakage from the product itself to the packaging is observed.

For formulations with fatty co-formulants (paste and block), the fatty acids may cause ballooning or deformation of the LDPE or LDPP membrane on a long-term basis, sufficiently to allow the migration of the active substance with the fatty co-formulant outside the sachet. Therefore, the information available from the stability studies of each product concerning the compatibility of the product with the packaging must be considered in the assessment. If no leakage from the plastic sachet is observed during the shelf-life as stated in the SPC, no dermal exposure is expected for the user during application of the product. If some product has passed through the plastic sachet, the exposure can then be considered equivalent to exposure from a paper sachet. 100% exposure has to be considered in the assessment.

Moreover, as the individual sachets (LDPE or LDPP) are not to be opened, the instruction for use “Do not open the sachets containing the bait”, as proposed in the SPC template for PT14 products, has to be added in all cases.

This conclusion is summarized in the following decision tree:



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