ECHA
EUROPEAN CHEMICALS AGENCY

Recommendation no. 6

of the BPC Ad hoc Working Group on Human Exposure

Methods and models to assess exposure to biocidal products in different product types

Version 4

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Document history		
Version	**Changes**	**Date**
1	First version	28 January 2015 at Human Health Working Group I
2	Main changes in the document following discussions during the HEAdhoc-1-2016: • The layout of the tables was changed; • References to new relevant HEAdhoc Recommendations were made; • The models for surface disinfection and disinfection by dipping were updated.	02 June 2016
3	Changes: • Ventilation rate for hoof bath disinfection during application and post-application was changed • Exposure duration for professional spray treatment on PT8 was changed • Scenarios related to professional teat disinfection (PT 3) are now described in HEAdhoc Recommendation 13	06 February 2017
4	Changes: • PT 18 professional exposure scenarios were added • Scenario for professional manual dipping of wooden articles in PT 8 was updated • Indicative values for PT 8 exposure under new gloves for scenarios "Professional automated dipping/immersion of wooden articles", "Fully automated dipping" and "Professional (double-vacuum treatment of wood)" were added. • Reference to Guidance on default human factor values for use in exposure assessments in biocidal products was updated. • Reference to Guidance on occupational exposure during application and removal of antifouling paints (PT21) was updated.	29 May 2020

1. Introduction

The availability of a document summarising the methods and models currently in use to assess human exposure to biocides would promote a harmonised approach across Member States, provide a level playing field for Industry, and ease the undertaking of exposure assessments. Such a document would also contribute to any discussions on harmonisation of exposure assessment within the EU and on the need for implementation of the methods and models.

2. Aim of the recommendation

This recommendation, based on a concept paper prepared by the Netherlands, aims at proposing methods and models for a harmonised exposure assessment to biocides in different products types.

3. Discussion and proposal for harmonisation

This recommendation gives an overview on the different methods and models currently used by Member States Competent Authorities to assess human exposure to biocides in different product types.

The methods and models considered for each product type are presented in Table 1 for primary exposure and in Table 2 for secondary exposure to biocides and primary or secondary exposure to treated articles.

In some cases, the models used for the exposure calculations are based on the exposure models used for the specific scenarios in the assessments or indicated in the guidance documents. When alternative models are proposed, the proposed preferred approach is specified.

The default human factor values for use in exposure assessments in biocidal products[1] will be used and will supersede any human factor values in the models.

Before using the information presented in the tables, it is important to note that the used Technical Note of Guidance models are predominantly based on measurement data from non-volatile substances. For volatile substances, specific measurement data should be used if available; otherwise it is recommended to apply models that can be used in modelling the distribution of a volatile substance in a room (e.g. ConsExpo).

Also, for information on the human health scenarios used in the assessment of active substances, the table in the BPC Opinion of each active substance under "Overall conclusion of the evaluation including need for risk management measures – Human health" can be consulted.

This recommendation will be revised in light of experience and as exposure assessments progress. Deviations from the proposed methods and models may be accepted, provided that such deviations are thoroughly justified in the assessment.

[1] HEAdhoc Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products

Table 1 Proposed models to assess primary exposure to biocides

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
1.	PT1	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): 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 cm^2, surface of both hands and forearms according to HEAdhoc Recommendation 14 - Default human factor values for use in exposure assessments for	Dermal exposure: • Number of applications per shift: 25/day • Contact time: see intended use, otherwise 1 minute • Surface area: 820 cm^2 (hands only; hygienic disinfection); 1950 cm^2 (hands and forearms, surgical disinfection) Inhalatory exposure to volatile compounds: Exposure to vapour, instantaneous release (Tier 1) and constant rate release (Tier 2) (ConsExpo 4.1) (HEAdhoc Recommendation no. 9 - Hand disinfection in hospitals by professionals – Inhalation and dermal exposure during hand disinfection) • Exposure duration = contact time • Room volume = 80 m^3 • Ventilation rate = 1.5/hour • Respiratory rate 1.25 m^3/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 – PT1 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 80 m^2 based on the HEAdhoc Recommendation no. 9 - Hand disinfection in hospitals by professionals – Inhalation and dermal exposure during hand disinfection. Harmonised values for a domestic room size are necessary; this of course will be dependent on where the product will be used. During the HEAdhoc-1-2016 meeting, it was agreed that when it is not specified where the product is used, the standard room size of 20 m^3 from ConsExpo General FactSheets is proposed.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				biocidal products) K = conversion factor (3.6 x 10^4) 2. Calculation of internal dermal exposure based on dermal flux: Dermal flux (mg/cm^2/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 m^3/hour x total exposure duration (contact time x 25 applications) / 60 kg bw		
2.	PT1	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	Dermal exposure: Number of application of hand disinfectant per shift: 10 Usual amount per use: 3 g Value for retention on skin after rinsing: 1% (assumed value taken from SCCS Notes of Guidance for the Testing of Cosmetic Ingredients & their Safety Evaluation (7th Revision)).	HEAdhoc Recommendation no.1 - Hand disinfection – PT1 harmonisation of exposure determinants for professional users and HEAdhoc Recommendation no. 9 - Hand disinfection in hospitals by professionals – Inhalation and dermal exposure during hand disinfection A duration of 1 min per task seems to be commonly used by the applicants.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				dishwashing liquids, exposure to vapour evaporation	Inhalatory exposure to volatile compounds: HEAdhoc Recommendation no. 9 - Hand disinfection in hospitals by professionals – Inhalation and dermal exposure during hand disinfection	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 cm^2 both hands or 1950 cm^2 hands and forearms according to HEAdhoc Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products A value of 1% of retention after rinsing is considered for the dermal exposure assessment. 1% is the assumed value taken from SCCS Notes of Guidance for the Testing of Cosmetic Ingredients & their Safety Evaluation (7th Revision). Inhalation exposure: • 20 applications per day • Exposure time: 1 min per task • Product amount: 3 g • Release area (both hands): 820 cm^2 • Room volume: 1 m^3 • Ventilation: 2.5/hour
3.	PT2[2]	Professional hard surfaces disinfection (floors, walls, ceilings) by	Liquid	Spraying Model 1 Spraying Model 1 can be used for low pressure spraying (spray pressures from 1 to 3	Indicative dermal exposure – Hand: 181 mg/min (without protective gloves) 10.7 mg/min (inside gloves)	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

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		coarse spraying		bar). For volatile compounds the assessment of vapour in addition is necessary.	– Body: 92 mg/min Indicative inhalation exposure to non-volatile compounds: 104 mg/m^3 Exposure duration 120 minutes. Area of disinfection is necessary for the assessment of volatile compounds.	UK-POEM model, mandatory within European crop pesticide regulation, provides information on the times and volumes used for exposure assessment of knapsack spraying. During the HEAdhoc-1-2016 meeting, the spraying time of 120 minutes was proposed, in line with the spraying time for insecticides. 181 mg/min = max of range 10.7 mg/min = 75th % value and 104 mg/m^3= 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/m^3) is not described in the TNsG 2002 User Guidance - Version 1.
4.	PT2, PT4[3]	Professional hard surfaces disinfection (floors, walls etc.) by ready-to-use trigger spray	Liquid	– Trigger spray consumer spraying and dusting model 2 - hand held trigger spray – Surface disinfection model 1 (only for dermal exposure)	Indicative dermal exposure – Trigger spray consumer spraying and dusting model 2 - hand held trigger spray Hand/forearm: 36.1 mg/min Exposure duration: 30 minutes – Surface disinfection model 1 Hand: 1030 mg/min (without protective gloves); 10.3 mg/min (inside glove) Exposure duration: 15 minutes Inhalation exposure: – Trigger spray consumer	This scenario was included after discussion during the HEAdhoc-1-2016.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					spraying and dusting model 2 - hand held trigger spray Indicative value: 10.5 mg/m^3	
5.	PT2, PT4[3]	Professional hard surfaces disinfection (floors, walls etc.) by wiping /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/m^3 Additional parameters for ConsExpo 4.1: • Room volume: 80 m^3 • 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	For the scenario of professional mopping, Mixing and loading is already covered by Surface Disinfection Model 1. Mixing and Loading Model 2 should be used only when mixing and loading is assessed separately (e.g. in case of different dermal absorption values for the concentrate and diluted product). The same considerations are valid for application by wiping. 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

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					Time Used for cleaning Hard Surfaces (PT2)	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
6.	PT2	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 (2006), "wet tissues", p. 63.	Dermal exposure: • Exposed area palm: 205 cm^2 (HEAdhoc Recommendation 14 - 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 m^3 • Ventilation rate: 0.6/hour (ConsExpo default for a non-	

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					specified room) • Constant evaporation rate model (emission duration is equal to exposure duration) • Surface size: 1.71 m^2 (Cleaning product Fact Sheet, RIVM report 320104003)	
7.	PT2	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). 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 cm^2 (HEAdhoc Recommendation 14 - 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.	
8.	PT2, PT3, PT4	Use of an immersion bath for dipping of equipment (e.g. small farmer equipment) in an agricultural	Liquid	Dermal exposure: – Dipping Model 1 (TNsG 2002, part 2, p.167) – Dipping Model 4 (TNsG 2002, part 2, p.170) Inhalation exposure:	Dermal exposure: – Dipping Model 1 Indicative value hands: 25.7 mg/min Indicative value body: 178 mg/min	For inhalation exposure: Duration: 30 min per day For dermal exposure: Duration: 30 min per day, 60 min During the HEAdhoc-1-2016 meeting, Dipping

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		environment or medical equipment		Dipping Model 4 (TNsG 2002, part 2, p.170)	– 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/m^3	Model 1 was considered appropriate for assessing dermal exposure in the scenario of manual dipping of equipment into disinfection bath, because it reflects the conditions of a range of dipping tasks. In case inhalation exposure has to be assessed, the evaporation model in ConsExpo was proposed. It was also agreed to maintain the duration of 30 minutes as the default.
9.	PT2, PT6	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/m^3 (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

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
						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.
10.	PT2, PT6	Professional mixing and	Solid/Powder	Mixing and loading Model 7 for powders	Indicative dermal exposure: 305 mg/min (without protective	Due to possible dust forming, inhalation exposure always needs to be taken into

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		loading, manual or (semi)automated addition (of the biocidal product to treated articles).			gloves) 3.05 mg/min (inside gloves) Indicative inhalation exposure: 7.2 mg/m^3 (HEEG opinion 1 - Mixing loading model 7 alternatives) Exposure duration: 10 min	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).
11.	PT3	Animal house disinfection by spraying	Liquid	Dermal exposure: – Spraying Model 2, TNsG 2002 Other models used in MSs: – 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 Other models used in MSs. – Spraying Models 2 and 3, TNsG 2002	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 m^2 • Contact rate: 540 mg/min • Release duration: 400 min (at least 120 min) Inhalation exposure: – Indicative value Spraying Model 2: 76 mg/m^3 – Indicative value Spraying	For assessing dermal exposure to an active substance, Spraying Model 7 was initially 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 During the HEAdhoc-1-2016 meeting, Spraying Model 2 was considered appropriate for both dermal and inhalation exposure, because it is conservative in comparison with Spraying Model 3 and Spraying Model 6 (only dermal exposure) in the TNsG 2002. 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

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				– Spraying Model 9, TNsG 2002 – ConsExpo 4.1	– Model 3: 17.3 mg/m^3 – Indicative value Spraying Model 9: 3600 mg/m^3	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. During the HEAdhoc-1-2016 meeting, the frequency for the highest exposed groups (such as contractors) was considered to be chronic, long-term exposure (minimum 3 months – greater than 6 months) (ECHA Guidance Volume III – Human Health - Part B, page 174). This was deemed to be the worst-case. It was also agreed that the duration of application should be of at least 120 minutes.
12.	PT3	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	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) Inhalation exposure: The value for ventilation rate for the application and post-application represents a

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					loading for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): • Application duration: 5 minutes • Ventilation rate: 10/hour • Room volume: 24 m^3 • Release area: 100 cm^2 – Defaults used for application for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): • Duration: 35 minutes • Ventilation rate: 2/hour • Room volume: 9630 m^3 • Release area: 3 m^2 – Defaults used for post-application for volatile compounds by ConsExpo 4.1 (evaporation-area of release constant): • Duration: 10 minutes • Ventilation rate: 2/hour • Room volume: 9630 m^3 • Release area: 3 m^2	compromise value between the minimum air exchanges for the animal species where hoof disinfection can be expected and represents a conservative value as it has been registered in winter in North Europe.
13.	PT3	Professional teat disinfection		HEAdhoc Recommendation 13 - Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3)		
14.	PT3	Disinfection foot	Liquid	Only dermal exposure was	– EUROPOEM 2 database:	Duration: 30 sec per day, Frequency 104 times

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		bath for rubber boots		assessed: – EUROPOEM II database (model the exposure (loading /pouring volumes up to 20L)) – Mixing and loading Model 5 (TNsG 2002, Part 2, p.137)	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	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).
15.	PT3	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.
16.	PT3, PT4	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	

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					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).	
17.	PT3, PT4	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/m^3 for inhalatory exposure. The exposure duration is considered to be 120 minutes.	During the HEAdhoc-1-2016 meeting, the spraying time of 120 minutes was proposed, in line with the spraying time for insecticides.
18.	PT3, PT4	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.	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/m^3 for inhalatory exposure. The indicative dermal	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.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				31)	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/m^3 for inhalatory exposure. The exposure duration is considered to be 6 hours.	
19.	PT8	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 (PT8)) Water-based products: Hands: 1080 mg/cycle (inside used gloves), 540 mg/cycle (inside new gloves) Body: 8570 mg/cycle Solvent-based products: Hands: 260 mg/cycle (inside used gloves), 130 mg/cycle (inside new	According to the HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT8) inhalation exposure resulting from aerosol formation should be negligible. New gloves are defined as gloves that are replaced in every cycle.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					gloves) Body: 158 mg/cycle	
20.	PT8	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 used gloves), 540 mg/cycle (inside new gloves) Body: 8570 mg/cycle Solvent-based products: Hands: 260 mg/cycle (inside used gloves), 130 mg/cycle (inside new 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 (PT8) inhalation exposure resulting from aerosol formation should be negligible. New gloves are defined as gloves that are replaced in every cycle.
21.	PT8	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 used gloves), 540 mg/cycle (inside new gloves) Body: 8570 mg/cycle Inhalation: 1.9 mg/m^3 Solvent-based products:	According to TNsG 2002 User Guidance - Version 1: • vacuum pressure impregnation: 3 cycles • double vacuum pressure impregnation: 6 cycles New gloves are defined as gloves that are replaced in every cycle.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					Hands: 260 mg/cycle (inside used gloves), 130 mg/cycle (inside new gloves) Body: 158 mg/cycle Inhalation: 0.6 mg/m^3 Exposure time (inhalation exposure): 30 min (opening the door, for 3 cycles)	
22.	PT8	Professional manual dipping of wooden articles (application) This exposure model was agreed by the HH WG during the WG-I-2020 meeting.	Liquid	**A realistic scenario should include the mixing and loading, application and the post-application phase. Maintenance which is conducted infrequently may also occur on a day of application.**		
				Mixing & Loading (3 options available)		
				Option 1: Manual mixing and loading		
				<u>Manual Pouring/Mixing and loading (packages up to 20 L):</u> Mixing and loading Model 4 for liquids, TNsG 2002 user guidance Inhalation exposure to aerosols is not considered to be relevant. For volatile compounds, the assessment of vapour in addition is necessary.	<u>Dermal exposure (hands):</u> • 0.5 ml b.p./loading (75th percentile; without protective gloves; based on 20 L container volume) • Number of loadings: 1 • Frequency: daily	According to the HEEG Opinion 1 (HEEG Opinion 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), a recommended approach for repeated manual loading for small quantities is Mixing and loading model 4. The value of 0.5 ml b.p./loading refers to containers of unspecified design. If applicable, lower values indicated by the model for wide necked containers may be used.
				Option 2: Semi-automated Mixing and loading		
				<u>Semi-automated Pouring/Mixing and loading:</u> RISKOFDERM Potential Dermal Exposure Model (version 2.2.1,	<u>Dermal exposure (hands):</u> • 13.5 µl/min (hands, without protective gloves) • Exposure duration: 10 min	This model may be considered for loading using a hand operated pump, especially in the case of drums < 20 L, if manual pouring results in a risk.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				November 2014): - *Normal or good ventilation* - *Rare contact frequency* - *Light skin contact* - *Liquid* - *No significant amounts of aerosols* - *Automated or semi-automated task* - *transfer rate: 10 L/min* - *90. Percentile* Inhalation exposure to aerosols is not considered to be relevant. For volatile compounds, the assessment of vapour in addition is necessary.	(cumulative duration per shift) • Frequency: daily	A duration of 10 min which includes handling of the pump as well as the actual pumping process is assumed.
				Option 3: Automated mixing and loading		
				Automated Pouring/Mixing and loading (packages > 20 L): HEEG opinion 1 - Mixing loading model 7 alternatives Inhalation exposure to aerosols is not considered to be relevant. For volatile compounds, the assessment of vapour in addition is necessary.	<u>Dermal exposure:</u> • 0.92 mg/min (hands, without protective gloves) • Exposure duration: 10 min • Frequency: daily	RISKOFDERM Toolkit: *Connecting lines.* This is required if bigger drums or IBCs are available. The exposure duration of 10 min is a default value used for connecting lines and transfer of unspecified amounts.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				Application		
				Dipping Model 1, TNsG 2002 For volatile compounds, the assessment of vapour in addition is necessary.	<u>Dermal exposure:</u> • Hands: 25.7 mg/min (inside gloves) • Body: 178 mg/min <u>Inhalation exposure:</u> • Inhalation (non-volatile compound): <1 mg/m^3 • Exposure duration: 30 min (HEEG opinion 8 – Defaults and appropriate models to assess human exposure for dipping processes (PT8) Frequency: daily	
				Post-Application (maintenance: 3 options available)		
				Option 1: Manual draining and reloading		
				<u>Emptying and refilling the dipping tank (manual):</u> Mixing and loading Model 4 for liquids, TNsG 2002 user guidance Inhalation exposure to aerosols is not considered to be relevant. For volatile compounds, the assessment of vapour in addition is necessary.	<u>Dermal exposure (hands):</u> • 0.5 ml b.p./loading (75th percentile; without protective gloves; based on 20 L container volume) • Number of loadings: 10 • Frequency: monthly	According to the HEEG Opinion 1 (HEEG Opinion 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), a recommended approach for repeated manual loading for small quantities is Mixing and loading model 4. The value of 0.5 ml b.p./loading refers to containers of unspecified design. If applicable, lower values indicated by the model for wide necked containers may be used. 10 loadings = 5 times emptying the dipping tank and 5 times refilling
				Option 2: Semi-automated draining and reloading		
				<u>Semi-automated emptying and</u>	<u>Dermal exposure (hands):</u>	This model may be considered for (un)loading

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				<u>refilling the dipping tank:</u> RISKOFDERM Potential Dermal Exposure Model (version 2.2.1, November 2014): - *Normal or good ventilation* - *Rare contact frequency* - *Light skin contact* - *Liquid* - *No significant amounts of aerosols* - *Automated or semi-automated task* - *transfer rate: 10 L/min* - *90. Percentile* Inhalation exposure to aerosols is not considered to be relevant. For volatile compounds, the assessment of vapour in addition is necessary.	• 13.5 µl/min (hands, without protective gloves) Exposure duration: 20 min (cumulative duration per shift) Frequency: monthly	using a hand operated pump. A duration of 20 min which includes handling of the pump as well as the actual pumping process is assumed.
				Option 3: Automated draining and reloading		
				<u>Automated emptying and refilling the dipping tank (packages > 20 L):</u> HEEG opinion 1 – Mixing loading model 7 alternatives Inhalation exposure to aerosols is not considered to be relevant.	<u>Dermal exposure:</u> • 0.92 mg/min (hands, without protective gloves) • Exposure duration: 10 min Frequency: monthly	RISKOFDERM Toolkit: *Connecting lines* To be used if a pump is foreseen. The exposure duration of 10 min is a default value used for connecting lines and transfer of unspecified amounts.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				For volatile compounds, the assessment of vapour in addition is necessary.		
23.	PT8	Professional brush treatment	Liquid	For volatile compounds the assessment of vapour in addition is necessary.	Indicative values normalized to 1 % active substance: <u>Dermal exposure:</u> Hands: 0.5417 mg/m^2 Body: 0.2382 mg/m^2 <u>Inhalation exposure:</u> Inhalation (non-volatile compounds): 0.0016 mg/m^2 Exposure duration: 240 min Application area : 31.6 m^2	Application area calculated (7.6 min/m^2) (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
24.	PT8	Professional spray treatment Application including Mixing and loading	Liquid	Spraying Model 2 For volatile compounds the assessment of vapour in addition is necessary.	<u>Indicative dermal exposure:</u> – Hands: 273 mg/min (without protective gloves) 7.8 mg/min (inside gloves) – Body: 222 mg/min <u>Indicative inhalation exposure (non-volatile compounds):</u> 76 mg/m^3 Exposure duration: 80 minutes (by two events of 40 minutes) without distinction between the M&L and	The model is appropriate for powered spray application at 4 to 7 bar pressure.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					application phases. The exposure duration of 80 minutes is valid for both the concentrate and the RTU products.	
25.	PT8	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	
26.	PT8	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/m^3 Exposure duration: 80 min	
27.	PT8	Professional borehole pressure impregnation Application including Mixing	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	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

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		and loading			hands: 240 cm^2	Council concerning the placing of biocide products on the market, European Commission 2003
28.	PT8	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/m^3 Exposure duration 60 min	
29.	PT8	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	
30.	PT12	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	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	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.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				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.	clothing.	
31.	PT13	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)	Indicative dermal exposure: Hands: 200 mg/min Body: 92 mg/min Exposure duration: 4 hours Indicative inhalation exposure Inhalation: 0.33 mg/m^3 Exposure duration: 8 hours	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
32.	PT14	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/m^3 Dermal: 52.34 mg per manipulation	HEEG opinion 12 - Harmonised approach for the assessment of rodenticides (anticoagulants)

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					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)	
33.	PT14	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	HEEG opinion 12 - Harmonised approach for the assessment of rodenticides (anticoagulants)

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					(no cleaning phase in sewage systems)	
34.	PT14	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 = [π 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)	
35.	PT14	Professional	Paste-like	Technical Guidance Document	Application and post-application:	

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		application (paste bait in bucket [with spatula])		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	• 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)	
36.	PT14	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	
37.	PT14	Professional application (foaming)	Liquid	ConsExpo 4.1 Do-It-Yourself Products Fact Sheet, RIVM report 320104007/2007 (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.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
38.	PT18	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.
39.	PT18	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/m^3 Exposure duration: 60 minutes (based on Excel Database human exposure)	
40.	PT18	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	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	Professional use: Approach 2 is better because it is based on TNsG 2007, while ConsExpo fact sheet is based on TNsG 2002. Application is not hand-held flexible duster but a spoon. Therefore, inhalation exposure is assumed negligible compared to dermal exposure. The value 2.73 + 2.74 is assumed to be the worst case, but there is no other data/model available. The duration of 1 hour should be used instead of 5 minutes. Non-professional use:

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				dusting of powder (consumers)	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). <u>Indicative dermal exposure:</u> Hand/forearm: 2.73 mg/min Legs/feet/face: 2.74 mg/min. <u>Indicative inhalation exposure:</u> Inhalation exposure: 2.47 mg/m^3 TNsG 2002 Consumer product Spraying and dusting Model 2: <u>75 μm:</u> – Hand and forearm: 2.83 mg/min (75th percentile) – Legs/feet/face: 2.15 mg/min (75th percentile) <u>180 μm:</u> – Hand and forearm: 2.5 mg/min (maximum value) – Legs/feet/face: 3.2 mg/min (maximum value) <u>Approach 3)</u>	Approach 2 is better because it is based on TNsG 2007, while ConsExpo fact sheet is based on TNsG 2002. Application is not hand-held flexible duster but a spoon. Therefore, inhalation exposure is assumed negligible compared to dermal exposure. The value 2.73 + 2.74 is assumed to be the worst case, but there is no other data/model available.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					ConsExpo 4.1, scenario Pest Control Products, Dusting Powders, Application. (consumer exposure=professional exposure)	
41.	PT18	Non-professional use of insecticide cassettes		ConsExpo 4.1, constant rate 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 m^3 • 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) for more default values.
42.	18	Manual Spray treatment (coarse or medium spray, in and around buildings) Application including mixing and loading	Liquid	Spraying Model 1 (professionals), TNsG 2002 user guidance This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	<u>Dermal exposure:</u> • Hands: 181 mg b.p./min (without protective gloves) (max. value) 10.7 mg b.p./min (inside glove) (75th percentile) • Body: 92 mg b.p./min (75th percentile) <u>Inhalation exposure:</u>	• Please note that for only downward spraying another scenario is to be used. • Please note that this model is appropriate for manual/handheld compression and powered spray application at 1 to 3 bar. • Please note that newer data and other models (e.g. SprayExpo) are available for refinement and in case characteristics of the spray equipment are known. • Defaults include dusting • Indicative exposure for inhalation based upon 50th of non-zero data (85th overall)

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					104 mg b.p./m^3 (50^{th} percentile) Exposure duration: 120 min (based on Biocides Human Health Exposure Methodology document PT 18)	(TNsG 2002 user guidance) Uncertainty for potential hand exposures is high. Indicative exposure based upon maximum of 5 data (TNsG 2002 user guidance)
43.	18	Manual Spray treatment for low pressure downward uses (in and around buildings)	Liquid	HEAdhoc Recommendation no. 3 - Spraying models for assessing exposure to insecticides for low pressure downward uses, ART and RISKOFDERM This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	<u>Dermal exposure:</u> • Hands: 56.2 mg b.p./min (without protective gloves) (75^{th} percentile) • Body: 354 mg b.p./min (75^{th} percentile) <u>Inhalation exposure:</u> 12 mg b.p./m^3 (75^{th} percentile) Defaults used for application rates between 0.3 - 3 l/min: Exposure duration: 120 min (based on Biocides Human Health Exposure Methodology document PT 18)	• For spraying pressure of 1-3 bar, data from industry allowed to confirm that an application rate of 0.3 to 3 l/min is a reasonable worst case. The data listed here is an output from ART and RISKOFDERM with medium application rate and near field exposure (Table 1 of HEAdhoc Recommendation no. 3); it is not applicable for higher spraying pressure. • If the exact application rate is unknown for spraying with manual low-pressure sprayers, an application rate of 3 l/min should be assumed for the assessment. Please note that the application rate is a sensible parameter for the assessment of dermal exposure. • Spraying with no or low compressed air use. • Please note that other models (e.g. SprayExpo) are available for refinement and in case characteristics of the spray equipment is known in more detail. Link for refinement of dermal exposure: Annex (HEEG opinion 1)
44.	18	Spray treatment of tall trees from	Liquid	Research project F 2343 "Comparative study on	<u>Dermal exposure:</u> • Hands: 1328 mg a.s./kg a.s.	• The model is developed for applications where relatively large amounts of product

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		ground using hand-held sprayers (outdoors) (Application including mixing and loading)		exposure of workers and bystanders during pest control of the Oak Processionary Moth by spray application" This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	handled (without protective gloves) (75th percentile) • Body: 2580 mg a.s./kg a.s. handled (75th percentile) <u>Inhalation exposure:</u> 0.73 mg a.s./kg a.s. handled (75th percentile) For measures to control oak processionary moth it was derived that 200 L of application liquid can be applied with hand-held sprayers by a worker per day.	are used. • Link to the research project F2343: Research project F2343 • The equipment and spray patterns covered by the studies on which EFSA opex model is based differ significantly from what is used for this scenario for treatment of tall trees, for example for control of oak processionary moth (OPM). The research report F2343 includes a comparison of exposure from OPM control measures with plant protection applications covered by EFSA opex in chapter 4.3.1.4, which underlines that exposure levels differ strongly. • Please note that the EFSA opex model (including "Joint development of a new Agricultural Operator Exposure Model" (January 2013)) could be a refinement option for other spraying scenarios outdoors (e.g. for only sideways and downward spraying of plants or for spraying from an elevated platform in height of the tree crowns): EFSA opex model The report from which the data was taken is available online: BAuA report - Research project F2343
45.	18	Spray treatment of tall trees – vehicle mounted	Liquid	Research project F 2343 "Comparative study on exposure of workers and	<u>Dermal exposure:</u> • Hands: 58.2 mg a.s./kg a.s. handled (without protective	• The model is developed for applications where relatively large amounts of product are used.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		(Application including mixing and loading)		bystanders during pest control of the Oak Processionary Moth by spray application" This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	gloves) (75th percentile) • Body: 15.8 mg a.s./kg a.s. handled (75th percentile) <u>Inhalation exposure:</u> 0.026 mg a.s./kg a.s. handled (75th percentile) For measures to control oak processionary moth it was derived that 2000 L of application liquid can be applied with vehicle mounted sprayers by a worker per day.	• Please note that the EFSA opex model (including "Joint development of a new Agricultural Operator Exposure Model" (January 2013)) could be a refinement option for other vehicle mounted spraying scenarios outdoors (e.g. for only sideways and downward spraying of plants): EFSA opex model The report from which the data was taken is available online: BAuA report - Research project F2343
46.	18	Aerial spray treatment	Liquid	Application: no exposure estimate required	none	Please note that exposure during mixing and loading into the tank and cleaning of the equipment is likely. Please see detailed parameters under "Mixing and loading of concentrated product into tank mounted on aircraft" and "cleaning of vehicle mounted spray equipment".
47.	18	Fogging	Liquid	Fogging and misting models 2 and 3, TNsG 2002 user guidance This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	<u>Dermal exposure:</u> • Hands: 0.33 mg b.p./min (inside glove) (max.) • Body: 21.8 mg b.p./min (75th percentile) <u>Inhalation exposure:</u> 70.2 mg b.p./m3 (75th percentile) Exposure duration: min. 60 min	• Please note that the uncertainty for inhalation and dermal exposure is high as the model is based on only up to 8 data points and little accompanying information supplied with the models. • Based on the reasons above the data from fogging model 2 and 3 are proposed to be used in combination. • Based on the reasons above the approach is considered to represent a reasonable

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
						scenario for both thermal and cold fogging with various application rates. • Please note that other models (e.g. SprayExpo) are available for refinement and in case characteristics of the spray equipment is known in more detail. Uncertainty for hands (inside glove) is high. Indicative exposures based upon maximum of 4 data.
48.	18	Small scale dusting (directly from package in downward direction) Or Scattering granules (directly from package or from bucket with spoon or beaker)	Solid	Consumer spraying and dusting model 2: Hand-held flexible Duster, TNsG 2002 user guidance	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). <u>Dermal exposure:</u> • Hand/forearm: 2.73 mg b.p./min (75^{th} percentile) • Legs/feet/face: 2.74 mg b.p./min (75^{th} percentile) <u>Inhalation exposure:</u> 2.47 mg b.p./m^3 (75^{th} percentile) Duration: : 120 min	• The dustiness of the product is assumed to have an impact on exposure level. However, with the model data at hand this differentiation cannot be made. Thus, for small scale dusting and manual scattering of granules the same model parameters are recommended. Exception: A reduction of exposure duration may be considered for spot application (<2m^2) provided that only a limited amount of spots are treated per site (e.g. treatment of a limited amount of insect nests per residential or public building).

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					(based on Biocides Human Health Exposure Methodology document PT 18) For treatment of ant nests (spot application) an exposure duration of 60 min may be assumed.	
49.	18	Dusting with manual and/or powered (bellows or piston type) hand-held dusting equipment (for treatment of localized nests) (Application including mixing and loading)	Solid	PHI (solid) (BEAT)	Dermal exposure: • Hands: 31.42 mg b.p./min (without protective gloves) (max. value) 2.31 mg b.p./min (inside glove) (95th percentile) • Body: 152 mg b.p./min (95th percentile) Inhalation exposure: 184 mg b.p./m^3 (95th percentile) Duration: : 120 minutes (based on Biocides Human Health Exposure Methodology document PT 18) For treatment of ant and wasp nests (spot application) an exposure duration of 60 min may be assumed. The exposure duration includes that the professional user is in the treated area, controls the success of the treatment and has contact to contaminated equipment and surfaces (dust of the product).	• For the present application, the dustiness of the product is assumed to have an impact on exposure level. However, with the model data at hand this differentiation cannot be made. • Exception: A reduction of exposure duration may be considered for spot application (<2m^2) provided that only a limited amount of spots are treated per site (e.g. treatment of a limited amount of insect nests per residential or public building): • According to BEAT the 90% confidence interval for the 75th percentile for the potential body exposure is 8.3 to 47. On this basis the 95th percentile is suggested as an appropriate indicative exposure value by BEAT. • Uncertainty for hands (without protective glove) is high. Indicative exposures based upon maximum of 3 data. • According to BEAT the 90% confidence interval for the 75th percentile for the actual hand (inside glove) exposure is 0.094 to 0.71. On this basis the 95th percentile is suggested as an appropriate

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
						indicative exposure value by BEAT. • According to BEAT the 90% confidence interval for the 75th percentile for inhalation exposure is 0.36 to 17. On this basis the 95th percentile is suggested as an appropriate indicative exposure value by BEAT.
50.	18	Brush treatment	Liquid	Consumer Product Painting Model 3, TNsG 2002 user guidance This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	<u>Dermal exposure:</u> • Hands: 5.91 mg b.p./min (without protective gloves) (75th percentile) • Body: 16.9 mg b.p./min (75th percentile) <u>Inhalation exposure:</u> 1.63 mg b.p./m^3 (50th percentile) Exposure duration: 120 minutes (based on Biocides Human Health Exposure Methodology document PT 18)	• Indicative exposure for inhalation based upon 50th of non-zero data (80th overall, 9 zero inhalation exposures out of 15) (TNsG 2002 user guidance)
51.	18	Pouring with a watering can	Liquid	Subsoil Treatment Model 2 - Watering can, TNsG 2002 user guidance This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	<u>Dermal exposure:</u> • Hands: 48.8 mg b.p./min (inside glove) (max. value) • Body: 38.2 mg b.p./min (max. value) <u>Inhalation exposure:</u> 4.15 mg b.p./m^3 (max. value) Exposure duration: 120 minutes	• Please note that the uncertainty for inhalation and dermal exposure is high as the model is based on only 4 data points. Exception: A reduction of exposure duration may be considered for spot application (<2m^2) provided that only a limited amount of spots are treated per site (e.g. treatment of a limited amount of insect nests per residential or public building).

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					(based on Biocides Human Health Exposure Methodology document PT 18). For treatment of ant nests (spot application) an exposure duration of 60 min may be assumed.	
52.	18	Application with a cartridge gun	Solid, gel-like	Expert judgement Inhalation exposure to aerosols is not considered relevant. This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	<u>Application:</u> <u>Dermal exposure:</u> Dermal exposure = [π x (d/2) ² x height] x density of product x no. of contacts Height h: length of the strand which gets to skin during each opening/closing considering the viscosity of the biocidal product Diameter d: diameter of the strand which equals the inner diameter of the nozzle No. of contacts (default): 5 openings + 5 closings = 10 contacts (may be adapted depending on product characteristics) <u>Post-Application:</u> <u>Dermal exposure:</u> Dermal exposure = [π x (d/2)² x height] x density of product x no. of contacts Height h: see above Diameter d: see above	As a rare event, it is assumed that the professional user gets into contact with product residues during cleaning once per day. Potential exposure from post application is assessed as equivalent to one opening of a cartridge.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					No. of contacts: 1	
53.	18	Ready-to-use bait station	Solid or immobilized liquid	expert judgement Inhalation exposure to aerosols is not considered relevant. This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	Application: Dermal exposure: Dermal exposure [mg]= product amount per bait station [mg] x product fraction accessible to hands through openings [%] x transfer efficiency to hands [%]	• The applicability of this approach may not be given for each individual bait station as the design of each bait station is different. • Please note that no exposure during application is expected when additional barrier layers prevent a direct contact to the b.p. upon perforating the seals or the bait station is equipped with other additional safety measures during opening. • As a rare event, it is expected that the contact of the b.p. to the hands might not occur more than once per day for a professional user, even if a higher number of applied baits is taken into account. • Exposure resulting from removing and disposing of bait stations is assumed to be negligible as hands do not need to be near openings. Reference to transfer coefficients - dislodgeable residues: Biocides Human Health Exposure Methodology document, Table p. 171 (TNsG 2002, part 2, p. 204)
54.	18	Refillable bait station	Liquid or solid	see mixing and loading of concentrated product into portable vessel This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	Application: No. of loadings: to be determined separately for each product depending e.g. on target organism, application rate, treated area, amount of product used per day Post-Application:	• Liquid: default value of 100 loadings is used for application and post-application when no information from applicant is given. • Granules: a treated area of 1500 m2 and a corresponding total amount of b.p. used per day is taken into account when no information from applicant is given.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					No. of loadings: to be determined separately for each product depending e.g. on target organism, application rate, treated area, product formulation	
55.	18	Manual Mixing and loading of concentrated product into portable vessel	Liquid	Mixing and loading Model 4 for liquids, TNsG 2002 user guidance Inhalation exposure to aerosols is not considered relevant. This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	<u>Dermal exposure:</u> • Hands: 0.5 mL b.p./loading (without protective gloves) (75th percentile) (based on 20 L container volume; default value to be adapted for other package sizes) Indicative value for hand exposure is 0.01 ml/treatment for 1L, 0.2 ml/treatment for 5L and 0.5 ml/treatment for 10L-20L. The value to be used should be in line with the total amount of required solution that is needed per day.	• <u>Liquid:</u> According to the HEEG Opinion 1 (*HEEG Opinion 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*), a recommended approach for repeated manual loading for small quantities is Mixing and loading model 4. • <u>Liquid:</u> Please note that Mixing and Loading Model 4, which is proposed in this recommendation to assess dermal exposure, contains container specific (volume and aperture) exposure values. • <u>Powder:</u> No dermal exposure values are available for mixing and loading powders into a portable vessel. Thus, the dermal values for mixing and loading granules into a portable vessel are recommended to be used instead. The task "mixing and loading granules into a portable vessel" is regarded to be more suitable than "mixing and loading powder into a stationary tank" because due to the stationary tank sizes especially dermal exposure to the tank walls is expected to be significantly different.
			Granules	Project report "Joint development of a new Agricultural Operator Exposure Model (2013)" - LCHH_1 study results for mixing & loading granules into knapsack (except operator 20 who loaded into a tank)	<u>Dermal exposure:</u> • Hands: 24.6 mg b.p./min (without protective gloves) (95th percentile) 0.15 mg b.p./min (inside glove) (95th percentile) • Body: 10.16 mg b.p./min (without	

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	protective coverall) (95th percentile) 0.31 mg b.p./min (inside coverall) (95th percentile) <u>Inhalation exposure:</u> 0.052 mg a.s./kg a.s. handled (95th percentile)	• <u>Granules:</u> ○ Uncertainty for hands (without glove) is high. Indicative exposure based upon the 95th percentile of 10 data. ○ Uncertainty for hands (inside glove) is high. Indicative exposure based upon the 95th percentile of 9 data. ○ Uncertainty for body (without coverall) is high. Indicative exposure based upon the 95th percentile of 10 data. ○ Uncertainty for body (inside coverall) is high. Indicative exposure based upon the 95th percentile of 7 data. ○ Uncertainty for inhalation is high. Indicative exposure based upon the max of 3 data.
			Powder	<u>Dermal exposure:</u> Project report "Joint development of a new Agricultural Operator Exposure Model (2013)" - LCHH_1 study results for mixing & loading granules into knapsack (except operator 20 who loaded into a tank) <u>Inhalation exposure:</u> Mixing and loading Model 5 for powders	<u>Dermal exposure:</u> • Hands: 24.6 mg b.p./min (without protective gloves) (95th percentile) 0.15 mg b.p./min (inside glove) (95th percentile) • Body: 10.16 mg b.p./min (without protective coverall) (95th percentile) 0.31 mg b.p./min (inside coverall) (95th percentile) <u>Inhalation exposure:</u> 1.5 mg a.s./kg a.s. handled (75th percentile)	
56.	18	Mixing and loading of concentrated product into tank mounted on aircraft	Liquid	Agricultural operator exposure model (AOEM) Exposure calculation spreadsheet available at: EFSA opex model	<u>Dermal exposure:</u> Scenario: outdoor application, vehicle mounted application equipment Area treated: 50 ha/day (default,	Filling the b.p. may be performed by pumping from a large container or by manual pouring from smaller (e.g. 20 l) containers. The latter was chosen to represent the reasonable worst case situation that has to be assessed for this application. 50 ha/day is considered as realistic-worst case scenario for biocidal treatment of forest edges. The treatment of

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				This approach is for non-volatile components only. For volatile components, an additional assessment of vapour is necessary.	required for estimation of the amount of active substance applied per day; application rate will be specific for the respective product)	extended forest areas most likely is out of the scope of the biocidal product regulation. However, a modification of the area treated per day may be considered.
57.	18	Cleaning of manual spray equipment	Liquid	Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure - Cleaning of spray equipment in antifouling use (PT21), BEAT Inhalation exposure to aerosols is not considered relevant.	Dermal exposure: • Hands: 35.87 mg b.p./min (without protective gloves) (75th percentile) • Body: 19.28 mg b.p./min (75th percentile) (assuming a density of 1 g/mL) Exposure duration: • 5 min (in case of waterbased solutions) 20 min (in case of cleaning of equipment used for outdoor treatment of tree crowns)	Expert judgement: A thorough cleaning for 20 minutes (see antifouling Reference No. 3) is not needed in case aqueous solutions are applied. 5 minutes shall be sufficient.
58.	18	Cleaning of vehicle mounted spray equipment using a pressure washer	Liquid	Research project F 2343 "Comparative study on exposure of workers and bystanders during pest control of oak processionary moth by spray application"	Dermal exposure: • Hands: 2.92 mg non-volatile ingredients of the b.p./min (without protective gloves) (max.) • Body: 0.8 mg non-volatile ingredients of the b.p./min (max.) Inhalation exposure: 2.07 µg non-volatile ingredients of	• Please note that the uncertainty for inhalation and dermal exposure is high as the model is based on only 3 data points. Only the non-volatile substances of the b.p. need to be taken into account. This is because it is assumed that cleaning is performed yearly at the end of the season / at the end of a spraying campaign. Thus only non-volatile components of the b.p. are of interest and for the exposure assessment only these components have to be taken into account.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					the b.p./m³ (max.) Duration: 60 min	Especially volatile liquid components such as water should not be taken into account.
59.	18	Washing out of a brush		HEEG opinion no. 11 - Primary exposure scenario – washing out of a brush which has been used to apply a paint Inhalation exposure to aerosols is not considered relevant, therefore no exposure calculations are required	Dermal exposure: See Annex of HEEG opinion 11	
60.	PT21	Professional spraying	Liquid	Spraying Model 3, TNsG 2002 User Guidance - Version 1	Indicative dermal exposure: HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Indicative inhalation exposure (non-volatile compounds): HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Exposure duration:180 min	
61.	PT21	Professional brushing and combined brush/roller painting	Liquid	Consumer product painting Model 4 (Recommended for brush or combined brush/roller painting)	Indicative dermal exposure: HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints	

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					Indicative inhalation exposure (non-volatile compounds): HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Exposure duration:90 min	
62.	PT21	Professional rolling and combined brush/roller painting	Liquid	Links et al. study, 2007 (Recommended for roller or combined brush/roller painting)	Indicative dermal exposure: HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Indicative inhalation exposure (non-volatile compounds): HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Exposure duration:90 min	
63.	PT21	Professional assistant workers (potmen and ancillary workers)	Liquid	Mixing and loading Model 6, TNsG 2002 User Guidance - Version 1	Indicative dermal exposure: HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Indicative inhalation exposure (non-volatile compounds): HEAdhoc Recommendation 17 - Occupational exposure during	

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					application and removal of antifouling paints Exposure duration:180 min	
64.	PT21	Professional paint removal (sand blasting, paint stripping)		Links et al., 2007	Indicative dermal exposure: HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Active substance in removed paints contains 90% of the original concentration of active substance in dry paint. Indicative inhalation exposure (non-volatile compounds): HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Exposure duration:180 min	
65.	PT21	Professional grit fillers		Links et al., 2007	Indicative dermal exposure: HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Active substance in removed paints contains 90% of the original concentration of active substance in dry paint.	

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					Indicative inhalation exposure (non-volatile compounds): HEAdhoc Recommendation 17 - Occupational exposure during application and removal of antifouling paints Exposure duration:180 min	

[1] *Due to large droplet size inhalation exposure can be disregarded and/or the vapour pressure of the substance is low. Calculation of the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account:*
- *the vapour pressure of the substance (a volatile substance has vapour pressure > 1 x 10^{-2} Pa at 20 °C) and/or*
- *the active substance is a powder containing a significant proportion (e.g. 1 % on a weight basis) of particles with particle size MMAD < 50 µm or*
- *the active substance is included in products that are powders or are applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size (MMAD <50 µm)*

However, if the substance causes local effects in the upper respiratory tract, inhalation exposure needs to be considered.
This precept of the vapour pressure > 1 x 10^{-2} Pa at 20 °C was used in early CARs, but it is not valid to assume that due to an active's low vapour pressure, risks from inhaling the vapour are negligible; as such assessments ignore the toxicology of the active's vapour. Therefore, the MOTA/HEEG Opinion on 'Assessment of Inhalation Exposure to Volatilised Biocide Active Substance' was agreed at TMIV 2011 and amended after TMIII2013 to take into account changed default human factor values. Therefore, this HEEG Opinion 13 should also be considered. Furthermore, to not take into account inhalation exposure to vapour, the vapour pressure of the substance to be assessed should be compared with the one from the model (going back to the raw data, report or publication to have this data).
At last, if available it should be indicated if the inhalation exposure is due to aerosol or vapour and the range of aerosol and the vapour pressure of the substance used. According to HEEG Opinion 8 inhalation exposure resulting from aerosol formation should be negligible.
Based on the guidance on information requirements version 1.0 July 2013 at Generation of new test data by inhalation. Take into account that droplets > 50µm will not go in the lung but will fall in the stomach and will be systematically absorbed. For professional use of spray equipment it is necessary that the applicant provides the measured distribution of droplet size with the product. The droplet size is a sensitive parameter which is influenced by spraying device, nozzle and compounds in the product. The droplet size changed over time by evaporation of the solvent. To be sure that we do not underestimate the exposure we propose to discuss the MMAD < 50 µm.

[2] *For PT2 and PT4 (wiping, spraying, mopping) the same models might be useful. However the surfaces, room size and ventilation might be different.*

[3] *This scenario was used in DE for a national authorization.*

Table 2 Proposed models to assess: - secondary exposure to biocides
- primary or secondary exposure to treated articles

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid /aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
1.	PT3	Rubbing against the teats or a drop falling from the teat on the hand	Foam	Use layer thickness of 0.01 cm in combination with contact area per contact event.	A calculation was made based on some general assumptions and the maximum concentrations of the substance in the products. According to the intended use ca. 5 mL per cow per milking is used. Considering 2 milkings per day and a frequency of teat disinfection of 2 times per day, this amounts to 10 mL per cow per day. Furthermore, it is assumed that one farm has 100 cows to be milked and therefore a total amount of 1000 mL product is used per day. As a worst-case, it can be assumed that hands can be exposed to 1% of the total amount used by rubbing by accident against the teats or a drop falling from the teat on the hand. The TGD uses a layer thickness of 0.01 cm for run-off liquids. The HEAdhoc Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products with a human default factor value of 820 cm^2 as surface area for two hands	Inhalation exposure is often expected to be negligible when a compound is mostly present in ionized form in the aqueous solution and will not volatilize. Note that currently, in the Netherlands, many farmers use milking gloves. Over the years now, young farmers have been trained to use gloves not only for hygienic measures, but also for personal care (to protect the texture of skin against the influence of water). It should be noted that the spilling model is no longer mentioned in TNsG 2007.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid /aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					should be used. This gives 8.2 mL (assuming a density of 1 g/mL). A surface of one or the back of one hand may be considered for foam. Foam has less potential for run-off, it has more potential for sticking to the skin, for instance to the back of the hand, while accidently contacting the treated teat. The RIVM would use 2.05 mL (back of one hand) per incident.	
2.	PT6	Manual paint spraying by professional and non-professional users (worst-case for paints, inks, polymer emulsions)		<u>Non-professional use:</u> ConsExpo 4.1, painting products, spray painting, pneumatic spraying <u>Professional use:</u> Approach 1) BEAT "masonry preservatives" Approach 2) BEAT "designated scenario for PT7 covers indoor decorative painting"	<u>Professional use:</u> 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. <u>Non-professional use:</u> 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 (2007)).

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid /aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
						Professional use: There is no worked example in BEAT which describes professional spray of painting (in general). The designated scenario for PT7 in BEAT which covers indoor decorative painting" seems the best suited "worst case" model (compared with Spray application of masonry preservative).
3.	PT6	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 (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.
4.	PT6	(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 (2007), plaster/equalizer, wall plaster Non-professional use:	Professional use: Approach 2) Plastering is heavy work, therefore an exposure duration of 8 hours is recommended. Non-professional use: Exposed area: 1950 cm^2 (hands and forearms, HEAdhoc Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products)	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.

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid /aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				ConsExpo 4.1 Do-It-Yourself Products Fact Sheet, RIVM report 320104007/2007 (2007), plaster/equalizer, wall plaster	Exposure duration: 120 minutes (default ConsExpo 4.1)	
5.	PT6	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 cm^2 (hands, HEAdhoc Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products) • Exposure duration: 15 minutes • Application duration: 15 minutes • Room volume: 15 m^3 • 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.
6.	PT6	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)	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	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

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid /aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				Washing hospital patients from BEAT <u>Approach 4)</u> Car washing from BEAT	<u>Indicative inhalation exposure:</u> 122 mg/m^3 Exposure period 3 hours <u>Approach 2)</u> – Potential body exposure: 108 µL/min x 4 – Actual hand exposure: 8.71 µL/min x 4 <u>Approach 3)</u> – 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	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. <u>Approach 3)</u> 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. <u>Approach 4)</u> 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

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid /aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
						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)
7.	PT6	Child touching treated surfaces and hand to mouth transfer		HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4	• Exposed area: 234 cm^2 (HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4) • Film thickness on a surface: 0.01 cm • Paint density: 1000 mg/cm^3 • Transfer coefficient of dried liquid from different types of surfaces: 18% (TNsG 2002, 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 and HEAdhoc Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products)	HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4 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.
8.	PT6	Exposure of a child to residues		The exposure is calculated based on the considerations of	• Product used for 5 kg laundry: 150 g	The approach is based on HERA, Guidance Document Methodology (2005).

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid /aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		in clothes		HERA, Guidance Document Methodology (2005). For 5 kg laundry, 150 g of product and 15 L of water are required (TGD on Risk Assessment, Part I, p. 239). According to the HERA, Guidance Document Methodology (2005): – the residues deposited on the clothes are 5 %; – the fabric density is assumed at 20 mg/cm^2; – the weight fraction transferred from the fabric to the skin is 1 %.	• Product deposit on clothes from laundry :5% • Pullover weight (20 mg/cm^2 fabric density): 70800 mg • Surface area (arms and trunk): 4646 cm^2 (HEAdhoc Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products) • Product transfer from pullover to skin: 1%	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 may be more realistic. A justification for the use of additional defaults is necessary.
9.	18	Secondary exposure – spray or brush treatment (Handling of processed cardboards)	Solid	Expert judgement Inhalation exposure to aerosol and vapour is not considered relevant, therefore no exposure calculations are required	Dermal exposure: Dermal exposure = application rate of b.p. x contaminated hand surface x transfer coefficient Application rate of b.p.: Amount of (dried) b.p. applied per treated surface (g b.p./m^2) is product specific Contaminated hand surface: palms of both hands x fraction of contaminated hand surface (only inner fingers' parts) = 410 cm^2 x 1/3 = 135 cm^2	• The contact is estimated to be incidental and can be minimized by the following risk mitigation measures: - Application by spray and brush treatment on cardboard should be carried out leaving an untreated area around the edge or stripe. - When the treated cardboard / hangboard is fixed to walls (or ceilings) or is collected for disposal only the untreated area around the edge or stripe should

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid /aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					Transfer coefficient (%) depends on consistency of the b.p. residues and the material of the cardboard/hangboard	be touched. - The cardboard / hangboard is only handled after drying. Reference to transfer coefficients - dislodgeable residues: Biocides Human Health Exposure Methodology document, Table p. 171 (TNsG 2002, part 2, p. 204)

4. Definitions and acronyms

Abbreviation	Definition
A.I.S.E.	Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (International Association for Soaps, Detergents & Maintenance Products)
ART	Advanced REACH Tool
BEAT	Bayesian Exposure Assessment Tool
Ctgb	The Netherlands Board for the Authorisation of Plant Protection Products and Biocides
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECETOC TRA	ECETOC Targeted Risk Assessment
HEAdhoc	BPC Ad hoc Working Group on Human Exposure
HEEG	Human Exposure Expert Group
HERA	Human & Environmental Risk Assessment
HSL	Health & Safety Laboratory
NL	The Netherlands
PT	Product type
RIVM	The Netherlands National Institute for Public Health and the Environment
TGD	Technical Guidance Document on Risk Assessment
TNsG	Technical Notes for Guidance
UK POEM	UK Predictive Operator Exposure Model

5. References

The evaluations of the mentioned referenced products can be found on the Ctgb website (www.ctgb.nl).
The mentioned HEEG Opinions, HEAdhoc recommendations and TNsGs can be found on the ECHA website (www.echa.europa.eu).
The mentioned factsheets can be found on the RIVM website (www.RIVM.nl).

6. Annexes

6.1 Annex I: explanation of the scenario for dipping textile

Dipping Model 3 exposure textile
In BEAT there is a scenario for product type Fibre, leather and polymerised materials preservatives. BEAT suggests a scenario "Manual grading and drying of leather skins".

Scenario description
Leather skins treated with diluted biocide solution are manually sorted, graded and dried by placing them over drying racks. The task is manual handling.

Data source
Indicative exposure values are 75th percentiles taken from HSE water-based timber pre-treatment data set but adjusted (4x) 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. By contrast, grading of leather skins in a continual process.

RIVM
Body exposures are based on 5 studies (timber is impregnated against insect of fungal attack in sealed treatment vessels, cleaning of cars using using a car shampoo dissolved in water and applied using a cloth or sponge dipped into a bucket containing dilute cleaning solution, washing hospital patients, large scale surface wiping and forestry: miscellaneous tasks).

Hand exposures are based on washing hospital patients, large scale surface wiping, car washing, graffiti removal and small scale surface wiping.

The BEAT algorithm considered these studies to calculate the defaults for hand, body and inhalation exposure:

- Defaults for timber:

Potential body exposure: 75th = 108 µg/min
Actual hand exposure: 75th = 8.71 µL/min

- Defaults for hospital patients:

Potential body exposure: 75th = 1140 µL/min
Potential hand exposure: 75th = 388 µL/min

- Defaults for car washing:

Potential body exposure: 75th = 2070 µL/min
Potential hand exposure: 75th = 517 µL/min

The approach proposed by NL is to select the only one best fitting study, depending on the task.

- When frequently touching wet textile, without grabbing, dragging or picking up the defaults of the BEAT model "Timber pre-treatment (water)", seems to be the best fitting. The dermal exposure in this model occurs primarily through contact with treated timber when it is removed from the vessel. The 75th 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.
- When frequently handling 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 defaults are suggested as appropriate indicative values.
- 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 defaults are suggested as appropriate indicative values.

Please note that in most situations "Washing hospital patients" will apply as the best option. The task option "Timber pre-treatment (water)" may underestimate the exposure.

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