Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR PROVISIONAL NATIONAL AUTHORISATION**

(submitted by the evaluating Competent Authority)



ACTICIDE C1

Product type 6

[5-chloro-2-methyl-2H-isothiazol-3-one (C(M)IT)]

Case Number in R4BP: [BC-DW041712-25]

Evaluating Competent Authority: FR

Date: December 2020

Table of Contents

[Table of Contents 2](#_Toc57800711)

[*1* CONCLUSION 4](#_Toc57800712)

[*2* ASSESSMENT REPORT 11](#_Toc57800713)

[2.1 Summary of the product assessment 11](#_Toc57800714)

[2.1.1 Administrative information 11](#_Toc57800715)

[2.1.1.1 Identifier of the product 11](#_Toc57800716)

[2.1.1.2 Authorisation holder 11](#_Toc57800717)

[2.1.1.3 Manufacturer(s) of the product 11](#_Toc57800718)

[2.1.1.4 Manufacturer(s) of the active substance 11](#_Toc57800719)

[2.1.2 Product composition and formulation 12](#_Toc57800720)

[2.1.2.1 Identity of the active substance 12](#_Toc57800721)

[2.1.2.2 Candidate(s) for substitution 12](#_Toc57800722)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product 13](#_Toc57800723)

[2.1.2.4 Information on technical equivalence 13](#_Toc57800724)

[2.1.2.5 Information on the substance(s) of concern 13](#_Toc57800725)

[2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product 13](#_Toc57800726)

[2.1.2.7 Type of formulation 13](#_Toc57800727)

[2.1.3 Hazard and precautionary statements 13](#_Toc57800728)

[2.1.4 Authorised use(s) 14](#_Toc57800729)

[2.1.4.1 Preservation of washing and cleaning fluids (general) and other detergents 14](#_Toc57800730)

[2.1.4.2 **Preservation of paints and coatings** 15](#_Toc57800731)

[2.1.4.3 **Preservation of additives used in Paper production** 16](#_Toc57800732)

[2.1.4.4 **Preservation of glues and adhesives** 18](#_Toc57800733)

[2.1.4.5 **Preservation of pigment paste** 19](#_Toc57800734)

[2.1.4.6 **Preservation of colourants** 20](#_Toc57800735)

[2.1.4.7 **Preservation of polymer dispersions** 21](#_Toc57800736)

[2.1.5 General directions for use 23](#_Toc57800737)

[2.1.5.1 Instructions for use 23](#_Toc57800738)

[2.1.5.2 Risk mitigation measures 23](#_Toc57800739)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 23](#_Toc57800740)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 24](#_Toc57800741)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 24](#_Toc57800742)

[2.1.6 Other information 24](#_Toc57800743)

[2.1.7 Packaging of the biocidal product 24](#_Toc57800744)

[2.1.8 Documentation 25](#_Toc57800745)

[2.1.8.1 Data submitted in relation to product application 25](#_Toc57800746)

[2.1.8.2 Access to documentation 25](#_Toc57800747)

[2.2 Assessment of the biocidal product 26](#_Toc57800748)

[2.2.1 Intended use(s) as applied for by the applicant 26](#_Toc57800749)

[2.2.2 Physical, chemical and technical properties 32](#_Toc57800750)

[2.2.3 Physical hazards and respective characteristics 38](#_Toc57800751)

[2.2.4 Methods for detection and identification 42](#_Toc57800752)

[2.2.5 Efficacy against target organisms 45](#_Toc57800753)

[2.2.5.1 Function and field of use 45](#_Toc57800754)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 45](#_Toc57800755)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 47](#_Toc57800756)

[2.2.5.4 Mode of action, including time delay 47](#_Toc57800757)

[2.2.5.5 Efficacy data 47](#_Toc57800758)

[2.2.5.6 Occurrence of resistance and resistance management 63](#_Toc57800759)

[2.2.5.7 Known limitations 64](#_Toc57800760)

[2.2.5.8 Evaluation of the label claims 64](#_Toc57800761)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 64](#_Toc57800762)

[2.2.6 Risk assessment for human health 65](#_Toc57800763)

[2.2.6.1 Assessment of effects on Human Health 65](#_Toc57800764)

[2.2.6.2 Exposure assessment and Risk characterization 68](#_Toc57800765)

[2.2.6.3 Risk characterisation for human health 172](#_Toc57800766)

[2.2.7 Risk assessment for animal health 172](#_Toc57800767)

[2.2.8 Risk assessment for the environment 173](#_Toc57800768)

[2.2.8.1 Effects assessment on the environment 173](#_Toc57800769)

[2.2.8.2 **Exposure assessment** 175](#_Toc57800770)

[2.2.8.3 **Risk characterisation** 207](#_Toc57800771)

[2.2.9 Measures to protect man, animals and the environment 217](#_Toc57800772)

[*3* Annexes 218](#_Toc57800773)

[3.1 List of studies for the biocidal product 218](#_Toc57800774)

[3.2 Output tables from exposure assessment tools 221](#_Toc57800775)

[3.3 Summaries of the efficacy studies (B.5.10.1-xx) 221](#_Toc57800776)

[3.4 Confidential annex 221](#_Toc57800777)

# CONCLUSION

**Context**

The French CA received an application for provisional authorisation of the biocidal product ACTICIDE C1 (Case Number: BC-DW041712-25). This product is the representative product of the CAR of the new active substance C(M)IT. The first draft CAR (FDCAR) of the active substance C(M)IT has been sent to MSCAs by ECHA and applicant for the peer-review according to the process flow 35. The Case number of the active substance approval (AS-APP) is BC-EE033569-45. The FDCAR has been discussed at the WG II-2020 in March 2020 and at the BPC-35 in June 2020. FR CA has submitted a recommendation for approval of the of the new active substance C(M)IT. This approval is in stand by, waiting for the additional Endocrine Disruptor data requested to the applicant.

This product application BC-DW041712-25 is related to article 55 (2) of the BPR and follows the mutual recognition on a provisional authorisation descibes in document CA-Sept14-Dec-Doc5.9 "Provisional authorisations granted or to be granted in accordance with Article 55(2) of the BPR and conversion to definitive authorisations".

The first draft PAR of ACTICIDE C1 has been sent to MSCAs, ECHA and applicant for the peer-review.

In line with Article 34(1) of the Regulation, a list of all other Member States where a provisional national authorisation was sought, was submitted to the reference Member State in a mutual recognition in parallel process and the SPC and PAR were made available for commenting on 18/10/2019. Two cMS (NL and DE) initiated a formal referral to the Coordination Group (CG) in accordance with Article 35(2) of Regulation EU No.528/2912 (BPR) on 21/01/2020 and 24/01/2020 respectively.

As no consensus on these two referrals could be reached, it was concluded that these particular points should be referred under Article 36(1) of Regulation 528/2012. Therefore, the subject of this referral to the Commission relates to these remaining open referral points.

**Introduction**

ACTICIDE C1 is a biocidal product containing the new active substance C(M)IT intended to be used for the preservation of manufactured products, other than food stuffs or feeding stuffs and cosmetics, in containers (product type 6) by the control of microbial deterioration to ensure their shelf life during storage.

ACTICIDE C1 is intended to be used as a wet-state preservation of a wide range of aqueous formulations such as washing and cleaning fluids (except human hygienic products) (6.1.2), paints (6.2), additives used in paper production (6.3.1), adhesives (6.6) and various other products (6.7) such as pigment pastes, slurries, polymer dispersions and colourants. ACTICIDE C1 will be used industrially by professional workers during the manufacturing process of the formulated products. The treated articles will be used in- and outdoor by professionals and general public, depending on the claimed.

**Conclusion of Physico-chemical and analytical method**

The product ACTICIDE C1 is another liquid (AL formulation). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a clear and colourless liquid with a faint mild odour. It is not expected to have explosive and oxidising properties. The product is not flammable nor has auto-ignition properties and has a flash point superior of 105°C. The product is not classified corrosive to metal. In 1% aqueous solution, it has a pH value of 5.1 at 23.6°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Its technical characteristics are acceptable for an AL formulation.

The formulation is not classified for the physico-chemical aspect.

Nevertheless, oxidising test should be provided at the submission of definitive authorisation of the biocidal product to confirm that the product is not classified.

The formulation must be stored at temperature > 0°C.

A description of the analytical methods used for the analysis of the active substance in the biocidal product is available. Other methods are included in the dossier for approval of the active substance for which a letter of access is available.

**Conclusion of Efficacy**

Efficacy of the product ACTICIDE C1 is demonstrated against bacteria, yeasts and fungi, with and without preconditioning[[1]](#footnote-2), for the following uses:

PT 6.1.2 Washing and cleaning fluids (general) and other detergents

PT 6.2 Paints and coatings

PT 6.3.1. Preservation of fluids used in Paper production

PT 6.6. Preservation of glues and adhesives.

PT 6.7 Other: Polymer dispersions

PT 6.7. Other: preservation of pigment pastes

PT 6.7. Other: preservation of colourants (bacteria, fungi (except yeasts))

PT 6.7. Other: preservation of slurries (TiO2) (Bacteria only)

However, considering the results of the efficacy data submitted, efficacy against yeasts in colourants and against bacteria in CaCO3 slurries is validated pending the submission of new data (with and without preconditioning) at the submission of the definitive authorisation application.

In the litterature, resistance to increasing levels of isothiazolones was shown for bacteria adapted in lab cultures. Depending on the authors, adaptation phenomena induced during exposure of bacteria can be stable or unstable, and may lead to resistance. It is important to emphasize that the use of preservatives induce a continuous contact between active substances and microorganisms, leading to a pressure of selection that maintains this adapted state whatever the stability of the phenomenon.

If the applicant becomes aware of any reports of resistance to the active substance and/or the products these should be reported to appropriate bodies (e.g. the efficacy working group and/or concerned member states) so that it can be determined if further action is required.

Resistance should be managed at the renewal of authorisation with appropriate guidelines.

**Substances of concern (SoCs)**

The biocidal product ACTICIDE C1 does not contain a non-active substance which is considered as a substances of concern.

**Conclusion of risk characterisation for human health**

For industrial users, the risk is considered acceptable for the mixing and loading and filling scenarios taking into account gloves and impermeable coverall.

**For the use of preserved detergents (use 6.1.2),** due to the skin sensitizing properties of the active substance (a.s) and to the approach taken that no personal protective equipement (PPE) can be considered in the risk assessment, the maximum concentration of the active substance in detergents product must be below the threshold value of 15 ppm of pure C(M)IT for professionnals and non professionals.

No unacceptable risk has been estimated regarding indirect exposure related to the use of the preserved detergents.

**For the use of the preserved paints (use 6.2),** the risk is considered acceptable for professionals during spraying of paint and during brush/roller application without PPE taking account a maximal concentration of 15 ppm of pure C(M)IT in paint. The risk is also deemed acceptable for non professionals using preserved paints.

However, unacceptable risks are identified for indirect exposure of the preserved paint:

* to volatilized residues of active substance contained in paint at a maximum concentration of 150 ppm of pure C(M)IT (adult, child, toddler and infant);
* to wet paint containing a maximum concentration of 150 ppm of pure C(M)IT.

A decrease of the maximum concentration contained in paint below the threshold value of 15 ppm of pure C(M)IT is required to reach an acceptable risk.

**For the other uses (6.3.1, 6.6, 6.7)**, no unacceptable risk is identified.

**Conclusion of risk characterisation for dietary exposure**

Regarding the estimation of theoretical exposure to C(M)IT via food contamination considering the intended uses that may load to food contamination (as preservative in detergent, or in fluids used in paper production), no dietary risk is identified .

**Conclusion of risk characterisation for environment**

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| **The use of ACTICIDE C1 leads to acceptable risks :**  **For the use of preserved detergents (use 6.1)** (other than those used for human hygien) at a maximal concentration of 15 ppm for professional and non-professional use.  **For the use of the preserved paints and coating (use 6.2)** at a maximal concentration of 15 ppm.  Risk mitigation measures are necessary to ensure acceptable risks at the application phase of the preserved paints and coating:   * The addition of the product ACTICIDE C1 in additives for paints and coatings must be carried out only in plants connected to industrial STPs.   Moreover, risk mitigation measure is necessary to ensure acceptable risks for the use of the product in paints and coatings:   * The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information: * Use indoor only.   **For the use Preservation of additives used in Paper production (use 6.3-1)** at a maximal concentration of 22.2 ppm for dry-end operation only.  Associated risk mitigation measures:   * Restrict the use of the product for the preservation of additives used in the paper industry for dry-end operations only. * The person responsible for the placing on the market of articles containing preserved polymer dispersions shall ensure that the label of these treated articles provides the following information: * The use of additives preserved by ACTICIDE C1 must be carried out in structures connected to industrial STPs.   **For the use Preservation of Glues and adhesives (use 6.6)** at a maximal concentration of 400 ppm.  **For the use Preservation of Polymer dispersions (use 6.7)** at a maximal concentration of 40 ppm incorporated in paints and coating.  Risk mitigation measure is necessary to ensure acceptable risks at the application phase of the product in polymer dispersions:   * The addition of the product ACTICIDE C1 in polymer dispersions must be carried out only in plants connected to industrial STPs.   Moreover, risk mitigation measures are necessary to ensure acceptable risks for the use of the preserved paints and coating, that include polymer dispersions:   * The person responsible for the placing on the market of articles containing preserved polymer dispersions shall ensure that the label of these treated articles provides the following information: * Use indoor only.   **For the use Preservation of Pigments paste (use 6.7)** at a maximal concentration of 40 ppm incorporated in paints.  **For the use Preservation of Colorants (use 6.7)** at a maximal concentration of 40 ppm incorporated in paints.  **The use of ACTICIDE C1 leads to unacceptable risks :**  **For the use Preservation of paints and coating (higher to 15 ppm) and plasters (use 6.2) when applied outdoor,** considering the risks for soil and aquatic compartments**.**  **For the use Preservation of Slurries (use 6.7)** because data is lacking thus, the assessment was not performed. | |
|  | |

***ED assessment :***

There is no indication of concern regarding ED properties of any of the co-formulants, hence the product is not an endocrine disruptor.

**GENERAL CONCLUSION:**

**FR CA considers that the product shall be authorised for:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Uses** | **Target organism** | **Application rates** | **Use conditions (RMM specific to each use)** |
| Use 1: Preservation of washing and cleaning fluids (general) and other detergents | Bacteria, yeasts, Fungi | Bacteria: 5.55 < 15 mg a.s./kg  Yeasts: 8.33 < 15 mg a.s./kg  Fungi: 2.78 < 15 mg a.s./kg | The person responsible for the placing on the market of articles for professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties. |
| Use 2: Preservation of paints and coatings | Fungi (except yeasts) | 5.55 < 15 mg a.s./kg | The addition of the product ACTICIDE C1 in paints must be carried out only in plants connected to industrial STPs.  The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:   * Use indoor only.   The person responsible for the placing on the market of articles for professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties. |
| Use 3: Preservation of additives used in paper production | Bacteria, yeasts, Fungi | Bacteria: 8.33 -22.2 mg a.s./kg  Yeasts: 22.2 mg a.s./kg  Fungi: 5.55 -22.2 mg a.s./kg | Restrict the use of the product for the preservation of additives used in the paper industry for dry-end operations only.  The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:  - The use of additives preserved by ACTICIDE C1 must be carried out in structures connected to industrial STPs. |
| Use 4: Preservation of glues and adhesives | Bacteria, yeasts, Fungi | Bacteria: 33.3 - 400 mg a.s./kg  Yeasts: 22.2 - 400 mg a.s./kg  Fungi: 5.55 -400 mg a.s./kg | - |
| Use 5: Preservation of pigment paste | Yeasts, Fungi | Yeasts: 16.65 - 40 mg a.s./kg  Fungi: 22.2 - 40 mg a.s./kg | - |
| Use 6: Preservation of colourants | Bacteria, Fungi (except yeasts) | Bacteria: 11.1 - 40 mg a.s./kg  Fungi: 5.55 - 40 mg a.s./kg | - |
| Use 7: Preservation of polymer dispersions | Bacteria, yeasts, Fungi | Bacteria: 8.33 - 40 mg a.s./kg  Yeasts: 10.55 - 40 mg a.s./kg  Fungi: 5.55 – 40 mg a.s./kg | The addition of the product ACTICIDE C1 in paints must be carried out only in plants connected to industrial STPs.  The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:   * Use indoor only.   The person responsible for the placing on the market of articles for professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties. |

The following RMMs apply for all the uses:

- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall (at least type category III type 4), respiratory mask and face shield, during handling product.

- Minimization of manual phases.

- Use of treated article:

The person responsible for the placing on the market of articles for non-professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[2]](#footnote-3)** | **Country (if relevant)** |
| --- | --- |
| ACTICIDE C1 |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Thor GmbH |
| **Address** | Landwehrstraße 1  67346 Speyer  Germany |
| **Authorisation number** | **FR-2021-0015** | |
| **Date of the authorisation** | **17/03/2021** | |
| **Expiry date of the authorisation** | **16/03/2024** | |

#### Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | Thor GmbH |
| **Address of manufacturer** | Landwehrstraße 1, 67346 Speyer, Germany |
| **Location of manufacturing sites** | Landwehrstraße 1, 67346 Speyer, Germany |

#### Manufacturer(s) of the active substance

|  |  |
| --- | --- |
| **Active substance** | 5-chloro-2-methyl-2H-isothiazol-3-one |
| **Name of manufacturer** | Thor GmbH |
| **Address of manufacturer** | Landwehrstraße 1, 67346 Speyer, Germany |
| **Location of manufacturing sites** | Landwehrstraße 1, 67346 Speyer, Germany |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Not available |
| **IUPAC or EC name** | 5-chloro-2-methyl-2h-isothiazol-3-one (C(M)IT) |
| **EC number** | 247-500-7 |
| **CAS number** | 26172-55-4 |
| **Index number in Annex VI of CLP** | Not available |
| **Minimum purity / content** | ≥ 1.0 % (w/w) C(M)IT in ACTICIDE C1  ≥ 29.3 % (w/w) C(M)IT calculated to dry substance |
| **Structural formula** |  |

#### Candidate(s) for substitution

Not relevant, the active substance is not a candidate for substitution.

#### Qualitative and quantitative information on the composition of the biocidal product

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| C(M)IT  (pure) | 5-chloro-2-methyl-2H-isothiazol-3-one | Active substance | 26172-55-4 | 247-500-7 | 1.11 |

#### Information on technical equivalence

Not applicable

#### Information on the substance(s) of concern

ACTICIDE C1 does not contain substances of concern as co-formulants.

#### Assessment of endocrine disruption (ED) properties of the biocidal product

There is no indication of concern regarding ED properties of any of the co-formulants, hence the product is not an endocrine disruptor. The discussion regarding the ED properties of the active substance will take place at European level for the approbation process.

Please see the confidential annex for further details.

#### Type of formulation

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| --- |
| Another liquid - AL |

### Hazard and precautionary statements

**Classification and labelling of the products according to the Regulation (EC) 1272/2008**

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| --- | --- |
| **Classification** | |
| Hazard category | Aquatic acute 1 and chronic 2  Skin Corr. 1C  Skin Sens. 1A  Eye Dam. 1 |
| Hazard statement | H314: Causes severe skin burns and eye damage  H317: May cause an allergic skin reaction  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H314: Causes severe skin burns and eye damages  H317: May cause an allergic skin reaction  H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P260: Do not breathe dust/fume/gas/mist/vapours/spray.  P264: Wash … thoroughly after handling.  P272: Contaminated work clothing should not be allowed out of the workplace.  P273: Avoid release to the environment  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P302 + P352: IF ON SKIN: Wash with plenty of water/…  P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER/doctor/ …  P321: Specific treatment (see … on this label).  P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.  P362 +P364: Take off contaminated clothing and wash it before reuse.  P391: Collect spillage  P405: Store locked up.  P501: Dispose of contents/container according to local regulation |
|  | |
| Note | **EUH071:** Corrosive to the respiratory tract.  Contains methyl-2H-isothiazol-3-one (MIT). |

### Authorised use(s)

#### Preservation of washing and cleaning fluids (general) and other detergents

**Table 1. Use # 1**

|  |  |
| --- | --- |
| **Product Type** | 6 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, yeasts, fungi |
| **Field of use** | Indoor. Preservation of household cleaning products, cleaning products for professionals, textile washing products and softener |
| **Application method(s)** | Automatic or manual |
| **Application rate(s) and frequency** | Bacteria: 5.55 < 15 mg a.s./kg  Yeasts: 8.33 < 15 mg a.s./kg  Fungi: 2.78 < 15 mg a.s./kg |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5 - 25 L HDPE Can  100 L HDPE Barrel  1000 L HDPE Container  25 – 220 L - HDPE Drum  600 – 1200L – IBC (HDPE)  The product may only be dispensed from pack sizes larger than 20 L using an automatic dosing system. |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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| - The person responsible for the placing on the market of articles for professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### **Preservation of paints and coatings**

**Table 2. Use # 2**

|  |  |
| --- | --- |
| **Product Type** | 6 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Fungi (except yeasts) |
| **Field(s) of use** | Indoor. Preservation of interior paints and coatings |
| **Application method(s)** | Automatic or manual |
| **Application rate(s) and frequency** | 5.55 < 15 mg a.s./kg |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5 - 25 L HDPE Can  100 L HDPE Barrel  1000 L HDPE Container  25 – 220 L - HDPE Drum  600 – 1200L – IBC (HDPE)  The product may only be dispensed from pack sizes larger than 20 L using an automatic dosing system. |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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| * The person responsible for the placing on the market of articles for professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties. * The addition of the product ACTICIDE C1 in additives for paints and coatings must be carried out only in plants connected to industrial STPs. * The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information: * Use indoor only. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### **Preservation of additives used in Paper production**

**Table 3. Use # 3**

|  |  |
| --- | --- |
| **Product Type** | 6 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Bacteria, yeasts, fungi |
| **Field(s) of use** | Indoor. Preservation of products used for paper production such as a photo paper coating, in the paper industry |
| **Application method(s)** | Automatic or manual |
| **Application rate(s) and frequency** | Bacteria: 8.33 -22.2 mg a.s./kg  Yeasts: 22.2 mg a.s./kg  Fungi: 5.55 -22.2 mg a.s./kg |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5 - 25 L HDPE Can  100 L HDPE Barrel  1000 L HDPE Container  25 – 220 L - HDPE Drum  600 – 1200L – IBC (HDPE)  The product may only be dispensed from pack sizes larger than 20 L using an automatic dosing system. |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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| * Restrict the use of the product for the preservation of additives used in the paper industry for dry-end operations only. * The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information: * The use of additives preserved by ACTICIDE C1 must be carried out in structures connected to industrial STPs. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### **Preservation of glues and adhesives**

**Table 4. Use # 4**

|  |  |
| --- | --- |
| **Product Type** | 6 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Bacteria, yeasts, fungi |
| **Field(s) of use** | Indoor. Preservation of water based glues and adhesives belonging to the group of Physical hardening adhesives, e.g. solvent-based adhesives, dispersion adhesives (latex), colloidal systems, contact adhesives, etc. |
| **Application method(s)** | Automatic or manual |
| **Application rate(s) and frequency** | Bacteria: 33.3 -400 mg a.s./kg  Yeasts: 22.2 - 400 mg a.s./kg  Fungi: 5.55 - 400 mg a.s./kg |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5 - 25 L HDPE Can  100 L HDPE Barrel  1000 L HDPE Container  25 – 220 L - HDPE Drum  600 – 1200L – IBC (HDPE)  The product may only be dispensed from pack sizes larger than 20 L using an automatic dosing system. |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### **Preservation of pigment paste**

**Table 5. Use # 5**

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| --- | --- |
| **Product Type** | 6 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Yeasts  Fungi |
| **Field(s) of use** | Indoor. Preservation of pigment paste.  Pigment pastes are highly concentrated additives which are incorporated into paints to dye the basic paint with different colours. |
| **Application method(s)** | Automatic or manual |
| **Application rate(s) and frequency** | Yeasts: 16.65 - 40 mg a.s./kg  Fungi: 22.2 - 40 mg a.s./kg |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5 - 25 L HDPE Can  100 L HDPE Barrel  1000 L HDPE Container  25 – 220 L - HDPE Drum  600 – 1200 L – IBC (HDPE)  The product may only be dispensed from pack sizes larger than 20 L using an automatic dosing system. |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### **Preservation of colourants**

**Table 6. Use # 6**

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| --- | --- |
| **Product Type** | 6 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Bacteria  Fungi (except yeasts) |
| **Field(s) of use** | Indoor. Preservation of colourants.  They are usually liquid mixtures in which the pigment is already dispersed in order to make the incorporation into the paint/varnish easier. |
| **Application method(s)** | Automatic or manual |
| **Application rate(s) and frequency** | Bacteria: 11.1 - 40 mg a.s./kg  Fungi: 5.55 - 40 mg a.s./kg |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5 - 25 L HDPE Can  100 L HDPE Barrel  1000 L HDPE Container  25 – 220 L - HDPE Drum  600 – 1200L – IBC (HDPE)  The product may only be dispensed from pack sizes larger than 20 L using an automatic dosing system. |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### **Preservation of polymer dispersions**

**Table 7. Use # 7**

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| --- | --- |
| **Product Type** | 6 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Bacteria, yeasts, fungi |
| **Field(s) of use** | Indoor. Preservation of polymer dispersions.  Polymer dispersions can be used for the production of various end-products such as paints, sealants, adhesives or pigment pastes. |
| **Application method(s)** | Automatic or manual |
| **Application rate(s) and frequency** | Bacteria: 8.33 - 40 mg a.s./kg  Yeasts: 10.55 - 40 mg a.s./kg  Fungi: 5.55 – 40 mg a.s./kg |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5 - 25 L HDPE Can  100 L HDPE Barrel  1000 L HDPE Container  25 – 220 L - HDPE Drum  600 – 1200L – IBC (HDPE)  The product may only be dispensed from pack sizes larger than 20 L using an automatic dosing system. |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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| * The addition of the product ACTICIDE C1 in polymer dispersions must be carried out only in plants connected to industrial STPs. * The person responsible for the placing on the market of articles containing preserved polymer dispersions shall ensure that the label of these treated articles provides the following information: * Use indoor only. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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### General directions for use

#### Instructions for use[[3]](#footnote-4)

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| * Always read the label or leaflet before use and follow all the instructions provided. * The product is preferably added to the system via a metering pump (continuous or discontinuous) at a location where it is distributed quickly and evenly in the product to be preserved. The addition may be effected at any stage of the production of the product. For optimum conservation it is recommended to make the addition as early as possible. * Microbiological tests to prove the adequacy of preservation have to be undertaken by the user of ACTICIDE C1 in order to determine the effective dose of the preservative for the specific matrix/location/system. * The duration and storage conditions of the preserved matrices may impact the efficacy of the product, microbiological tests should be conducted to determine the appropriate application rate without exceeding the maximum authorised application rate. * If needed, consult the manufacturer of the preservative product. * Inform the registration holder if the treatment is ineffective. |

#### Risk mitigation measures

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| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall (at least category III type 4), respiratory protection and face shield, during handling of product. * Minimization of manual phases. * The person responsible for the placing on the market of articles for non-professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting. * Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. * Keep the container or label available. |

#### Instructions for safe disposal of the product and its packaging

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| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging (….) and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

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| * Shelf-life: 2 years. * Store at a temperature > 0°C. |

### Other information

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### Packaging of the biocidal product

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| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user** | **Compatibility of the product with the proposed packaging materials \* (Yes/No)** |
| Can | 5-25 liter | Polyethylene  HDPE | Locking cap  Polyethylene, HDPE | Industrial | Yes |
| Barrel | 100 liter | Polyethylene  HDPE | Screw cap  Polyethylene, HDPE | Industrial | Yes |
| Container | 1000 liter | Polyethylene,  UV stabilised  HDPE | Spigot, cylindrical  EPDM | Industrial | Yes |
| Drum | 25 – 220 L | Polyethylene  HDPE | Lid/bung plugs, HDPE, sealant EPDM | Industrial | Yes |
| IBC | 600 – 1200 L | Polyethylene  HDPE | Tap with screw cap, HDPE, sealant EPDM | Industrial | Yes |

*\*HDPE container was stable during accelerated/long term storage*

### Documentation

#### Data submitted in relation to product application

No new data were generated with the biocidal product ACTICIDE C1 other than those already submitted for the approval of the active substance 5-chloro-2-methyl-2H-iso­thia­zol-3-one.

#### Access to documentation

Please note that Thor GmbH is the data owner for the active substance data set and therefore has access to all of the data.

## Assessment of the biocidal product

### Intended use(s) as applied for by the applicant

**Table 1. Use # 1 – In can preservative for detergent**

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| --- | --- |
| **Product Type** | PT 6 |
| **Where relevant, an exact description of the authorised use** | PT 6.1.2 Washing and cleaning fluids (general) and other detergents |
| **Target organism (including development stage)** | bacteria, yeasts, fungi |
| **Field of use** | Preservation of household cleaning products, cleaning products for professionals, textile washing products and softener |
| **Application method(s)** | Dosing installation (90 %): automatically adding in-can preservatives into the processing vessel,  Manually adding (10 %) the in-can preservatives into the processing vessel; filling, mixing manually of by use of a dosage pump, waste disposal of the empty container |
| **Application rate(s) and frequency** | Automatically (90% of use) adding product into the processing vessel: daily - 10 min each time connecting a 1000 l container of product.  Manually adding (10%) product into the processing vessel: daily - each 10 time with 30 kg product packages.  Detergent mopping/laundry/dish-washing: daily 8h/day  Application rate: 2,83 - 250 mg active substance /L |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | IBC: 600 – 1200 L - Polyethylene, HDPE  Closures: Tap with screw cap, HDPE, sealant EPDM  Drum: 25 – 220 L – Polyethylene, HDPE  Closures: Lid/bung plugs, HDPE, sealant EPDM  Can: 5-25 L – Polyethylene, HDPE  Closures: Locking cap Polyethylene, HDPE  Barrel: 100 L – Polyethylene, HDPE  Closures: Screw cap Polyethylene, HDPE  Container: 1000L - Polyethylene UV stabilised, HDPE  Closures: Spigot, cylindrical, EPDM |

**Table 2. Use # 2 – In can preservative for paints and coatings**

|  |  |
| --- | --- |
| **Product Type** | PT 6 |
| **Where relevant, an exact description of the authorised use** | PT 6.2. Paints and coatings |
| **Target organism(s) (including development stage)** | bacteria, yeasts, fungi |
| **Field(s) of use** | Preservation of interior and exterior paints and coatings |
| **Application method(s)** | Dosing installation (90 %): automatically adding in-can preservatives into the processing vessel,  Manually adding (10 %) the in-can preservatives into the processing vessel; filling, mixing manually of by use of a dosage pump, waste disposal of the empty container |
| **Application rate(s) and frequency** | Automatically (90% of use) adding product into the processing vessel. daily - 10 min each time connecting a 1000 l container of product.  Manually adding (10%) product into the processing vessel: daily - each 10 time with 30 kg product packages.  Brushing or rolling with paint or application of plaster containing product daily 6 h/day.  Application rate: 5,64 - 200 mg active substance / L; |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | IBC: 600 – 1200 L - Polyethylene, HDPE  Closures: Tap with screw cap, HDPE, sealant EPDM  Drum: 25 – 220 L – Polyethylene, HDPE  Closures: Lid/bung plugs, HDPE, sealant EPDM  Can: 5-25 L – Polyethylene, HDPE  Closures: Locking cap Polyethylene, HDPE  Barrel: 100 L – Polyethylene, HDPE  Closures: Screw cap Polyethylene, HDPE  Container: 1000L - Polyethylene UV stabilised, HDPE  Closures: Spigot, cylindrical, EPDM |

**Table 3. Use # 3** – **In-can preservative for fluids used in Paper production**

|  |  |
| --- | --- |
| **Product Type** | PT 6 |
| **Where relevant, an exact description of the authorised use** | PT 6.3.1. Fluids used in Paper production |
| **Target organism(s) (including development stage)** | bacteria, yeasts, fungi |
| **Field(s) of use** | Products used for paper production such as colourants, sizing agents |
| **Application method(s)** | Dosing installation (90 %): automatically adding in-can preservatives into the processing vessel,  Manually adding (10 %) the in-can preservatives into the processing vessel; filling, mixing manually of by use of a dosage pump, waste disposal of the empty container |
| **Application rate(s) and frequency** | Dosing installation (90 %): automatically adding in-can preservatives into the processing vessel,  Manually adding (10 %) the in-can preservatives into the processing vessel; filling, mixing manually of by use of a dosage pump, waste disposal of the empty container  Application rate: 5,65 - 85 mg active substance/L |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | IBC: 600 – 1200 L - Polyethylene, HDPE  Closures: Tap with screw cap, HDPE, sealant EPDM  Drum: 25 – 220 L – Polyethylene, HDPE  Closures: Lid/bung plugs, HDPE, sealant EPDM  Can: 5-25 L – Polyethylene, HDPE  Closures: Locking cap Polyethylene, HDPE  Barrel: 100 L – Polyethylene, HDPE  Closures: Screw cap Polyethylene, HDPE  Container: 1000L - Polyethylene UV stabilised, HDPE  Closures: Spigot, cylindrical, EPDM |

**Table 4. Use # 4 – In-can preservative for glues and adhesives**

|  |  |
| --- | --- |
| **Product Type** | PT 6 |
| **Where relevant, an exact description of the authorised use** | PT 6.6. Preservation of glues and adhesives. |
| **Target organism(s) (including development stage)** | Bacteria, yeasts, fungi |
| **Field(s) of use** | Preservation of glues and adhesives |
| **Application method(s)** | The product is preferably added to the system via a metering pump (continuous or discontinuous) at a location where it is distributed quickly and evenly in the product to be preserved. The addition may be effected at any stage of the production of the product. For optimum conservation it is recommended to make the addition as early as possible.  Dosing installation (90 %): automatically adding in-can preservatives into the processing vessel,  Manually adding (10 %) the in-can preservatives into the processing vessel; filling, mixing manually by use of a dosage pump, waste disposal of the empty container. |
| **Application rate(s) and frequency** | Automatically (90% of use) adding product into the processing vessel: daily - 10 min each time connecting a 1000 l container of product.  Manually adding (10%) product into the processing vessel: daily- each 10 time with 30 kg product packages.  Application rate: 5,65 – 400 mg a.s. per kg |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | IBC: 600 – 1200 L - Polyethylene, HDPE  Closures: Tap with screw cap, HDPE, sealant EPDM  Drum: 25 – 220 L – Polyethylene, HDPE  Closures: Lid/bung plugs, HDPE, sealant EPDM  Can: 5-25 L – Polyethylene, HDPE  Closures: Locking cap Polyethylene, HDPE  Barrel: 100 L – Polyethylene, HDPE  Closures: Screw cap Polyethylene, HDPE  Container: 1000L - Polyethylene UV stabilised, HDPE  Closures: Spigot, cylindrical, EPDM |

**Table 5. Use # 5 – In can preservative for Polymer dispersions**

|  |  |
| --- | --- |
| **Product Type** | PT 6 |
| **Where relevant, an exact description of the authorised use** | PT 6.7. Other: Polymer dispersions |
| **Target organism(s) (including development stage)** | Bacteria, yeasts, fungi |
| **Field(s) of use** | Preservation of polymer dispersions.  Polymer dispersions can be used for the production of various end products such as paints, plaster, sealants, adhesives or pigment pastes. |
| **Application method(s)** | The product is preferably added to the system via a metering pump (continuous or discontinuous) at a location where it is distributed quickly and evenly in the product to be preserved. The addition may be effected at any stage of the production of the product. For optimum conservation it is recommended to make the addition as early as possible.  Dosing installation (90 %): automatically adding in-can preservatives into the processing vessel,  Manually adding (10 %) the in-can preservatives into the processing vessel; filling, mixing manually by use of a dosage pump, waste disposal of the empty container. |
| **Application rate(s) and frequency** | Automatically (90% of use) adding product into the processing vessel: daily - 10 min each time connecting a 1000 l container of product.  Manually adding (10%) product into the processing vessel: daily- each 10 time with 30 kg product packages.  Application rate: 5,65 - 400 mg active substance / L |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | IBC: 600 – 1200 L - Polyethylene, HDPE  Closures: Tap with screw cap, HDPE, sealant EPDM  Drum: 25 – 220 L – Polyethylene, HDPE  Closures: Lid/bung plugs, HDPE, sealant EPDM  Can: 5-25 L – Polyethylene, HDPE  Closures: Locking cap Polyethylene, HDPE  Barrel: 100 L – Polyethylene, HDPE  Closures: Screw cap Polyethylene, HDPE  Container: 1000L - Polyethylene UV stabilised, HDPE  Closures: Spigot, cylindrical, EPDM |

**Table 11. Use # 6 – In can preservative for slurries**

|  |  |
| --- | --- |
| **Product Type** | PT 6 |
| **Where relevant, an exact description of the authorised use** | PT 6.7. Other: Slurries (Clay, mica and other fillers) |
| **Target organism(s) (including development stage)** | Bacteria, yeasts, fungi |
| **Field(s) of use** | Preservation of slurries(Clay, mica and other fillers) |
| **Application method(s)** | Automated dosing via dosage pump of biocidal product into the mixing vessel and mixing of slurry. The biocide can also be directly dosed (dosage installation) to the truck delivering the slurry to the customer. |
| **Application rate(s) and frequency** | Application rate: 1,13 - 400 mg active substance /L  If the tank shows bacteria infestation > 104 CFU the biocidal product should be added. |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 25 L HDPE can  100 L HDPE Barrel  1000 L HDPE Container |

**Table 7. Use # 7 – In can preservative for pigment paste and colourants**

|  |  |
| --- | --- |
| **Product Type** | PT 6 |
| **Where relevant, an exact description of the authorised use** | PT 6.7. Other: Pigment paste and colourants |
| **Target organism(s) (including development stage)** | Bacteria, yeasts, fungi |
| **Field(s) of use** | Preservation of pigment paste, colourants.  Pigment pastes are highly concentrated additives which are incorporated into paints to dye the basic paint with different colours. They are usually liquid mixtures in which the pigment is already dispersed in order to make the incorporation into the paint/varnish easier. |
| **Application method(s)** | The product is preferably added to the system via a metering pump (continuous or discontinuous) at a location where it is distributed quickly and evenly in the product to be preserved. The addition may be effected at any stage of the production of the product. For optimum conservation it is recommended to make the addition as early as possible.  Dosing installation (90 %): automatically adding in-can preservatives into the processing vessel,  Manually adding (10 %) the in-can preservatives into the processing vessel; filling, mixing manually by use of a dosage pump, waste disposal of the empty container. |
| **Application rate(s) and frequency** | Automatically (90% of use) adding product into the processing vessel: daily - 10 min each time connecting a 1000 l container of product.  Manually adding (10%) product into the processing vessel: daily- each 10 time with 30 kg product packages.  Application rate: 16,95 - 400 mg active substance / L |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | IBC: 600 – 1200 L - Polyethylene, HDPE  Closures: Tap with screw cap, HDPE, sealant EPDM  Drum: 25 – 220 L – Polyethylene, HDPE  Closures: Lid/bung plugs, HDPE, sealant EPDM  Can: 5-25 L – Polyethylene, HDPE  Closures: Locking cap Polyethylene, HDPE  Barrel: 100 L – Polyethylene, HDPE  Closures: Screw cap Polyethylene, HDPE  Container: 1000L - Polyethylene UV stabilised, HDPE  Closures: Spigot, cylindrical, EPDM sealant |

### Physical, chemical and technical properties

Formulation type: any other liquid (AL)

Hydrocarbons and H304 co-formulant content is not above 10%.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **Acceptability / comment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6303 | 1.10 | ACTICIDE C1 is a clear and colourless liquid with a faint mild odour. | Wannenwetsch, 2016, Determination of Colour, Physical State and Odour of ACTICIDE C1 | Acceptable |
| Colour at 20 °C and 101.3 kPa | EPA OPPTS 830.6302 |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS 830.6304 |
| Acidity / alkalinity | CIPAC MT 75, EPA OPPTS 830.7000 | 1.10 | ACTICIDE C1:pH 3.3 at 23.7°C 1%(w/v): pH 5.1 at 23.6°C | Wannenwetsch, 2016, Determination of the pH value and the acidity of ACTICIDE C1 | Acceptable |
| CIPAC MT 191 | 0.032 (% m/m H2SO4) |
| Relative density / bulk density | OCSPP 830.7300; OECD 109 | 1.10 | D204 : 1.016 | Wannenwetsch, 2016, Determination of the density of ACTICIDE C1 | Acceptable |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Validated HPLC/UV method (Report: 1011-A 1012-13.0-FKI-0029-3) see Section 2.2.4 | 1.10 | |  |  |  | | --- | --- | --- | |  | Initial | After storage 14d at 54°C in HDPE bottle | | Appearance / packaging stability | No visual change of ACTICIDE C1 after storage. The storage container showed no signs of corrosion. | | | AS content (HPLC/UV) | 1.11% | 1.13% | | pH (neat/1%) | 3.3/5.1 | 3.2/5.2 | | Acidity | 0.032% H2SO4 | 0.012% H2SO4 | | Wannenwetsch, 2016, ACTICIDE C1: Determination of the accelerated storage stability, the corrosion characteristics, the pH-value and the acidity at 54°C over 14 days as well as the validation of the sample specific parameters | Acceptable  No visual change of ACTICIDE C1 after storage. The storage container showed no signs of corrosion.” Therefore, we can conclude that no sediment is present after storage in the product and the container is stable. |
| Storage stability test – **long term storage at ambient temperature** | OCSPP Harmonized Test Guideline 830.6317  Monograph 17  ECHA Guidance on the BPR, Vol I  Validated HPLC/UV method (Report: 1011-A 1012-13.0-FKI-0029-3)see Section 2.2.4 | 1.10 | |  |  |  | | --- | --- | --- | |  | Initial | After 2year storage at 19°C in HDPE bottle | | Appearance / packaging stability | No visual change after storage. The storage container showed no signs of corrosion for up to 24 months. | | | AS content (HPLC/UV) | 1.11% | 1.17% | | pH (neat/1%) | 3.3/5.1 | 3.4/6.0 | | Acidity | 0.032% H2SO4 | 0.015% H2SO4 | | Wannenwetsch, 2018, ACTICIDE C1: Determination of the storage stability, the corrosion characteristics, the pH-value and the acidity of ACTICIDE C1 at room temperature over 24 months | Acceptable  No visual change of ACTICIDE C1 after storage. The storage container showed no signs of corrosion.” Therefore, we can conclude that no sediment is present after storage in the product and the container is stable. |
| Storage stability test – **low temperature stability test for liquids** | Label gives clear instructions that the product must not be stored under conditions ≤0°C. Therefore, the low temperature storage does not need to be addressed.  Furthermore, due to the salt content the product will not freeze at temperatures below 0°C. So no negative effect to the technical characteristics are expected | | | | Low temperature storage is waived.  Considering the composition of the authorization submitted biocidal product, no negative effect of cold temperature can be derived.  Nevertheless, a noted on the label of the product should be added: **Store at temperature > 0°C** |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Monograph 17  ECHA Guidance on the BPR, Vol I | 1.10 | See long term storage study | Addressed in the long term storage at ambient temperature study | Acceptable  The active substance is not light sensitive |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | CIPAC MT 46.3Monograph 17  ECHA Guidance on the BPR, Vol I | 1.10 | Based on the CropLife international monograph 17 and ECHA it can be concluded that ACTICIDE C1 will most likely be stable for 14 days at 54°C and after two years at ambient temperature. No visual changes of ACTICIDE C1 were observed during storage time. | Wannenwetsch, 2016, ACTICIDE C1: Determination of the accelerated storage stability, the corrosion characteristics, the pH-value and the acidity at 54°C over 14 days as well as the validation of the sample specific parameters | Acceptable  Biocidal product is stable after accelerated storage. Moreover, the product is an aqueous solution, so the substance is not expected to be sensible to humidity. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46.3 Monograph 17  ECHA Guidance on the BPR, Vol I | 1.10 | The HDPE container showed no signs of corrosion after 14 days at 54°C and after two years at ambient temperature. | Wannenwetsch, 2016, ACTICIDE C1: Determination of the accelerated storage stability, the corrosion characteristics, the pH-value and the acidity at 54°C over 14 days as well as the validation of the sample specific parameters | Acceptable |
| Wettability | Waived (technically not feasible as the product is not a wettable powder preparation, water soluble powder, water soluble granule or water dispersible granule) | | | | Not relevant |
| Suspensibility, spontaneity and dispersion stability | Waived (technically not feasible as the product is not a wettable powder, aqueous suspension concentrate, water dispersible granule, water dispersible powder or suspension formed on dilution with water) | | | | Not relevant |
| Wet sieve analysis and dry sieve test | Waived (technically not feasible as the product is not a wettable powder, suspension concentrate, capsule suspension, water dispersible granule, dispersible concentrate, suspo-emulsion, water soluble granule, water soluble powders, dustable powder or granule) | | | | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | Waived (technically not feasible as the product is no emulsion or is planned to be used as an emulsion) | | | | Not relevant |
| Disintegration time | Waived (technically not feasible as the product is no tablet) | | | | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | Waived (technically not feasible as the product is a liquid) | | | |  |
| Persistent foaming | CIPAC MT 47.2 | 1.10 | The test item does not show persistent foaming  At 0.05% and 0.4%: 0mL of foam after 10s, 1min, 3min and 12min | Wannenwetsch, 2016, Determination of the foaming of ACTICIDE C1 | Acceptable |
| Flowability/Pourability/Dustability | Waived (technically not feasible as the product is not a granule, not a suspension concentrate, not a capsule suspension, not a suspo-emulsion or a dust) | | | | Not relevant |
| Burning rate — smoke generators | Waived (technically not feasible as the product is not intended to be applied as smoke) | | | | Not relevant |
| Burning completeness — smoke generators | Waived (technically not feasible as the product is not intended to be applied as smoke) | | | | Not relevant |
| Composition of smoke — smoke generators | Waived (technically not feasible as the product is not intended to be applied as smoke) | | | | Not relevant |
| Spraying pattern — aerosols | Waived (technically not feasible as the product is no aerosol or aerosol pack) | | | | Not relevant |
| Physical compatibility | Waived  According to the Guidance on the BPR: Volume I (Version 2.0 May 2018), Part A Chapter 3 “Dossier Requirements for Biocidal Products” under “3.6.6 Point 3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised” the following is stated:  “Data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products (e.g. dyes).  If all properties of each component are known and it can be clearly demonstrated that a chemical reaction can be excluded then data to demonstrate the chemical compatibility will not be required.  Any known incompatibilities (physical and chemical) should be mentioned. | | | | For ACTICIDE C1 no label recommendations are made to co-apply for authorisation purposes with other substances, mixtures or biocidal or non-biocidal products. With reference to this section of the guidance it is not necessary to provide additional information.  Therefore, no further data required |
| Chemical compatibility |
| Degree of dissolution and dilution stability | Waived (technically not feasible as the product is no tablet or water soluble bag) | | | | Not relevant |
| Surface tension | OECD 115 | 9.0% solution: | The surface tension of an aqueous solution of ACTICIDE C1 (90.1 g/l ACTICIDE C1, equivalent to 1.0 g CMIT/l) was determined to be:  71.9 mN/m at 20.0 °C ± 0 °C | Wannenwetsch, 2016, Determination of the surface tension of an aqueous solution of ACTICIDE C1 | Acceptable  Not surface active product |
| Viscosity | OECD 114; OPPTS 830.7100 | 1.10 | Dynamic viscosity at 20 °C: 1.30 mPa\*s (60 rpm to 100 rpm)  Dynamic viscosity at 40 °C: 1.24 mPa\*s (100 rpm)  Kinematic viscosity at 20 °C: 1.28 mm2/s (60 rpm to 100 rpm)  Kinematic viscosity at 40 °C: 1.22 mm2/s (100 rpm); ACTICIDE C1 shows at 20 °C the properties of a Newtonian liquid | Wannenwetsch, 2016, Determination of the viscosity of ACTICIDE C1 | Acceptable |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | | **Reference** | **Acceptability / comment** |
| --- | --- | --- | --- | --- | --- | --- |
| Explosives | UN-MTC | Nominal 1.10 | ;  An statement was provided. The product is an aqueous solution, therefore, ACTICIDE C1 does not expected to show explosive properties. | | Simonides, 2017, Expert Statement: Determination of the explosive properties of ACTICIDE C1 | No explosive properties according to CLP regulation. According to Manual UN RTDG and REACH Annex VII, the test can be waived if an expert judgement is provided based on molecular structures. |
| Flammable gases | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Flammable aerosols | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Oxidising gases | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Gases under pressure | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Flammable liquids | EEC A9  DIN EN ISO 2719  UN Transport Regulation Class 3  (Pensky-Martens) | ACTICIDE C1  1.06%  Batch RP-4006211-2101 | | The test was performed starting at 68°C to 105°C with a stirrer speed of 90-120 rpm and a heating rate of 5-6K/min. No ignition was observed.  The test item has no flash point up to a temperature of 105°C | S. Dreisch, 2020  CSL-20-0246.01 | Acceptable.  The product ACTICIDE C1 is not classified as flammable. |
| Flammable solids | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Self-reactive substances and mixtures | UN-MTC | Nominal 1.10 | Not self-reactive based on molecular structures | | Simonides, 2017, Expert Statement: Determination of the self-reactive properties of ACTICIDE C1 | Acceptable  product have no self-reactive properties according to CLP regulation. |
| Pyrophoric liquids | Waived (scientifically not necessary/ other information available due to company experience) | | | | | Not relevant |
| Pyrophoric solids | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Self-heating substances and mixtures | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Substances and mixtures which in contact with water emit flammable gases | Waived (scientifically not necessary/ other information available due to company experience) | | | | | Not relevant as the biocidal product is an aqueous solution |
| Oxidising liquids | UN-MTC | Nominal 1.10 | One of the co-formulant is classified as having oxidizing properties.  Nevertheless, as the biocidal product is a water based content with a low content of stabilizer, the product ACTICIDE C1 is considered not classified oxidizing. | | Simonides, 2017, Expert Statement: Determination of the oxidising properties of ACTICIDE C1 | Biocidal product is not expecting to have oxidizing properties. Nevertheless, this test should be provided at the authorization of the product to confirm that the biocidal product is not classified as having oxidizing properties. |
| Oxidising solids | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Organic peroxides | Waived (technically not feasible as the product does not contain organic substances which contain the bivalent -O-O- structure) | | | | | Not relevant |
| Corrosive to metals | UN MTC C.1 | 1.10 | The test item is no dangerous good of class 8 “corrosive substances” according to UN MTC and not “corrosive to metals” according to GHS/CLP  After 7 days at 55°C, small signs of corrosion on the samples are observed but there is less loss of weight of 5% for treated and untreated steel/aluminium, which is under the classified limit for this time (<13.5%).  The steel sheet shows surface corrosion while the aluminium sheet shows only minor signs of corrosion before pickling (rust stains on the surface).  No sign of localized corrosion in terms of formation of holes were detectable for steel and aluminium after pickling.  Study was amended with the monitoring of the depth of hole on steel sheet. 10 measurement were performed.  Maximum depth: 81µm  The maximum depth does not exceed the limit of 120µm given for corrosion within 7 days according to CLP regulation test. | | Kirsch, 2017, Assessment of the corrosive effect of ACTICIDE C1 for its classification as dangerous good of class 8 “Corrosive Substances”  Amended 02/2020 | Acceptable  No metal corrosive properties according to CLP regulation. |
| Auto-ignition temperatures of products (liquids and gases) | EEC A15  DIN 51794  DIN EN 14522 | ACTICIDE C1  Batch RP-4006211-2101  1.06% | According to DIN 51794, auto-ignition temperature rounded down to the nearest multiple 5°C was determinaed as 630°C.  According to DIN EN 14522, auto-ignition temperature reduced by 1.5% and rounded to the nearer temperature was determinaed as 623°C. | | L. Rosenfeldt, 2020, Study CSL-20-0246.02 | Acceptable  ACTICIDE C1 has no auto-ignition properties according to CLP regulation. |
| Relative self-ignition temperature for solids | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |
| Dust explosion hazard | Waived (technically not feasible as the product is a liquid) | | | | | Not relevant |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| ACTICIDE C1 is an another Liquid formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a clear and colourless liquid with a faint mild odour. It is not explosive and is not expecting to have oxidising properties. The product is not flammable nor to have auto-ignition properties. Nevertheless, oxidising test should be provided at the authorisation of the biocidal product to confirm that the product is not classified. The product is not classified as flammable or corrosive to metal.  In 1% aqueous solution, it has a pH value of 5.1 at 23.6°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for an AL formulation.  The formulation is not classified for the physico-chemical aspect.  The formulation must be stored at a temperature > 0°C. |

### Methods for detection and identification

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | **Limit of quantification (LOQ) or other limits** | **Reference** | **Comment** |
| Mean | RSD |
| *ACTICIDE MW: Active substance (C(M)IT)* | HPLC-DAD (275 nm)  After homogenisation of the test sample, an aliquot of approximatively 250-300 mgwas weighed into a 100 mL volumetric flask and filled up with mobile phase. Three independent sample solutions were prepared and each was injected once. | (n=7) at 1.1% of C(M)IT (11 mg/L) | 0.91-45.29 mg/L, r²=1.000, n=9  Y=39.75x+1.08 | No interference of signals at the retention time of the reference items in blank, reference, sample and matrix solution  UV spectra is priovided | At 1.117%: 100.4 | At 1.14% of C(M)IT : 0.2% < RSD Horwitz | Not applicable, content method | Wannenwetsch, 2016, ACTICIDE C1: Determination of the accelerated storage stability, the corrosion characteristics, the pH-value and the acidity at 54°C over 14 days as well as the validation of the sample specific parameters | Acceptable |

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| **Test substance** | **Method** | **Validation data** | **Conclusion** |
| C(M)IT in ACTICIDE C1 | HPLC-UV (275 nm) | Principle:  After homogenization of the test item aliquots of approximately 200mg sample were weighed into 100mL volumetric flasks. The volumetric flasks were filled up with mobile phase (acetonitrile/water/phosphoric acid [85%] 10/90/0.05 w/w/w). Column: Orbit C8, 5µm, 150x3.0mm  Validation in Acticide C1 formulation  Linearity: 9 conc, 0.91-45.29 mg/L (r=1.000)  Accuracy and repeatability: seven samples injected, 100.4±0.52%  Specificity: verified via method HPLC/UV in Acticide C1 | Validated |

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| **Analytical methods for soil** |

No methods were provided to determine C(M)IT in soil and sediment. As the degradation of C(M)IT in soil is rapid, it is acceptable. In BPR Annex III it is stated that the analytical methods 5.2 and 5.3 are to be provided if so far not covered by Annex II. The required information has already been covered by Annex II, please refer to the active substance part of the dossier. Therefore, the endpoint is waived according to BPR Annex IV 1.1 use of existing data as the required information has already been covered by Annex II, please refer to the active substance part of the dossier.

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| **Analytical methods for air** |

In BPR Annex III it is stated that the analytical methods 5.2 and 5.3 are to be provided if so far not covered by Annex II. The required information has already been covered by Annex II, please refer to the active substance part of the dossier. Therefore, the endpoint is waived according to BPR Annex IV 1.1 use of existing data as the required information has already been covered by Annex II, please refer to the active substance part of the dossier.

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| **Analytical methods for water** |

In BPR Annex III it is stated that the analytical methods 5.2 and 5.3 are to be provided if so far not covered by Annex II. The required information has already been covered by Annex II, please refer to the active substance part of the dossier. Therefore, the endpoint is waived according to BPR Annex IV 1.1 use of existing data as the required information has already been covered by Annex II, please refer to the active substance part of the dossier.

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| **Analytical methods for animal and human body fluids and tisues** |

According to assessment report CMIT/MIT PT 6:

It has been accepted that no method for determination of residues of C(M)IT and MIT in animals and human body fluids and tissues was provided, according to toxicological consideration.

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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |

According to Point 5.3 of Annex II to the BPR it is stated that analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant are not necessary if neither the active substance nor articles treated with it come into contact with food producing animals, food of plant or animal origin, or feeding stuffs. The ECHA Guidance on information requirements Version 1.1 November 2014 states in chapter 5.3 that analytical methods for residues are required, presuming that the biocidal product may come into contact with food, foodstuffs and feeding stuffs. This is always the situation for product-types 3, 4, 5 and also for certain uses of other product-types. For biocides of product-type 21 residue analytical methods must be submitted for fish and shellfish. CMIT and ACTICIDE C1 are planned to be authorized for PT 6. No applications for direct food contact are intended. Therefore, testing does not appear scientifically necessary. The study is waived according to BPR Annex. IV Nr. 1.

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| **Conclusion on the methods for detection and identificationof the product** |
| A description of analytical methods used for the analysis of the active substance in the biocidal product is available. Other methods are included in the active substance dossier where a letter of access is available. |

### Efficacy against target organisms

#### Function and field of use

ACTICIDE C1 is a biocidal product contatining the new active substance C(M)IT intended to be used for the preservation of manufactured products, other than food stuffs or feeding stuffs and cosmetics, in containers (product type 6) by the control of microbial deterioration to ensure their shelf life during storage.

ACTICIDE C1 is intended to be used as wet-state preservation of a wide range of aqueous formulations such as washing and cleaning fluids (except human hygienic products) (6.1.2), paints (6.2), additives used in paper production (6.3.1), adhesives (6.6) and various other products (6.7) such as pigment pastes, slurries, polymer dispersions and colourants. ACTICIDE C1 will be used industrially by professional workers during the manufacturing process of the formulated products. The treated articles will be used in- and outdoor by professionals and general public.

#### Organisms to be controlled and products, organisms or objects to be protected

Organisms to be controlled are bacteria, yeasts and fungi.

The applicant provided following justification for the representativeness of the tested matrices:

The intended application of the product ACTICIDE C1 in general is as in-can preservative for various formulations. Products to be preserved are aqueous formulations that are prone to microbial attack. This premise already narrows the broadness of the possible test matrices down, e.g. solvent based products do not fall under this description or products that are too viscous to be tested.

**PT 6.1.2 Washing and cleaning fluids and other detergents**

For household and detergent applications a standard dishwashing liquid (pH 5-6) was used as representative test matrix. In general, a detergent is a surfactant or a mixture of surfactants with cleaning properties in dilute aqueous solutions. All of these products, consisting of water, tensidic components and additives have the aim of cleaning which means they remove organic/inorganic compounds on hard surfaces or fibres.

Therefore, it can be said that the differences in the general properties of the various detergents are only marginal and often solely based on different dyes or perfumes which do not contribute to the needed amount of preservation.

The tested dishwashing liquid is considered to be representative for all other matrices of the PT 6.1.2 subgroup.

**PT 6.2 Paints and coatings**

Standard paints that can be found in huge quantities on the market consist in general of the following ingredients in varying amounts: water, pigments and additives (thickener, defoamer, emulsifier, binding agents, cellulose, filler).

The most common ones, especially for the industrial uses, are paints that contain titanium dioxide as pigment. This representative paint is included in a German guidance[[4]](#footnote-5). This document is the most recent “Blue Angel” testing method developed and published from BAM and UBA, in which the testing of one representative paint is the recommended testing strategy. Annex 2 of this document details a guide formulation of such a standard dispersion paint, consisting exactly of the above mentioned components, which represents the most common application.

For testing the efficacy of ACTICIDE C1 in paints and coatings, interior aqueous emulsion paint (pH 7-8 at 20°C) from a leading paint producer was used. The selected paint to be tested corresponds to the indications mentioned in the Annex of the Blue Angel testing proposal. As the tested paint is compliant with this standard formulation as proposed by the German authorities, it is considered to be representative for all other matrices of this PT 6 subgroup.

**PT 6.3.1 Fluids used in paper production**

In order to prove the efficacy in the application field for paper production, the applicant has tested a photo paper coating. According to the “Papierkompass 2018” done by the German paper industry association (Verband Deutscher Papierfabriken e.V.), the main paper types are paper for packaging, e.g. brown paper, millboard etc. (50.8%), graphic paper, e.g. LWC paper, paper for catalogues, writing paper and also photo paper (36.2%) and others which includes hygienic paper and paper / carton for specific and technical applications (13.0%). Compared to paper for packaging, graphic paper is the type of paper that requires more refinement of the finished good, and testing a coating for this kind of paper therefore represents the main application for this PT 6 subgroup.

**PT 6.6 Glues and adhesives**

According to the Guideline “Adhesive Bonding – the Right Way” (prepared by the German Adhesives industry association Industrieverband Klebstoffe e.V.) adhesives can be distinguished in four main groups:

* Chemically curing adhesives, e.g. Epoxides, Polyurethanes, Silicones, MMA adhesives…
* Physical hardening adhesives, e.g. solvent-based adhesives, dispersion adhesives (latex), colloidal systems, contact adhesives…
* Materials precoated with adhesive, e.g. self-adhesive labels, sealing films…
* Adhesives with a dual curing/hardening mechanism.

Not every adhesive group has the problem of susceptibility against microorganisms and the need for preservation. Also, it is necessary that the glue/adhesive is a liquid formulation in order to make efficacy testing technically feasible.

The products in the first group are mainly solvent-based polymer systems which contain usually only polymer, binder, curing agent, stabilizer, thixotroping agent, catalyst, additives, pigments and fillers. These products are not aqueous and therefore not prone to microbial attack. The same applies to the products in the last two groups. Therefore, only products that belong to the second group, physical hardening adhesives, are relevant for a biocidal application.

The dispersion adhesive used in the efficacy report is a very basic formulation (pH 7.1) which consists of water, binder and additives and therefore represents the main product type of adhesives belonging to the second group with a very broad application field and the problem of microbial spoilage. Testing such an adhesive therefore represents the most relevant application for this PT 6 subgroup.

**PT 6.7 Other: Polymer dispersions**

Polymer dispersions (PD) have a very broad application field as additives in paints, automobile manufacturing, sealants, adhesives, inks, packaging, coatings, varnishes, plasters and many others. A standard PD (pH 7-8.5, aqueous dispersion of a polymer based on acrylic ester and methacrylic ester) was used as representative test product for efficacy testing - an all-purpose dispersion which is used as a raw material for many of the above mentioned applications, therefore covering the broadest spectrum.

**PT 6.7 Other: Pigment pastes and Colourants**

Pigment pastes and colourants have very similar applications; they are both used to transfer coloured particles to a matrix such as paints, varnishes, textiles, paper etc. As they both differ greatly in their chemical properties, i.e. pigment pastes are water insoluble whereas colourants are water soluble, both systems have been tested.

The applications in the printing and paint industries cover the main uses for such pigments. Therefore the tested matrices are a printing paint and a tinting paste.”

**PT 6.7 Other: Slurries**

In this application field, the two major types of slurries are Titanium dioxide and Calcium carbonate slurries. Based on their composition, i.e. water content and solids content, these two types are very different and thus show different behaviour in efficacy testing. Therefore, the applicant has tested both types, covering the main application spectrum of this application.

#### Effects on target organisms, including unacceptable suffering

C(M)IT exhibits rapid inhibition of growth at low levels and cidal effects at higher levels and for longer contact periods. C(M)IT may function as a bacteristat, bactericide, fungistat and fungicide.

#### Mode of action, including time delay

C(M)IT is an isothiazolinone biocide. It uses a two steps mechanism: nucleophilic attack at the activated N-S bound of isothiazolinones by amino, amido, thiol groups of large molecular systems such as proteins or nucleic acids of the micro-organisms. Consequently there is a rapid inhibition (minutes) of growth and metabolism, followed by irreversible cell damage resulting in loss of viability (hours). Cells are inhibited by disruption of the metabolic pathways and critical physiological functions are affected (respiration, ATP synthesis).

#### Efficacy data

Applicant provided two sets of efficacy data in the course of the assessment.

* The first one includes tests with ACTICIDE C1 (1.11% C(M)IT pure), ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) and ACTICIDE M 20 (20% MIT). The applicant provided several studies, conducted with C(M)IT-MIT and/or MIT in order to justify that only C(M)IT should be considered as the active substance and propose a read-across between C(M)IT and C(M)IT-MIT
* The second one includes complementary efficacy test with ACTICIDE C1 (1.11% C(M)IT). Those data were provided after read-accross above mentioned has been rejected by eCA.

**Read accros between C(M)IT and C(M)IT- MIT (please refer to confidential PAR)**

This issue has been discussed at the WG-VI-2018, all MSs agreed to conclude that read-across between C(M)IT-MIT and C(M)IT was not acceptable.

Following discussions of the WG-VI-2018, new studies performed with ACTICIDE C1 have been submitted by the applicant in order to complete this dossier and support all claimed uses.

Results of the studies provided are presented in the table below.

Tests highlighted in grey concern ACTICIDE MV and have not been taken into account in the evaluation.

Controls: Efficacy criteria have been respected. A weak and regular growth has been observed throughout the tests but no decrease.

Note that all challenge tests have been performed with both unconditioned treated matrices and preconditioned treated matrices. Except for CaCO3 slurries, before inoculation samples were pre-conditionned by storing them at 40°C during 8 weeks in order to simulate a long storage (e.g. shipment). Preconditionned CaCO3 slurries, were samples stored at 60°C during 3 days in order to simulate storage at high temperature.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | |
| Function | Field of use envisaged | Test substance | Test organism(s) | Test method | Test system / concentrations applied / exposure time | Test results: effects | Reference |
| Bactericide  Fungicide  Yeasticide | PT 6 In-can preservative | ACTICIDE C1 (1.11% C(M)IT pure)  ACTICIDE MV (1.48% C(M)IT-MIT (3:1))  ACTICIDE M 20 (20% MIT)  ACTICIDEM 20 was used as control substance of testing MIT, to prove that no significant biocidal activity occurs in the tested range of C(M)IT. | ***BACTERIA***  *P. aeruginosa*  (ATCC 15442)  *P. aeruginosa* (ATCC 9027)  *P. aeruginosa* (customer isolate)  *S. aureus* (ATCC 6538)  ***YEAST***  *C. albicans* (ATCC 10231)  ***MOULD***  *A. brasiliensis* (ATCC 16404) | THOR test method 711 | **Tested C(M)IT a.i. concentrations (ACTICIDE C1 and ACTICIDE MV)**: 0.5 / 0.75 / 1 / 1.5 / 2 / 3 / 4 / 5 / 7.5 / 9 ppm  **Tested MIT a.i. concentrations (ACTICIDE M 20):** 10 to 800 ppm  **Liquid media:** stock solution was diluted into duplicate sterile capped test tubes pipette (1ml of each) of:  Appropriate biocide solution, 3 fold concentrated  Liquid culture medium, 3 fold concentrated  Microorganism suspension.  **Test temperature:** Yeast/Mould: 25 +/- 1°C  Bacteria: 30°C +/-1°C  **Incubation time:** Yeast/Mould: 72 hours  Bacteria: 48 hours  **Inoculum strength**  3.0 x 106 cfu/ml for each microorganism | **Bacteria**  91 mg/kg to 455 ppm ACTICIDE MV resp. ACTICIDE C1, i.e. 1.0 ppm to 5.0 ppm C(M)IT pure  For ACTICIDEM 20 a range of 125 to 325 ppm i.e. 25 mg/kg to 65 ppm MIT  **Yeasts**  136 ppm ACTICIDE MV resp.  ACTICIDE C1 i.e. 1.5 ppm C(M)IT pure  For ACTICIDEM 20: 1000 ppm, corresponding to 200 ppm MIT  **Moulds**  136 ppm ACTICIDE MV (MIT/C(M)IT 1:3) resp. ACTICIDE C1, corresponding to 1.5 ppm C(M)IT  For ACTICIDEM 20: 3750 ppm, corresponding to 750 ppm MIT | *Goldbach M (2018g)*  Report n°54446  RI = 1 |
| MG 02  preservative | PT 6.1.2 Washing and cleaning fluids (general) and other detergents | ACTICIDE C1 (1.11% C(M)IT pure)  ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *Escherichia coli*  *P. aeruginosa*  *P. putida*  *Burkholderia cepacia*  *S. aureus*  *Alcaligenes faecalis*  ***Yeasts***  *Candida valida*  *Rhodotorula rubra*  *Saccharomyces cerevisiae*  ***Moulds***  *Aspergillus oryzae*  *Cladosporium cladosporioides*  *Geotrichum candidum*  *Paecilomyces variotii*  *Penicillium ochrochloron* | Repetitive challenge test  THOR microbiological test method 720 – Wet State Bacterial Resistance Test.  THOR microbiological test method 740 – Wet State Yeasts Resistance Test  THOR microbiological test method 730 – Wet State Fungal Resistance Test | A dishwashing liquid preserved with 0.025, 0.05, 0.075 and 0.10 % (w/w)  ACTICIDE C1 or ACTICIDE MV was tested according to Thor Test Method D720, D730 and D740 and compared to a blank sample of same material.  Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested.  Efficacy criteria:  Bacteria / yeasts:  At least 105 cfu/ml or a rate of 4 or higher in the unpreserved test sample and no growth in the preserved sample.  Moulds:  At least 1 – 10 colonies on whole strike-out in the unpreserved sample and no growth or surviving spores in the preserved sample (rating 0). | **Bacteria**  0.05% (w/w) ACTICIDE C1 (5.5 ppm C(M)IT pure) as well as ACTICIDE MV (5.5 ppm C(M)IT and 1.85 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample.  **Yeasts**  0.075 % (w/w) ACTICIDE C1 (8.325 ppm C(M)IT pure) as well as ACTICIDE MV (8.33 ppm C(M)IT and 2.78 ppm MIT) were necessary for the unconditioned sample, and for the preconditioned sample.  **Moulds**  0.025 % (w/w) ACTICIDE C1 (2.78 ppm C(M)IT pure) as well as ACTICIDE MV (2.78 ppm C(M)IT and 0.95 ppm MIT) were necessary for the unconditioned sample, and for the preconditioned sample. | *Goldbach (2018a)*  Report n°51361/3  RI = 2 |
| MG 02  preservative | PT 6.1.2 Washing and cleaning fluids (general) and other detergents | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | *Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria, yeast and mould.* | THOR Test method D 700 (Screening for Microbial Contamination)  THOR Test method D 710 (Microbial Kill Dose Test) | Heavily contaminated sample was preserved with 0.025, 0.05, 0.075, 0.10, 0.15, 0.20, 0.30, 0.40 and 0.50 % (w/w) ACTICIDE MV. The sterility was checked after 2d, 7d and 14d incubation time. | ≥ 0.50% (w/w) ACTICIDE MV (55 ppm C(M)IT and 18.5 ppm MIT), added to dishwashing liquid was effective to reduce the microbial contamination after 2 days  and  ≥ 0.075% (w/w) ACTICIDE MV (8.33 ppm C(M)IT and 2.78 ppm MIT) after 7 days completely.  In the active substance dossier MIT, MIC related to bacteria is ranged from 17.5 from 750 ppm. | *Goldbach*  *(2016a)*  *Report n°51361/2*  *RI=3* |
| MG 02  preservative | PT 6.1.2 Washing and cleaning fluids (general) and other detergents | ACTICIDE C1 (1.11% C(M)IT pure) | Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria, yeast and mould. | THOR Test method D 700 (Screening for Microbial Contamination)  THOR Test method D 710 (Microbial Kill Dose Test) | Heavily contaminated sample was preserved with 0.025, 0.05, 0.075, 0.10, 0.15, 0.20, 0.30, 0.40 and 0.50 % (w/w) ACTICIDE C1. The sterility was checked after defined incubation times.  The sterility was checked after 2d, 7d and 14d incubation time. | ≥ 0.50% (w/w) ACTICIDE C1 (55 ppm C(M)IT pure), added to dishwashing liquid was effective to reduce the microbial contamination after 2 days and ≥ 0.075% (w/w) ACTICIDE C1 (8.33 ppm C(M)IT pure) after 7 days completely. | *Goldbach*  *(2018b)*  *Report n°51361/4*  RI = 2 |
| MG 02  preservative | PT 6.2  Paints and coatings | ACTICIDE C1 (1.11% C(M)IT pure)  ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *A. oryzae*  *C. cladosporioides*  *G. candidum*  *P. variotii*  *P. ochrochloron* | THOR test methods 720, 740 and 730 | An interior paint preserved with 0.05, 0.10, 0.15, 0.20, 0.30, 0.40 and 0.50 % (w/w)  ACTICIDE C1 or ACTICIDE MV was tested according to Thor Test Method D720, D730 and D740 and compared to a blank sample of same material.  Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | **Bacteria**  0.30% (w/w) ACTICIDE C1 (33.3 ppm C(M)IT pure) as well as ACTICIDE MV (33.3 ppm C(m)IT and 11.1 ppm MIT) was necessary for the unconditioned sample, and, for the preconditioned sample 0.50 % (w/w) ACTICIDE C1 (55.5 ppm C(M)IT pure) as well as ACTICIDE MV (55.5 ppm C(M)IT and 18.5 ppm MIT).  **Yeasts**  0.2 % (w/w) ACTICIDE C1 (22.2 ppm C(M)IT pure) as well as ACTICIDE MV (22.2 ppm C(M)IT and 7.4 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.30 % (w/w) ACTICIDE C1 (33.3 ppm C(M)IT pure) as well as ACTICIDE MV (33.3 ppm C(M)IT and 11.1 ppm MIT).  **Moulds**  0.05 % (w/w) ACTICIDE C1 (5.55 ppm C(M)IT) as well as ACTICIDE MV (5.55 ppm C(M)IT and 1.85 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample. | *Goldbach*  *(2018c)*  *Report n°51693/3*  *RI = 2* |
| MG 02  preservative | PT 6.2  Paints and coatings | ACTICIDE C1 (1.11% C(M)IT pure) | Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria. | THOR Test methods D 700 and D 710 | Heavily contaminated sample was preserved with 0.10, 0.25, 0.50, 0.75 and 1.00 % (w/w) ACTICIDE C1. The sterility was checked after defined incubation times.  The sterility was checked after 2d, 7d and 14d incubation time. | ≥ 1.00 % (w/w) ACTICIDE C1 (111 ppm C(M)IT pure), added to contaminated paint was effective to reduce the microbial contamination after 7 days completely. | *Goldbach*  *(2018d)*  *Report n°51696/4*  *RI = 2* |
| MG 02  preservative | PT 6.2  Paints and coatings | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | *Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria.* | THOR Test method D 700 (Screening for Microbial Contamination)  THOR Test method D 710 (Microbial Kill Dose Test) | Heavily contaminated sample was preserved with 0.10, 0.25, 0.50, 0.75 and 1.00 % (w/w) ACTICIDE MV. The sterility was checked after 2d, 7d and 14d incubation time. | ≥ 1.00 % (w/w) ACTICIDE MV (111 ppm C(M)IT and 37 ppm MIT), added to contaminated paint was effective to reduce the microbial contamination after 7 days completely.  The concentration of MIT is included in the range of MIC related to bacteria (25 à 65 ppm in the study Goldbach 2018g and 17.5 to 40 ppm in the active substance dossier MIT) | *Goldbach*  *(2017c) Report n°51696/2*  *RI = 3* |
| MG 02  preservative | PT 6.3.1 Fluids used in paper production | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *A. oryzae*  *C. cladosporioides*  *G. candidum*  *P. variotii*  *P. ochrochloron* | THOR test methods 720, 740 and 730 | A paper coating preserved with 0.05, 0.075, 0.10, 0.15 and 0.20 % (w/w) ACTICIDE MV was tested after three inoculations after 6 and 14 days for bacteria and yeasts and after 28 days for moulds and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | **Bacteria**  0.075% (w/w) ACTICIDE MV (8.33 ppm C(M)IT and 2.78 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample.  **Yeasts**  0.20 % (w/w) ACTICIDE MV (22.2 ppm C(M)IT and 7.4 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample.  **Moulds**  0.05 % (w/w) ACTICIDE MV (5.55 ppm C(M)IT and 1.9 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample. | *Goldbach*  *(2016b)*  *Report n°52837*  *RI = 3* |
| MG 02  preservative | PT 6.6 Adhesives | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *A. oryzae*  *C. cladosporioides*  *G. candidum*  *P. variotii*  *P. ochrochloron* | THOR test methods 720, 740 and 730 | An adhesive preserved with 0.05, 0.075, 0.10, 0.15, 0.20, 0.30, 0.40 and 0.50 % (w/w) ACTICIDE MV was tested after three inoculations after 6 and 14 days for bacteria and yeasts and after 28 days for moulds and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | **Bacteria**  0.30% (w/w) ACTICIDE MV (33.3 ppm C(M)IT and 11.1 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.50% (w/w) ACTICIDE MV (55.5 ppm C(M)IT and 18.5 ppm MIT).  **Yeasts**  0.20 % (w/w) ACTICIDE MV (22.2 ppm C(M)IT and 7.4 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.40 % (w/w) ACTICIDE MV (44.4 ppm CMIT and 14.8 ppm MIT).  **Moulds**  0.05 % (w/w) ACTICIDE MV (5.55 ppm C(M)IT and 1.85 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.075% (w/w) ACTICIDE MV (8.33 ppm C(M)IT and 2.78 ppm MIT). | *Goldbach*  *(2016c)*  *Report n°51731*  *RI = 3* |
| MG 02  preservative | PT 6.6 Adhesives | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria, yeast and mould. | THOR Test methods D 700 and D 710 | Heavily contaminated sample was preserved with 0.10, 0.15, 0.20, 0.30, 0.40, 0.50, 0.75 and 1.00 % (w/w) ACTICIDE MV. The sterility was checked after 2d, 7d and 14d incubation time. | **Bacteria**  ≥ 1.00% (w/w) ACTICIDE MV (111 ppm C(M)IT and 37 ppm MIT), added to an adhesive was effective to reduce the microbial contamination after 7 days and ≥ 0.40 % (w/w) ACTICIDE MV (44.4 ppm C(M)IT and 14.8 ppm MIT), after 14 days completely.  **Yeasts**  ≥ 1.00% (w/w) ACTICIDE MV (111 ppm C(M)IT and 37 ppm MIT), added to an adhesive was effective to reduce the microbial contamination after 2 days and ≥ 0.20 % (w/w) ACTICIDE MV (22.2 ppm C(M)IT and 7.4 ppm MIT), after 7 days completely.  **Moulds**  ≥ 1.00% (w/w) ACTICIDE MV (111 ppm C(M)IT and 37 ppm MIT), added to an adhesive was effective to reduce the microbial contamination after 2 days and ≥ 0.30 % (w/w) ACTICIDE MV (33.3 ppm C(M)IT and 11.1 ppm MIT), after 7 days completely.  The concentration of MIT is included in the range of MIC related to bacteria (25 à 65 ppm in the study by Goldbach 2018g and 17.5 to 40 ppm in the active substance dossier MIT) | *Goldbach*  *(2016d)*  *Report n°51731/2*  *RI = 3* |
| MG 02  preservative | PT 6.7 Polymer dispersion | ACTICIDE C1 (1.11% C(M)IT pure)  ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *A. oryzae*  *C. cladosporioides*  *G. candidum*  *P. variotii*  *P. ochrochloron* | THOR TEST METHODs 720, 740 and 730 | An acrylic waterborne polymer dispersion preserved with 0.05, 0.075 and 0.095 % (w/w)  ACTICIDE C1 or ACTICIDE MV was tested according to Thor Test Method D720, D730 and D740 and compared to a blank sample of same material.  Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | **Bacteria**  0.075% (w/w) ACTICIDE C1 (8.33 ppm C(M)IT pure) as well as ACTICIDE MV (8.33 ppm C(M)IT and 2.78 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.095% (w/w) ACTICIDE C1 (10.55 ppm C(M)IT pure) as well as ACTICIDE MV (10.55 ppm C(M)IT and 3.52 ppm MIT).  **Yeasts**  0.095% (w/w) ACTICIDE C1 (10.55 ppm C(M)IT pure) as well as ACTICIDE MV (10.55 ppm C(M)IT and 3.52 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample.  **Moulds**  0.05 % (w/w) ACTICIDE C1 (5.55 ppm C(M)IT pure) as well as ACTICIDE MV (5.55 ppm C(M)IT and 1.85 ppm MIT) were necessary for the unconditioned sample, and for the preconditioned sample. | *Goldbach*  *(2018e)*  *Report n°47314*  *RI = 2* |
| MG 02  preservative | PT 6.7 Polymer dispersion | ACTICIDE C1 (1.11% C(M)IT pure) | Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria. | THOR Test methods D 700 and D 710 | Heavily contaminated sample was preserved with 0.10, 0.25, 0.50 and 0.75 % (w/w) ACTICIDE C1. The sterility was checked after defined incubation times.  The sterility was checked after 2d, 7d and 14d incubation time. | ≥ 0.75% (w/w) ACTICIDE C1 (83.25 ppm C(M)IT pure), added to copolymer of styrene-butadiene was effective to reduce the microbial contamination after 2 days completely. | *Goldbach*  *(2018f)*  *Report n°52355/2*  *RI = 2* |
| MG 02  preservative | PT 6.7 Polymer dispersion | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | *Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria.* | THOR Test methods D 700 and D 710 | Heavily contaminated sample was preserved with 0.10, 0.25, 0.50 and 0.75 % (w/w) ACTICIDE MV. The sterility was checked after 2d, 7d and 14d incubation time. | ≥ 0.75% (w/w) ACTICIDE MV (83.25 ppm C(M)IT and 27.8 ppm MIT), added to polymer dispersion was effective to reduce the microbial contamination after 2 days completely.  The concentration of MIT is included in the range of MIC related to bacteria (25 à 65 ppm in the study Goldbach 2018g and 17.5 to 40 ppm in the active substance dossier MIT) | *Goldbach*  *(2016e)*  *Report n°52355*  *RI = 3* |
| MG 02  preservative | PT 6.7 Colourants | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *A. oryzae*  *C. cladosporioides*  *G. candidum*  *P. variotii*  *P. ochrochloron* | THOR TEST METHODs 720, 740 and 730 | A colourant preserved with 0.05 0.10, 0.20, 0.30 and 0.40 % (w/w) ACTICIDE MV was tested after three inoculations after 6 and 14 days for bacteria and yeasts and after 28 days for moulds and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | **Bacteria**  0.10% (w/w) ACTICIDEMV (11.1 ppm C(M)IT and 3.7 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.40% (w/w) ACTICIDEMV (44.4 ppm C(M)IT and 14.8 ppm MIT).  **Yeasts**  0.20% (w/w) ACTICIDEMV (22.2 ppm C(M)IT and 7.4 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.40% (w/w) ACTICIDEMV (44.4 ppm C(M)IT and 14.8 ppm MIT).  **Moulds**  0.05 % (w/w) ACTICIDEMV (5.55 ppm C(M)IT and 1.85 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample. | *Goldbach*  *(2016f)*  *Report n°52950*  *RI = 3* |
| MG 02  preservative | PT 6.7 Pigment paste | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *Mucor spec. (Thor isolate 161)*  *Fusarium spec. (Thor isolate 160)*  *Aspergillus spec. (Thor isolate 102)* | THOR TEST METHODs 720, 740 and 730.2 Wet State Fungal Resistance Test (Agar plate method Colorants and pigment pastes) | A pigment paste preserved with 0.10, 0.15, 0.20, 0.30, 0.40, 0.50, 0.75 and 1.0 % (w/w) ACTICIDE MV was tested after three inoculations after 6 and 14 days for bacteria and yeasts and after 28 days for moulds and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested.  The sterility was checked after 24h, 48h and 72h incubation time. | **Bacteria**  0.40% (w/w) ACTICIDEMV (44.4 ppm C(M)IT and 14.8 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.75% (w/w) ACTICIDEMV (83.25 ppm C(M)IT and 27.8 ppm MIT).  **Yeasts**  0.15% (w/w) ACTICIDEMV (16.65 ppm C(M)IT and 5.55 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.30% (w/w) ACTICIDEMV (33.3 ppm C(M)IT and 11.1 ppm MIT).  **Moulds**  0.20 % (w/w) ACTICIDEMV (22.2 ppm C(M)IT and 7.4 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample 0.40% (w/w) ACTICIDEMV (44.4 ppm C(M)IT and 14.8 ppm MIT).  The concentration of MIT is included in the range of MIC related to bacteria (25 à 65 ppm in the study Goldbach 2018g and 17.5 to 40 ppm in the active substance dossier MIT) | *Goldbach*  *(2016g)*  *Report n°51921*  *RI = 3* |
| MG 02  preservative | PT 6.7 Pigment paste | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria, yeast and mould. | THOR Test methods D 700 and D 710 | Heavily contaminated pigment pastes, contaminated by yeasts and moulds or contaminated by bacteria were preserved with 0.025, 0.05, 0.10, 0.25, 0.50, 0.75 and 1.0 % (w/w) ACTICIDE MV. The sterility was checked after 2d, 7d and 14d incubation time. | Bacteria  0.75 % (w/w) ACTICIDE MV (83.3 ppm CIT and 27.8 MIT), and 1.00 % (w/w) ACTICIDE MV (111 ppm C(M)IT and 37 ppm MIT),, was effective to reduce the bacterial contamination after 14 days completely.  Yeasts  ≥ 0.10% (w/w) ACTICIDE MV (11.1 ppm C(M)IT and 3.7 ppm MIT) was effective to reduce the contamination of yeasts after 2 days and ≥ 0.05% (w/w) ACTICIDE MV after 7 days completely.  Moulds  ≥ 0.05% (w/w) ACTICIDE MV (5.55 ppm C(M)IT and 1.85 ppm MIT) reduced the mould contamination after 2days completely.  The concentration of MIT is included in the range of MIC related to bacteria (25 à 65 ppm in the study by Goldbach 2018g and 17.5 to 40 ppm in the active substance dossier MIT) | *Goldbach*  *(2016h)*  *Report n°51812*  *RI = 3* |
| MG 02  preservative | PT 6.7 Slurries: CaCO3 | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis* | THOR TEST METHOD 720 | Calcium carbonate slurry preserved with 0.01, 0.02, 0.03, 0.05, 0.075, 0.10, 0.15, 0.20, 0.25 and 0.30 % (w/w) ACTICIDE MV was tested after three inoculations after **24 to 72h** for bacteria and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 3 days at 60°C in hermetic sealed vessels, were tested. | **Bacteria**  0.15% (w/w) ACTICIDEMV (16.65 ppm C(M)IT and 5.55 ppm MIT) was necessary for the unconditioned sample, and for the preconditioned sample the highest concentration of 0.30% (w/w) ACTICIDEMV (33.3 ppm C(M)IT and 11.1 ppm MIT) was not efficient enough. | *Goldbach*  *(2016i)*  *Report n°51598/2*  *RI = 3* |
| MG 02  preservative | PT 6.7 Slurries: CaCO3 | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | Not applicable – purpose of the test was to reduce an existing microbial contamination of bacteria. | THOR Test methods D 700 and D 710 | Heavily contaminated calcium carbonate slurry was preserved with 0.01, 0.02, 0.025 and  0.03% (w/w) ACTICIDE MV. The sterility was checked after 2d, 7d and 14d incubation time. | 0.03% (w/w) ACTICIDE MV (3.33 ppm C(M)IT and 1.11 ppm MIT), added to calcium carbonate slurry was effective to reduce the bacterial contamination after 2 days completely. | *Goldbach*  *(2016j)*  *Report n°51598*  *RI = 3* |
| MG 02  preservative | PT 6.7 Slurries: TiO2 | ACTICIDE MV (1.48% C(M)IT-MIT (3:1)) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis* | THOR TEST METHOD 720 | Titanium dioxide slurry preserved with 0.0125, 0.025, 0.05, 0.075, 0.10 and 0.15% (w/w) ACTICIDE MV was tested after three inoculations after 24 to 72h for bacteria and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | Without preconditioning: 0.025 % (w/w) ACTICIDE MV (2.78 ppm C(M)IT and 0.93 ppm MIT)  With preconditioning:0.15% (w/w) ACTICIDE MV (16.65 ppm C(M)IT and 5.55 ppm MIT) | *Goldbach*  *(2016k)*  *Report n°51600*  *RI = 3* |

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| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | | |
| Function | Field of use envisaged | Test substance | Test organism(s) | Test method | Test system / concentrations applied / exposure time | Test results: effects | Reference |
| MG 02  preservative | PT 6.3.1 Fluids used in paper production | ACTICIDE C1 (1.11% C(M)IT pure) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *A. oryzae*  *C. cladosporioides*  *G. candidum*  *P. variotii*  *P. ochrochloron* | THOR test methods 720, 740 and 730 | A paper coating preserved with 0.05, 0.075, 0.10, 0.15 and 0.20 % (w/w) ACTICIDE C1 was tested after three inoculations after 6 and 14 days for bacteria and yeasts and after 28 days for moulds and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | **Bacteria**  0.075% (w/w) ACTICIDE C1 (8.33 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample.  **Yeasts**  0.20 % (w/w) ACTICIDE C1 (22.2 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample.  **Moulds**  0.05 % (w/w) ACTICIDE C1 (5.55 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample. | *Goldbach*  *(2018g)*  *Report n°52837-3*  *RI = 2* |
| MG 02  preservative | PT 6.6 Glues and Adhesives | ACTICIDE C1 (1.11% C(M)IT pure) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *A. oryzae*  *C. cladosporioides*  *G. candidum*  *P. variotii*  *P. ochrochloron* | THOR test methods 720, 740 and 730 | An adhesive preserved with 0.05, 0.075, 0.10, 0.15, 0.20, 0.30, 0.40 and 0.50 % (w/w) ACTICIDE C1 was tested after three inoculations after 6 and 14 days for bacteria and yeasts and after 28 days for moulds and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | **Bacteria**  0.30% (w/w) ACTICIDE C1 (33.3 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample 0.50% (w/w) ACTICIDE C1 (55.5 ppm C(M)IT pure).  **Yeasts**  0.20 % (w/w) ACTICIDE C1 (22.2 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample 0.40 % (w/w) ACTICIDE C1 (44.4 ppm C(M)IT pure).  **Moulds**  0.05 % (w/w) ACTICIDE C1 (5.55 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample 0.075% (w/w) ACTICIDE C1 (8.33 ppm C(M)IT pure). | *Goldbach*  *(2018h)*  *Report n°51731-3*  *RI = 2* |
| MG 02  preservative | PT 6.7 Colourants | ACTICIDE C1 (1.11% C(M)IT pure) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *A. oryzae*  *C. cladosporioides*  *G. candidum*  *P. variotii*  *P. ochrochloron* | THOR TEST METHODs 720, 740 and 730 | A colourant preserved with 0.05 0.10, 0.20, 0.30 and 0.40 % (w/w) ACTICIDE C1 was tested after three inoculations after 6 and 14 days for bacteria and yeasts and after 28 days for mould and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | **Bacteria**  0.10% (w/w) ACTICIDE C1 (11.1 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample 0.40% (w/w) ACTICIDE C1 (44.4 ppm C(M)IT pure).  **Yeasts**  Efficacy against yeasts is not validated. At 0.20%, 0.30% and 0.4% there is growth in the unconditioned samples until 6 days after the 3rd inoculum. However, there is no growth in the pre-conditionned sample at 0.40%.  **Moulds**  0.05 % (w/w) ACTICIDEC1 (5.55 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample. | *Goldbach*  *(2018i)*  *Report n°52950-2*  *RI = 2* |
| MG 02  preservative | PT 6.7 Pigment paste | ACTICIDE C1 (1.11% C(M)IT pure) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis*  ***Yeasts***  *C. valida*  *R. rubra*  *S. cerevisiae*  ***Moulds***  *Mucor spec. (Thor isolate 161)*  *Fusarium spec. (Thor isolate 160)*  *Aspergillus spec. (Thor isolate 102)* | THOR TEST METHODs 720, 740 and 730.2. | A pigment paste preserved with 0.10, 0.15, 0.20, 0.30, 0.40, 0.50, 0.75 and 1.0 % (w/w) ACTICIDE C1 was tested after three inoculations after 6 and 14 days for bacteria and yeasts and after 28 days for moulds and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested.  The sterility was checked after 24h, 48h and 72h incubation time. | **Bacteria**  0.40% (w/w) ACTICIDE C1 (44.4 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample 0.75% (w/w) ACTICIDE C1 (83.25 ppm C(M)IT pure).  **Yeasts**  0.15% (w/w) ACTICIDE C1 (16.65 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample 0.30% (w/w) ACTICIDE C1 (33.3 ppm C(M)IT pure).  **Moulds**  0.20 % (w/w) ACTICIDE C1 (22.2 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample 0.40% (w/w) ACTICIDE C1 (44.4 ppm C(M)IT pure). | *Goldbach*  *(2018j)*  *Report n°51921-2*  *RI = 2* |
| MG 02  preservative | PT 6.7 Slurries: CaCO3 | ACTICIDE C1 (1.11% C(M)IT pure) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis* | THOR TEST METHOD 720 | Calcium carbonate slurry preserved with 0.01, 0.02, 0.03, 0.05, 0.075, 0.10, 0.15, 0.20, 0.25 and 0.30 % (w/w) ACTICIDE C1 was tested after three inoculations after **24 to 72h** for bacteria compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 3 days at 60°C in hermetic sealed vessels, were tested. | **Bacteria**  0.020% (w/w) ACTICIDEC1 (2.22 ppm C(M)IT pure) was necessary for the unconditioned sample, and for the preconditioned sample the highest concentration of 0.30% (w/w) ACTICIDE C1 (33.3 ppm C(M)IT pure) was not efficient enough. | *Goldbach*  *(2018k)*  *Report n°51598-3*  *RI = 2* |
| MG 02  preservative | PT 6.7 Slurries: TiO2 | ACTICIDE C1 (1.11% C(M)IT pure) | ***Bacteria***  *E. coli*  *P. aeruginosa*  *P. putida*  *B. cepacia*  *S. aureus*  *A. faecalis* | THOR TEST METHOD 720 | Titanium dioxide slurry preserved with 0.0125, 0.025, 0.05, 0.075, 0.10 and 0.15% (w/w) ACTICIDE C1 was tested after three inoculations after **24 to 72h** for bacteria and compared to a blank sample of same material. Parallel unconditioned (u. c.) and preconditioned (c.) samples, stored for 8 weeks at 40°C in hermetic sealed vessels, were tested. | Without preconditioning: 0.025 % (w/w) ACTICIDE C1 (2.78 ppm C(M)IT pure)  With preconditioning: 0.10% (w/w) ACTICIDE C1 (11.1 ppm C(M)IT pure). | *Goldbach*  *(2018l)*  *Report n°51600-2*  *RI = 2* |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| FR CA concludes that efficacy of the product ACTICIDE C1 (1.11% C(M)IT pure) has been demonstrated for the preservation of washing and cleaning fluids (general) and other detergents (PT 6.1.2), paints and coatings (PT 6.2), Fluids used in paper production (PT 6.3.1), Glues and Adhesives (PT 6.6), polymer dispersion (PT 6.7) and Pigment paste (PT 6.7) against bacteria, yeasts and fungi; and for the preservation of TiO2 slurries (PT 6.7) against bacteria.  Considering the results of the challenge tests performed with:  - colourants where efficacy against yeasts in the unconditioned samples is not sufficiently demonstrated at the highest dose of 0.4% but demonstrated in the preconditioned samples at the dose of 0.4%;  - CaCO3 slurry where efficacy against bacteria in the preconditioned samples is not sufficiently demonstrated at the highest dose of 0.3% but demonstrated in the unconditioned sample at 0.20%;  Efficacy of the product ACTICIDE C1 for these applications will be validated pending the submission of new data (with and without preconditioning) at the submission of the authorisation application.  Taking into account all submitted data, preservative efficacy of the product ACTICIDE C1 (1.11% C(M)IT pure) has been demonstrated for the uses described in section 2.2.5.8 below. |

#### Occurrence of resistance and resistance management

The organisms with most frequently reported resistance to isothiazolones are Gram-negative bacteria, such as *Pseudomonas, Enterobacter* and *Burkholderia*. In the literature, resistance to increasing levels of isothiazolones was shown for bacteria adapted in lab cultures. At this stage of the knowledge, the mechanisms known to be involved in the resistance to isothiazolones are those already known for other molecules, namely the loss of permeability (loss of specific outer membrane proteins (porins)), the increase of the efflux (over-expression of genes producing efflux pumps) and the responses to stress. Depending on the authors, adaptation phenomena induced during exposure of bacteria can be stable or unstable, and may lead to resistance. it is important to emphasize that the use of preservatives induce a continuous contact between active substances and microorganisms, leading to a pressure of selection that maintains this adapted state whatever the stability of the phenomenon. It is also reported that microorganisms deemed resistance to isothiazolones have also shown varying degrees of cross-resistance to other Biocides and to antibiotics.

In conclusion, in the litterature, resistance to increasing levels of isothiazolones was shown for bacteria adapted in lab cultures. Depending on the authors, adaptation phenomena induced during exposure of bacteria can be stable or unstable, and may lead to resistance. It is important to emphasize that the use of preservatives induce a continuous contact between active substances and microorganisms, leading to a pressure of selection that maintains this adapted state whatever the stability of the phenomenon.

if the applicant becomes aware of any reports of resistance to the active substance and/or the products these should be reported to appropriate bodies (e.g. the efficacy working group and/or concerned member states) so that it can be determined if further action is required

Resistance should be managed at the renewal of authorisation with appropriate guidelines.

#### Known limitations

Due to the chemical properties of C(M)IT biocidal products containing this active are known to be sensitive to elevated temperatures and pH values (alkaline conditions).

#### Evaluation of the label claims

Following uses and application rates can be validated:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Unconditioned  [c(m)it] in ppm | | | Preconditioned[[5]](#footnote-6)  [c(m)it] en ppm | | |
| Bacteria | Yeasts | Fungi | Bacteria | Yeasts | Fungi |
| Washing and cleaning fluids (general) and other detergents (PT 6.1.2) | 5.55 | 8.33 | 2.78 | 5.55 | 8.33 | 2.78 |
| Paints and coatings (PT 6.2) | 33.3 | 22.2 | 5.55 | 55.5 | 33.3 | 5.55 |
| Polymer dispersion (PT 6.7) | 8.33 | 10.55 | 5.55 | 10.55 | 10.55 | 5.55 |
| Fluids used in paper production (PT 6.3.1) | 8.33 | 22.2 | 5.55 | 8.33 | 22.2 | 5.55 |
| Glues and Adhesives (PT 6.6) | 33.3 | 22.2 | 5.55 | 55.5 | 44.4 | 8.33 |
| Pigment paste (PT 6.7) | 44.4 | 16.65 | 22.2 | 83.25 | 33.3 | 44.4 |
| Colourants (PT 6.7) | 11.1 | (44.4)\* | 5.55 | 44.4 | 44.4 | 5.55 |
| Slurries: CaCO3 (PT 6.7) | 2.22 |  |  | (33.3)\* |  |  |
| Slurries: TiO2 (PT 6.7) | 2.78 |  |  | 11.1 |  |  |

\*Efficacy against yeasts in colourants and against bacteria in CaCO3 slurries is validated under the condition of the submission of new data (with and without preconditioning) in the application for non-provisional authorisation.

Following instruction will be added in the SPC:

The duration and storage conditions of the preserved matrices may impact the efficacy of the product, microbiological tests should be conducted to determine the appropriate application rate without exceeding the maximum authorised application rate.

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

According to the applicant, biocidal products formulated with C(M)IT are used in the final application in combination with a wide variety of biocidal products with other actives, such as BIT, Bronopol or TMAD.

However, as efficacy in combination with other biocidal products as not been demonstrated, the product is not intended to be used with other biocidal products.

### Risk assessment for human health

#### Assessment of effects on Human Health

No specific toxicological data have been provided on the product ACTICIDE C1. The classification of the product has therefore been determined by applying the calculation rules laid down in the regulation 1272/2008 (CE).

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Corrosive to skin |
| Justification for the value/conclusion | A SCL ≥ 0.45% for skin corrosion has been set for the active substance C(M)IT.  The product containing a content of C(M)IT higher than 0.45%, the classification for skin corrosion is required. |
| Classification of the product according to CLP | Skin Corr. 1C – H314 |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Eye damages |
| Justification for the value/conclusion | A SCL ≥ 0.45% for skin corrosion (including eye damages) has been set for the active substance C(M)IT.  The product containing a content of C(M)IT higher than 0.45%, the classification for eye damages is required. |
| Classification of the product according to CLP | Eye Dam. 1 – H318 |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The product ACTICIDE C1 is classified for skin corrosion.  Considering the low content of a.s in the product, no acute inhalation toxicity is foreseen. Inhalation exposure to the product containing 1.11% being expected, a labelling EUH071 is required. |
| Classification of the product according to CLP | EUH071: Corrosive to the respiratory tract. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Skin sensitizer |
| Justification for the value/conclusion | A SCL > 15 ppm for skin sensitization has been set for the active substance C(M)IT. The content of a.s in the product ACTICIDE C1 is higher than 15 ppm, a classification for skin sensitization is therefore required. |
| Classification of the product according to CLP | Skin Sens. 1A – H317 |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitization |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitization. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Oral acute toxicity |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for oral acute toxicity. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Inhalation acute toxicity |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal acute toxicity |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for dermal acute toxicity. |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | C(M)IT |
| Value(s)\* | 50% for non corrosive concentration  100% for corrosive concentration (≥ 0.45%) |
| Justification for the selected value(s) | These values have been set for active substance C(M)IT and its representative product ACTICIDE C1. |

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

The product contains no substance of concern according to the definition of a SoC laid down in the BPR Guidance Volume III HH Part B&C Risk Assessment (December 2017).

***Available toxicological data relating to a mixture***

None

***Other***

None

#### Exposure assessment and Risk characterization

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

For PT 6 applications, primary exposure is related to the addition of preservatives into product to be preserved (industrial users).

Secondary exposure is divided in two parts:

* Secondary (direct) exposure that is related to the use of product to be preserved by professional and non-professional users;
* Secondary (indirect) exposure that is related to the incidental exposure to the product to be preserved (general public).

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: relevant paths of human exposure** | | | | | | | | | | | |
|  | **Primary (direct) exposure** | | | **Secondary (direct) exposure** | | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | Yes | n.a | n.a | n.a | Yes | Yes | n.a | n.a | No | Yes | n.a |
| Dermal | Yes | n.a | n.a | n.a | Yes | Yes | n.a | n.a | No | Yes | n.a |
| Oral | No | n.a | n.a | n.a | No | No | No | n.a | No | Yes | Yes |

**Reference values used for the Risk characterization**

* AEL determination

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | 90-d dog study | 16.5 mg pure C(M)IT /kg bw/d | 100 | 50% | **0.083 mg pure C(M)IT/kg bw/d** |
| AELmedium-term |
| AELlong-term | 2-y rat study | 12.9 mg pure C(M)IT /kg bw/d | 100 | 50% | **0.065 mg pure C(M)IT /kg bw/d** |
| ARfD | Developmental rat study  (gavage) | 3 pure C(M)IT /kg bw/d | 100 | n.a | **0.03 mg pure C(M)IT /kg bw/d** |
| ADI | 2-y rat study (drinking water) | 1.5 pure C(M)IT /kg bw/d | 100 | n.a | **0.015 mg pure C(M)IT /kg bw/d** |

1 Default factor of 10 for interspecies variability and intraspecies variability

* AEC determination

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEC** | **AF1** | **Correction for oral absorption** | **Value** |
| **AEC Short Term** | 90-d inhalation rat study | 0.26 mg  pure C(M)IT /m3 | 8 | n.a | **0.032 mg  pure C(M)IT /m3** |
| **AEC Medium Term** |
| **AEC Long Term** | 16 | **0.016 mg  pure C(M)IT /m3** |
| **AEC Long Term (8h TWA)** | 0.26 x 6h/8h = 0.195 mg  **pure C(M)IT** /m3 | **0.012 mg  pure C(M)IT /m3** |

1 For short and medium term AEC values, an assessment factor of 8 is proposed taking into account:

* an interspecies variability factor of 2.5 because only local effects were observed and therefore, due to the local effect at the port of entry, toxicokinetics do not contribute to interspecies differences;
* an intraspecies variability factor of 3.2 since toxicokinectics does not contribute to intraspecies differences and it is therefore reduced to 1.

For long-term AEC, an additional time duration extrapolation factor of 2 is proposed from sb-chronic to chronic.

*Systemic effects*

It is evident from a range of repeated dose toxicity studies that isothiazolinones cause point of contact toxicity in form of irritation and/or corrosion and that systemic toxicity is secondary to the local effects. However, in accordance with the assessment already performed for other isothiazolinones, a systemic risk assessment has been performed for the active substance C(M)IT and therefore for product ACTICIDE C1.

**List of scenarios**

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Mixing/ loading | Primary exposure.  Automated loading of a liquid biocidal product into products to be preserved. | Industrial worker. |
| 2. | Mixing/ loading | Primary exposure.  Manual loading of a liquid biocidal product into products to be preserved. | Industrial worker. |
| 3. | Mixing/ loading | Primary exposure.  Filling of preserved formulation. | Industrial worker. |
| **Washing and cleaning fluids (general) and other detergents** | | | |
| 4. | Application exposure | Secondary exposure.  Use of detergents during hand washing laudry. | Professionals,  Non-professionals |
| 5 | Application exposure | Secondary exposure.  Use of detergents during pre-treatment of clothes | Professionals,  Non-professionals |
| 6 | Application exposure | Secondary exposure.  Use of detergents during hand dishwashing. | Professionals,  Non-professionals |
| 7 | Application exposure | Secondary exposure.  Use of detergents during surface cleaning (household). | Professionals,  Non-professionals |
| 8 | Post-application exposure | Secondary exposure.  Exposure towards residues of the AS on textiles. | General public |
| 9 | Post-application exposure | Secondary exposure.  Exposure towards residues of the AS on ustensils and dishware. | General public |
| 10 | Post-application exposure | Secondary exposure.  Exposure towards residues of the AS on surfaces | General public |
| **Paints and coatings** | | | |
| 11 | Application exposure | Secondary exposure.  Spraying paints and coatings. | Professionals,  non-professionals |
| 12 | Application exposure | Secondary exposure.  Applying paints and coatings with brush or roller. | Professionals,  non-professionals |
| 13 | Application exposure | Secondary exposure.  Applying plaster via airless spraying and then working with trowels. | Professionals,  non-professionals |
| 14 | Post-application exposure | Secondary exposure.  Dermal exposure from direct contact with C(M)IT in wet paint and oral exposure from hand to mouth transfer . | General public |
| 15 | Post-application exposure | Secondary exposure.  Dermal exposure from direct contact with C(M)IT in dried paint and oral exposure from hand to mouth transfer | General public |
| 16 | Post-application exposure | Secondary exposure  Ingestion of painted chips by toddler | General public |
| 17 | Post-application exposure | Secondary exposure.  Inhalation of volatilized residues | General public |
| **Additives used in paper production** | | | |
| 18 | Application exposure | Secondary exposure.  Use of preserved additives in paper production. | Professionals |
| **Glues and adhesives** | | | |
| 19 | Application exposure | Secondary exposure.  Use of preserved glues and adhesives. | Professionals,  non-professionals |
| **Preservation of polymer dispersions, pigment paste and colourants** | | | |
| 20 | Application exposure | Secondary exposure.  Use of preserved polymer dispersions, pigment paste and colourants. | Professionals |
| **Preservation of slurries** | | | |
| 21 | Application exposure | Secondary exposure.  Use of preserved mineral and pigment slurries. | Professionals |

|  |
| --- |
| For each exposure scenarios considered below, both external and internal exposures were calculated for all routes, in order to estimate the risk for local and systemic effects.  Dermal external exposure is expressed as concentration of the pure C(MI)T deposed on skin (ppm).  Inhaled external exposure is expressed as the pure C(M)IT concentration in inhaled air.  Concentration during task as well as daily mean concentration, i.e. 8-hour time weighted average (TWA), is calculated for chronic effects for professionnals. |

**INDUSTRIAL Exposure**

**Scenario [1] - Primary exposure: Automated loading of a liquid biocidal product into products to be preserved**

| ***Description of Scenario [1]*** | | | | |
| --- | --- | --- | --- | --- |
| The IBC with the BP, ACTICIDE C1 (1.1% C(M)IT), is directly attached to the process tanks where the formulation is mixed with the BP solution. The BP is pumped automatically into these process tanks. Exposure only occurs during attaching and detaching of the transfer lines.  Exposure potential is predominantly to the hands, resulting from accidental touching of contaminated surfaces.  Inhalation exposure to C(M)IT is considered negligible because the process is automated..  To assess dermal exposure during automated loading of ACTICIDE C1 into process tanks, the Connecting Line model from RISKOFDERM Toolkit has been used as recommended in HEEG Opinion 1.  The indicative exposure value from the model is 0.92 mg pb/min.  An exposure duration of 15 min/event and 4 events/day is considered (Applicant’s data). | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of pure C(M)IT in the product ACTICIDE C1 | 1.11% | Applicant’s data |
| Exposure value from the model (mg/min) | 0.92 | HEEG Opinion 1 |
| Exposure duration (min/event) | 15 | Applicant’s data |
| Frequency of exposure (event/day) | 4 | Applicant’s data |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 100% (corrosive concentration) | Active substance data |
| **Tier 22** | Gloves penetration factor | 10% | HEEG Opinion 9 |

**Calculations for Scenario [1]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1] | Tier 1/no PPE | negligible | 1.02 x 10-2 | - | 1.02 x 10-2 |
| Scenario [1] | Tier 2/ PPE (gloves) | negligible | 1.02 x 10-3 | - | 1.02 x 10-3 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [1] | Tier 1/no PPE | negligible | negligible | 11 100 |

**Scenario [2] – Primary exposure: Manual loading of a liquid biocidal product into products to be preserved**

| ***Description of Scenario [2]*** | | | | |
| --- | --- | --- | --- | --- |
| Exposure of the industrial worker to the BP may occur during manual dosing of the BP from the IBC to a receiving vessel for transport.  Exposure potential is predominantly to the hands, resulting from accidental touching of contaminated surfaces.  Inhalation exposure to C(M)IT during manual product transfer is also considered.  To assess dermal and inhalation exposure during manual loading of ACTICIDE C1, the Mixing and Loading Model 7 from TNsG 2008 has been used as recommended in HEEG Opinion 1.  The indicative exposure value from the model are as follows :   * 101 mg/min (total body without gloves) ; * 1.01 mg/min (total body with clothes and gloves) ; * 0.94 mg/m3 (inhalation).   An exposure duration of 15 min/event and 4 events/day is considered (Applicant’s data). | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of pure C(M)IT in the product ACTICIDE C1 | 1.11% | Applicant’s data |
| Exposure value from the model | 101 mg/min (total body)  0.94 mg/m3 (inhalation) | HEEG Opinion 1 |
| Exposure duration (min/event) | 15 | Applicant’s data |
| Frequency of exposure (event/day) | 4 | Applicant’s data |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 100% (corrosive concentration) | Active substance data |
| **Tier 22** | Exposure value from the model | 1.01 mg/min (total body)  0.94 mg/m3 (inhalation) | HEEG Opinion 1 |
| Gloves penetration factor | Included in the model | - |
| Coverall penetration factor (impermeable coverall) | Included in the model | - |

**Calculations for Scenario [2]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [2] | Tier 1/no PPE | 2.17 x 10-4 | 1.12 | - | 1.12 |
| Scenario [2] | Tier 2/ PPE (impermeable coverall + gloves) | 2.17 x 10-4 | 1.12 x 10-2 | - | 1.14 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT /m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [2] | Tier 1/no PPE | 1.04 x 10-2 | 1.3 x 10-3 | 11 100 |

**Scenario [3] – Primary Exposure: Filling of preserved formulation**

| ***Description of Scenario [3]*** | | | | |
| --- | --- | --- | --- | --- |
| The exposure of industrial workers operating a filling line for filling the preserved formulations into buckets or drums that are supplied to the end user is considered.  Information on the filling task and respective exposure were found in the study used in BEAT (data base for TNsG version 2) for scenarios Loading and Filling DEGBE.  For body exposure and Tier 1 of hand exposure, 95th percentile indicative values were chosen, as recommended by the software; for Tier 2 of hand exposure, the 27th from 30 values was chosen, considering that the higher three values were outliers[[6]](#footnote-7) .  Exposure via inhalation during filling task was considered negligible because of very low potential to volatilization and aerosol formation. Indeed, the partial vapour pressure of C(M)IT at 20°C is very low: 1.6 Pa; and would be even lower in preserved products. As such, there is only a slight potential for volatilization of the a.i. during the filling process. Moreover, the presence of general or Local Exhaust Ventilation (LEV), and (semi-) closed systems, will maintain airborne concentrations of all volatile constituents to a minimum, and prevent significant formation and dispersion of aerosol.  The indicative exposure values from the model are as follows :   * 6.19 mg/min (body) ; * 389 mg/min (hands in Tier 1) ; * 88.6 mg/min (hands in Tier 2). | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of pure C(M)IT in the product to be preserved | Up to 0.04% pure C(M)IT (400 ppm pure C(M)IT) | Applicant’s data |
| Exposure value from the model | 6.19 mg/min (total body)  389 mg/min (hands) | BEAT model |
| Exposure duration (min) | 360 | Applicant’s data |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |
| **Tier 2** | Exposure value from the model | 88.6 mg/min (hands) | HEEG Opinion 1 |
| Gloves penetration factor | 10% | HEEG Opinion 9 |
| Impermeable coverall | 5% | HEEG Opinion 9 |

**Calculations for Scenario [3]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [3] | Tier 1/no PPE | negligible | 4.74 x 10-1 | - | 4.74 x 10-1 |
| Scenario [3] | Tier 2/ PPE (impermeable + gloves) | negligible | 1.10 x 10-2 | - | 1.10 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT /m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [3] | Tier 1/no PPE | negligible | negligible | Max 400 |

**Combined Exposure: Scenario [1,3] and [2,3]**

Formulators may be involved in both tasks (loading ACTICIDE C1 in prodcut to be preserved and filling preserved product into vessels).

**Calculations for Scenario [1,3]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1,3] | Tier 1/no PPE | negligible | 4.84 x 10-1 | - | 4.84 x 10-1 |
| Scenario [1,3] | Tier 2/ PPE (Impermeable coverall + gloves) | negligible | 1.20 x 10-2 | - | 1.20 x 10-2 |

**Calculations for Scenario [2,3]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [2,3] | Tier 1/no PPE | 2.17 x 10-4 | 1.6 | - | 1.6 |
| Scenario [2,3] | Tier 2/ PPE (impermeable coverall + gloves) | 2.17 x 10-4 | 2.22 x 10-2 | - | 2.24 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [1,3] | Tier 1/no PPE | negligible | negligible | n.a |
| Scenario [2,3] | Tier 1/no PPE | 1.04 x 10-2 | 1.3 x 10-3 | n.a |

No cleaning and maintenance phase has been presented following the same approach than for the active substance C(M)IT/MIT. In-can preservative is typically supplied in one metric tonne intermediate bulk containers (IBC), 20 kg pails, or 110 kg drums, and these vessels are sited in a dedicated storage area. In many cases, IBC will be connected (via a dry-break coupling system) to dedicated pipework which will allow charging of a day vessel or blend tank via a volumetric metering system. For smaller lines, the transfer can be done manually.

**Risk characterization for Industrial users**

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [1]**  Automated loading | Tier 1/no PPE | 0.065 | 1.02 x 10-2 | 15.7 | yes |
| **Scenario [2]**  Manual loading | Tier 1/no PPE | 0.065 | 1.12 | 1725 | **No** |
| Tier 2/PPE (gloves + impermeable coverall) | 0.065 | 1.14 x 10-2 | 17.6 | yes |
| **Scenario [3]**  Filling product to be preserved with 400 ppm pure C(M)IT | Tier 1/no PPE | 0.065 | 4.74 x 10-1 | 729 | **No** |
| Tier 2/PPE (gloves + impermeable coverall) | 0.065 | 1.10 x 10-2 | 16.9 | yes |
| **Scenario [1,3]** | Tier 1/no PPE | 0.065 | 4.84 x 10-1 | 745 | **No** |
| Tier 2/PPE (gloves + impermeable coverall) | 0.065 | 1.20 x 10-2 | 18.5 | Yes |
| **Scenario [2,3]** | Tier 1/no PPE | 0.065 | 1.60 | 2455 | **No** |
| Tier 2/PPE (gloves + impermeable coverall) | 0.065 | 2.24 x 10-2 | 34.5 | yes |

* Considering a maximal concentration of 400 ppm of pure C(M)IT, the risk is considered acceptable for manual/automated mixing and loading and filling, and for the combined scenario, provided wear gloves and impermeable coverall during manual mixing and loading and filling.

*Local effects*

* Quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3 (8h TWA)** | **Estimated Inhalation Concentration**  **(mg/m3)** | **Estimated Concentration/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [1]**  Automated loading | Tier 1/no PPE | 0.012 | negligible | negligible | yes |
| **Scenario [2]**  Manual loading | Tier 1/no PPE | 0.012 | 1.3 x 10-3 | 10.9 | yes |
| **Scenario [3]**  Filling product to be preserved with 400 ppm a.i | Tier 1/no PPE | 0.012 | negligible | negligible | yes |
| **Scenario [1,3]** | Tier 1/no PPE | 0.012 | negligible | negligible | yes |
| **Scenario [2,3]** | Tier 1/no PPE | 0.012 | 1.3 x 10-3 | 10.9 | yes |

* No unacceptable risk is observed for local effects by inhalation.
* Qualitative risk assessement (dermal exposure)

Please refer to the table below.

**Primary Exposure – Use of concentrated product ACTICIDE C1 (1.11% pure C(M)IT) and use of diluted product ACTICIDE C1 for filling packages**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | **Risk** |
| **Hazard Category** | **Effects in terms of C&L** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** |
| **Addition of biocides into product to be preserved** | | | | | | | | | |
| High | Skin Corr 1C (H314)  EUH 071 | 6 | Industrial  users | Addition of biocidal product (1.11% a.s.) into products to be preserved | Skin | Daily | Manual loading:  Small exposure to spills  Semi automated and fully automated loading systems:  Accidental exposure to spills during connection of container to the pumping system | All measures to eliminate exposure as much as possible, such as:  **RMM Technics:**  - Very high level of containment required  - Design closed system to allow for easy maintenance;  - If possible keep equipment under negative pressure;  - Regular cleaning of equipment and work area;  **RMM Organisation:**  - Control staff entry to work area;  - Ensure all equipment well maintained;  - Permit to work for maintenance work;  - Management/supervision in place to check that the RMMs in place are being used  **PPE:**  - Face shield;  - Substance/task appropriate gloves;  - protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);  - Chemical goggles,  Substance/task appropriate respirator | Acceptable considering:  - Minimization of manual phases;  - Professionals using PPE;  - Professionals following instructions for use. |
| High | Skin Sens 1A (H317) | 6 | Industrial  users | Addition of biocidal product (1.11% a.s.) into products to be preserved | Skin | Daily | Manual loading:  Small exposure to spills  Semi automated and fully automated loading systems:  Accidental exposure to spills during connection of container to the pumping system | **All measures to eliminate exposure as**  **much as possible, such as:**  **Technics**  - Very high level of containment required,  except for short term exposures e.g. taking  samples;  - Design closed system to allow for easy  maintenance;  - If possible keep equipment under  negative pressure;  - Regular cleaning of equipment and work  area;  **Organisation**  - Control staff entry to work area;  - Ensure all equipment well maintained;  - Permit to work for maintenance work;  - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;  - Training for staff on good practice;  - Procedures and training for emergency decontamination and disposal;  - Good standard of personal hygiene  - Recording of any 'near miss' situations.  Sensitisers - Pre-employment screening and appropriate health surveillance  **Personal protective equipment**  All skin and mucous membranes with potential exposure protected with appropriate PPE | Acceptable considering:  - Minimization of manual phases;  - Professionals using PPE;  - Professionals following instructions for use. |
| **Manual filling packages** | | | | | | | | | |
| High | Skin Sens 1A (H317) | 6 | Industrial  users | End-use application products (containing up to 400 ppm a.i) are manually packaged | Skin | Daily | Manual filling:  Small exposure to spills | **All measures to eliminate exposure as**  **much as possible, such as:**  **Technics**  - Very high level of containment required,  except for short term exposures e.g. taking  samples;  - Design closed system to allow for easy  maintenance;  - If possible keep equipment under  negative pressure;  - Regular cleaning of equipment and work  area;  **Organisation**  - Control staff entry to work area;  - Ensure all equipment well maintained;  - Permit to work for maintenance work;  - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;  - Training for staff on good practice;  - Procedures and training for emergency decontamination and disposal;  - Good standard of personal hygiene  - Recording of any 'near miss' situations.  Sensitisers - Pre-employment screening and appropriate health surveillance  **Personal protective equipment**  All skin and mucous membranes with potential exposure protected with appropriate PPE | Acceptable considering:  - Minimization of manual phases;  - Professionals using PPE;  - Professionals following instructions for use. |

|  |
| --- |
| **Use of detergents** |

**Professional exposure**

**Scenario [4] - Secondary direct exposure during application : Use of detergents during hand washing laundry**

ACTICIDE C1 is incorporated into liquid detergents at a maximum final pure C(M)IT concentration of up to 250 ppm.

Exposure to C(M)IT may occur when individuals use liquid detergent products containing the active ingredient during hand washing laundry.

Whereas professionals will more often wash clothes in machine, hand washing is a worst-case scenario for professional laundry washers.

The task is divided in two scenarios assessed separately:

- Scenario [4a]: Mixing&Loading (common to machine- or hand-laundry);

- Scenario [4b]: Application (for hand-laundry only).

| ***Description of Scenario [4a]*** | | | | |
| --- | --- | --- | --- | --- |
| Dermal contact to the concentrated treated article (liquid dertergent) may occur and represents the worst-case scenario.  To assess dermal exposure to a.s during the Mixing and Loading phase of the detergents, ConsExpo web has been used in combination with default values of the Cleaning Product fact sheet (updated version 2018)[[7]](#footnote-8).  Taking into account 10 minutes application duration (Consexpo default value) and time needed for preparation and other tasks, it is assumed that the cycle (loading + washing) may be repeated twice an hour, i.e. 16 times per day. | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of pure C(M)IT in the detergent | Up to 0.025% (250 ppm pure C(M)IT) | Applicant’s data |
| Exposure frequency (1/day) | 16 | RMS assumption |
| Ventilation rate (1/h) | 0.6 | Default value for unspecified room (ConsExpo General fact sheet) |
| Inhalation rate (m3/h) | 1.25 | HEAd Hoc Recommendation 14 |
| Room volume (m3)  (personal breathing zone) | 1 | Cleaning products fact sheet (ConsExpo) |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |

The use of gloves is not expected even for professionals.

**Calculations for Scenario [4a]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4a] | Tier 1/no PPE | 4.89 x 10-9 | 3.3 x 10-4 | - | 3.3 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [4a] | Tier 1/no PPE | 1.17 x 10-6 | 2.9 x 10-8 | 250 |

| ***Description of Scenario [4b]*** | | | | |
| --- | --- | --- | --- | --- |
| Dermal contact to the diluted treated article (liquid detergent) occurs during handwashing laudry.  To assess dermal exposure to a.s during the application phase, ConsExpo web has been used in combination with default values of the Cleaning Product fact sheet (updated version 2018).  Taking into account 10 minutes of dermal contact time per cycle (ConsExpo) for the application (hand washing) and 30 minutes exposure duration by inhalation per cycle, a total 8 hours per day is considered with a frequency of 16/d (see above)).  The relevant a.s. concentration is the weight fraction in the water, e.g. dishwashing water. In accordance with ECHA’s Biocides Human Health Exposure Methodology (p. 139, Version 1, October 2015) and the Cleaning products fact sheet (updated version 2018) the weight fraction is < 0.36 ppm (< 250 ppm C(M)IT concentration in detergent divided by dilution factor 700, due to product dilution in 15 L water).  Compared to the defaults values from ConsExpo scenario, an exposed body surface area of 1950 cm2 (instead of 2200 cm2 in ConsExpo) is taken into account. Considering a layer thickness of 0.01 cm for liquid (BPR Guidance), the volume of water that comes into contact with the skin is calculated as follows :  1 950 cm2 x 0.01 cm = 19,5 cm3 eq. to 19.5 mL (with a density = 1).  The default product amount presented in ConsExpo is calculated from a dilution factor of 110 (regular liquid) and an exposed body surface area of 2200 cm2 (leading to a volume of water in contact with skin of 22 mL). Considering the parameters that have been chosen for biocidal product (see above), the following calculations have been undertaken in order to obtain a product amount coming into contact with skin :   * Amount of product per wash : 17L (volume of a sink) / 700 (dilution factor) = 0.024 L (= 24 g) * Concentration of biocidal product in washing water : 24g / 17L = 1.41 g/L * **Product amount in contact with skin** : 1.41 g/L x 19.5 mL / 1000 mL = 0.027g (= **27 mg** instead of 194 mg as stated by ConsExpo for a dilution rate of 110 and a surface area of 2200 cm2). | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | 0.36 ppm a.i | Applicant’s data (considering a dilution factor of 700) |
| Exposure frequency (1/day) | 16 | RMS assumption |
| Ventilation rate (1/h) | 0.6 | Default value for unspecified room (ConsExpo General fact sheet) |
| Inhalation rate (m3/h) | 1.25 | HEAd Hoc Recommendation 14 |
| Release are (cm2)[[8]](#footnote-9) | 3000 | Cleaning products fact sheet (ConsExpo) |
| Exposed area (cm2)  (Hands and forearms) | 1950 | HEAd Hoc Recommendation 14 |
| Product amount in conatct with skin (mg) | 27 | See above |
| Room volume (m3) | 20 | Unspecified room - General fact sheet (ConsExpo) |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |

The use of gloves is not expected even for professionals.

**Calculations for Scenario [4b]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4b] | Tier 1/no PPE | 1.57 x 10-8 | 9.0 x 10-4 | - | 9.0 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [4b] | Tier 1/no PPE | 9.4 x 10-8 | 2.4 x 10-9 | 0.36 |

**Estimated exposure scenario [4] : combined exposure scenario [4a] +[4b]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4] | Tier 1/no PPE | 2.1 x 10-8 | 1.23 x 10-3 | - | 1.23 x 10-3 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [4] | Tier 1/no PPE | 1.26 x 10-6 | 8.0 x 10-8 | n.a\* |

\*As for local dermal effect, it is the concentration of the C(M)IT during the event of contact that is relevant, combined exposures have only been assessed for systemic exposures.

**Scenario [5] - Secondary direct exposure during application : Use of detergents during pre-treatment of clothes**

| ***Description of Scenario [5]*** | | | |
| --- | --- | --- | --- |
| ACTICIDE C1 is incorporated into liquid detergents at a maximum final of C(M)IT a.i. concentration of 250 ppm.  Exposure to C(M)IT may occur when individuals use the liquid detergent products containing the active ingredient during pre-treatment of clothes (spot removers).  Direct skin contact with C(M)IT is possible when clothing stains are being removed by spot-treatment with neat liquid (undiluted product). This scenario covers also the potential exposure following incidental splash and spillage of product, e.g. while pouring the product in a washing-machine.  To assess dermal exposure during pre-treatment of clothes, ConsExpo web and the Cleaning products fact sheet (updated version 2018) have been used.  Only dermal route is considered. Exposure by inhalation is negligible because of short duration. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | 0.025% a.i (250 ppm a.i or 0.25 mg/cm3) | Applicant’s data |
| Exposure frequency (1/day) | 16 | RMS assumption |
| Exposed area (cm2) | 410 | HEAd Hoc Recommendation 14 |
| Applied product amount (g) | 1.3 | Cleaning products fact sheet (ConsExpo) |
| Product fraction in contact with the skin | 25% | Cleaning products fact sheet (ConsExpo) |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |

**Calculations for Scenario [5]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [5] | Tier 1/no PPE | negligible | 1.08 x 10-2 | - | 1.08 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [5] | Tier 1/no PPE | negligible | negligible | 250 |

*Combined scenarios*

Combination of these scenarios is possible: a professional pre-treating and washing clothes on the same day.

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4,5] | Tier 1/no PPE | 2.06 x 10-8 | 1.20 x 10-2 | - | 1.20 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [4,5] | Tier 1/no PPE | 1.26 x 10-6 | 8.0 x 10-8 | n.a |

**Scenario [6] - Secondary exposure during application : Use of detergents during hand dishwashing**

ACTICIDE C1 is incorporated into liquid detergents at a maximum final C(M)IT a.i. concentration of up to 250 ppm.

Exposure to C(M)IT may occur when individuals use liquid detergent products containing the active ingredient during hand dishwashing

Whereas professionals will more often wash dishes in machine, hand dishwshing is a worst-case scenario for professional dish washers.

The task is divided in two scenarios assessed separately:

- Scenario [6a]: Mixing&Loading (common to machine- or hand-dishwashing);

- Scenario [6b]: Application (for hand- dishwashing only).

| ***Description of Scenario [6a]*** |
| --- |
| The same scenario than the one used for hand washing laundry is considered but with a frequency of 24 tasks/day.  Please see scenario [4a]. |

**Calculations for Scenario [6a]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [6a] | Tier 1/no PPE | 7.33 x 10-9 | 5.0 x 10-4 | - | 5.0 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [6a] | Tier 1/no PPE | 1.17 x 10-6 | 4.39 x 10-8 | 250 |

| ***Description of Scenario [6b]*** | | | | |
| --- | --- | --- | --- | --- |
| Dermal contact to the diluted treated article occurs during hand dishwashing.  To assess dermal exposure to a.s during the application phase, ConsExpo web has been used in combination with default values of the Cleaning Product fact sheet (updated version 2018).  Taking into account an application duration and a dermal contact time of 16 min per cycle (ConsExpo) for the application (hand dishwashing) and a conservative maximum occupational task frequency of 24 washes per day, a total daily task duration of 6.4 hours is assumed.  20 minutes exposure duration per task for inhalation is considered (total 8h per day).  The same aprameters than those calculated for the scenario application of detergents applied here :   * A dilution factor of 700 ; * A product concentration < 0.36 ppm a.i (in dilution) ; * A product amount in contact with skin of 27 mg. | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | 0.36 ppm a.i | Applicant’s data (considering a dilution factor of 700) |
| Exposure frequency (1/day) | 24 | RMS assumption |
| Ventilation rate (1/h) | 2.5 | Default value for kitchen (ConsExpo General fact sheet) |
| Inhalation rate (m3/h) | 1.25 | HEAd Hoc Recommendation 14 |
| Release are (cm2)[[9]](#footnote-10) | 3000 | Cleaning products fact sheet (ConsExpo) |
| Exposed area (cm2)  (Hands and forearms) | 1949 | HEAd Hoc Recommendation 14 |
| Product amount in contact with skin (mg) | 27 | See above |
| Room volume (m3) | 15 | For kitchen (general fact sheet ConsExpo) |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

The use of gloves is not expected even for professionals.

**Calculations for Scenario [6b]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [6b] | Tier 1/no PPE | 7.01 x 10-8 | 1.35 x 10-3 | - | 1.35 x 10-3 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [6b] | Tier 1/no PPE | 7.0 x 10-8 | 2.6 x 10-9 | 0.36 |

**Estimated exposure scenario [6] : combined exposure scenario [6a] +[6b]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [6] | Tier 1/no PPE | 1.90 x 10-5 | 1.85 x 10-3 | - | 1.85 x 10-3 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT /m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [6] | Tier 1/no PPE | 1.24 x 10-6 | 4.7 x 10-8 | n.a\* |

\*As for local dermal effect it is the concentration of the C(M)IT during the event of contact that is relevant, combined exposure have only been assessed for systemic exposure.

**Combined Exposure**

The relevance of the combination of the above mentionned scenarios is questionnable (scenario 4 +5 +6).

Taking into account the task duration and the task frequencies assumed for washing clothes and washing dishes manually, it is not relevant to consider a professionnal performing these tasks in the same day. Moreover, the exposure scenario fo the M&L phase is similar for the use on clothes or dishes and the application scenarios for both uses are quite similar. It is therefore considered that the exposure assessment performed for each use is conservative enough and can cover a combined exposure for professionals.

**Scenario [7] - Secondary exposure during application : Use of detergents during surface cleaning (Household)**

| ***Description of Scenario [7]*** | | | |
| --- | --- | --- | --- |
| ACTICIDE C1 is incorporated into liquid detergents at a maximum final C(M)IT a.i. concentration of up to 250 ppm.  Exposure to C(M)IT may occur when individuals use liquid detergent products containing the active ingredient during surface cleaning. The representative use for this kind of products is wiping or mopping hard surfaces such as floors.  To assess dermal exposure during cleaning surfaces, the « Surface disinfection Model » 1 & 3 have been used from the TNsG version 2. The M&L and diluted phases are already included in the model.  The exposure values from the model are as follows :   * 1030 mg/min (without protective gloves) ; * 10.3 mg/min (inside gloves) ; * 87.6 mg/min (body) ; * 22.9 mg/m3 (inhalation).   The relevant AS concentration is the weight fraction in the water, e.g. dishwashing water.  Considering a dilution factor of 20 (corresponding to 250 mL in 5L), the weight fraction is < 12.5 ppm (< 250 ppm C(M)IT concentration in detergent divided by dilution factor 20, due to product dilution in 5 L water) | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | < 12.5 ppm a.i  (0.00125%) | Applicant’s data (considering a dilution factor of 20) |
| Exposure duration (min) | 330 | HEAdhoc Recommendation 2 |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |
| **Tier 2** | Gloves penetration factor | Included in the model | - |
| Coverall penetration factor  (coated coverall) | 20% | HEEG Opinion 9 |

**Calculations for Scenario [7]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [7] | Tier 1/no PPE | 3.28 x 10-5 | 3.84 x 10-2 | - | 3.85 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT /m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [7] | Tier 1/no PPE | 2.86 x 10-4 | 1.97 x 10-4 | 12.5 |

**Risk characterization for professionals – Detergents uses**

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [4]**  Detergents – Hand washing laundry | Tier 1/no PPE | 0.065 | 1.23 x 10-3 | 1.90 | yes |
| **Scenario [5]**  Detergents – pre-treatment of clothes | Tier 1/no PPE | 0.065 | 1.08 x 10-2 | 16.6 | yes |
| **Scenario [4,5]** | Tier 1/no PPE | 0.065 | 1.20 x 10-2 | 18.5 | yes |
| **Scenario [6]**  Detergents – Hand dishwashing | Tier 1/no PPE | 0.065 | 1.85 x 10-3 | 2.85 | yes |
| **Scenario [7]**  Detergents – Household | Tier 1/no PPE | 0.065 | 3.85 x 10-2 | 59.2 | yes |

*Local effects*

* Quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3 (8h TWA)** | **Estimated Inhalation Concentration**  **(mg/m3)** | **Estimated Concentration/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [4]**  Detergents – Hand washing laundry | Tier 1/no PPE | 0.012 | 8.0 x 10-8 | 0.001 | yes |
| **Scenario [5]**  Detergents – pre-treatment of clothes | Tier 1/no PPE | 0.012 | negligible | - | yes |
| **Scenario [4,5]** | Tier 1/no PPE | 0.012 | 8.0 x 10-8 | 0.001 | yes |
| **Scenario [6]**  Detergents – Hand dishwashing | Tier 1/no PPE | 0.012 | 4.7 x 10-8 | 0.0004 | yes |
| **Scenario [7]**  Detergents – Household | Tier 1/no PPE | 0.012 | 1.97 x 10-4 | 1.64 | yes |

* Qualitative risk assessement (dermal exposure)
* The maximal concentration intended to be used to preserved detergents is 250 ppm pure C(M)IT. Since no PPE are considered for the use of detergents by professionals and the handling of detergents before dilution is expected, the decrease of the concentration of pure C(M)IT below the threshold value of 15 ppm pure C(M)IT is required. Considering this maximal concentration, the risk is deemed acceptable for local dermal effect.

**Non-professional exposure**

**Scenario [4] - Secondary direct exposure during application : Use of detergents during hand washing laundry**

As stated by the applicant, for the application of washing and cleaning fluid and other detergent by non-professionals it is not possible to consider that people who will use the end-product are trained. Therefore, washing and cleaning fluid and other detergent (treated articles) placed on the market for the general public contain C(M)IT concentrations below 15 ppm a.i.

Exposure to C(M)IT may occur when individuals use liquid detergent products containing the active ingredient during hand washing laundry.

Hand washing represents a worst-case scenario for non-professional that may wash clothes in machine.

The task is divided in two scenarios assessed separately:

- Scenario [4a]: Mixing&Loading (common to machine- or hand-laundry);

- Scenario [4b]: Application (for hand-laundry only).

| ***Description of Scenario [4a]*** | | | | |
| --- | --- | --- | --- | --- |
| Dermal contact to the concentrated treated article may occur and represents the worst-case scenario.  To assess dermal exposure to a.s during the Mixing and Loading phase of the detergents, ConsExpo web has been used in combination with default values of the Cleaning Product fact sheet (updated version 2018). | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | < 0.0015% a.i (15 ppm a.i) | Applicant’s data |
| Exposure frequency (1/day) | 1 | RMS assumption |
| Ventilation rate (1/h) | 0.6 | Default value for unspecified room (ConsExpo General fact sheet) |
| Inhalation rate (m3/h) | 1.25 | HEAd Hoc Recommendation 14 |
| Room volume (m3)  (personal breathing zone) | 1 | Cleaning products fact sheet (ConsExpo) |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [4a]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4a] | Tier 1/no PPE | 1.83 x 10-11 | 1.25 x 10-6 | - | 1.25 x 10-6 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT /m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [4a] | Tier 1/no PPE | 7.04 x 10-8 | < 15 |

| ***Description of Scenario [4b]*** | | | | |
| --- | --- | --- | --- | --- |
| Dermal contact to the diluted treated article occurs during handwashing laundry.  To assess dermal exposure to a.s during the application phase, ConsExpo web has been used in combination with default values of the Cleaning Product fact sheet (updated version 2018).  Taking into account 10 minutes dermal contact time per cycle (ConsExpo) for the application (hand washing) and 30 minutes exposure duration by inhalation per cycle, a task frequency of 1/day has been considered.  The relevant AS concentration is the weight fraction in the water, e.g. dishwashing water. In accordance with ECHA’s Biocides Human Health Exposure Methodology (p. 139, Version 1, October 2015) and the Cleaning products fact sheet (updated version 2018) the weight fraction is < 0.021 ppm (< 15 ppm C(M)IT concentration in detergent divided by dilution factor 700, due to product dilution in 15 L water).  Compared to the defaults values from ConsExpo scenario, an exposed surface area of 1950 cm2 (instead of 2200 cm2 in ConsExpo) is taken into account. Considering a layer thickness of 0.01 cm for liquid (BPR Guidance, the volume of water that comes into contact with the skin is calculated as foolows :  1 950 cm2 x 0.01 cm = 19,5 cm3 eq. to 19.5 mL (with a density = 1).  The default product amount presented in ConsExpo is calculated from a dilution factor of 110 (regular liquid) and an exposed surface area of 2200 cm2 (leading to a volume of water in contact with skin of 22 mL). Considering the parameters that have been chosen for biocidal product (see above), the following calculations have been undertaken in order to obtain a product amount coming into contact with skin :   * Amount of product per wash : 17L (volume of a sink) / 700 (dilution factor) = 0.024 L (= 24 g) * Concentration of biocidal product in washing water : 24g / 17L = 1.41 g/L ; * **Product amount in contact with skin** : 1.41 g/L x 19.5 mL / 1000 mL = 0.027g (= **27 mg** instead of 194 mg as stated by ConsExpo for a dilution rate of 110 and a surface area of 2200 cm2). | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | <0.021 ppm a.i  (0.0000021%) | Applicant’s data (considering a dilution factor of 700) |
| Exposure frequency (1/day) | 1 | RMS assumption |
| Ventilation rate (1/h) | 0.6 | Default value for unspecified room (ConsExpo General fact sheet) |
| Inhalation rate (m3/h) | 1.25 | HEAd Hoc Recommendation 14 |
| Release are (cm2) | 1500 | Cleaning products fact sheet (ConsExpo) |
| Exposed area (cm2)  (Hands and forearms) | 1950 | HEAd Hoc Recommendation 14 |
| Room volume (m3) | 20 | Unspecified room - General fact sheet (ConsExpo) |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [4b]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4b] | Tier 1/no PPE | 3.0 x 10-11 | 3.38 x 10-6 | - | 3.38 x 10-6 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT/m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [4b] | Tier 1/no PPE | 2.88 x 10-9 | < 0.021 |

**Estimated exposure scenario [4] : combined exposure scenario [4a] +[4b]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4] | Tier 1/no PPE | 4.83 x 10-11 | 4.63 x 10-6 | - | 4.63 x 10-6 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT /m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [4] | Tier 1/no PPE | 7.33 x 10-8 | n.a |

**Scenario [5] - Secondary exposure during application : Use of detergents during pre-treatment of clothes**

| ***Description of Scenario [5]*** | | | |
| --- | --- | --- | --- |
| As stated above, washing and cleaning fluid and other detergent (treated articles) placed on the market for the general public contain C(M)IT concentrations below 15 ppm a.i.  Exposure to C(M)IT may occur when individuals use liquid detergent products containing the active ingredient during pre-treatment of clothes (spot removers).  Direct skin contact with C(M)IT/MIT is possible when clothing stains are being removed by spot-treatment with neat liquid (undiluted product). This scenario covers also well the potential exposure following incidental splash and spillage of product, e.g. while pouring the product in a washing-machine.  To assess dermal exposure during pre-treatment of clothes, ConsExpo web and the Cleaning products fact sheet (updated version 2018) have been used.  Only dermal route is considered. Exposure by inhalation is negligible because of short duration. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | < 15 ppm a.i (= 0.0015% a.i) | Applicant’s data |
| Exposure frequency (1/day) | 1 | RMS assumption |
| Exposed area (cm2) | 410 | HEAd Hoc Recommendation 14 |
| Applied product amount (g) | 1.3 | Cleaning products fact sheet (ConsExpo) |
| Product fraction in contact with the skin | 25% | Cleaning products fact sheet (ConsExpo) |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [5] | Tier 1/no PPE | negligible | 4.06 x 10-5 | - | 4.06 x 10-5 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [5] | Tier 1/no PPE | negligible | < 15 |

**Combined Exposure**

Combination of these scenarios is possible: a non-professional pre-treating and washing clothes on the same day.

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4,5] | Tier 1/no PPE | 4.83 x 10-11 | 4.52 x 10-5 | - | 4.52 x 10-5 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [4,5] | Tier 1/no PPE | 7.33 x 10-8 | n.a |

**Scenario [6] - Secondary exposure during application : Use of detergents during hand dishwashing**

Exposure to C(M)IT may occur when individuals use liquid detergent products containing the active ingredient during hand dishwashing

Whereas non-professionals will more often wash dishes in machine, hand dishwashing is a worst-case scenario for non-professional.

The task is divided in two scenarios assessed separately:

- Scenario [6a]: Mixing&Loading (common to machine- or hand-dishwashing);

- Scenario [6b]: Application (for hand- dishwashing only).

| ***Description of Scenario [6a]*** |
| --- |
| The same scenario than the one used for hand washing laundry is considered but with a frequency of 2 tasks/day.  Please see scenario [4a]. |

**Calculations for Scenario [6a]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [6a] | Tier 1/no PPE | 3.67 x 10-11 | 2.50 x 10-6 | - | 2.50 x 10-6 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [6a] | Tier 1/no PPE | 7.04 x 10-8 | < 15 |

| ***Description of Scenario [6b]*** | | | | |
| --- | --- | --- | --- | --- |
| Dermal contact to the diluted treated article occurs during hand dishwashing.  To assess dermal exposure to a.s during the application phase, ConsExpo web has been used in combination with default values of the Cleaning Product fact sheet (updated version 2018).  An application duration and a dermal contact time of 16 min per cycle (ConsExpo) for the application (hand dishwashing) and a task frequency of 2 washes per day are assumed.  20 minutes exposure duration per task for inhalation is considered.  The same parameters than those calculated for the scenario application of detergents applied here :   * A dilution factor of 700 ; * A product concnetration < 0.021ppm C(M)IT (in the dilution); * A product amount in contact with skin of 27 mg. | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | 0.021 ppm a.i  (0.0000021%) | Applicant’s data (considering a dilution factor of 700) |
| Exposure frequency (1/day) | 2 | RMS assumption |
| Ventilation rate (1/h) | 2.5 | Default value for kitchen (ConsExpo General fact sheet) |
| Inhalation rate (m3/h) | 1.25 | HEAd Hoc Recommendation 14 |
| Release are (cm2) | 1500 | Cleaning products fact sheet (ConsExpo) |
| Exposed area (cm2)  (Hands and forearms) | 1950 | HEAd Hoc Recommendation 14 |
| Product amount in contact with skin (mg) | 27 | See above |
| Room volume (m3) | 15 | For kitchen (general fact sheet ConsExpo) |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [6b]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [6b] | Tier 1/no PPE | 3.91 x 10-11 | 6.75 x 10-6 | - | 6.75 x 10-6 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [6a] | Tier 1/no PPE | 2.82 x 10-9 | < 0.021 |

**Estimated exposure scenario [6] : combined exposure scenario [6a] +[6b]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [6] | Tier 1/no PPE | 7.58 x 10-11 | 9.25 x 10-6 | - | 9.25 x 10-6 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [6] | Tier 1/no PPE | 7.32 x 10-8 | n.a |

**Total combined expousre : Non professionals using detergents to clean laundry (spot pre-treatment + hand washing laundry) and to clean dishes (manual dishwashing) – Scenario [4,5] + scenario [6]**

Combination of these scenarios is possible: a non-professional cleaning clothes and dishes on the same day.

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4,5,6] | Tier 1/no PPE | 1.24 x 10-10 | 5.45 x 10-5 | - | 5.45 x 10-5 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [4,5,6] | Tier 1/no PPE | 1.47 x 10-7 | n.a |

**Scenario [7] - Secondary exposure during application : Use of detergents during surface cleaning (Household)**

Exposure to C(M)IT may occur when individuals use liquid detergent products containing the active ingredient during surface cleaning. The representative use for this kind of products is wiping or mopping hard surfaces such as floors.

The scenario is divided in 2 tasks :

- Scenario [7a]: Mixing & Loading;

- Scenario [7b]: Application by wiping or mopping.

| ***Description of Scenario [7a]*** |
| --- |
| ConsExpo web was used to estimate the exposure while cleaning surfaces with liquid detergents.  The default assumptions reported in the Cleaning products fact sheet (Updated version, 2018) for the application of "Floor, carpet and furniture products – Floor cleaning liquid" were used.  For M&L, the same scenario than the one used for hand washing laundry and manual dishwashing is considered.  Please see scenario [4a]. |

**Calculations for Scenario [7a]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [7a] | Tier 1/no PPE | 1.83 x 10-11 | 1.25 x 10-6 | - | 1.25 x 10-6 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [7a] | Tier 1/no PPE | 7.04 x 10-8 | < 15 |

| ***Description of Scenario [7b]*** | | | | |
| --- | --- | --- | --- | --- |
| Dermal contact to the diluted treated article occurs during cleaning the surfaces.  To assess dermal exposure to a.s during the application phase, ConsExpo web has been used in combination with default values of the Cleaning Product fact sheet (updated version 2018).  An application duration of 20 minutes (= duration of the cleaning task) and an exposure duration of 240 min (ConsExpo) has been taken into account. A frequency of 1 task per day is assumed.  The relevant AS concentration is the weight fraction in the water. In accordance with ECHA’s Biocides Human Health Exposure Methodology (p. 139, Version 1, October 2015) and the Cleaning products fact sheet (updated version 2018) the weight fraction is < 0.24 ppm (< 15 ppm C(M)IT concentration in detergent divided by dilution factor 62, due to product dilution in 5 L water).  Compared to the defaults values from ConsExpo scenario, an exposed surface area of 1950 cm2 (instead of 2200 cm2 in ConsExpo) is taken into account. Considering a layer thickness of 0.01 cm for liquid (BPR Guidance), the volume of water that comes into contact with the skin is calculated as follows :  1 950 cm2 x 0.01 cm = 19,5 cm3 eq. to 19.5 mL (with a density = 1).  The concentration of product in the bucket is 16.4 g/L (considering a dilution of 62 times and a water volume of 5L in the bucket, as recommended in the Cleaning Fact sheet). Considering a volume of water that comes into contact with the skin of 19.5 mL, a product amount in contact with skin can be calculated as follows :   * **Product amount in contact with skin** : 16.4 g/L x 19.5 mL / 1000 mL = 0.320g (= **320 mg**). | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the detergent | < 0.24 ppm a.i  (0.000024%) | Applicant’s data (considering a dilution factor of 62) |
| Exposure frequency (1/day) | 1 | RMS assumption |
| Ventilation rate (1/h) | 0.6 | Default value for unspecified room (ConsExpo General fact sheet) |
| Inhalation rate (m3/h) | 1.25 | HEAd Hoc Recommendation 14 |
| Release are (m2) | 22 | Cleaning products fact sheet (ConsExpo) |
| Exposed area (cm2)  (Hands and forearms) | 1950 | HEAd Hoc Recommendation 14 |
| Product amount in contact with skin (mg) | 320 | See above |
| Room volume (m3) | 58 | For living room (general fact sheet ConsExpo) |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [7b]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [7b] | Tier 1/no PPE | 1.93 x 10-7 | 4.0 x 10-5 | - | 4.02 x 10-5 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [7b] | Tier 1/no PPE | 2.3 x 10-6 | < 0.24 |

**Estimated exposure scenario [7] : combined exposure scenario [7a] +[7b]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [7] | Tier 1/no PPE | 1.93 x 10-7 | 4.13 x 10-5 | - | 4.14 x 10-5 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [7] | Tier 1/no PPE | 2.39 x 10-6 | n.a |

**Risk characterization for non professionals – Detergents uses**

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [4]**  Detergents – Hand washing laundry | Tier 1/no PPE | 0.083 | 4.63 x 10-6 | 0.01 | yes |
| **Scenario [5]**  Detergents – pre-treatment of clothes | Tier 1/no PPE | 0.083 | 4.06 x 10-5 | 0.05 | yes |
| **Scenario [4,5]** | Tier 1/no PPE | 0.083 | 4.52 x 10-5 | 0.05 | yes |
| **Scenario [6]**  Detergents – Hand dishwashing | Tier 1/no PPE | 0.083 | 9.25 x 10-6 | 0.01 | yes |
| **Scenario [4,5,6]** | Tier 1/no PPE | 0.083 | 5.45 x 10-5 | 0.07 | yes |
| **Scenario [7]**  Detergents – Household | Tier 1/no PPE | 0.083 | 4.14 x 10-5 | 0.05 | yes |

* No unacceptable risk is observed for non professional users of preserved detergents.
* Quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3 )** | **Estimated Inhalation Concentration**  **(mg/m3)** | **Estimated Concentration/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [4]**  Detergents – Hand washing laundry | Tier 1/no PPE | 0.032 | 7.33 x 10-8 | 0.0002 | yes |
| **Scenario [5]**  Detergents – pre-treatment of clothes | Tier 1/no PPE | 0.032 | negligible | - | yes |
| **Scenario [4,5]** | Tier 1/no PPE | 0.032 | 7.33 x 10-8 | 0.0002 | yes |
| **Scenario [6]**  Detergents – Hand dishwashing | Tier 1/no PPE | 0.032 | 7.32 x 10-8 | 0.0002 | yes |
| **Scenario [4,5,6]** | Tier 1/no PPE | 0.032 | 1.47 x 10-7 | 0.0005 | yes |
| **Scenario [7]**  Detergents – Household | Tier 1/no PPE | 0.032 | 2.39 x 10-6 | 0.01 | yes |

* Regarding local effects by inhalation, no unacceptable risk is observed.
* Qualitative risk assessement (dermal exposure)
* The maximal concentration intended by the applicant in product used by non-professionals is below the threshold value of 15 ppm pure C(M)IT. The risk is therefore acceptable for local dermal effects.

**General public**

**Scenario [8] - Secondary indirect exposure: Dermal exposure towards residues of C(M)IT on textiles**

| ***Description of Scenario [8]*** | | | |
| --- | --- | --- | --- |
| Residues of components of laundry detergents may remain on textiles after washing and could come in contact with the skin via migration from textile to skin.  The quantity of residues migrated to skin can be estimated by ConsExpo using the ***dermal-direct product contact-migration*** model.  In ConsExpo, the default product amount for adult is set at 1000g, corresponding to the weight of clothes worn by an adult. Considering an exposed area of 16600 cm2 (HEAd hoc Recommendation 14), a specific product amount per surface area of 0.6 kg/m2 is calculated (= 1 kg / 1.66 m2).  It is assumed that the weight of clothes is proportional to the area of fabric in contact with skin (= exposed area), then the default product amounts per age group is calculated by multiplying the surface area by 0.6 kg/m2.  For a toddler, a product amount of 288 g is calculated (0.48 m2 x 0.6).  For an infant , a product amount of 246 g is calculated (0.41 m2 x 0.6).  As a worst case, the maximal concentration considered for this scenario is 15 ppm pure C(M)IT since the concentration of C(M)IT in detergents should be below the threshold value for skin sensitization.  The leachable fraction is therefore calculated as follows :  LF = 0.076 g/kg x 0.0015%  LF = 1.14 10-6  \* ConsExpo Cleaning Product Fact Sheet | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Maximal concentration of C(M)IT in textiles | < 15 ppm pure C(M)IT (0.0015%) | Applicant’s data |
| Frequency (d/y) | 365 | RMS assumption |
| Exposed area (m2) | 1.66 m2 (adult)  0.46 m2 (toddler)  0.41 m2 (infant) | HEAd hoc Recommendation 14 |
| Product amount (g) | 1000 g (adult)  288 g (toddler)  246 g (infant) | See above |
| Leachable fraction | 1.14 10-6 | See above |
| Skin contact factor | 0.8 | ConsExpo Cleaning Product fact sheet |
| Body weight (kg) | 60 (adult)  10 (toddler)  8 (infant) | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |

*Systemic effects*

| **Summary table: estimated exposure from general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [8] | Tier 1/Adult | - | 7.6 x 10-4 | - | 7.6 x 10-4 |
| Tier 1/Toddler | - | 1.3 x 10-2 | - | 1.3 x 10-2 |
| Tier 1/Infant | - | 1.4 x 10-2 | - | 1.4 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from general public** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** |
| **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [8] | Tier 1 | < 15 |

**Scenario [9] - Secondary indirect exposure: oral exposure towards residues of C(M)IT on ustensils and dishware**

| ***Description of Scenario [9]*** |
| --- |
| Potential oral exposure to C(M)IT can occur from residues remaining on eating utensils and dishes washed with dishwashing detergents preserved with C(M)IT.  This exposure scenario is considered covered by the exposure scenario presented below for dietary risk assessment. |

**Scenario [10] - Secondary indirect exposure: Dermal and oral exposure towards residues of C(M)IT on cleaned surfaces**

| ***Description of Scenario [10]*** | | | |
| --- | --- | --- | --- |
| Children are exposed to residues of preserved liquid detergents on cleaned surfaces, while crawling on these surfaces and ingesting by hand-mouth transfer.  The detergent product (containing < 15 ppm pure C(M)IT) is diluted by factor 20 in the bucket (i.e. 250 mL in 5 liters), thus the applied solution contains < 0.75 ppm pure C(M)IT (corr. to 0.75 x 10-3 mg/cm3).  The solution is applied on surface with a film thickness of 0.01 cm, thus the surface concentration is :  0.75 x 10-3 mg/cm3 x 0.01 cm = 0.75 x 10-5 mg/cm2. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of C(M)IT in solution applied on surfaces | < 0.75 ppm pure C(M)IT | See above |
| Indoor Transfer Coefficient (cm2/h) | 2100 | HEAd Hoc Recommendation 12 |
| Transfer coefficient from treated surface to hand | 30% | Default value from ConsExpo Pesticide fact sheet |
| Proportion of palms of hands in contact with the paint | 40% | HEAd Hoc Recommendation 5 |
| Transferable fraction from hand to mouth | 10% | From ConsExpo : The hands form about 20% of the uncovered skin and 50% of the product on the hands is transferred to mouth |
| Body weight (kg) | 10 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |
| Oral absorption | 50% | Active substance data |

*Systemic effects*

| **Summary table: estimated exposure from general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [10] | Tier 1 | - | 2.4 x 10-4 | 2.4 x 10-5 | 2.6 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from general public** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** |
| **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [10] | Tier 1 | < 15 |

**Risk characterization for general public – Detergents uses**

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [8]** | Tier 1/Adult | 0.065 | 7.6 x 10-4 | 1.17 | Yes |
| Tier 1/Toddler | 0.065 | 1.3 x 10-2 | 20.15 | Yes |
| Tier 1/Infant | 0.065 | 1.4 x 10-2 | 21.54 | Yes |
| **Scenario [10]** | Tier 1 | 0.083 | 2.6 x 10-4 | 0.31 | Yes |

* No unacceptable risk is observed for secondary indirect exposure to detergents preserved with C(M)IT.
* Qualitative risk assessment (dermal exposure)
* Considering maximal concentration in detergents is less than 15 ppm C(M)IT, the risk is deemed acceptable for local dermal effect.

|  |
| --- |
| **Use of Paints** |

**Professional exposure**

**Scenario [11] - Secondary direct exposure during application : Spraying paints and coatings**

ACTICIDE C1 is incorporated into paints and coatings at a maximum final pure C(M)IT. concentration of up to 150 ppm.

Paints containing C(M)IT may be used in occupational settings where they are applied using airless sprayers. Such equipment is used in a variety of settings, including painting equipment, cars, storage tanks, buildings and structures, etc. Spraying paints containing C(M)IT could result in potential inhalation and dermal exposures.

To produce worst-case exposure estimates, exposure is assumed throughout an entire work day, and divided in three different tasks, each task being done by the same operator.

* Scenario [11a]: Mixing and loading of the spray equipement;
* Scenario [11b]: Application of the paint by spraying;
* Scenario [11c]: Cleaning of the spray equipment.

Exposure of the professional is assumed throughout an entire work day with 1 hour devoted to paint sprayer loading, 1 hour to cleaning the equipement and 6 hours devoted to spraying.

| ***Description of Scenario [11a]*** | | | |
| --- | --- | --- | --- |
| To assess dermal and inhalation exposure during the Mixing and Loading phase, the « Mixing & Loading model 6 » (loading antifouling paints for airless sprayer) from the TNsG 2007 is used.  The exposure values from the model are as follows :   * 30 mg/min (without protective gloves) ; * 8.2 mg/min (inside gloves) ; * 92 mg/min (body) ; * 1.9 mg/m3 (inhalation). | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | 15 ppm pure C(M)IT | Maximal concentration leading to an acceptable risk for indirect secondary exposure |
| Exposure duration (min) | 60 | - |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |

**Calculations for Scenario [11a]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [11a] | Tier 1/no PPE | 5.94 x 10-7 | 9.15 x 10-4 | - | 9.16 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [11a] | Tier 1/no PPE | 2.85 x 10-5 | 3.56 x 10-6 | < 15 |

| ***Description of Scenario [11b]*** | | | |
| --- | --- | --- | --- |
| To assess dermal and inhalation exposure during the Application phase, the « Spraying model 3 » (airless sprayer) from the TNsG 2007 is used.  Spraying Model 3 describes a task involving an airless spray application for liquid antifoulant. While this model pertain to application of antifoulants, such scenarios are believed to represent a high-end exposure for airless sprayer applications of paints in general.  The exposure values from the model are as follows :   * 119 mg/min (without protective gloves) ; * 2.04 mg/min (inside gloves) ; * 250 mg/min (body) ; * 17.3 mg/m3 (inhalation). | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | 15 ppm pure C(M)IT | Maximal concentration leading to an acceptable risk for indirect secondary exposure |
| Exposure duration (min) | 360 | - |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [11b]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [11b] | Tier 1/no PPE | 3.24 x 10-5 | 1.66 x 10-2 | - | 1.66 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [11b] | Tier 1/no PPE | 2.60 x 10-4 | 1.95 x 10-4 | < 15 |

| ***Description of Scenario [11c]*** | | | |
| --- | --- | --- | --- |
| To assess dermal and inhalation exposure during the Cleaining phase, the « Cleaning of spray equipment model » from the data base BEAT is used.  The exposure values from the model are as follows :   * 35.87 µL/min (without protective gloves) ; * 19.28 µL/min (body).   As no inhalation data are presented in BEAT's study, data from TNsG's Spraying model 3 is used as a worst-case : 17.3 mg/m3. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | 15 ppm pure C(M)IT | Maximal concentration leading to an acceptable risk for indirect secondary exposure |
| Exposure duration (min) | 60 | - |
| Product density (paint) (g/cm3) | 1.6 | HEAD hoc Recommendation 4 |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [11c]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [11c] | Tier 1/no PPE | 5.41 x 10-6 | 6.62 x 10-4 | - | 6.68 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [11c] | Tier 1/no PPE | 2.60 x 10-4 | 3.24 x 10-5 | < 15 |

**Estimated exposure scenario [11] : combined exposure scenario [11a] +[11b] + [11c]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [11] | Tier 1/no PPE | 3.84 x 10-5 | 1.82 x 10-2 | - | 1.82 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [11] | Tier 1/no PPE | 5.48 x 10-4 | 2.31 x 10-4 | n.a\* |

\*As for local dermal effect it is the concentration of the C(M)IT during the event of contact that is relevant, combined exposure have only been assessed for systemic exposure.

**Scenario [12] - Secondary exposure during application : paints applied with brush and roller.**

ACTICIDE C1 is incorporated into paints and coatings at a maximum final pure C(M)IT concentration of up to 150 ppm.

Exposure of professionals to C(M)IT in paint and/or primer may occur when the coatings containing the biocide are applied by brush and roller to surfaces by professional painters. Application of paints containing C(M)IT could result in potential inhalation and dermal exposures.

To produce worst-case exposure estimates, exposure is assumed throughout an entire work day, and divided in three different tasks, each task being done by the same operator.

- Scenario [12a]: Mixing and loading of the paint into a receiving vessel;

- Scenario [12b]: Application of the paint using a brush or a roller;

- Scenario [12c]: Cleaning of the equipment (brush or roller).

Exposure of the professional is assumed throughout an entire work day with 1 hour devoted to paint loading, 1 hour to clean the equipemen and 6 hours devoted to brush/roller application.

| ***Description of Scenario [12a]*** |
| --- |
| To assess dermal and inhalation exposure during the Mixing and Loading phase, the « Mixing & Loading model 6 » (loading antifouling paints for airless sprayer) from the TNsG 2007 is used. It is considered a worst-case scenario for this phase since the other available models for M&L present lower exposure values.  Since C(M)IT may be used to preserve anitfouling paint, this scenario has been deemed appropriate.  The same parameter than those used for the secnario [11a] has been applied.  For details, please refer to this scenario. |

**Calculations for Scenario [12a]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [12a] | Tier 1/no PPE | 5.94 x 10-7 | 9.15 x 10-4 | - | 9.16 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [12a] | Tier 1/no PPE | 2.85 x 10-5 | 3.56 x 10-6 | < 15 |

| ***Description of Scenario [12b]*** | | | |
| --- | --- | --- | --- |
| To assess dermal and inhalation exposure during the Application phase, the exposure values from the HEAd hoc Recommendation 10 have been used.  The exposure values from the model are as follows :   * 9.14 µL/min (hands) ; * 1.12 µL/min (body) ; * 1.63 mg/m3 (inhalation).   As a worst-case scenario, exposure values for solvent-based paint are used since C(M)IT may be used to preserved such paint.  Only inhalation exposure through aerosols has been taken into account. It has been assumed that despite a vapor pressure > 10 mPa, paint has a matrix effect sufficient to retain the preservative in the formulation in order to maintain its inner properties. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | 15 ppm pure C(M)IT | Maximal concentration leading to an acceptable risk for indirect secondary exposure |
| Exposure duration (min) | 360 | - |
| Product density (paint) (g/cm3) | 1.6 | HEAD hoc Recommendation 4 |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [12b]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [12b] | Tier 1/no PPE | 3.06 x 10-6 | 7.39 x 10-4 | - | 7.42 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [12b] | Tier 1/no PPE | 2.45 x 10-5 | 1.83 x 10-5 | < 15 |

| ***Description of Scenario [12c]*** | | | |
| --- | --- | --- | --- |
| To assess dermal and inhalation exposure during the cleaning phase, the exposure model from the HEEG opinion 11 is used. As no inhalation data are presented in this recommendation, exposure value from the brush application has been taken into account to simulate inhalation exposure during this task.  This scenario only applies for non-water based paints and it has been choses as a worst-case since C(M)IT may be used to preserve such paint. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | 15 ppm pure C(M)IT | Maximal concentration leading to an acceptable risk for indirect secondary exposure |
| Exposure duration (min) | 60 | - |
| Product density (paint) (g/cm3) | 1.6 | HEAD hoc Recommendation 4 |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [12c]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [12c] | Tier 1/no PPE | 3.06 x 10-6 | 2.60 x 10-4 | - | 2.63 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [12c] | Tier 1/no PPE | 2.45 x 10-5 | 1.83 x 10-5 | 15 |

**Estimated exposure scenario [12] : combined exposure scenario [12a] +[12b] + [12c]**

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [12] | Tier 1/no PPE | 6.71 x 10-6 | 1.91 x 10-3 | - | 1.92 x 10-3 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| Scenario [12] | Tier 1/no PPE | 5.30 x 10-5 | 2.19 x 10-5 | n.a\* |

\*As for local dermal effect it is the concentration of the C(M)IT during the event of contact that is relevant, combined exposure have only been assessed for systemic exposure.

**Risk characterization for professionals – Paints and coatings uses**

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [11]**  Paints - spraying | Tier 1/no PPE | 0.065 | 1.82 x 10-2 | 28.03 | Yes |
| **Scenario [12]**  Paints – brush/roller | Tier 1/no PPE | 0.065 | 1.92 x 10-3 | 2.95 | yes |

* The risk is considered acceptable for professionnals spraying paints and coatings andfor brush/roller application without PPE.

*Local effects*

* Quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated Inhalation Concentration**  **(mg/m3)** | **Estimated Concentration/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [11]**  Paints - spraying | Tier 1/no PPE | 0.012 | 5.48 x 10-4 | 3.42 | yes |
| **Scenario [12]**  Paints – brush/roller | Tier 1/no PPE | 0.012 | 2.2 x 10-5 | 0.18 | yes |

* No unacceptable risk is observed for the inhalation route.
* Qualitative risk assessement (dermal exposure)

Due to indirect exposure (ditrect contact with fresh paint), a reduction of the concentration of C(M)IT in preserved paints below the threshold value of 15 ppm is required. Considering this, the use of paints by profesionnals with an in use concentration below 15 ppm is deemed acceptable.

**Non-professional exposure**

**Scenario [11] - Secondary direct exposure during application : Spraying paints and coatings**

As stated by the applicant, for the application of paints and other coatings by non-professionals it is not possible to consider that people who will use the end-product are trained. Therefore, paints and coatings placed on the market for the general public contain C(M)IT concentrations below 15 ppm.

Paints containing C(M)IT may be applied using airless sprayers.

Spraying paints containing C(M)IT could result in potential inhalation and dermal exposures.

Exposure estimates have been divided in three different tasks:

* Scenario [11a]: Mixing and loading of the spray equipement;
* Scenario [11b]: Application of the paint by spraying;
* Scenario [11c]: Cleaning of the spray equipment.

Exposure of the non-professional is assumed as follows :

* 10 min devoted to the loading of the spray equipment ;
* 240 min devoted to the paint application (as a worst case it is assumed that a spray application is chosen to paint large surfaces) ;
* 10 min devoted to the cleaning of the spray equipment.

| ***Description of Scenario [11a]*** | | | |
| --- | --- | --- | --- |
| As a worst-case scenario, the « Mixing & Loading model 6 » (loading antifouling paints for airless sprayer) from the TNsG 2007 has been used to assess non professional dermal and inhalation exposure during spray painting. It has been assumed that non-professional may applied antifouling paint containing C(M)IT.  The exposure values from the model are as follows :   * 30 mg/min (without protective gloves) ; * 92 mg/min (body) ; * 1.9 mg/m3 (inhalation). | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | < 15 ppm a.i | Applicant’s data |
| Exposure duration (min) | 10 | - |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [11a]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [11a] | Tier 1/no PPE | 9.90 x 10-8 | 1.53 x 10-4 | - | 1.53 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT/m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [11a] | Tier 1/no PPE | 2.85 x 10-5 | < 15 |

| ***Description of Scenario [11b]*** | | | |
| --- | --- | --- | --- |
| As stated above, the « Spraying model 3 » from the TNsG 2007 is used to assess dermal and inhalation exposure during the non professional application phase.  The exposure values from the model are as follows :   * 119 mg/min (without protective gloves) ; * 250 mg/min (body) ; * 17.3 mg/m3 (inhalation). | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | < 15 ppm a.i | Applicant’s data |
| Exposure duration (min) | 240 | - |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [11b]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [11b] | Tier 1/no PPE | 2.16 x 10-5 | 1.11 x 10-2 | - | 1.11 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT/m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [11b] | Tier 1/no PPE | 2.60 x 10-4 | < 15 |

| ***Description of Scenario [11c]*** | | | |
| --- | --- | --- | --- |
| To assess dermal and inhalation non-professional exposure during the Cleaining phase, the « Cleaning of spray equipment model » from the data base BEAT is used.  The exposure values from the model are as follows :   * 35.87 µL/min (without protective gloves) ; * 19.28 µL/min (body).   As no inhalation data are presented in BEAT's study, data from TNsG's Spraying model 3 is used as a worst-case : 17.3 mg/min. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | < 15 ppm a.i | Applicant’s data |
| Exposure duration (min) | 10 | - |
| Product density (paint) (g/cm3) | 1.6 | HEAD hoc Recommendation 4 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [11c]**

*Systemic effects*

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [11c] | Tier 1/no PPE | 9.01 x 10-7 | 1.10 x 10-4 | - | 1.10 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT/m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [11c] | Tier 1/no PPE | 2.60 x 10-4 | < 15 |

**Estimated exposure scenario [11] : combined exposure scenario [11a] +[11b] + [11c]**

*Systemic effects*

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [11] | Tier 1/no PPE | 2.26 x 10-5 | 1.13 x 10-2 | - | 1.14 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT/m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [11] | Tier 1/no PPE | 5.48 x 10-4 | n.a |

**Scenario [12] - Secondary direct exposure during application : paints applied with brush and roller.**

Exposure of non-professionals to C(M)IT in paint and/or primer may occur when the coatings containing the biocide are applied by brush and roller to surfaces. Application of paints containing C(M)IT could result in potential inhalation and dermal exposures.

Exposure is divided in three different tasks, each task being done by the same people :

- Scenario [12a]: Mixing and loading of the paint into a receiving vessel;

- Scenario [12b]: Application of the paint using a brush or a roller;

- Scenario [12c]: Cleaning of the equipment (brush or roller).

Exposure of the non-professional is assumed as follows :

* 10 min devoted to the loading of paint in receiving vessel ;
* 240 min devoted to the paint application ;
* 10 min devoted to the cleaning of brush and roller.

| ***Description of Scenario [12a]*** |
| --- |
| To assess dermal and inhalation exposure during the Mixing and Loading phase, the same model as presented above for spray application has been used. It is considered a worst-case scenario for this phase since the other available models for M&L present lower exposure values.  The same parameter than those used for the scenario [11a] has been applied.  For details, please refer to this scenario. |

**Calculations for Scenario [12a]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [12a] | Tier 1/no PPE | 9.90 x 10-8 | 1.53 x 10-4 | - | 1.53 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT/m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [12a] | Tier 1/no PPE | 2.85 x 10-5 | < 15 |

| ***Description of Scenario [12b]*** | | | |
| --- | --- | --- | --- |
| To assess dermal and inhalation exposure during the Application phase, the exposure values from the HEAd hoc Recommendation 10 have been used.  The exposure values from the model are as follows :   * 9.14 µL/min (hands) ; * 1.12 µL/min (body) ; * 1.63 mg/m3 (inhalation).   As a worst-case scenario, exposure values for solvent-based paint are used since C(M)IT may be used to preserved such paint.  Only inhalation exposure through aerosols has been taken into account. It has been assumed that despite a vapor pressure > 10 mPa, paint has a matrix effect sufficient to retain the preservative in the formulation in order to maintain its inner properties. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | < 15 ppm a.i | Applicant’s data |
| Exposure duration (min) | 240 | - |
| Product density (paint) (g/cm3) | 1.6 | HEAD hoc Recommendation 4 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [12b]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [12b] | Tier 1/no PPE | 2.04 x 10-6 | 4.92 x 10-4 | - | 4.95 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg a.i/m3)** | **Dermal**  **(ppm a.i)** |
| Scenario [12b] | Tier 1/no PPE | 2.45 x 10-5 | < 15 |

| ***Description of Scenario [12c]*** | | | |
| --- | --- | --- | --- |
| To assess dermal and inhalation exposure during the cleaning phase, the exposure model from the HEEG opinion 11 is used. As no inhalation data are presented in this recommendation, exposure value from the brush application has been taken into account to simulate inhalation exposure during this task.  This scenario only applies for non-water based paints and it has been choses as a worst-case since C(M)IT may be used to preserve such paint. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | < 15 ppm a.i | Applicant’s data |
| Exposure duration (min) | 10 | - |
| Product density (paint) (g/cm3) | 1.6 | HEAD hoc Recommendation 4 |
| Body weight (kg) | 60 | HEAdhoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Acitve substance data |

**Calculations for Scenario [12c]**

*Systemic effects*

| **Summary table: estimated exposure from non professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [12c] | Tier 1/no PPE | 2.04 x 10-6 | 2.60 x 10-4 | - | 2.62 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT/m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [12c] | Tier 1/no PPE | 2.45 x 10-5 | < 15 |

**Estimated exposure scenario [12] : combined exposure scenario [12a] +[12b] + [12c]**

*Systemic effects*

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [12] | Tier 1/no PPE | 4.17 x 10-6 | 9.05 x 10-4 | - | 9.09 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** | |
| **Inhalation**  **(mg pure C(M)IT/m3)** | **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [12] | Tier 1/no PPE | 7.748 x 10-5 | n.a |

**Risk characterization for non professionals – Paints and coatings uses**

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [11]**  Paints - spraying | Tier 1/no PPE | 0.083 | 1.14 x 10-2 | 13.7 | yes |
| **Scenario [12]**  Paints – brush/roller | Tier 1/no PPE | 0.083 | 9.09 x 10-4 | 1.09 | yes |
| **Scenario [13]**  Plaster | Tier 1/no PPE | 0.083 | 9.09 x 10-4 | 1.09 | yes |

* No unacceptable risk is observed for the use of paints and coatings by non professionnals.

*Local effects*

* Quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated Inhalation Concentration**  **(mg/m3)** | **Estimated Concentration/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [11]**  Paints - spraying | Tier 1/no PPE | 0.032 | 5.48 x 10-4 | 1.7 | yes |
| **Scenario [12]**  Paints – brush/roller | Tier 1/no PPE | 0.032 | 7.74 x 10-5 | 0.24 | yes |
| **Scenario [13]**  Plaster | Tier 1/no PPE | 0.032 | 7.74 x 10-5 | 0.24 | yes |

* No unacceptable risk is observed for the inhalation route.
* Qualitative risk assessement (dermal exposure)
* The maximal concentration used for products intended to be applied by non professionals is below the threshold value of 15 ppm pure C(M)IT.

**General public**

**Scenario [14] - Secondary indirect exposure: Dermal exposure from contact with C(M)IT in wet paint and oral exposure from hand to mouth transfer**

| ***Description of Scenario [14]*** | | | |
| --- | --- | --- | --- |
| Secondary indirect exposure to C(M)IT may occur during a dermal contact with wet paint.  To estimate exposure during this scenario, the parameters set in the HEAd hoc Recommendation 5 have been considerd.  The most critical population for this exposure is the toddler (10 kg body weight).  The following parameters have been taken into account :   * Skin surface in contact with paint : 115.2 cm2 (palm of both hands) ; * Transfer coefficient of paint from treated surface to hand : 50% ; * Proportion of palms of hand in contact with the paint : 100%.   The paint density is of 1.6 g/cm3, equivalent to 0.24 mg pure C(M)IT/cm3 paint (containing 150 ppm pure C(M)IT) in Tier 1 or 0.024 mg pure C(M)IT/cm3 paint (containing 15 ppm pure C(M)IT) in Tier 2. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Hand deposit concentration (ppm) | 150 ppm pure C(M)IT | Applicant’s data |
| Product density (paint) (g/cm3) | 1.6 | HEAD hoc Recommendation 4 |
| Concentration of a.s in paint (mg/cm3 paint) | 0.24 | See above |
| Skin surface in contact with paint (cm2) | 115.2 | HEAd Hoc Recommendation 5 |
| Transfer coefficient of paint from treated surface to hand | 50% (wet paint) | HEAd Hoc Recommendation 5 |
| Proportion of palms of hands in contact with the paint | 100% | HEAd Hoc Recommendation 5 |
| Transferable fraction of paint from hand to mouth | 10% | HEAd Hoc Recommendation 5 |
| Body weight (kg) | 10 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |
| Oral absorption | 50% | Active substance data |
| **Tier 2** | Hand deposit concentration (ppm) | 15 ppm pure C(M)IT | Applicant’s data |
| Concentration of a.s in paint (mg/cm3 paint) | 0.024 | See above |

*Systemic effects*

| **Summary table: estimated exposure from general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [14] | Tier 1 | - | 0.07 | 0.007 | 0.076 |
| Tier 2 | - | 0.007 | 0.0007 | 0.0076 |

*Local effects*

| **Summary table: estimated exposure concentration from general public** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** |
| **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [14] | Tier 1 | 150 |
| Scenario [14] | Tier 2 | < 15 |

**Scenario [15] - Secondary indirect exposure: Dermal exposure from contact with C(M)IT in dried paint and oral exposure from hand to mouth transfer**

| ***Description of Scenario [15]*** | | | |
| --- | --- | --- | --- |
| Secondary indirect exposure to C(M)IT may occur during a dermal contact with dried paint.  To estimate exposure during this scenario, the parameters set in the HEAd hoc Recommendation 5 have been considerd.  The most critical population for this exposure is the toddler (10 kg body weight).  The following parameters have been taken into account :   * Skin surface in contact with paint : 115.2 cm2 (palm of both hands) ; * Transfer coefficient of paint from treated surface to hand : 3% ; * Proportion of palms of hand in contact with the paint : 40%.   The paint density is of 1.6 g/cm3, equivalent to 0.24 mg pure C(M)IT/cm3 paint (containing 150 ppm pure C(M)IT) in Tier 1 or 0.024 mg pure C(M)IT/cm3 paint (containing 15 ppm pure C(M)IT) in Tier 2. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Hand deposit concentration (ppm) | 150 ppm pure C(M)IT | Applicant’s data |
| Product density (paint) (g/cm3) | 1.6 | HEAD hoc Recommendation 4 |
| Concentration of a.s in paint (mg/cm3 paint) | 0.24 | See above |
| Skin surface in contact with paint (cm2) | 115.2 | HEAd Hoc Recommendation 5 |
| Transfer coefficient of paint from treated surface to hand | 3% (dried paint) | HEAd Hoc Recommendation 5 |
| Proportion of palms of hands in contact with the paint | 40% | HEAd Hoc Recommendation 5 |
| Transferable fraction of paint from hand to mouth | 50% | HEAd Hoc Recommendation 5 |
| Body weight (kg) | 10 | HEAdhoc recommendation 14 |
| Dermal absorption | 50% (non corrosive concentration) | Active substance data |
| Oral absorption | 50% | Active substance data |
| **Tier 2** | Hand deposit concentration (ppm) | 15 ppm pure C(M)IT | Applicant’s data |
| Concentration of a.s in paint (mg/cm3 paint) | 0.024 | See above |

*Systemic effects*

| **Summary table: estimated exposure from general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [15] | Tier 1 | - | 1.7 x 10-3 | 8.3 x 10-4 | 2.5 x 10-3 |
| Tier 2 | - | 1.7 x 10-4 | 8.3 x 10-5 | 2.5 x 10-4 |

*Local effects*

| **Summary table: estimated exposure concentration from general public** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** |
| **Dermal**  **(ppm pure C(M)IT)** |
| Scenario [15] | Tier 1 | 150 |
| Scenario [15] | Tier 2 | < 15 |

**Scenario [16] - Secondary indirect exposure: Ingestion of painted chips by toddler**

In theory, a toddler could intentionally ingest paint chips or coated surfaces containing dried paint with C(M)IT/MIT in the coating.

For the purposes of a worst-case exposure scenario, a child with “pica” - the habitual practice of eating non-food objects (such as soil and paint) - is assumed to ingest as much as 10 grams of paint per day[[10]](#footnote-11).

It is also assumed that 100% of the ingested C(M)IT is absorbed[[11]](#footnote-12) into the body of the 10 kg toddler.

Assuming the C(M)IT is concentrated by a factor of 2 as the paint dries[[12]](#footnote-13) (i.e., 30 ppm w/w in the dried paint), the systemic exposure in this scenario is calculated as follows:

0.0030% x 10g/day x 50% / 10 kg = **1.5 x10-5 g/kg/day**

This scenario relates short-term exposure and covers conservatively the potential hand-to-mouth transfer of paint.

**Scenario [17] - Secondary indirect exposure: Inhalation of volatilized residues of AS**

| ***Description of Scenario [17]*** | | | |
| --- | --- | --- | --- |
| Indirect inhalation exposures to infant, toddler, child and adult residents of bedroom painted with paint containing C(M)IT were estimated using ConsExpo web and the evaporation model.  As a worst-case, an exposure duration of 24h is considered.  This exposure is considered to be a long-term expousre.  Default values of 27 m3 (approximatively 5 m lenght x 2.2 m wide x 2.5 m height) for a bedroom size are taken into account from the General fact sheet.  The release are is assumed to be the 4 walls of the bedroom plus the ceiling.  The release area (RA) is calculated as follows :  RA = 2 x (5m x 2.5m) + 2 x (2.2m x 2.5m) + (5m x 2.2m)  RA = 25 + 11 + 11  **RA = 47 m2**  In order to estimate the amount of paint applied on the surfaces, the following parameters have been taken into consideration:   * Paint coverage : 12 – 15 m2/L for a solvent rich paint (from the Paint fact sheet) ; * Paint density : 1.6 g/cm3 (HEAd Hoc Recommendation 4).   The amount of paint applied on surfaces is claculated as follows :  Amount of paint = (RA/paint coverage) x density of paint x 1000  **Amount of paint** = (47 m2 / 15 m2/L) x 1.6 g/cm3 x 1000 = **5 013 g**. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Highest concentration of a.s in the paint | 150 ppm pure C(M)IT (= 0.015%) | Applicant’s data for professionnal product |
| Exposure frequency (1/y) | 1 | RMS assumption |
| Exposure duration (h) | 24 | RMS assumption |
| Release area (m2) | 47 | See above |
| Applied product amount (g) | 5013 | See above |
| Ventiltion rate (/h) | 0.6 | General fact sheet default value for a bedroom with no specific ventilation |
| Inhalation rate (m3/24h) | Adult : 16  Child (6 to < 12y) : 12  Child (2 to < 6y) : 10.1  Toddler : 8  Infant : 5.4 | HEAd hoc recommendation 14 |
| Body weight (kg) | Adult : 60  Child (6 to < 12y) : 23.9  Child (2 to < 6y) : 15.6  Toddler : 10  Infant : 8 | HEAd hoc recommendation 14 |
| **Tier 2** | Highest concentration of a.s in the paint | 15 ppm pure C(M)IT (= 0.0015%) | Applicant’s data for non professional product |

*Systemic effects*

| **Summary table: estimated exposure from general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [17] | Tier 1  Adult | 7.5 x 10-3 | - | - | 7.5 x 10-3 |
| Tier 1  Child (6 to 12) | 1.41 x 10-2 | - | - | 1.41 x 10-2 |
| Tier 1  Child (2 to 6) | 1.81 x 10-2 | - | - | 1.81 x 10-2 |
| Tier 1  Toddler | 2.24 x 10-2 | - | - | 2.24 x 10-2 |
| Tier 1  Infant | 1.89 x 10-2 | - | - | 1.89 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from general public** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated concentrations during the task** |
| **Inhalation**  **(mg pure C(M)IT/m3)\*** |
| Scenario [17] | Tier 1  Adult, child, toddler and infant | 2.8 x 10-2 |
| Scenario [17] | Tier 2 | 2.8 x 10-3 |

\* External dose therefore no impact of the body weight and the inhalation rate values.

**Risk characterization for general public – Paints and coatings uses**

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [14]** | Tier 1 | 0.083 | 0.076 | 91.6 | Yes |
| Tier 2 | 0.083 | 0.0076 | 9.6 | yes |
| **Scenario [15]** | Tier 1 | 0.083 | 2.5 x 10-3 | 3.0 | Yes |
| Tier 2 | 0.083 | 2.5 x 10-4 | 0.3 | yes |
| **Scenario [16]** | Tier 1 | 0.083 | 1.5 x 10-2 | 18.07 | Yes |
| **Scenario [17]**  *Inhalation volatilized residues* | Tier 1/Adult | 0.065 | 7.5 x 10-3 | 11.5 | yes |
| Tier 1/Child (6 to 12) | 0.065 | 1.41 x 10-2 | 21.7 | yes |
| Tier 1/Child (2 to 6) | 0.065 | 1.81 x 10-2 | 27.9 | yes |
| Tier 1/Toddler | 0.065 | 2.24 x 10-2 | 34.5 | yes |
| Tier 1/Infant | 0.065 | 1.89 x 10-2 | 29.1 | yes |

* No unacceptable risk is observed for general public considering systemic effects.

*Local effects*

* Quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated Inhalation Concentration**  **(mg/m3)** | **Estimated Concentration/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [17]**  *Inhalation volatilized residues* | Tier 1 | 0.016 | 2.8 x 10-2 | 175 | No |
| Tier 2 | 0.016 | 2.8 x 10-3 | 17.5 | yes |

* Unacceptable risk is observed for the inhalation of volatilized residues scenario considering the use of paint containing 150 ppm pure C(M)IT. The risk is considered acceptable for the use of paint conatining a C(M)IT concentration below 15 ppm.
* Qualitative risk assessment (dermal exposure)

Direct dermal contact (including hand to mouth transfer) may occur with paint containing 150 ppm pure C(M)IT. This concentration being higher than the threshold value of 15 ppm for skin sensitization the risk is considered not acceptable. The C(M)IT concentration in paint must be below the skin sensitization threshold value to lead to an acceptable risk for general public.

|  |
| --- |
| **Other uses** |

**Professional exposure**

**Scenario [13] - Applying plaster via airless spraying and then working with trowels.**

This use is considered covered by the exposure assessment performed for the application of paint.

**Scenario [18,19,20,21] - Secondary exposure during application : other uses including use of preserved additives in paper production, use of preserved glues and adhesives, use of preserved polymer dispersion, pigment paste and colourants, use of preserved minneral slurries.**

As stated in the HEEG opinion 14, the intended uses liquid detergents (including household) and paints and coatings have been considered compared to the other intended uses.

However, the maximum concentration of C(M)IT claimed by the applicant for the other scenarios (preservation of glues and adhesives, mineral sluries…) is higher that the maximum concentration taken into account for the uses presented in exposure assessment (400 ppm pure C(M)IT vs 250 and 150 ppm pure C(M)IT)

In order to take into account the exposure during the uses of high concentration of C(M)IT, it has been decided to perform an envelop exposure assessment by using the concentration of 400 ppm pure C(M)IT and the exposure scenarios presented for the application of paint by brush/roller. These scenarios have been judged conservative enough regarding the intended uses.

For glues and adhesives, the surface available for contact shall be limited compared to a painted wall.

The maximum concentration used to preserved polymer, pigment paste, colourants and mineral slurries is 400 ppm pure C(M)IT, however these formulants are added to final product like paints and the exposure concentration to C(M)IT is then lower (the preservative is diluted in the receiving matrix). Moreover, the exposure during the addition of formulants containing 400 ppm pure C(M)IT is covered by the exposure assessment of Industrial users considering the loading of ACTICIDE 1.11% a.s in final products to be preserved.

**Estimated exposure scenario [18,19,20,21]**

The same parameters than those preseneted for Scenario [12] have been applied but considering a concentration of 400 ppm pure C(M)IT.

Only combined exposure (exposure during M&L, application and cleaning phase) is presented. The details of calculations for the different tasks is available in Appendix.

*Systemic effects*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Scenario [18,19,20,21]** | Tier 1/no PPE | 9.73 x 10-5 | 4.50 x 10-2 | - | 4.51 x 10-2 |

*Local effects*

| **Summary table: estimated exposure concentration from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration**  **(mg pure C(M)IT/m3)** | | **Estimated dermal concentration**  **(ppm pure C(M)IT)** |
| **During the task** | **Daily mean concentration (8h TWA)** |
| **Scenario [18,19,20,21]** | Tier 1/no PPE | 1.41 x 10-3 | 5.84 x 10-4 | n.a\* |

\*As for local dermal effect it is the concentration of the C(M)IT during the event of contact that is relevant, combined exposure have only been assessed for systemic exposure.

**Risk characterization for professionals – Other uses**

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [13]**  Plaster | Tier 1/no PPE | 0.065 | 3.38 x 10-2 | 52.1 | yes |
| **Scenario [18,19,20,21]**  Other uses (max conc. 400 ppm pure C(M)IT) | Tier 1/no PPE | 0.065 | 9.0 x 10-2 | 138.3 | **No** |
| Tier 2/ Gloves + coated coverall | 0.065 | 1.83 x 10-2 | 28.2 | yes |

* The risk is considered acceptable for use of colorants, pigments, mineral slurries… by professionals taking into account gloves and a coated coverall. No PPE is necessary for application of plasters.

*Local effects*

* Quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated Inhalation Concentration**  **(mg/m3)** | **Estimated Concentration/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [13]**  Plaster | Tier 1/no PPE | 0.012 | 2.2 x 10-4 | 1.83 | yes |
| **Scenario [18,19,20,21]**  Other uses (max conc. 400 ppm pure C(M)IT) | Tier 1/no PPE | 0.012 | 5.84 x 10-4 | 4.87 | yes |

* No unacceptable risk is observed for the inhalation route.
* Qualitative risk assessement (dermal exposure)

The maximum concentration used to preserved polymer, pigment paste, colourants and mineral slurries is 400 ppm pure C(M)IT, however these formulants are added to final product like paints and the exposure concentration to C(M)IT is then lower (the preservative is diluted in the receiving matrix).

For final concentration of pure C(M)IT higher than 15 ppm, please refer to the table presented above for use of paints and detergents.

**Non Professional exposure**

**Scenario [13] - Applying plaster via airless spraying and then working with trowels.**

This use is considered covered by the exposure assessement performed for the application of paint.

**Scenario [19] - Secondary exposure during application : use of preserved preserved glues and adhesives.**

As stated by the applicant, the a.s concentration is intended to be < 15 ppm in glue and adhesive for non-professionals.

Exposure assessment during the use of glue is considered covered by the scenario presented above for the use of paint with brush and roller. As stated in the HEEG opinion 14, the surface available for contact shall be limited, e.g adhesives on wall paper, when compared to a painted wall.

***Monitoring data***

None

***Dietary exposure***

The intended uses of the PT6 disinfectant products can be very diverse and can result in different scenarios for dietary exposure. Considering the intended uses in sub-PTs 6.1.2 (Washing and cleaning fluids (general) and other detergents), 6.2 (Paints and coatings) and 6.3.1 (Fluids used in paper production), there is potential food contamination with the pure active substance C(M)IT. Hence, a dietary risk assessment is performed in accordance with:

* the Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses (Chapter 5 of Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017)
* the draft Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods –professional Uses (not yet published – eCA proposal),
* the “DRAWG Opinion on identifying worst-case exposure scenarios for PT6 biocidal products in order to minimize the number of scenarios to be assessed for dietary risk”,
* Cleaning Products Fact Sheet Default parameters for estimating consumer exposure - Updated version 2018 - RIVM Report 2016/0179.

In the following, the relevant dietary exposure scenarios are summarised:

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** | | |
| --- | --- | --- |
| **Scenario number** | **Description of scenario** | **Subject of exposure** |
| Use 6.1.2 Washing and cleaning fluids (general) and other detergents | | |
| DRA 1.a | Dietary exposure from dishware. | Treated article used by General public |
| DRA 1.b | Dietary exposure from cleaned surfaces | Treated article used by General public |
| Use 6.2 Paints and coatings, 6.3.1 Fluids used in paper production, 6.6 Glues and adhesives | | |
| DRA 2 | Dietary exposure from Food contact material | Treated article used by General public for food and feed |

No calculation was realized by the applicant. The applicant considers that no dietary assessment is necessary considering the argumentation presented below:

| ***Applicant arguments for Dietary Exposure Scenario DRA 1*** |
| --- |
| It must be considered that washing and cleaning fluid and other detergent (treated articles) placed on the market for the general public contain C(M)IT concentrations below 15 ppm. This is also in accordance with the Commission Implementing Regulation EU No. 2016/131 for the AS C(M)IT/MIT (3:1), which states that “*[…] mixtures treated with or incorporating C(M)IT and placed on the market for use by the general public shall not contain C(M)IT at a concentration triggering classification as skin sensitizer […]*”, i.e. concentrations ≥ 15 ppm.  However, as described in Scenario 4 above [Scenario 4- Detergents – Hand washing laundry], the more relevant AS concentration is the weight fraction in the water, e.g. dishwashing water. In accordance with ECHA’s Biocides Human Health Exposure Methodology (p. 139, Version 1, October 2015) the weight fraction is <0.021 ppm (<15 ppm C(M)IT concentration in detergent divided by dilution factor 714, due to product dilution in 15 L water).  The concentration of 0.021 ppm is further diluted in the amount of food, leading to negligible active substance concentrations. |
| ***Applicant arguments for Dietary Exposure Scenario DRA 2*** |
| Use of PT 6 products in coatings (sub-PT 6.2) or fluids used in paper production (sub-PT 6.3.1). CIT-preserved products are used in production of food contact materials, components thereof, or feed packaging. Dietary exposure may occur if residues from food contact materials or components thereof transfer into food that comes in contact with such materials. Or, if residues from feed packaging transfer to feed that is consumed by livestock animals and results in a deposition in edible animal matrices.  Products in coatings (sub-PT 6.2): Coatings that are used in food contact materials contain C(M)IT concentrations < 15 ppm.  Paper production (sub-PT 6.3.1): The additives to be preserved contain up to max. 85 ppm C(M)IT and are diluted during the paper making process to concentrations < 15 ppm. |

To confirm the applicant arguments, and ensure that no dietary risk is expected with the use of ACTICIDE C1, eCA has performed calculations as presented in the following paragraphes.

*Information on non biocidal use of the active substance*

The active substance C(M)IT has not been assessed under another regulation (PPP, VMP, …).

*Other Information relative to the active substance*

The biocide active substance C(M)IT/MIT, a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1), was already assessed and authorized in biocide legislation for the uses in PT2, 4, 6, 11, 12 and 13. No MRLs exist for C(M)IT and C(M)IT/MIT.

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | Biocide C(M)IT/MIT | PT2, 4, 6, 11, 12 and 13 | ADI: 0.02 mg/kg b.w./d  ARfD: 0.063 mg/kg b.w./d |

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

The assessment is realized using theoretical estimation of food contamination linked to the intended uses of biocide pure active substance. Although this pure active substance can be used in different conditions of temperature and pressure (in dishwasher or during process of paint, coating, paper, glues, adhesive), the active substance is considered as sufficiently stable (see the part about properties of a.s.: low Pvap = 1.6 Pa at 20°C, substances decomposed above 167°C), and no metabolites are expected. Hence, the “biocide residue” (defined as “the residue in food resulting from the use of a biocidal product”) taken into account in this dossier is the pure active substance only C(M)IT.

1. **Liquid detergents:**

For uses of PT 6 products in washing and cleaning fluids (general) and other detergents (sub-PT 6.1.2), dietary exposure may occur from residues remaining on eating utensils, dishes and surfaces washed with dishwashing detergents preserved with C(M)IT at a maximal final a.i. concentration of 250 ppm (expressed as pure active substance). Hence, all calculations are performed using this value of 250 ppm, nevertheless the final concentration in the in-used final detergent should be limited to 15 ppm as explained in section 3.4 of CAR:“ Based on the read-across with C(M)IT/MIT, a specific concentration limit ≥ 15 ppm is also proposed”. This is in line with human health conclusions for primary exposure scenarios.

For the non-professional user, the final concentration of preservative a.s. in the detergent is intended at a maximum level of 15 ppm (expressed as pure active substance). This low dose is therefore considered sufficiently covered by the exposure estimations from the professional uses presented here below.

**Scenario DRA 1.a: Exposure from dishware**

The daily exposure to C(M)IT from eating with utensils and dishware that have been washed with hand dishwashing detergents preserved with C(M)IT was estimated following the default values of Non-professional Guidance on Estimating Dietary Risk Uses, 5.6.2 In-can preservatives and disinfectants in dishwashing detergents, and Cleaning Products Fact Sheet 2018 , 7.3 Manual dishwashing.

|  |  |
| --- | --- |
| **Scenario DRA1.a: In-can preservatives and disinfectants in dishwashing detergents** | |
| **Parameters used** | **values** |
| In use concentration of a.s. in biocidal product (expressed as pure active substance)  F1 : percentage of a.s. in dishwashing detergent | 250 ppm or mg a.s./L equivalent to 0.00025 mg a.s/mg) of detergent  max value given by the Applicant and for which efficacy is acceptable |
| C´ : concentration of detergent in dish wash solution (mg/L) | 1400 mg/L  default value equivalent to dilution factor of 700 – Consexpo Cleaning Factsheet 2018 |
| Ta´: amount of water left on dishes after rinsing (dilution factor for rinsing: 1/10 not justified) (L/cm2) | 5.5 x 10-7 L/cm2  default value without dilution factor for rinsing |
| Sa : area of dishes in daily contact with food (cm2/d) | 5400 cm2/d  default value |
| F : percentage of a.s. transferred from article and ingested | 100%  default value; refinement possible if based on real data |
| bw : body weight (kg) | 10 kg / 60 kg  default value for toddler / adult |
| D : dietary intake fraction: acute | 1.0/day and chronic = 0.5/day |

Default values mentioned in Example 5.6.1 and in Appendix 5-1 of the non professional Guidance

**Estimation of acute and chronic consumer exposure:**

Expcons = [F1 x C’ x Ta’ x Sa x F] ÷ bw

Adult (acute) Expcons =

[(0.00025) x (1400 mg/L) x (5.5x10-7 l/cm2) x (5400 cm2) x (1)] x 1/d ÷ 60 kg =

1.73 x 10-5 mg/kg bw/d

Adult (chronic) Expcons =

[(0.00025) x (1400 mg/L) x (5.5x10-7 l/cm2) x (5400 cm2) x (1)] x 0.5/d ÷ 60 kg =

0.86 x 10-4 mg/kg bw/d

Toddler (acute) Expcons =

[(0.00025) x (1400 mg/L) x (5.5x10-7 l/cm2) x (5400 cm2) x (1)] x 1/d ÷ 10 kg =

1.04 x 10-4 mg/kg bw/d

Toddler (chronic) Expcons =

[(0.00025) x (1400 mg/L) x (5.5x10-7 l/cm2) x (5400 cm2) x (1)] x 0.5/d ÷ 10 kg =

0.52 x 10-4 mg/kg bw/d

**Scenario DRA 1.b: Exposure from cleaned surfaces**

The daily exposure to C(M)IT from food contact with treated surfaces such as kitchen counters or dining tables was estimated following the default values of Non-professional Guidance on Estimating Dietary Risk Uses, 5.6.1 Disinfectants and Preserved Cleaners in domestic kitchens, and Cleaning Products Fact Sheet 2018 , 8 overall cleaning.

|  |  |
| --- | --- |
| **Scenario DRA 1.b: In-can preservatives and disinfectants in domestic kitchen** | |
| **Parameters used** | **values** |
| In use concentration of a.s. in biocidal product (expressed as pure active substance) | 250 ppm or mg a.s./L equivalent to 250 mg a.s./kg of detergent  max value given by the Applicant and for which efficacy is acceptable |
| Dilution factor expected in the in-used solution | 78  default value from Cleaning Products Fact Sheet 2018- 8.1 cleaning liquid |
| film thickness | 0.002 cm  default value |
| application rate expected considering the film detergent used on the surface | 0.02 L/m² |
| Rsurface : biocide residues on surface (mg a.s./m2) | = 250 mg a.s./L / 78 x 0.02 L/m²  = 0.064 mg a.s./m2 |
| Afood contact : area in contact with food (m2) | 0.2 m2  default value for acute and chronic exposure |
| TF : mass transfer efficiency factor (fraction of biocide residue transferred from surface to food) | 100%  default value in absence of product-specific data |
| bw : body weight (kg) | 10 kg / 60 kg  default value for toddler / adults |
| D : dietary intake fraction: acute | 1.0/day and chronic = 0.5/day |

Default values mentioned in Example 5.6.1 and in Appendix 5-1 of the non professional Guidance

**Estimation of acute and chronic consumer exposure:**

Expcons = Rsurface x Afood contact x TF x D ÷ bw

Adult (acute) Expcons =

0.064 mg a.s./m2 x 0.2 m2 x 1/d x 100% ÷ 60 kg = 0.00021 mg/kg bw/d

Adult (chronic) Expcons =

0.064 mg a.s./m2 x 0.2 m2 x 0.5/d x 100% ÷ 60 kg = 0.00001 mg/kg bw/d

Toddler (acute) Expcons =

0.064 mg a.s./m2 x 0.2 m2 x 1/d x 100% ÷ 10 kg = 0.00128 mg/kg bw/d

Toddler (chronic) Expcons =

0.064 mg a.s./m2 x 0.2 m2 x 0.5/d x 100% ÷ 10 kg = 0.00064 mg/kg bw/d

1. **Food contact materials:**

Considering the intended uses in coatings (sub-PT 6.2) or fluids used in paper production (sub-PT 6.3.1), C(M)IT may be present as residues in food or feed packaging materials at a maximal final a.i. concentration of 150-85 ppm (expressed as pure active substance) respectively following its use as in-can preservative. Dietary exposure may occur if residues from food contact materials or components thereof transfer into food that comes in contact with such materials. Or, if residues from feed packaging transfer to feed that is consumed by livestock animals and may be found in edible animal matrices. Hence, the calculations are performed using this value of 85 ppm (expressed as pure active substance) considering the worst case scenario ”PT 6.3.1. Fluids used in Paper production” for which no dilution factor is available.

The daily exposure to C(M)IT from food contact with treated material was estimated following the default values of draft professional Guidance on Estimating Dietary Risk Uses, 5.3. Food contact materials treated or equipped with biocides. This draft guidance refers to assessment realized in framework of FCM Regulation. For the biocide, the similar default value are used.

It should be noted that children, no exposure scenario is available.

**Scenario DRA 2: Food contact materials**

|  |  |
| --- | --- |
| **Scenario DRA 2: In-can preservatives and disinfectants in food contact material** | |
| **Parameters used** | **values** |
| concentration of a.s. in fluids used in Paper production (expressed as pure active substance) | 85 ppm or mg a.s./L equivalent to 85 mg a.s./kg  max value given by the Applicant for paint uses and considered acceptable for efficacy |
| Dilution factor expected in the paper | Unknown, therefore no dilution factor is used |
| paper density | 80 g/m² equivalent to 0.080 kg/m²  default value : 25-300 g.m-2 for papers |
| Rsurface : biocide residues on surface (mg a.s./m2) | = 85 mg a.s./kg x 0.08 kg/m² = 6.8 mg a.s./m2 |
| Afood contact : area in contact with food (m2) | 0.06 m2  default value for acute and chronic exposure, used in FCM |
| TF : mass transfer efficiency factor (fraction of biocide residue transferred from surface to food) | 100%  default value in absence of product-specific data |
| bw : body weight (kg) | 60 kg  default value for adults |
| D : dietary intake fraction: acute | 1.0/day and chronic = 0.5/day |

Default values mentioned in Appendix 6-1: Default Value Working Tables of the Guidance

**Estimation of acute and chronic consumer exposure :**

Expcons = Rsurface x Afood contact x TF x D ÷ bw

Adult (acute) Expcons =

6.8 mg a.s./m2 x 0.06 m2 x 1/d x 100% ÷ 60 kg = 0.0068 mg/kg bw/d

Adult (chronic) Expcons =

6.8 mg a.s./m2 x 0.06 m2 x 0.5/d x 100% ÷ 60 kg = 0.0034 mg/kg bw/d

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Regarding the low levels of food contamination from a direct contact with treated FCM, the contamination of food from animal livestock fed with feedstuff in contact with treated FMC origin is foreseen to be negligible. Therefore, no livestock exposure was considered necessary in framework of this dossier.

#### Risk characterisation for human health

***Risk for consumers via residues in food***

|  |  |  |
| --- | --- | --- |
| ***Risk for consumers via residues in food*** | | |
| **Dietary exposure** (mg/kg bw/d) | | **Dietary Risk** % of ADI (0.015 mg/kg b.w./d) or ARfD (0.03 mg/kg b.w.) |
| **Scenario DRA 1.a: In-can preservatives and disinfectants in dishwashing detergents** | | |
| Adult (chronic) | 0.086 x10-4 | 0.058% |
| Toddler (chronic) | 0.52 x10-4 | 0.347% |
| Adult (acute) | 0.17 3 x10-4 | 0.058% |
| Toddler (acute) | 1.04 x10-4 | 0.347% |
| **Scenario DRA 1.b: In-can preservatives and disinfectants in domestic kitchen** | | |
| Adult (chronic) | 0.1 x10-4 | 0.71% |
| Toddler (chronic) | 6.4 x10-4 | 4.27% |
| Adult (acute) | 2.1 x10-4 | 0.71% |
| Toddler (acute) | 12.8 x10-4 | 4.27% |
| **Scenario DRA 2: In-can preservatives and disinfectants in food contact material** | | |
| Adult (chronic) | 0.0034 | 22.66% |
| Toddler (chronic) | no scenario available | |
| Adult (acute) | 0.0068 | 22.66% |
| Toddler (acute) | no scenario available | |

**Conclusion**

It is highlighted that the exposure is likely overestimated using worst case situation and protective scenario approach. Regarding the estimation of theoretical exposure to C(M)IT via food contamination considering the intended uses in PT 6, no dietary risk is identified for the use as preservative in detergent or in paper.

### Risk assessment for animal health

See paragraph *“Estimating Livestock Exposure to Active Substances used in Biocidal Products”.*

### Risk assessment for the environment

#### Effects assessment on the environment

| **Compartment** | **PNEC** | **Remarks/Justification** |
| --- | --- | --- |
| Freshwater | 0.037 µg pure C(M)IT/L | Organism: Algae (*Skeletonema costatum)*  Endpoint: NOEC (48 h) 0.37 µg a.i. /L for C(M)IT derived from C(M)IT/MIT: 0.49 µg a.i./L x 0.75  Assessment factor: 10  Extrapolation method: assessment factor  Justification: Since the three taxonomic groups (fish, invertebrates, algae) are covered and chronic data for all three trophic levels are available an assessment factor of 10 is justified. |
| STP | 0.0338 mg pure C(M)IT/L | Organism: activated sludge  Endpoint: EC50 (3h) 3.38 mg a.i. /L for C(M)IT derived from C(M)IT/MIT: 4.5 mg/L x 0.75  Assessment factor: 100  Extrapolation method: assessment factor  Justification: According to the guidance document (Vol. IV Part B) an assessment factor of 100 is justified to be applied on an EC50. |
| Soil | * 6.6 µg pure C(M)IT/kg ww * TWA: 4.8 µg pure C(M)IT/kg ww | Organism: soil microorganisms  Endpoint:   * NOEC (28 d) 0.75 mg a.i./kg dw for C(M)IT derived from C(M)IT/MIT: 1 mg a.i. /kg dw * NOEC TWA = 0.67 mg a.i./kg dw for C(M)IT derived from C(M)IT/MIT: 0.90 mg a.i. /kg dw   Assessment factor: 100  Extrapolation method: assessment factor  Justification: A safety factor of 100 is applied since one long-term toxicity test is available.  Equation 18 of Guidance on BPR Vol IV Part B+C has been applied to calculate the wet weight PNEC. |
| Sediment | Not calculated | As the Koc of C(M)IT is below 500 L/ kg (Koc = 45.3 L/kg) no risk assessment is required for this compartment and therefore, no PNECsediment is calculated. |

The log Kow of C(M)IT is below 1 indicating a negligible potential for bioconcentration in biota. EPIWIN estimates of the BCF are 3.16 L/kg for C(M)IT. As such it can be stated that the active substance C(M)IT, does not possess any bioconcentration potential. Therefore, accumulation of the substances in the food chain is not expected and the risk of secondary poisoning in aquatic and terrestrial predators is not further assessed.

***Further Ecotoxicological studies***

No data is available.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

No data is available.

***Supervised trials to assess risks to non-target organisms under field conditions***

No data is available.

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No data is available.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No data is available. Not relevant.

***Further studies on fate and behaviour in the environment (ADS)***

No data is available.

***Testing for distribution and dissipation in soil (ADS)***

No data is available.

***Testing for distribution and dissipation in water and sediment (ADS)***

No data is available.

**Dissipation**

No data is available.

***Testing for distribution and dissipation in air (ADS)***

No data is available.

**Dissipation**

No data is available.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

No data is available.

**Chronic aquatic toxicity**

No data is available.

**Estimated aquatic bioconcentration**

No data is available.

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

No data is available.

#### **Exposure assessment**

The environmental risk assessment is based on the ESDs described in the next table and on the Guidance on BPR Vol IV Part B+C, 2017. The required information to assess the PT 6 uses is summarized in the following table.

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 6 |
| Assessed scenarios | **Formulation of in-can preserved end-products:**  *PT 6.1, 6.2, 6.3-1, 6.6, 6.7: (Confidential)*  **Use of preserved products:**  PT *6.1 Preservation of detergent and cleaning fluids*  **PT 6.1.2 A)** Preservation of washing and cleaning fluids for professional use (Use area: detergents used in industry for large surfaces, in large-scale laundry)  Scenario 6.1.2 - 1: Emission scenario for calculating the release of preservatives applied in professional detergents used for laundry from hospitals in washing streets.  Scenario 6.1.2 - 2: Emission scenario for calculating the release of preservatives used in professional detergents for surface cleaning in industrial areas  **PT 6.1.2 B)** Preservation of washing and cleaning fluids for non-professional use (Use area: detergents for dish washing, fabric washing, surface cleaning)  Scenario 6.1.2 – 3: Emission scenario for calculating the release of preservatives used in non- professional detergents for fabric washing  Scenario 6.1.2 – 4: Emission scenario for calculating the release of preservatives used in non-professional detergents for dish washing, non-professional  Scenario 6.1.2 – 5: Emission scenario for calculating the releases of preservatives used in detergents for sanitary purposes based on average consumption  *PT 6.2 Preservation of paints and coatings*  **Application phase**  Scenario 6.2 – 1: House scenario (City and Countryside) - Emission scenario for calculating the releases from a façade treated by sprayer  Scenario 6.2 – 2: House scenario (City and Countryside) - Emission scenario for calculating the releases from a façade treated with roller or brush  Scenario 6.2 – 3: Bridge over pond scenario (Countryside) - Emission scenario for calculating the releases from a bridge treated with a brush  **Service life**  Scenario 6.2 – 4: City scenario : Emission scenario for calculating the releases during service life from a façade  Scenario 6.2 – 5: Countryside scenario: Emission scenario for calculating the direct releases to soil during service life from a façade  Scenario 6.2 – 6: Countryside scenario: Emission scenario for calculating the releases during service life from a bridge  *PT 6.3 Preservation of additives used in paper, textile and leather production*  PT 6.3.1: Paper production  Scenario 6.3.1 - 1: Emission scenario for calculating the release from “broke”  Scenario 6.3.1 – 2: Emission scenario for paper recycling (Confidential)  *PT 6.6: Glues and adhesives*  Scenario 6.6 – 1 : Emission estimations from glues and adhesives uses (Confidential)  *PT 6.7: Other*  Scenario 6.7 – 1: Use of preserved polymer dispersions  Qualitative assessment  Scenario 6.7 – 2: Use of preserved slurries  Qualitative assessment  Scenario 6.7 – 3: P Use of preserved colorants  Qualitative assessment  Scenario 6.7 – 4: Use of preserved pigment paste  Qualitative assessment |
| ESD(s) used | PT 6 :  Emission Scenario Document for Product Type 6: Preservatives for Products during Storage (2018)  PT 8 :  [Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)](https://echa.europa.eu/documents/10162/16908203/pt8_ground_water_assessment_en.pdf/ddbc2a33-4fcb-47e1-a01f-6c79403a457e)  PT 10 :  [ESD for PT 10: Emission scenarios for biocides used as masonry preservatives (EUBEES, 2002)](https://echa.europa.eu/documents/10162/16908203/pt10_masonry_preservatives_en.pdf/5bab4221-3156-4d4e-a57c-ab0cdc42ea18)  [City scenario: Leaching from paints, plasters and fillers applied in urban areas (NL, 2015)](https://echa.europa.eu/documents/10162/16908203/pt10_city_scenario_en.pdf/18d9f122-4471-446e-9912-3b184ca7d3cc)  The assessment of direct emission to surface water  in urban areas : PT 6.2/6.3 and 7-10 (DE, 2014) |
| Approach | Formulation of in-can preserved end-products:  Scenario 6.0: Tonnage based (Confidential)  Uses of preserved products:  Scenario 6.1: Consumption based  Scenario 6.2: Consumption based  Scenario 6.3: Tonnage based (Confidential)  Scenario 6.6: Tonnage based (Confidential) |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017). |
| Groundwater simulation | Yes - Focus PEARL (v 4.4.4) calculations |
| Confidential Annexes | Yes |
| Life cycle steps assessed | Scenario 6.1:  Production: No  Formulation of preserved products: Yes  Use of preserved products: Yes  Service life: No  Scenario 6.2:  Production: No  Formulation of preserved products: Yes  Use of preserved products: Yes  Service life: Yes  Scenario 6.3:  Production: No  Formulation of preserved products: Yes  Use of preserved products: Yes  Service life (paper recycling): Yes  Scenario 6.6  Production: No  Formulation of preserved products: Yes  Use of preserved products: Yes  Service life: No  Scenario 6.7  Production: No  Formulation of preserved products: Yes  Use of preserved products: No  Service life: No |
| Remarks | [-] |

**Biocidal product specific data**

Due to the composition of the biocidal product ACTICIDE C1, which does not contain any further substances of concern, there is no need for product specific data. Available data on the pure C(M)IT are valid for the product as well.

##### ***Emission estimation***

The following sections will address the relevant environmental exposure routes for ACTICIDE C1, the representative biocidal product for the use as in-can preservative (PT06) containing the active substance C(M)IT. The environmental exposure assessment is based on pure C(M)IT, i.e. without water and stabilizers.

ACTICIDE C1 is added as an in-can preservative into matrices (for example: detergents or paints/coatings) before these products are used. After this “Product Formulation” stage, the in-can preservative may be left on the shelf in the containers for a long period. This is effectively the “Use stage” for C(M)IT since it acts as a biocide in the product containers prior to these being opened and used. The use of the paint or detergent could be seen as the disposal phase of C(M)IT since it is no longer required to prevent organisms growing in the container of product. However it is clear that this “Disposal phase” for C(M)IT will involve the potential for significant environmental exposure.

Therefore, in this assessment the life cycle phases of the ultimate products are those that are considered:

* the “re-formulation” of ACTICIDE C1 into those products has been termed “Formulation of in-can preserved end-products”;
* the use of the paint, glue, detergent, etc., has been termed “Use of preserved end-products”.

However, it is noteworthy that the “use” phase as defined above, is beyond the intended useful life span of the in-can preservative. The term "disposal" is used to denote the disposal of the spent or unused fluid which may also contain some C(M)IT.

* **Formulation** (Tonnage-based, Confidential)

Scenario 6.0: Formulation

Please refer to the confidential annex.

* **Use of preserved products**

**6.1: Preservation of detergents and cleaning fluids**

Biocidal products containing C(M)IT are used for the in-can preservation of general detergents such as household cleaning products, fabric washing products or dishwashing liquids for professionals and non-professionnals with use concentrations of 2.83 ppm to 15 ppm of pure C(M)IT, the threshold value for skin sensitization in accordance with conclusion on the human health risk assessment. According to the applicant, it is not intended to be used in human hygienic products.

***PT 6.1.2 A) Preservation of washing and cleaning fluids for professional use***

Scenario 6.1.2 - 1: Emission scenario for calculating the release of preservatives applied in professional detergents used for laundry from hospitals in washing streets

The following input parameters are used to calculate the local emissions to the STP.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission – Use step** | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **Remarks** |
| Scenario 6.1.2 -1: Emission scenario for calculating the release of preservatives applied in professional detergents used for laundry from hospitals in washing streets (ESD for PT06, 2018) | | | | |
| Number of washing tubes | Nm | 3 | [-] |  |
| Capacity of washing tube | Cap | 8000 | [kg/d] |  |
| Amount of detergent for laundry | Vproduct | 0.006 | [L/kg] |  |
| Max. concentration of active substance in detergent | Cdetergent | 1.50E-05 | [kg/L] | 15 ppm |
| Concentration reduction in washing process | Fred | 0 | [-] |  |
| Market penetration factor | Fpenetr | 1 | [-] |  |
| **Output** | | | | |
| **Local release to waste water** | **Elocalwater** | **2.16E-03** | **[kg/d]** |  |

Scenario 6.1.2 – 2: Emission scenario for calculating the release of preservatives used in professional detergents for surface cleaning in industrial areas

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission – Use step** | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **Remarks** |
| Scenario 6.1.2 - 2 – Emission scenario for calculating the release of preservatives used in professional detergents for surface cleaning in industrial areas (ESD for PT06, 2018) | | | | |
| Application rate of the diluted detergent | Vform | 0.1 | [L/m²] |  |
| Max. concentration of a.i. in the concentrate detergent | Cform | 1.50E-05 | [kg/L] | 15 ppm |
| Fraction of concentrate in the diluted detergent | Fconc | 0.01 | [-] |  |
| Surface area to be cleaned | AREAsurface | 2000 | [m²] |  |
| Number of applications per day | Nappl | 1 | [-] |  |
| Fraction of substance disintegrated during or after application (before release to sewer) | Fdis | 0 | [-] |  |
| Fraction released to wastewater | Fwater | 1 | [-] |  |
| Market penetration factor | Fpenetr | 1 | [-] |  |
| **Output** | | | | |
| **Local release to waste water** | **Elocalwater** | **3.00E-05** | **[kg/d]** |  |

***PT 6.1.2 B) Preservation of washing and cleaning fluids for non-professional use***

Scenario 6.1.2 – 3: Emission scenario for calculating the release of preservatives used in non-professional detergents for fabric washing

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission – Use step** | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **Remarks** |
| Scenario 6.1.2 – 3: Emission scenario for calculating the release of preservatives used in non-professional detergents for fabric washing (ESD for PT06, 2018) | | | | |
| Number of houses feeding one STP | Nhouse | 4000 | [-] |  |
| Number of laundry washes per household per day | Nwash | 0.61 | [d-1] |  |
| Fraction released to wastewater | Fwater | 1 | [-] |  |
| Fraction of washes performed with laundry detergents | Fliquid | 0.6 | [-] |  |
| Dosage of liquid laundry detergents | DOSEliquid | 0.075 | [-] |  |
| Dosage of fabric softeners | DOSEfabricsoftener | 0.04 | [-] |  |
| Active substance in the product | Cformvolume | 1.50E-05 | [kg/L] | 15 ppm |
| Market penetration factor | Fpenetr | 0.5 | [-] |  |
| **Output** | | | | |
| **Local release to waste water** | **Elocalwater** | **1.56E-03** | **[kg/d]** |  |

Scenario 6.1.2 – 4: Emission scenario for calculating the release of preservatives used in non-professional detergents for dish washing, non-professional

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission – Use step** | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **Remarks** |
| Scenario 6.1.2 – 4: Emission scenario for calculating the release of preservatives used in non-professional detergents for dish washing, non-professional (ESD for PT06, 2018) | | | | |
| Number of inhabitants feeding one STP | Nlocal | 10 000 | [-] |  |
| Consumption rate of detergent per inhabitant per day | Vforminh | 2.90E-03 | [L/d] |  |
| Fraction released to wastewater | Fwater | 1 | [-] |  |
| Active substance in the product | Cformvolume | 1.50E-05 | [kg/L] | 15 ppm |
| Market penetration factor | Fpenetr | 0.5 | [-] |  |
| **Output** | | | | |
| **Local release to waste water** | **Elocalwater** | **2.18E-04** | **[kg/d]** |  |

Scenario 6.1.2 – 5: Emission scenario for calculating the releases of preservatives used in detergents for sanitary purposes based on average consumption

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission – Use step** | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **Remarks** |
| Scenario 6.1.2 – 5: Emission scenario for calculating the releases of preservatives used in detergents for sanitary purposes based on average consumption (ESD for PT06, 2018) | | | | |
| Number of inhabitants feeding one STP | Nlocal | 10 000 | [-] |  |
| Fraction released to wastewater | Fwater | 1 | [-] |  |
| Concentration at which active substance is used | Cform | 1.50E-05 | [kg/kg] | 15 ppm |
| Consumption per capita | Qform | 10E-02 | [kg/d] |  |
| Fraction of substance disintegrated during or after application (before release to the sewer system) | Fdis | 0 | [-] |  |
| Market penetration factor | Fpenetr | 0.5 | [-] |  |
| **Output** | | | | |
| **Local release to waste water** | **Elocalwater** | **7.50E-04** | **[kg/d]** |  |

Scenario 6.1 – Aggregated local emissions to STP

The emissions from all PT 6.1 uses can be directed to the same STP and are therefore aggregated for the subsequent PEC calculation and the risk assessment.

| **Resulting local emissions to STP – Use step** | | | | |
| --- | --- | --- | --- | --- |
| **Output** | **Symbol** | **Value** | **Unit** | **Remarks** |
| Local release to waste water - Aggregated | Elocalwater | 4.71E-03 | [kg/d] | Total emissions from all PT 6.1 scenarios |

**6.2: Preservation of paints and coatings**

Biocidal products containing C(M)IT are used for the in-can preservation of paints and plasters used indoor and outdoor:

* Paints, with use concentrations of 5.55 ppm to 15 ppm (non-professional) or 55.5 ppm (professional only) of pure C(M)IT.
* Plasters, with use concentrations of 5.55 ppm to 15 ppm (professional and non-professional) of pure C(M)IT.

15 ppm is the threshold value for skin sensitisation that must be applied for non-professional uses. 55.5 ppm represents the minimum effective value against bacteria, yeasts and fungi considering a storage of two weeks and is used in the risk assessment.

The preserved products may be used indoor and outdoor. The outdoor uses are chosen as worst case covering also the indoor use.

According to the ESD for PT 8 (2013), ESD for PT 10 (2002) and the scenario document for the leaching in urban areas (2015), two relevant locations can be differentiated.

* In the city (urban area), the C(M)IT is likely to enter paved ground during application and service life (House scenario). It is washed with rain to the sewer system subsequently reaching the sewage treatment plant (STP) or directly the surface water via STP bypass or direct rainwater discharge.
* In the countryside (rural area), the C(M)IT directly reaches the soil (House scenario) or surface water (Bridge over pond scenario) due to application and leaching during service life.

The relevant scenarios are assessed according to the ESD for PT 8 (2013) as indicated in the ESD for PT06. Calculations are carried out for the application phase and service-life of the treated surfaces.

The scenario for decorative paints proposed in the ESD for PT06 (2018) is tonnage basedAs no information is available on which part of the tonnage for paints provided by the applicant will be used in decorative paints a simulation is performed taking into account that all the paints containing C(M)IT will be used as decorative paints. As the Elocal calculated is lower than those from consumption based scenario (Application step of a paint with a spray for instance), it is considered that the Decorative paint scenario is covered and will not be presented in the PAR.

Life cycle step: Application – Paints and coatings

Emissions to the environment may occur due to the application of paints and plasters applied outside. Paints may be applied via spraying and brushing, while plasters are expected to be applied only by brushing covering other application types, e.g. plastering.

The following input parameters from the ESD for PT 8 (2013) (also reported in the ESD for PT06, 2018) and the city scenario document (2015)[[13]](#footnote-14) are used to calculate the release of the C(M)IT used as preservative in paints and plasters during application via brushing (due to dripping) or spraying (due to runoff and drift).

For brushing, only the amateur use is assessed representing the worst case.  
Spray application of paints is not relevant for the bridge over pond scenario and therefore not further assessed.

Scenario 6.2 – 1: City and Countryside scenario (House) - Emission scenario for calculating the releases from a façade treated by sprayer

In Tier 1, emissions by runoff and drift are considered. In Tier 2, emissions due to runoff are negligible thanks to the use of a tarpaulin on the ground, only drift is considered.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Input** | **Symbol** | **Value** | | | **Unit** | **Remarks** |
| Paints – 15 ppm | Paints – 55.5 ppm | Plasters – 15 ppm |
| Scenario 6.2 – 1: City and Countryside scenario (House) - Emission scenario for calculating the releases from a façade treated by sprayer | | | | | | |
| Treated area of a house facade | AREAfaçade | 125 | 125 | 125 | [m²] |  |
| Volume applied | Qapplication,product | 0.25 | 0.25 | - | [L/m²] | Scenario document for the leaching in urban areas (2015) |
| Quantity applied | Qapplication,product | - | - | 4.0 | [kg/m²] |
| Fraction of a.i. in preserved product | Fai | 1.50E-05 | 5.55E-05 | 1.50E-05 | [-] | 15/55.5 ppm |
| Density of product | RHOproduct | 1400 | 1400 | 1000\* | [kg/m³] |  |
| Fraction of paint lost during application by runoff | Frunoff | 0.2 | 0.2 | n.r. | [-] |  |
| Soil volume adjacent to treated surface and exposed by runoff | Vsoil,runoff | 13 | 13 | n.r. | [m3] |  |
| Fraction of paint lost during application by spray drift | Fdrift | 0.1 | 0.1 | n.r. | [-] |  |
| Fraction of spray drift depositing to 0.5m wide soil band 1-1.5m distant from the house (Tier 2) | Fdep | 0.33 | 0.33 | n.r. | [-] |  |
| Soil volume to which deposition occurs (Tier 1) | Vsoil,drift-tier1 | 13 | 13 | n.r. | [m3] |  |
| Soil volume to which deposition occurs (Tier 2) | Vsoil,drift-tier2 | 15 | 15 | n.r. | [m3] |  |
| Number of houses treated per day in urban areas | Nhouse,applic | 3 | 3 | 1 | [-] | TAB 2.0 ENV 119 |
| **Output** | | | | | | |
| **City - Local release to waste water/rainwater** | **Elocalwater** | **5.91E-04** | **2.19E-03** | **n.r.** | **[kg/d]** |  |
| **Countryside – Local release to soil – Tier 1** | **Elocal,soil,tier1** | **1.97E-04** | **7.28E-04** | **n.r.** | **[kg/d]** |  |
| **Countryside - Local release to soil – Tier 2** | **Elocal,soil,tier2** | **2.17E-05** | **8.01E-05** | **n.r.** | **[kg/d]** |  |

n.r.: non relevant

\*The dose to be applied is already in kg/m². Therefore, the density was set to 1000 kg/m³ (Cover note to: Leaching from paints, plasters, and fillers applied in urban areas (2015)).

Scenario 6.2 – 2: City and Countryside scenario (House) - Emission scenario for calculating the releases from a façade treated with a brush

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Input** | **Symbol** | **Value** | | | **Unit** | **Remarks** |
| Paints – 15 ppm | Paints – 55.5 ppm | Plasters – 15 ppm |
| Scenario 6.2 – 2: City and Countryside scenario (House) - Emission scenario for calculating the releases from a façade treated with a brush | | | | | | |
| Treated area of a house facade | AREAfaçade | 125 | 125 | 125 | [m²] |  |
| Volume applied | Qapplication,product | 0.25 | 0.25 | - | [L/m²] | [City scenario: Leaching from paints, plasters and fillers applied in urban areas (NL, 2015)](https://echa.europa.eu/documents/10162/16908203/pt10_city_scenario_en.pdf/18d9f122-4471-446e-9912-3b184ca7d3cc) |
| Quantity applied | Qapplication,product | - | - | 4.0 | [kg/m²] |
| Fraction of a.i. in preserved product | Fai | 1.50E-05 | 5.55E-05 | 1.50E-05 | [-] | 15/55.5 ppm |
| Density of product | RHOproduct | 1400 | 1400 | 1000\* | [kg/m³] |  |
| Fraction of preserved product (paint or plaster) lost during brush application due to dripping | Fdripping | 0.05 | 0.05 | 0.05 | [-] | Amateurs |
| Soil volume adjacent to surface treated | Vsoil | 13 | 13 | 13 | [m3] |  |
| Number of houses treated per day in urban areas | Nhouse,applic | 3 | 3 | 1 | [-] | TAB 2.0 ENV 119 |
| **Output** | | | | | | |
| **City - Local release to waste water / rainwater** | **Elocalwater** | **9.84E-05** | **3.64E-04** | **3.75E-04** | **[kg/d]** |  |
| **Countryside – Local release to soil** | **Elocal,soil** | **3.28E-05** | **1.21E-04** | **3.75E-04** | **[kg/d]** |  |

n.r.: non relevant

\*The dose to be applied is already in kg/m². Therefore, the density was set to 1000 kg/m³ (Cover note to: Leaching from paints, plasters, and fillers applied in urban areas (2015)).

Scenario 6.2 – 3: Countryside scenario (Bridge over Pond) - Emission scenario for calculating the releases from a bridge treated with a brush

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Input** | **Symbol** | **Value** | | | **Unit** | **Remarks** |
| Paints – 15 ppm | Paints – 55.5 ppm | Plasters – 15 ppm |
| Scenario 6.2 – 3: Countryside scenario (Bridge over Pond) - Emission scenario for calculating the releases from a bridge treated with a brush | | | | | | |
| Treated wood area | AREAbridge | 10 | 10 | 10 | [m²] |  |
| Application rate of the product | Qapplication,product | 0.25 | 0.25 | - | [L/m²] | [City scenario: Leaching from paints, plasters and fillers applied in urban areas (NL, 2015)](https://echa.europa.eu/documents/10162/16908203/pt10_city_scenario_en.pdf/18d9f122-4471-446e-9912-3b184ca7d3cc) |
| Quantity applied | Qapplication,product | - | - | 4.0 | [kg/m²] |
| Fraction of a.i. in preserved product | Fai | 1.50E-05 | 5.55E-05 | 1.50E-05 | [-] | 15/55.5 ppm |
| Density of product | RHOproduct | 1400 | 1400 | 1000\* | [kg/m³] |  |
| Fraction of product lost to water during application | Fbrush | 0.05 | 0.05 | 0.05 | [-] | Amateurs |
| Water volume under bridge | Vwater | 1000 | 1000 | 1000 | [m³] |  |
| **Output** | | | | | | |
| **Countryside – Local release to surface water** | **Elocal,surfacewater** | **2.63E-06** | **9.71E-06** | **3.00E-05** | **[kg/d]** |  |

\*The dose to be applied is already in kg/m². Therefore, the density was set to 1000 kg/m³ (Cover note to: Leaching from paints, plasters, and fillers applied in urban areas (2015)).

Life cycle step: Application – Paints and coatings - Summary

| **Resulting local emissions to STP/rainwater systems surface water, and soil – Application step** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Compartment** | | **Local emission (Elocal) [kg/d]** | | | **Remarks** |
| Paints – 15 ppm | Paints – 55.5 ppm | Plasters – 15 ppm |
| Scenario 6.2 – 1: City scenario – House | Elocalwaste water / rainwater  Brush application | 9.84E-05 | 3.64E-04 | 3.75E-04 |  |
| Elocalwaste water / rainwater  – Spray application | 5.91E-04 | 2.19E-03 | n.r. |  |
| Scenario 6.2 – 2: Countryside scenario – House | Elocal,soil –  Brush application | 3.28E-05 | 1.21E-04 | 3.75E-04 |  |
| Elocal,soil,tier1 – Spray application (Tier 1) | 1.97E-04 | 7.28E-04 | n.r. |  |
| Elocal,soil,tier2 – Spray application (Tier 2) | 2.17E-05 | 8.01E-05 | n.r. |  |
| Scenario 6.2 – 3:  Countryside scenario -Bridge over pond | Elocal,surface water – Brush application | 2.63E-06 | 9.71E-06 | 3.00E-05 |  |

n.r.: not relevant

Life cycle step: Service life – Paints and coatings

Further emissions to the environment may occur due to leaching during service life of the paints and plasters. 100% leaching during the initial assessment period (Time 1: 30 days) and service life (Time 2: 1825 days for paints and 9125 days for plasters) is considered.

For the assessment of the urban area, the worst case approach (leaching data is lacking) according to the city scenario document (2015) is used.

For the assessment in rural area, Elocalsoil are calculated separately for Time 1 and Time 2, and they are not aggregated as 100% leaching are considered for both exposure time.

The following input parameters from the ESD for PT 6 (2018) and the city scenario document (2015)[[14]](#footnote-15) are used to calculate the release of the C(M)IT used as preservative in paints and plasters during service life.

Scenario 6.2 – 4: City scenario (House) - Emission scenario for calculating the releases during service life from a façade

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Input** | **Symbol** | **Value** | | | **Unit** | **Remarks** |
| Paints – 15 ppm | Paints – 55.5 ppm | Plasters – 15 ppm |
| Scenario 6.2 – 4: City scenario - Emission scenario for calculating the releases during service life from a façade | | | | | | |
| Service life | Tservice-life | 1825 | 1825 | 9125 | [d] | Time 2 |
| Cumulative quantity of a.s leached out during the assessment period | Qleach | 6.56E-04 | 2.43E-03 | 7.50E-03 | [kg/house] | Equation 5 of the [City scenario: Leaching from paints, plasters and fillers applied in urban areas (NL, 2015)](https://echa.europa.eu/documents/10162/16908203/pt10_city_scenario_en.pdf/18d9f122-4471-446e-9912-3b184ca7d3cc): leaching data is lacking |
| Fraction of houses in a city, on which paints and plasters are applied | fhouse | 1 | 1 | 1 | [-] |  |
| Number of houses in a city | Nhouse | 4000 | 4000 | 4000 | [-] |  |
| **Output** | | | | | | |
| **City – Local release to waste water / rainwater** | **Elocalwater** | **1.44E-03** | **5.32E-03** | **3.29E-03** | **[kg/d]** | Equation 6 of the [City scenario: Leaching from paints, plasters and fillers applied in urban areas (NL, 2015)](https://echa.europa.eu/documents/10162/16908203/pt10_city_scenario_en.pdf/18d9f122-4471-446e-9912-3b184ca7d3cc) |

Scenario 6.2 – 5: Countryside scenario (House) - Emission scenario for calculating the direct releases to soil during service life from a façade

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Input** | **Symbol** | **Value** | | | **Unit** | **Remarks** |
| Paints – 15 ppm | Paints – 55.5 ppm | Plasters – 15 ppm |
| Scenario 6.2 – 5: Countryside scenario - Emission scenario for calculating the direct releases to soil during service life from a façade | | | | | | |
| Treated area of a house façade | AREAfaçade | 125 | 125 | 125 | [m²] |  |
| Duration of the initial assessment period | TIME1 | 30 | 30 | 30 | [d] |  |
| Time for the longer assessment period (remaining service life) | TIMElonger | 1795 | 1795 | 9095 | [d] |  |
| Service life | TIME2 | 1825 | 1825 | 9125 | [d] |  |
| Soil volume | Vsoil | 13 | 13 | 13 | [m3] |  |
| Cumulative quantity of a.s leached out over the first 30 days | Qleach,time1 | 5.25E-06 | 1.94E-05 | 6.00E-05 | [kg/m²] |  |
| Cumulative quantity of a.s leached out during the longer assessment period | Qleach,time2 | 5.25E-06 | 1.94E-05 | 6.00E-05 | [kg/m²] |  |
| **Output** | | | | | | |
| **Countryside - Local release to soil – TIME 1** | **Elocalsoil,time1** | **2.19E-05** | **8.09E-05** | **2.50E-04** | **[kg/d]** |  |
| **Countryside - Local release to soil - TIME 2** | **Elocalsoil,time2** | **3.60E-07** | **1.32E-06** | **8.22E-07** | **[kg/d]** |  |

For direct emission to soil, a refinement is realised and presented below, according to the TAB v2.1 (ENV-A4, 2019) and considering more realistic default leaching rates.

The following default leached quantities for all relevant times:

* Time 1 (30 days): 50% of the applied substance leaches out
* Time 2 (365 days): 75% of the applied substance leaches out
* Time 3 (service life): 100% of the applied substance leaches out.

The new calculations are gathered in the table below:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Input** | **Symbol** | **Value** | | | **Unit** | **Remarks** |
| Paints – 15 ppm | Paints – 55.5 ppm | Plasters – 15 ppm |
| Scenario 6.2 – 5: Countryside scenario - Emission scenario for calculating the direct releases to soil during service life from a façade | | | | | | |
| Treated area of a house façade | AREAfaçade | 125 | 125 | 125 | [m²] |  |
| Duration of the initial assessment period | TIME1 | 30 | 30 | 30 | [d] |  |
| Time for the longer assessment period (remaining service life) | TIME2 | 365 | 365 | 365 | [d] |  |
| Service life | TIME3 | 1825 | 1825 | 9125 | [d] |  |
| Soil volume | Vsoil | 13 | 13 | 13 | [m3] |  |
| Cumulative quantity of a.s leached out over the first 30 days | Qleach,time1 | 2.63E-06 | 9.71E-06 | 3.00E-05 | [kg/m²] |  |
| Cumulative quantity of a.s leached out over 365 days | Qleach,time2 | 3.94E-06 | 1.46E-05 | 4.50E-06 | [kg/m²] |  |
| Cumulative quantity of a.s leached out during the service life | Qleach,time3 | 5.25E-06 | 1.94E-05 | 6.00E-05 | [kg/m²] |  |
| **Output** | | | | | | |
| **Countryside - Local release to soil – TIME 1** | **Elocalsoil,time1** | **1.09E-05** | **4.05E-05** | **1.25E-04** | **[kg/d]** |  |
| **Countryside - Local release to soil - TIME 2** | **Elocalsoil,time2** | **1.35E-06** | **4.99E-06** | **1.54E-05** | **[kg/d]** |  |
| **Countryside - Local release to soil – TIME 3** | **Elocalsoil,time3** | **3.60E-07** | **1.33E-06** | **8.22E-07** | **[kg/d]** |  |

Scenario 6.2 – 6: Countryside scenario (Bridge over pond) - Emission scenario for calculating the releases during service life from a bridge

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Input** | **Symbol** | **Value** | | | **Unit** | **Remarks** |
| Paints – 15 ppm | Paints – 55.5 ppm | Plasters – 15 ppm |
| Scenario 6.2 – 6: Countryside scenario - Emission scenario for calculating the releases during service life from a bridge | | | | | | |
| Treated area of a bridge | AREAbridge | 10 | 10 | 10 | [m²] |  |
| Duration of the initial assessment period | TIME 1 | 30 | 30 | 30 | [d] |  |
| Time for the longer assessment period (remaining service life) | TIMElonger | 1795 | 1795 | 9095 | [d] |  |
| Service life | TIME 2 | 1825 | 1825 | 9125 | [d] |  |
| Cumulative quantity of a.s leached out over the first 30 days | Qleach,time1 | 5.25E-06 | 1.94E-05 | 6.00E-05 | [kg/m²] |  |
| Cumulative quantity of a.s leached out during the longer assessment period | Qleach,time2 | 5.25E-06 | 1.94E-05 | 6.00E-05 | [kg/m²] |  |
| Water volume | Vwater | 1000 | 1000 | 1000 | [m3] |  |
| **Output** | | | | | | |
| **Countryside – Local release to surface water – TIME 1** | **Elocal,surface water,time1** | **1.75E-06** | **6.48E-06** | **2.00E-05** | **[kg/d]** |  |
| **Countryside – Local release to surface water – TIME 2** | **Elocal,surface water,time2** | **2.88E-08** | **1.06E-07** | **6.58E-08** | **[kg/d]** |  |

Life cycle step: Service life – Paints and coatings - Summary

The emissions to the STP/rainwater system (application in urban areas) and to surface water or soil (application in the countryside) are calculated according to the ESD for PT 6 (2018) and the city scenario document (2015)[[15]](#footnote-16). Results are summarized in the following table.

| **Resulting local emissions during service life to STP/rainwater systems, surface water and soil – Service life step** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Compartment** | | **Local emission (Elocal) [kg/d]** | | | **Remarks** |
| Paints | | Plasters |
| 15 ppm | 55.5 ppm | 15 ppm |
| Scenario 6.2 – 4: City scenario (House) | Elocalwaste water/rainwater | 1.44E-03 | 5.32E-03 | 3.29E-03 |  |
| Scenario 6.2 – 5: Countryside scenario (House) | Elocal,soil - Time 1 | 1.09E-05 | 4.05E-05 | 1.25E-04 |  |
| Elocal,soil –Time 2 | 1.35E-06 | 4.99E-06 | 1.54E-05 |  |
| Elocal,soil –Time 3 | 3.60E-07 | 1.33E-06 | 8.22E-07 |  |
| Scenario 6.2 – 6: Countryside scenario (Bridge over pond) | Elocal,surfacewater – Time 1 | 1.75E-06 | 6.48E-06 | 2.00E-05 |  |
| Elocal,surfacewater – Time 2 | 2.88E-08 | 1.06E-07 | 6.58E-08 |  |

**6.3 Fluids used in paper, textile and leather production**

**6.3.1 Fluids used in paper production**

Biocidal products containing C(M)IT are used for the in-can preservation of additives used during paper production such as retention aids, sizing agents, binders or coating agents with use concentrations of 5.65 ppm to 22.2 ppm of pure C(M)IT. 22.2 ppm is the minimum effective value against bacteria, yeasts and fungi in paper production considering a storage of two weeks and is therefore used in the risk assessment.

The ESD for PT 6 (2018) is used for the exposure assessment and the different paper types (i.e. newsprint, tissues and printing and writing paper) are considered. The ESD deals with paper production, coating and recycling step. However, considering a vapour pressure of 1.6 Pa at 20°C and a Henry's law constant of 4,26E-04 Pa.m3.mol-1 at 20°C, C(M)IT can be classified as moderately volatile. Moreover, any C(M)IT lost to air will be rapidly degraded by oxidation with hydroxyl radicals, with a half-life of 17.5 hours. Therefore, the emission scenario to calculate the release from drying sections after size pressing and coating has not been assessed.

The quantity of C(M)IT applied per ton of paper is derived by taking additive usage as specified in the OECD ESD no. 16 (2006)[[16]](#footnote-17) into account.For printing and writing paper, the preservation of all chemicals listed in Table 12 and 13 of the OECD ESD is assumed. For tissues and newsprint, the same approach is used, but no fillers are considered, as they are expected to be already included in the pulp produced mainly from recycled paper (See the Table below).

**Realistic worst-case scenarios: paper type, amount of additives and daily paper production (EC BAT, 2001 and Tissier and Migné, 2001)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Additive amounts**  **used\*, kg tpaper -1** | **Printing and**  **writing** | | **Tissue** | **Newsprint** |
| **Daily paper production, Qproduct, tpaper day-1** |  | 66 | | 222 | 449 |
| **Additive** |  | | **Additive used for this paper type** | | | |
| **Stock preparation** | | | | | | |
| Fillers | 210 | y | | n | n |
| Others | 56 | y | | y | y |
| **Paper machine (sizing and process chemicals)** | | | | | | |
| Total | 23 | y | | y | y |
| **Coating** | | | | | | |
| Fillers | 210 | n | | n | n |
| Others | 25 | n | | n | n |
| **Total additive used per ton of paper produced\*,**  **Qagent(stock,machine), kg tpaper-1** |  | **289** | | **79** | **79** |

\*OECD 16, (2006): Emission scenario document on non-integrated paper mills, Tables 12, 13 and 14. Paper types not specified in that reference.

Scenario 6.3.1 – 1: Emission scenario for calculating the release from “broke”

The following input parameters from the OECD ESD for PT 6 (2018) are applied for calculating the releases of C(M)IT used as preservative in additives in paper production.

Considering the diversity of the additives that can be preserved, FR assumes a penetration factor of 0.5. Other MS do not agree with this value and support the value of 1 defined in the ESD for TP6 (2018).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Input** | **Symbol** | **Value** | | | **Unit** | **Remarks** |
| Scenario 6.3.1 – 1: Emission scenario for calculating the release from “broke” | | | | | | |
|  |  | Newsprint | Tissues | Printing and writing paper |  |  |
| Quantity of paper produced per day | Qpaper | 449 | 222 | 66 | [t/d] |  |
| Quantity of additives used per tonne | Qadditive | 79\* | 79\* | 289\* | [kg/t] |  |
| Concentration of a.i. in the additive | Ca.i. | 22.2 | 22.2 | 22.2 | [mg/kg] | 22.2 ppm |
| Fraction of coated broke produced compared to overall production | Fbroke | 0.2 | 0.2 | 0.2 | [-] |  |
| Degree of closure of the water cycle | Fclosuer | 0.75 | 0.55 | 0.55 | [-] |  |
| Fraction of additives with active substance (market share) | Fa.i. | 1 | 1 | 1 | [-] |  |
| Fixation rate | Ffix | 0 | 0 | 0 | [-] |  |
| Penetration factor | Fpenetr | 0.5 | 0.5 | 0.5 |  |  |
| **Output** | | | | | | |
| **Local release to waste water** | **Elocalwater -**  **In-can preservatives solely used for dry-end operation** | **1.97E-02** | **1.75E-02** | **1.91E-02** | **[kg/d]** |  |
| **Elocalwater -**  **Preserved additives in the paper industry (other cases)** | **9.84E-02** | **8.76E-02** | **9.53E-02** | **[kg/d]** |  |

\*EC BAT, 2001 and Tissier and Migné, 2001

Scenario 6.3.1 – 2: Emission scenario for paper recycling (Tonnage-based, Confidential).

Please refer to the confidential annex.

Scenario 6.3 – Local emissions to STP - Summary

| **Resulting local emissions to STP by paper type** | | | |
| --- | --- | --- | --- |
| **Compartment** | **Symbol** | **Local emission (ElocalSTP) [kg/d]** | **Remarks** |
| **Use of preserved additives in the paper industry solely used for dry-end operation** | | | |
| Total emission from Newsprint | Elocalwater,total | 1.97E-02 |  |
| Total emission from Tissues | Elocalwater,total | 1.75E-02 |  |
| Total emission from Printing and writing papers | Elocalwater,total | 1.91E-02 |  |
| **Use of preserved additives in the paper industry** | | | |
| Total emission from Newsprint | Elocalwater,total | 9.84E-02 |  |
| Total emission from Tissues | Elocalwater,total | 8.76E-02 |  |
| Total emission from Printing and writing papers | Elocalwater,total | 9.53E-02 |  |
| **Recycling of paper** |  |  |  |
| Total emission | Elocalwater,total | Refer to confidential annex |  |

**6.6: Glues and adhesives**

Biocidal products containing C(M)IT are intended to be used for the in-can preservation of glues and adhesives with use concentrations of 5.65 ppm to 400 ppm of pure C(M)IT. No emissions scenario has been described for the application phase of glues according to the ESD for PT 6 (2018).

According to ESD for PT 6 (2018), direct emission into the environmental compartments like surface water and soil can be excluded, however, exposition to the STP may occur.

Therefore, a tonnage based approach has been conducted in the confidential annex.

Scenario 6.6: Emissions estimations from glues and adhesives uses (Tonnage-based, Confidential)

Please refer to the confidential annex.

**6.7: Other**

6.7 – 1: Preservation of polymer dispersions

Biocidal products containing C(M)IT are used for the in-can preservation of polymer dispersions with use concentrations of 5.65 ppm to 40 ppm of pure C(M)IT. The preserved products are raw products, which are further processed and formulated into products for end users such as paints, adhesives or papers.

According to the applicant, polymer dispersions are used as binding agents with concentrations up to 40% in outdoor paints and less than 20% in indoor paints. As a worst case, a pure C(M)IT concentration of 40 ppm in polymer dispersions will contribute to an increase of 16 ppm in outdoor paints and 8 ppm in indoor paints.

The paint scenario (6.2) calculations already cover the polymer dispersions “use step” and assesses direct and indirect emissions to the environment.

6.7 – 2: Preservation of slurries

Biocidal products containing C(M)IT are used for the in-can preservation of slurries such as calcium carbonate slurries and titanium dioxide slurries with use concentrations of 1.13 ppm to 40 ppm of pure C(M)IT.

As no scenario concerning slurries formulation exists, and as no data was provided to define precisely this step process, no risk assessment was performed and therefore the use is not proposed for authorisation.

6.7 – 3: Preservation of colorants

Biocidal products containing C(M)IT are used for the in-can preservation of colourants with use concentrations of 5.65 ppm to 40 ppm of pure C(M)IT. The preserved products are raw products, which are further processed and formulated into products for end users such as papers or paints.

The paint scenario (6.2) calculations already cover the colorants “use step” and assesses direct and indirect emissions to the environment.

6.7 – 4: Preservation of pigment paste

Biocidal products containing C(M)IT are used for the in-can preservation of polymer dispersions with use concentrations of 5.65 ppm to 40 ppm of pure C(M)IT. The preserved products are raw products, which are further processed and formulated into products for end users such as paints.

According to the applicant, pigment paste are used with concentrations up to 10% in paints. As a worst case, a pure C(M)IT concentration of 40 ppm in pigments paste will contribute to an increase of 4 ppm in paint.

The paint scenario (6.2) calculations already cover the pigment paste “use step” and assesses direct and indirect emissions to the environment.

##### **Fate and distribution in exposed environmental compartments**

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | Freshwater\* | STP | Air | Soil | Groundwater |
| Scenario 6.0 – 1/2/3/4/5/6/7 Formulations | Yes | Yes | No | Yes | Yes |
| Scenario 6.1.2 -1/2/3/4/5 - Detergents and cleaning fluids | Yes | Yes | No | Yes | Yes |
| Scenario 6.2 – 1 – Paints and coating | Yes | Yes | No | Yes | Yes |
| Scenario 6.2 – 2 - Paints and coating | No | No | No | Yes | Yes |
| Scenario 6.2 – 3 - Paints and coating | Yes | No | No | No | No |
| Scenario 6.2 – 4 - Paints and coating | Yes | Yes | No | Yes | Yes |
| Scenario 6.2 – 5 - Paints and coating | No | No | No | Yes | Yes |
| Scenario 6.2 – 6 - Paints and coating | Yes | No | No | No | No |
| Scenario 6.3.1 – Paper production | Yes | Yes | No | Yes | Yes |
| Scenario 6.6 - Glues | Yes | Yes | No | Yes | Yes |
| Scenario 7.7 - Others | Yes | Yes | No | Yes | Yes |

\* The assessment conducted for the aquatic compartment covers also to the sediment compartment due to rapid degradation and low log Kow of the C(M)IT

The input parameters to calculate the fate and distribution of C(M)IT are shown in the following table:

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on relevant physico-chemical and fate and behaviour parameter of the active substance** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 149.6 | g/mol |  |
| Vapour pressure (at 20°C) | 1.6 | Pa | C(M)IT data |
| Water solubility | 1000 | g/L | C(M)IT data |
| Log Octanol/water partition coefficient | 0.401 | Log 10 | A.R. C(M)IT/MIT 2015 |
| Organic carbon/water partition coefficient (Koc) | 45.3 | L/kg | C(M)IT data |
| Henry’s Law Constant (at 20°C / at 12°C) | 4.26E-04 / 1.67E-04 | Pa/m3/mol | C(M)IT data |
| Biodegradability\* | Readily biodegradable\* | - |  |
| DT50 for biodegradation in surface water (whole system) | 5.82\*\* | d (at 12°C) | A.R. C(M)IT/MIT 2015 as a worst case |
| DT50 for degradation in soil | 30 | d (at 12°C) |  |
|  | | | |
| Kvolat (agricultural soil) | 2.04E-05 | /d |  |
| Kleach (agricultural soil) | 1.54E-03 | /d |  |
| Kbio sol (agricultural soil) | 2.31E-02 | /d |  |
| Ktotal (agricultural soil) | 2.47E-02 | /d |  |
|  | | | |
| Kvolat (bare soil) | 7.37E-05 | /d |  |
| Kleach (bare soil) | 6.16E-03 | /d |  |
| Kbio sol (bare soil) | 2.31E-02 | /d |  |
| Ktotal (bare soil) | 2.93E-02 | /d |  |

\* The criteria for ready biodegradability are fulfilled in the test provided by the applicant. Nevertheless, in the A.R. C(M)IT/MIT (2015), a test was provided on C(M)IT alone by another applicant, in which the threshold for readily biodegradability was reached but without the 10-d window. The difference in results could not be explained by the testing procedure (C(M)IT concentrations, inoculum density…). Nevertheless information from the simulation studies support that C(M)IT is readily biodegradable with the fulfillment of the 10-d window.

In the STP simulation test (C(M)IT-MIT CAR, 2015), >95% C(M)IT were removed from the effluent. It was not clarified if the removal actually results from biodegradation or adsorption however based on low Koc, the removal of C(M)IT can be assimilated to degradation. . Moreover, as C(M)IT is readily biodegradable, quantification and identification of potential relevant metabolite is not required. The resulting emission to the STP effluent (<5%) is lower than the fraction predicted by Simple treat when C(M)IT is considered as readily biodegradable with the 10-d window (8%, v 4.0)

In the water sediment study, the worst case DT50 for the whole system is 3.86 d a 12°C in the Thor study. Although some adsorption on sediment would occur, it should be negligible according to the low Koc. This assumption is supported by the DT50 for the phase water only (3.72 d) which is very close to the DT50 for the whole system. Therefore, it can be concluded that the DT50 for the water phase is below the default value when considering the substance as readily biodegradable with the 10-d window.

\*\* worst case value from the combined AR for CMIT/MIT (2015)

|  |  |  |
| --- | --- | --- |
| **Fate and distribution in the STP** | | |
| Compartment | Percentage [%]  C(M)IT | Remarks |
| Air | 7.22E-05 | Fractions to air and sludge were calculated with SimpleTreat 4.0 (considering the modifications proposed in the TAB).  A STP simulation study presented in section 4.1 STP stimulation test allows to refine the fraction degraded in the STP to 95% and therefore to estimate a fraction to water of 5% |
| Water | 5 |
| Sludge | 0.42 |
| Degradation | 95 |

Metabolites

According to the relevant AR for PT 6 (2015), no environmental risk assessment was done for metabolites of C(M)IT as they are considered to be not ecotoxicological or environmentally relevant (C(M)IT is readily biodegradable). Therefore, they are not considered in the PAR.

Substances of concern (SoCs)

The product does not contain substances, which change the environmental classification. Therefore, an assessment of environmentally relevant SoCs is not necessary.

##### ***Calculated PEC values***

PECair: Emissions to air from biocidal uses are not relevant. Indeed, C(M)IT degrades quickly in air due to the low DT50 value of 17.5 h (CMIT-MIT AR, 2015).

PECsediment: The sediment is not considered, since the C(M)IT does not fulfil criteria for sediment risk assessment. Indeed, it has a log Kow less than 3 and a Koc < 500 L/kg (CMIT-MIT AR, 2015).

The soil pore water concentration is assessed using Guidance Vol IV Part B+C on BPR IV/B (2017) using default values for the PEC calculation in soil pore water according to equation 20-22 and using the time weighted concentrations in soil after 180 days.

**Indirect emissions:**

For indirect emissions to environmental compartments (via STP), there is no further specific guidance in the ESDTP6 for calculation of PEC values and hence the standard assumptions in the Vol IV Part B+C (2017) were used to develop concentrations in STP, surface water, soil and groundwaters.

**Direct emissions:**

Only the use of paints, coating or plasters could lead to direct emission to the environment.

Direct emissions to surface water may occur through direct rainwater discharge in separate sewer systems and storm water events leading to a STP bypass[[17]](#footnote-18).

##### **PT 6 – Formulation**

Please refer to the confidential annex.

##### **PT 6.1 – Preservation of detergent and cleaning fluids**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (indirect emissions via STP)** | | | | | |
| **Scenario** | **Elocal STP** | **PECSTP** | **PECwater** | **PECsoil initial concentration** | **PECGW** |
| [kg/d] | [mg/L] | [mg/L] | [mg/kg ww] | [mg/L] |
|  | | | | | |
| Scenario 6.1.2 - 1 – Detergents pro - Laundry | 2.16E-03 | 5.40E-05 | 5.40E-06 | 1.69E-05 | 4.10E-06 |
| Scenario 6.1.2 – 2 – Detergent pro - Surface | 3.00E-05 | 7.50E-07 | 7.50E-08 | 2.35E-07 | 5.69E-08 |
| Scenario 6.1.2 – 3 – Detergent Non Pro – Fabric washing | 1.56E-03 | 3.89E-05 | 3.89E-06 | 1.22E-05 | 2.95E-06 |
| Scenario 6.1.2 – 4 – Detergent Non pro – Dish washing | 2.18E-04 | 5.44E-06 | 5.44E-07 | 1.70E-06 | 4.13E-07 |
| Scenario 6.1.2 – 5 – Detergent Non pro - Surface | 7.50E-04 | 1.88E-05 | 1.87E-06 | 5.86E-06 | 1.42E-06 |
|  | | | | | |
| Scenario 6.1  Detergent and cleaning fluids – Use - Aggregated | 4.71E-03 | 1.18E-04 | 1.18E-05 | 3.68E-05 | 8.94E-06 |

##### **PT 6.2 – Preservation of paints and coatings**

###### **Indirect releases via the STP**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (indirect emissions via STP)** | | | | | | |
| **Scenario** | | **Elocal STP** | **PECSTP** | **PECwater** | **PECsoil initial concentration** | **PECGW** |
| [kg/d] | [mg/L] | [mg/L] | [mg/kg ww] | [mg/L] |
|  | | | | | | |
| Scenario 6.2 – 1 and 2 - City scenario - Applications (worst-case) | Paints (spray as a worst case) – 15 ppm | 5.91E-04 | 1.48E-05 | 1.48E-06 | 4.62E-06 | 1.12E-06 |
| Paints (spray as a worst case) – 55.5 ppm | 2.19E-03 | 5.46E-05 | 5.46E-06 | 1.71E-05 | 4.15E-06 |
| Plasters – 15 ppm | 3.75E-04 | 9.38E-06 | 9.37E-07 | 2.93E-06 | 7.12E-07 |
| Scenario 6.2 – 4  City scenario  Service life | Paints – 15 ppm | 1.44E-03 | 3.60E-05 | 3.60E-06 | 1.12E-05 | 2.73E-06 |
| Paints – 55.5 ppm | 5.32E-03 | 1.33E-04 | 1.33E-05 | 4.16E-05 | 1.01E-05 |
| Plasters – 15 ppm | 3.29E-03 | 8.22E-05 | 8.22E-06 | 2.57E-05 | 6.24E-06 |
| Aggregated emissions – City scenario - Application + Service life | Paints (spray as a worst case) – 15 ppm | 2.03E-03 | 5.07E-05 | 5.07E-06 | 1.59E-05 | 3.85E-06 |
| Paints (spray as a worst case) – 55.5 ppm | 7.51E-03 | 1.88E-04 | 1.88E-05 | 5.87E-05 | 1.42E-05 |
| Plasters – 15 ppm | 3.66E-03 | 9.16E-05 | 9.16E-06 | 2.86E-05 | 6.95E-06 |

###### **Direct releases**

1. **Surface water**

***Bridge over pond***

The bridge over pond scenario is a worst case scenario to cover direct emissions to surface water during application and service life in the countryside.

Brushing is the recommended method for application of paints and plasters on a bridge.

Refinement for static water bodies:

|  |  |
| --- | --- |
| According to the Item 4.6: Example calculations of a 3 phases pond-water system (NL)Follow up on WGII2018\_ENV\_7-3c\_PT6-10\_PECsediment\_C(Agreed at the AHEE WG-VII-2018, September 2019)**,** the PECsurface water from a static pond-water system should be calculated with the equation presented below, and represents the concentration in water at the end of the assessment period considering adsorption on suspended matter and sediment as well as degradation. | (5) |

With:

* Vwater = 1 000 m3
* Vsed = 6 m3
* k (whole system) = Ln (2)/5.82 d = 0.12 d-1
* Ksed-water equivalent to Ksusp-water

***Mixed sewer system and separate sewer system***

In urban areas, direct emissions to surface may occur due to bypass of STP (mixed sewer system) and direct rainwater discharge (separate sewer systems). The concentrations in surface water are calculated according to the guidance document to assess direct emissions to surface water in urban areas (2015). According to the TAB (2016), emissions due to application are not relevant for direct emissions in urban areas, bypass scenario since it is unrealistic to assume that application of paint will occur during or shortly before a storm event. However, the scenario discharge seems relevant.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Resulting local concentrations of C(M)IT in surface water after direct discharge** | | | | |
| Scenario | **PECwater** | | | |
| [mg/L] | | | |
| Paints | | | Plasters |
| 15 ppm | | 55.5 ppm | 15 ppm |
| **Countryside - Bridge - PEC calculations without refinement (Tier 1)** | | | | |
| Bridge over pond – Application - Brush | | 2.63E-06 | 9.71E-06 | 3.00E-05 |
| Bridge over pond – Service life - Time 1 | | 5.25E-05 | 1.94E-04 | 6.00E-04 |
| Bridge over pond – Service life - Time 2 | | 5.25E-05 | 1.94E-04 | 6.00E-04 |
| **Countryside - Bridge - PEC calculations considering degradation and potential adsorption to suspended matter and sediment (Tier 2)** | | | | |
| Bridge over pond – Service life - Time 1 | | 1.42E-05 | 5.25E-05 | 1.64E-04 |
| Bridge over pond – Service life - Time 2 | | 2.40E-07 | 8.89E-07 | 5.40E-07 |
| **Urban area - Mixed sewer system** | | | | |
| Service-life | | 7.19E-05 | 2.66E-04 | 1.64E-04 |
| **Urban area - Direct rainwater discharge** | | | | |
| Application brush | | 1.64E-05 | 6.07E-05 | 6.25E-05 |
| Application spray | | 9.84E-05 | 3.64E-04 | n.r. |
| Service-life | | 2.40E-04 | 8.87E-04 | 5.48E-04 |

n.r.: non relevant

1. **Soil**

The house scenario is a worst case scenario to cover direct emissions to soil during application and service life in the countryside.

For paint application, spraying is the worst case application considering:

Tier 1: emissions by runoff and drift

Tier 2: emissions due to runoff are negligible thanks to the use of a tarpaulin on the ground, only drift is considered.

For plasters application, brushing is the recommended method and is further assessed.

For the application phase, the intial concentrations just after the applications have been calculated. For service-life, the concentration at the end of the assessment period according to the equation 3.11 and 3.12 of the ESD for PT08 and considering the ktotal value defined for the bare soil.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Resulting local concentrations of C(M)IT (Tier 1 and Tier 2) and in soil** | | | | | |
| Scenario - House | **PECsoil** | | | | |
| [mg/kg ww] | | | | |
| Paints (spray) | | Paints (brush) | | Plasters (brush) |
| 15 ppm | 55.5 ppm | 15 ppm | 55.5 ppm | 15 ppm |
| Application (initial concentration) | 8.91E-03 (Tier 1)  8.49E-04 (Tier 2) | 3.30E-02 (Tier 1)  3.14E-03 (Tier 2) | 1.48E-03 | 5.49E-03 | 1.70E-02 |
| Service-life only – Time 1  (concentration at the end of the assessment period) | 1.97E-02 | 7.31E-02 | 1.97E-02 | 7.31E-02 | 2.26E-01 |
| Service-life only – Time 2  (concentration at the end of the assessment period) | 5.55E-04 | 2.05E-03 | 5.55E-04 | 2.05E-03 | 1.27E-03 |

A refinement of service life scenario was also realised, according to the TAB v2.1 (ENV-A4, 2019), considering more realistic default leaching rates.

The following default leached quantities for all relevant times:

* Time 1 (30 days): 50% of the applied substance leaches out
* Time 2 (365 days): 75% of the applied substance leaches out
* Time 3 (service life): 100% of the applied substance leaches out.

The new calculations are gathered in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Resulting local concentrations of C(M)IT (Tier 1 and Tier 2) and in soil** | | | | | |
| Scenario - House | **PECsoil** | | | | |
| [mg/kg ww] | | | | |
| Paints (spray) | | Paints (brush) | | Plasters (brush) |
| 15 ppm | 55.5 ppm | 15 ppm | 55.5 ppm | 15 ppm |
| Application (initial concentration) | 8.91E-03 (Tier 1)  8.49E-04 (Tier 2) | 3.30E-02 (Tier 1)  3.14E-03 (Tier 2) | 1.48E-03 | 5.49E-03 | 1.70E-02 |
| Service-life only – Time 1  (concentration at the end of the assessment period) | 9.87E-03 | 3.65E-02 | 9.87E-03 | 3.65E-02 | 1.13E-01 |
| Service-life only – Time 2  (concentration at the end of the assessment period) | 2.08E-03 | 7.70E-03 | 2.08E-03 | 7.70E-03 | 2.38E-02 |
| Service-life only – Time 3  (concentration at the end of the assessment period) | 5.55E-04 | 2.05E-03 | 5.55E-04 | 2.05E-03 | 1.27E-03 |

1. **Groundwater**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Resulting local concentrations of C(M)IT (Tier 1 and Tier 2) in groundwaters** | | | | | |
| Scenario - House | **PECGW** | | | | |
| [µg/L] | | | | |
| Paints (spray tier 2\*) | | Paints (brush) | | Plasters (brush) |
| 15 ppm | 55.5 ppm | 15 ppm | 55.5 ppm | 15 ppm |
| Application (initial concentration) | **9.26E-01** | **3.43E+00** | **1.62E+00** | **5.99E+00** | **1.85E+01** |
| Service-life only – Time 1  (concentration at the end of the assessment period) | **2.15E+01** | **7.97E+01** | **2.15E+01** | **7.97E+01** | **2.46E+02** |
| Service-life only – Time 2  (concentration at the end of the assessment period) | **6.05E-01** | **2.23E+00** | **6.05E-01** | **2.23E+00** | **1.38E+00** |

\* Only Tier 2 for spray was considered as the risks for soil are unacceptable for Tier 1

The resulting groundwater concentrations are higher than the threshold value of 0.1 µg/L for this use. Thus, the FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwaters assessment.

Scenario associated with the use of Paints and plasters for direct emissions (6.2) was evaluated. The resulting groundwater concentrations are lower than the threshold value of 0.1 µg/L (See the Tables below).

This section will be updated according the new results from the soil section (see above) during the normal authorisation.

|  |  |  |  |
| --- | --- | --- | --- |
| **Emissions to Groundwater : Input for refinement (FOCUS PEARL 4.4.4)** | | | |
| **Input parameters related to Active Substance** | | | |
|  | **Value** | | **Reference** |
| Molecular weight (g/mol) | 149.6 | |  |
| Water solubility (g/l) at 20°C | 1000 | |  |
| Koc (L/kg) | 45.3 | |  |
| Saturated vapour pressure (Pa) at 20°C | 1.6 | |  |
| DT50 in soil (d) at 12°C | 30 | |  |
| Kom (=Koc/1.724) (L/kg) | 26.276 | | TAB 2.0 ENV 23 |
| 1/n | 1 | |  |
| Plant uptake factor | 0 | | TAB 2.0 ENV 23 |
| Molar activation energy (kJ/mol) | 54 | | TAB 2.0 ENV 23 |
|  | | | |
| **Input parameters related to Scenario** | | | |
| **Direct emissions (6.2 – Paints and coating)** | | | |
|  | **Service life of Paints (15 ppm) – Time 2** | **Service life of Paints (55.5 ppm) – Time 2** | **Service life of Plasters (15 ppm) – Time 2** |
| Local emission of active substance for FOCUS application input (kg/d) | 3.60E-07 | 1.32E-06 | 8.22E-07 |
| Number of houses estimated per hectare | 16 | | |
| Local emission of active substance for FOCUS application input (kg/ha/month) | 1.73E-04 | 6.34E-04 | 3.95E-04 |
| Application date | Absolute application : On the 1st day of each month (12 applications) | | |
| Application type | To soil surface | | |
| Crop | Grassland | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Emissions to Groundwater : Output (FOCUS PEARL 4.4.4) in µg/L** | | | |
| **Direct emissions (6.2 – Paints and coating )** | | | |
| **Location** | **Grassland (alfalfa)** | | |
|  | | | |
| **Direct emissions (6.2 – Paints and coating – Service life of Paints and coating– Time 2)** | **Paints – 15 ppm (µg/L)** | **Paints – 55.5 ppm (µg/L)** | **Plasters – 15 ppm (µg/L)** |
| Châteaudun | 0.001830 | 0.006706 | 0.004174 |
| Hamburg | 0.005223 | 0.019142 | 0.011914 |
| Jokioinen | 0.003882 | 0.014225 | 0.008853 |
| Kremsmünster | 0.001982 | 0.007263 | 0.004520 |
| Okehampton | 0.005485 | 0.020102 | 0.012512 |
| Piacenza | 0.004718 | 0.017290 | 0.010761 |
| Porto | 0.005043 | 0.018482 | 0.011503 |
| Sevilla | 0.001294 | 0.004744 | 0.002952 |
| Thiva | 0.001102 | 0.004037 | 0.002513 |

##### **PT 6.3.1 Fluids used in paper production**

For paper production and recycling, the emission to the STP was estimated (Elocalwater) with an effluent discharge rate of 5000 m3.d-1 considering the releases to an industrial STP. The dilution to the receiving aquatic compartment was left to 10.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (indirect emissions via STP)** | | | | | |
| **Scenario** | **Elocal STP** | **PECSTP** | **PECwater** | **PECsoil initial** | **PECGW** |
| [kg/d] | [mg/L] | [mg/L] | [mg/kg ww] | [mg/L] |
| **Additives used in dry-end operations only** | | | | | |
| Scenario 6.3.1 – Newsprint | 1.97E-02 | 1.97E-04 | 1.97E-05 | 6.16E-05 | 1.49E-05 |
| Scenario 6.3.1 – Tissues | 1.75E-02 | 1.75E-04 | 1.75E-05 | 5.48E-05 | 1.33E-05 |
| Scenario 6.3.1 – Printing and writing papers | 1.91E-02 | 1.91E-04 | 1.91E-05 | 5.96E-05 | 1.45E-05 |
| **All additives** | | | | | |
| Scenario 6.3.1 – Newsprint | 9.84E-02 | 9.84E-04 | 9.84E-05 | 3.08E-04 | 7.47E-05 |
| Scenario 6.3.1 – Tissues | 8.76E-02 | 8.76E-04 | 8.76E-05 | 2.74E-04 | 6.65E-05 |
| Scenario 6.3.1 – Printing and writing papers | 9.53E-02 | 9.53E-04 | 9.53E-05 | 2.98E-04 | 7.23E-05 |
| **Recycling** | | | | | |
| (Refer to confidential annex) | | | | | |

##### **PT 6.6 - Glues and adhesives**

Please refer to the confidential annex.

##### **PT 6.7 – Others**

No PEC was calculated for these uses as they are covered by use 6.2.

***Primary and secondary poisoning***

Primary poisoning

Due to the intended uses the direct uptake of the b.p. containing C(M)IT by non-target organisms is unlikely. Therefore, primary poisoning is not further assessed.

Secondary poisoning

The log Kow of C(M)IT is below 1 indicating a negligible potential for bioconcentration in biota. Therefore, accumulation of the substances in the food chain is not expected and the risk of secondary poisoning in aquatic and terrestrial predators is not further assessed.

#### **Risk characterisation**

Concerning the atmosphere, according to the AR for C(M)IT/MIT (2015), emissions to air from biocidal uses are not relevant. C(M)IT degrades quickly in air due to the low DT50 value of 17.5 h.

The sediment is not considered, since the a.i. does not fulfil criteria for sediment risk assessment. Indeed, it has a log Kow less than three and a Koc < 500 L/kg (according to the C(M)IT/MIT AR, 2015).

Concerning primary and secondary poisoning:

Primary poisoning

Due to the intended uses, the direct uptake of the b.p. containing C(M)IT by non-target organisms is unlikely. Therefore, primary poisoning is not further assessed.

Secondary poisoning

The log Kow of C(M)IT is below 1 indicating a negligible potential for bioconcentration in biota. Therefore, accumulation of the substances in the food chain is not expected and the risk of secondary poisoning in aquatic and terrestrial predators is not further assessed.

##### **PT 6 – Formulation/preservation of treated articles**

Please refer to the confidential annex.

Conclusion: The requirements for acceptable risk according to the Guidance for BPR are met for the formulation step of the following uses:

* Formulation of Washing and cleaning fluids,
* Formulation of Paints and coatings
* Formulation of Fluids used in paper production,
* Formulation of Glues and adhesives,
* Formulation of Polymer dispersions product,
* Formulation of Pigments pastes and colorants.

The preservation step of Slurries (Clay, mica and other fillers) has not been conducted in the absence of a proper scenario proposed by the applicant.

##### **PT 6.1 – Preservation of detergent and cleaning fluids**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (indirect emissions via STP) and calculated concentrations in groundwater** | | | | |
| **Scenario** | **STP** | **Surface water** | **Soil** | **GW**  **(µg/L)** |
|  | | | | |
| Scenario 6.1.2 – 1: Professional detergents used for laundry from hospitals in washing streets | 1.60E-03 | 1.46E-01 | 2.56E-03 | 4.10E-03 |
| Scenario 6.1.2 – 2: Professional detergents for surface cleaning in industrial areas | 2.22E-05 | 2.03E-03 | 3.55E-05 | 5.69E-05 |
| Scenario 6.1.2 – 3: Non-professional detergents for fabric washing | 1.15E-03 | 1.05E-01 | 1.84E-03 | 2.95E-03 |
| Scenario 6.1.2 – 4: Non-professional detergents for dish washing, non-professional | 1.61E-04 | 1.47E-02 | 2.58E-04 | 4.13E-04 |
| Scenario 6.1.2 – 5: Detergents for sanitary purposes based on average consumption | 5.55E-04 | 5.07E-02 | 8.88E-04 | 1.42E-02 |
|  | | | | |
| Scenario 6.1  Detergent and cleaning fluids – Use - Aggregated | 3.49E-03 | 3.18E-01 | 5.58E-03 | 8.94E-03 |

Conclusion:

The requirements for acceptable risk according to the Guidance for BPR are met for the following scenarios, with a concentration of pure C(M)IT up to 15 ppm:

* 6.1.2 – 1: Professional detergents used for laundry from hospitals in washing streets
* 6.1.2 – 2: Professional detergents for surface cleaning in industrial areas
* 6.1.2 – 3: Non-professional detergents for fabric washing
* 6.1.2 – 4: Non-professional detergents for dish washing, non-professional
* 6.1.2 – 5: Detergents for sanitary purposes based on average consumption

Considering that for PT06 the different scenarios have to be aggregated as separate uses are not realistic, no unacceptable risks are foreseen for preservation of both professional and non-professional end-products.

##### **PT 6.2 – Preservation of paints and coatings**

###### **Indirect releases via the STP**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (indirect emissions via STP) and calculated concentrations in groundwater** | | | | | |
| **Scenario** | | **STP** | **Surface water** | **Soil** | **GW** |
|  | | | | | |
| Scenario 6.2 – 1 and 2 - City scenario – Application | Paints - 15 ppm (spraying as a worst-case) | 4.37E-04 | 3.99E-02 | 7.00E-04 | 1.12E-03 |
| Paints – 55.5 ppm (spraying as a worst-case) | 1.62E-03 | 1.48E-01 | 2.59E-03 | 4.15E-03 |
| Plasters – 15 ppm | 2.77E-04 | 2.53E-02 | 4.44E-04 | 7.12E-04 |
| Scenario 6.2 – 4  City scenario  Service life | Paints - 15 ppm | 1.06E-03 | 9.72E-02 | 1.70E-03 | 2.73E-03 |
| Paints – 55.5 ppm | 3.94E-03 | 3.60E-01 | 6.30E-03 | 1.01E-02 |
| Plasters – 15 ppm | 2.43E-03 | 2.22E-01 | 3.89E-03 | 1.51E-02 |
| Aggregated emissions – City scenario - Application + Service life | Paints - 15 ppm | 1.50E-03 | 1.37E-01 | 2.40E-03 | 3.85E-03 |
| Paints – 55.5 ppm | 5.55E-03 | 5.07E-01 | 8.89E-03 | 1.42E-02 |
| Plasters – 15 ppm | 2.71E-03 | 2.47E-01 | 4.34E-03 | 6.95E-03 |

Conclusion: The requirements for acceptable risk for the scenarios with releases via the STP (in urban areas) according to the Guidance for BPR are met for the use of:

* Paints and plasters at a concentration in end-product of 15 ppm of pure C(M)IT.
* Paints at a concentration in end product up to 55.5 ppm of pure C(M)IT.

###### **Direct releases to the aquatic and terrestrial compartment**

**Surface water**

|  |  |  |  |
| --- | --- | --- | --- |
| **Resulting local concentrations of C(M)IT in surface water after direct discharge** | | | |
| Scenario | **PECwater/PNEC** | | |
| Paints (brush) | | Plasters (brush) |
| 15 ppm | 55.5 ppm | 15 ppm |
| **Countryside - Bridge - Without refinement (Tier 1)** | | | |
| Bridge over pond – Application - brush | 7.09E-02 | 2.63E-01 | 8.11E-01 |
| Bridge over pond – Service life - Time 1 | **1.42E+00** | **5.25E+00** | **1.62E+02** |
| Bridge over pond – Service life - Time 2 | **1.42E+00** | **5.25E+00** | **1.62E+02** |
| **Countryside - Bridge - Considering degradation and potential adsorption to suspended matter and sediment (Tier 2)** | | | |
| Bridge over pond – Service life - Time 1 | 3.84E-01 | **1.42E+00** | **4.43E+00** |
| Bridge over pond – Service life - Time 2 | 6.50E-03 | 2.40E-02 | 1.46E-02 |
| **Urban area - Mixed sewer system** | | | |
| Service-life | **1.94E+00** | **7.19E+00** | **4.44E+00** |
| **Urban area - Direct rainwater discharge** | | | |
| Application brush | 4.43E-01 | **1.64E+00** | **1.69E+00** |
| Application spray | **2.66E+00** | **9.84E+00** | n.r. |
| Service-life | **6.48E+00** | **2.40E+01** | **1.48E+01** |

Conclusion:

Concerning the direct releases to surface water in rural area (bridge over the pond scenario), the application phase leads to acceptable risks.

Unacceptable risks are foreseen for the Time 1 of service-life for both application types (paints at 55.5 ppm and plasters at 15 ppm) and acceptable risks are foreseen for the use of paints at 15 ppm

Concerning the direct releases to surface water in urban areas, the requirements for acceptable risk according to the Guidance for BPR are not met for the use of paints and plasters for both application and service-life phases. It worths noting that the two scenarios presented (mixed sewer system and direct rainwater discharge) are Tier 1 approaches (WGII2018) and in absence of available refinement, the results of these scenarios should be considered with care as worst case values. Pending agreement on the definition of a Tier 2 assessment, a RMM preventing the use of the preserved paint will be applied as follows:

* The addition of the product ACTICIDE C1 in additives for paints and coatings must be carried out only in plants connected to industrial STPs.
* The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:
* Use indoor only.

For all these reasons, it can be considered that requirements for acceptable risk to surface water according to the Guidance for BPR are met for the use of:

* Paints and coatings at a concentration in end-product of 15 ppm of pure C(M)IT.

They are not met for the use of:

* Paints and coatings at a concentration in end product up to 55.5 ppm of pure C(M)IT and plasters at a concentration of 15 ppm of pure C(M)IT.

**Soil**

Concerning the risks after direct releases to the terrestrial compartment, the initial PNECsoil was considered for the application phase and the PNECsoil twa for the service-life as for this phase, the soil concentrations remain stable over time due to the constant release from treated surfaces balanced with degradation.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Tier 1 and Tier 2) in soil (direct emissions)** | | | | | |
| Scenario - House | **PECsoil/PNEC** | | | | |
| Paints (spray) | | Paints (brush) | | Plasters (brush) |
| 15 ppm | 55.5 ppm | 15 ppm | 55.5 ppm | 15 ppm |
| Application (initial concentration) | **1.35E+00**  **(Tier 1)**  1.29E-01  (Tier 2) | **4.99E+00 (Tier 1)**  4.76E-01  (Tier 2) | 2.25E-01 | 8.32E-01 | **2.57E+00** |
| Service-life only – Time 1  (concentration at the end of the assessment period) | **4.11E+00** | **1.52E+01** | **4.11E+00** | **1.52E+01** | **4.70E+01** |
| Service-life only – Time 2  (concentration at the end of the assessment period) | 1.16E-01 | 4.28E-01 | 1.16E-01 | 4.28E-01 | 2.64E-01 |

A refinement of service life scenario was also realised, according to the TAB v2.1 (ENV-A4, 2019), considering more realistic default leaching rates.

The following default leached quantities for all relevant times:

* Time 1 (30 days): 50% of the applied substance leaches out
* Time 2 (365 days): 75% of the applied substance leaches out
* Time 3 (service life): 100% of the applied substance leaches out.

The new calculations are gathered in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Tier 1 and Tier 2) in soil (direct emissions)** | | | | | |
| Scenario - House | **PECsoil/PNEC** | | | | |
| Paints (spray) | | Paints (brush) | | Plasters (brush) |
| 15 ppm | 55.5 ppm | 15 ppm | 55.5 ppm | 15 ppm |
| Application (initial concentration) | **1.35E+00**  **(Tier 1)**  1.29E-01  (Tier 2) | **4.99E+00 (Tier 1)**  4.76E-01  (Tier 2) | 2.25E-01 | 8.32E-01 | **2.57E+00** |
| Service-life only – Time 1  (concentration at the end of the assessment period) | **2.06E+00** | **7.61E+00** | **2.06E+00** | **7.61E+00** | **2.35E+01** |
| Service-life only – Time 2  (concentration at the end of the assessment period) | 4.33E-01 | **1.60E+00** | 4.33E-01 | **1.60E+00** | **4.95E+00** |
| Service-life only – Time 3  (concentration at the end of the assessment period) | 1.16E-01 | 4.28E-01 | 1.16E-01 | 4.28E-01 | 2.64E-01 |

Risks are acceptable in Time 2 and 3 for paints at the maximal concentration of 15 ppm. Risks are acceptable in Time 3 only for paints up to 55.5 ppm and plasters.

Conclusion:

Service life:

For the use of paint at 15 ppm in rural area:

Based on a 50-75-100% approach the PEC at day 30 exceeds the PNEC, but decreases below the PNEC within 365 days. Considering that C(M)IT-MIT rapidly disappears from soils due to degradation, the PNEC will be exceeded, but only for a few days. Therefore, possible risks may only last a few days and considering the use, the total soil volume affected will be limited. Thus, no risk over time is foreseen for this use and it can be authorised.

For the use of paints at 55.5 ppm and plasters at 15 ppm in rural area:

The uses present unacceptable risks in Time 1 and 2, therefore they should not be authorised.

Application phase:

For the Application phase, risks are foreseen in Tier 1. The final proposed RMM is not the use of a tarpaulin (taken into account in Tier 2 calculations), which would mitigate risk to soil only, but a RMM that prevents risk from all routes of exposure from paints:

* The addition of the product ACTICIDE C1 in additives for paints and coatings must be carried out only in plants connected to industrial STPs.
* The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:
* “Use indoor only”.

Please note that even if the risk for service-life has been presented only for this phase without application, it was verified in case of application phase leaded to acceptable risk without the need of RMM (paints applied by brush) that aggregated exposure from application and service-life did not change the conclusions.

**Groundwater**

Refined estimations of releases to groundwater (FOCUS 4.4.4, please see section [2.2.8.2.6.2 3) Groundwater](#groundwater)) are lower than the threshold value of 0.1 µg/L. Thus, requirements for acceptable risk to groundwater according to the Guidance for BPR are met for this use.

##### **PT 6.3.1 Fluids used in paper production**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (indirect emissions via STP) and calculated concentrations in groundwater** | | | | |
| **Scenario** | **STP** | **Water** | **Soil (initial)** | **GW**  **(µg/L)** |
| **Additives used in dry-end operations only** | | | | |
| Scenario 6.3.1 –Newsprint | 5.82E-03 | 5.32E-01 | 9.33E-03 | 1.49E-02 |
| Scenario 6.3.1 –Tissues | 5.18E-03 | 4.73E-01 | 8.30E-03 | 1.33E-02 |
| Scenario 6.3.1 –Printing and writing papers | 5.64E-03 | 5.15E-01 | 9.03E-03 | 1.45E-02 |
| **All additives** | | | | |
| Scenario 6.3.1 –Newsprint | 2.91E-02 | **2.66E+00** | 4.66E-02 | 7.47E-02 |
| Scenario 6.3.1 –Tissues | 2.59E-02 | **2.37E+00** | 4.15E-02 | 6.65E-02 |
| Scenario 6.3.1 –Printing and writing papers | 2.82E-02 | **2.57E+00** | 4.51E-02 | 7.23E-02 |
| **Recycling** | | | | |
| Please refer to the confidential annex | | | | |

Conclusion: The requirements for acceptable risk according to the Guidance for BPR are met for the use of preserved paper production additives, only if the C(M)IT is used in additives used in dry-end operations only with a concentration of pure C(M)IT of 22.2 ppm in the end-product.

Risk mitigation measures are necessary to ensure acceptable risks of the preserved paper production additives:

* Restrict the use of the product for the preservation of additives used in the paper industry for dry-end operations only.
* The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:
* The use of additives preserved by ACTICIDE C1 must be carried out in structures connected to industrial STPs.

They are not met if the C(M)IT is to be used in additives applied in other operations, (all preserved additives scenario).

Concerning Recycling assessment, this is a recent scenario which can be considered as a large overestimation of the emissions estimations. Therefore, in absence of available refinement, the results of this scenario should be considered with care as worst case values.

##### **PT 6.6 - Glues and adhesives**

Please refer to the confidential annex.

Conclusion: The requirements for acceptable risk according to the Guidance for BPR are met for the use of glues and adhesives, with concentrations of pure C(M)IT up to 400 ppm.

##### **PT 6.7 - Others**

PT6.7 – Polymer dispersions:

The paint scenario (6.2) calculations are used to cover the preserved polymer dispersions “use step” as this scenario is a worst case considering higher concentration of pure C(M)IT and assessing direct and indirect emissions to the environment. In fact, the intended dose rate for polymer preservation is 40 ppm and polymers are usually included in paints at a maximum of 40% that leads to a final concentration in paints of 16 ppm.

As the use 6.2 complies with Guidance for BPR requirements if a RMM is applied, it is also the case for the Polymer dispersions use.

PT 6.7 – Slurries:

As no scenario concerning slurry formulation exists, and as no data was provided to define precisely the use step process, no risk assessment was performed and therefore the use is not authorised.

PT 6.7 – Pigment paste:

The paint scenario (6.2) calculations are used to cover the preserved pigment paste “use step” as this scenario is a worst case considering higher concentration of pure C(M)IT (15 ppm) and assessing direct and indirect emissions to the environment.

As the use 6.2 complies with Guidance for BPR requirements, it is also the case for the pigments paste use.

PT 6.7 – Colorants:

The preserved polymer dispersions “use step” is covered by the scenario 6.2 (Paints and coatings). Considering that, in paint, the percentage of colorants is lower than the intended dose rate for polymer dispersions, the scenario 6.2 (Paints and coatings) also cover the preserved colorants “use step”.

As the use 6.2 complies with Guidance for BPR requirements, it is also the case for the Colorants use.

***Mixture toxicity***

As no SOC was identify in the product, mixture toxicity assessment is not relevant.

***Aggregated exposure (combined for relevant emmission sources)***



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

C(M)IT is a new substance which has limited uses apart from their use in biocidal products to control bacteria, yeasts and fungi and at present, this product represents the first authorisation granted for C(M)IT.

Dispersive uses leading to emissions to the STP were considered in the aggregated exposure assessment, such as use 6.1 (Detergents), 6.2 (Paints and coating) or 6.6 (Glues).  
Please note that even if calculations considering the emissions due to the use 6.6 (Glue, worst-case, emission by professional) are not presented, it was verified that adding this use in the calculations did not change the conclusions.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **ElocalSTP (kg/d)** | **ElocalSTP**  **(kg/d)** | **PEC/ PNECSTP** | **PEC/PNECwater** | **PEC/PNEC soil** | **PECGW** |
| 6.1 – Detergents – 15 ppm | 4.71E-03 | 8.37E-03 | 6.19E-03 | 5.66E-01 | 9.92E-03 | 1.59E-02 |
| 6.2 – Paints and Coatings (worst-case, application+service life of plasters) – 15 ppm | 3.66E-03 |

Conclusion: Aggregated exposure of the use 6.1 (Detergents other than those used in human hygiene), 6.2 (Paints and coatings), and 6.6 (Glues) does not lead to unacceptable risks for the environment.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| **The use of ACTICIDE C1 leads to acceptable risks :**  **For the use of preserved detergents (use 6.1)** (other than those used for human hygien) at a maximal concentration of 15 ppm for professional and non-professional use.  **For the use of the preserved paints and coating (use 6.2)** at a maximal concentration of 15 ppm.  Risk mitigation measures are necessary to ensure acceptable risks at the application phase of the preserved paints and coating:   * The addition of the product ACTICIDE C1 in additives for paints and coatings must be carried out only in plants connected to industrial STPs.   Moreover, risk mitigation measure is necessary to ensure acceptable risks for the use of the product in paints and coatings:   * The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information: * Use indoor only.   **For the use Preservation of additives used in Paper production (use 6.3-1)** at a maximal concentration of 22.2 ppm for dry-end operation only.  Associated risk mitigation measures:   * Restrict the use of the product for the preservation of additives used in the paper industry for dry-end operations only. * The person responsible for the placing on the market of articles containing preserved polymer dispersions shall ensure that the label of these treated articles provides the following information: * The use of additives preserved by ACTICIDE C1 must be carried out in structures connected to industrial STPs.   **For the use Preservation of Glues and adhesives (use 6.6)** at a maximal concentration of 400 ppm.  **For the use Preservation of Polymer dispersions (use 6.7)** at a maximal concentration of 40 ppm incorporated in paints and coating.  Risk mitigation measure is necessary to ensure acceptable risks at the application phase of the product in polymer dispersions:   * The addition of the product ACTICIDE C1 in polymer dispersions must be carried out only in plants connected to industrial STPs.   Moreover, risk mitigation measures are necessary to ensure acceptable risks for the use of the preserved paints and coating, that include polymer dispersions:   * The person responsible for the placing on the market of articles containing preserved polymer dispersions shall ensure that the label of these treated articles provides the following information: * Use indoor only.   **For the use Preservation of Pigments paste (use 6.7)** at a maximal concentration of 40 ppm incorporated in paints.  **For the use Preservation of Colorants (use 6.7)** at a maximal concentration of 40 ppm incorporated in paints.  **The use of ACTICIDE C1 leads to unacceptable risks :**  **For the use Preservation of paints and coating (higher to 15 ppm) and plasters (use 6.2) when applied outdoor,** considering the risks for soil and aquatic compartments**.**  **For the use Preservation of Slurries (use 6.7)** because data is lacking and thus, the assessment was not realized. |

### Measures to protect man, animals and the environment

*Please refer to summary of the product assessment and to the relevant sections of the assessment report.*

# Annexes[[18]](#footnote-19)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Title** | **Author** | **Data owner** | **IUCLID Section** | **Data protection claimed (Yes/No)** |
|
| Determination of Colour, Physical State and Odour of ACTICIDE C1 | Wannenwetsch, 2016 | Thor GmbH | 3.1 and 3.1 (biocidal product dossier) | Yes |
| Determination of the pH value and the acidity of ACTICIDE C1 | Wannenwetsch, 2016 | Thor GmbH | 3.3 and 3.2 (biocidal product dossier) | Yes |
| Determination of the density of ACTICIDE C1 | Wannenwetsch, 2016 | Thor GmbH | 3.3 (biocidal product dossier) | Yes |
| Determination of the surface tension of an aqueous solution of ACTICIDE C1 | Wannenwetsch, 2016 | Thor GmbH | 3.8 (biocidal product dossier) | Yes |
| Determination of the viscosity of ACTICIDE C1 | Wannenwetsch, 2016 | Thor GmbH | 3.9 (biocidal product dossier) | Yes |
| Expert Statement: Determination of the explosive properties of ACTICIDE C1 | Simonides, 2017 | Thor GmbH | 4.1 and 4.1 (biocidal product dossier) | Yes |
| Expert Statement: Determination of the oxidising properties of ACTICIDE C1 | Simonides, 2017 | Thor GmbH | 4.4 and 4.13 (biocidal product dossier) | Yes |
| Expert Statement: Determination of the self-reactive properties of ACTICIDE C1 | Simonides, 2017 | Thor GmbH | 4.8 and 4.8 (biocidal product dossier) | Yes |
| Determination of physico-chemical properties – Flash Point | S. Dreisch, 2020 | Thor GmbH | - | Yes |
| Determination of physico-chemical properties – Auto-ignition temperature | L. Rosenfeldt, 2020 | Thor GmbH | - | Yes |
| Assessment of the corrosive effect of ACTICIDE C1 for its classification as dangerous good of class 8 “Corrosive Substances” | Kirsch, 2017  Amended 2020 | Thor GmbH | 4.16 and 4.16(biocidal products dossier) | Yes |
| ACTICIDE C1: Determination of the accelerated storage stability, the corrosion characteristics, the pH-value and the acidity at 54°C over 14 days as well as the validation of the sample specific parameters | Wannenwetsch, 2016 | Thor GmbH | 5.1; 3.1 and 3.4 (biocidal product dossier) | Yes |
| ACTICIDE C1: Determination of the storage stability, the corrosion characteristics, the pH-value and the acidity of ACTICIDE C1 at room temperature over 24 months | Wannenwetsch, 2018 | Thor GmbH | 5.1; 3.4 (biocidal product dossier) | Yes |
| Determination of the foaming of ACTICIDE C1 | Wannenwetsch, 2016 | Thor GmbH | 3.5.7 (biocidal product dossier) | Yes |
| ACTICIDE C1, ACTICIDE MV Examination of microbiological efficacy for washing and cleaning fluids and other detergents | Goldbach, 2018a | Thor GmbH | 6.7 (biocidal product dossier) | Yes |
| ACTICIDE MV Examination of microbiological efficacy for washing and cleaning fluids and other detergents, Kill dose test | Goldbach, 2016a | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for washing and cleaning fluids and other detergents, Kill dose test | Goldbach, 2018b | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1, ACTICIDE MV Examination of microbiological efficacy for paints and coatings | Goldbach, 2018c | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for paints and coatings, Kill dose test | Goldbach, 2017c | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for paints and coatings, Kill dose test | Goldbach, 2018d | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for fluids used during paper production | Goldbach, 2016b | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for glues and adhesives | Goldbach, 2016c | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for glues and adhesives, Kill dose test | Goldbach, 2016d | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1, ACTICIDE MV Examination of microbiological efficacy in polymer dispersions | Goldbach, 2018e | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for polymer dispersions, Kill dose test | Goldbach, 2016e | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for polymer dispersions, Kill dose test | Goldbach, 2018f | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for colourants | Goldbach, 2016f | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for pigment pastes | Goldbach, 2016g | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for pigment pastes, Kill dose test | Goldbach, 2016h | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for slurries (CaCO3) | Goldbach, 2016i | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for slurries (CaCO3), Kill dose test | Goldbach, 2016j | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV Examination of microbiological efficacy for slurries (TiO2) | Goldbach, 2016k | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE MV, ACTICIDE C1 Evaluation of Minimum Inhibitory Concentrations (MIC) | Goldbach, 2017 | Thor GmbH | 6.6 | Yes |
| ACTICIDE MV, ACTICIDE C1 and ACTICIDE M 20 Evaluation of Minimum Inhibitory Concentrations (MIC) | Goldbach, 2018 | Thor GmbH | 6.6 | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for fluids used during paper production | 2018g | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for glues and adhesives | Goldbach, 2018h | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for colourants | Goldbach, 2018i | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for pigment pastes | Goldbach, 2018j | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for slurries (CaCO3) | Goldbach, 2018k | Thor GmbH | 6.7 (biocidal product dossier | Yes |
| ACTICIDE C1 Examination of microbiological efficacy for slurries (TiO2) | Goldbach, 2018l | Thor GmbH | 6.7 (biocidal product dossier | Yes |

## Output tables from exposure assessment tools

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## Summaries of the efficacy studies (B.5.10.1-xx)[[19]](#footnote-20)

See the IUCLID file

## Confidential annex

See the separated confidential annex.

1. According to tier 2 requirements and to simulate long term storage resp. overseas shipping the samples were stored at 40°C for 8 weeks (at 60°C for 3 days for slurries to simulate temperature storage) in hermetic sealed vessels before testing. [↑](#footnote-ref-2)
2. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-3)
3. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-4)
4. Checkliste gemäß überarbeiteten Anhang A (neu) zu den Vergabekriterien DE-UZ 102 „Emissionsarme Innenwandfarben“ zur stofflichen Bewertung im Rahmen des Aufnahmeverfahrens für weitere Topfkonservierungsmittel“(*Checklist in accordance with revised Annex A (new) to the award criteria DE-UZ 102 "Low-emission interior wall paints" for material evaluation as part of the acceptance procedure for further in-can preservatives.* Draft version from the German Bundesamt für Materialforschung (BAM) and Umweltbundesamt (UBA) (May 2018, only in German) [↑](#footnote-ref-5)
5. According to tier 2 requirements and to simulate long term storage resp. overseas shipping the samples were stored at 40°C for 8 weeks (at 60°C for 3 days for slurries to simulate temperature storage) in hermetic sealed vessels before testing. [↑](#footnote-ref-6)
6. RMS expert statement : in raw data of the model, 27 values were between 0 and 80.59 mg/min whereas the three higher values were between 242 and 339 mg/min, which has been considered as outliers, not representative for trained professionals handling hazardous products. [↑](#footnote-ref-7)
7. The exposure duration of 0.75 min recommended by ConsExpo has been kept for the estimation of professionnal exposure during M&L of detergent. RMS has considered that the time necessary to perform the task was not different between a professional and a non professional. However, a higher frequency has been applied for professional exposure. [↑](#footnote-ref-8)
8. The sink area of 1500 cm2 proposed by ConsExpo is doubled ; RMS assuming that sinks for professionals are larger than those for amateurs. Moreover, this modification has no impact on the concentration of pb in washing water. [↑](#footnote-ref-9)
9. The sink area of 1500 cm2 proposed by ConsExpo is doubled ; RMS assuming that sinks for professionals are larger than those for amateurs. [↑](#footnote-ref-10)
10. EPA's Child-Specific Exposure Factors Handbook, section 5.4 [↑](#footnote-ref-11)
11. Oral absorption determined in Document IIA rounded to 100% in the calculations. [↑](#footnote-ref-12)
12. A typical latex paint contains about 50% solids, according to ConsExpo Paint products fact sheet. [↑](#footnote-ref-13)
13. City scenario: Leaching from paints, plasters and fillers applied in urban areas (2015) [↑](#footnote-ref-14)
14. City scenario: Leaching from paints, plasters and fillers applied in urban areas (2015) [↑](#footnote-ref-15)
15. City scenario: Leaching from paints, plasters and fillers applied in urban areas (2015) [↑](#footnote-ref-16)
16. Emission scenario document on non-integrated paper mills, OECD n°16, 2006 [↑](#footnote-ref-17)
17. (The assessment of direct emission to surface water in urban areas: PT 6.2/6.3 and 7-10 (DE, 2014). [↑](#footnote-ref-18)
18. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-19)
19. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-20)