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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



[ORAPI CRESYL FAMILY]

Product type(s) [2&3]

[Chlorocresol (CMK) as included in the Union list of approved active substances]

Case Number in R4BP: [BC-LG039247-40]

Evaluating Competent Authority: [FR]

Date: [June 2020]

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# CONCLUSION

***Intended uses***

*Products of the ORAPI CRESYL FAMILY are intended for use as PT2, disinfection of surfaces in private and public areas and PT3, disinfection of private domestic animal housing. Products contained on 0.319 % to 2.9 % of chlorocresol. The family is composed by 2 META SPC. The first is the CRESYL CONCENTRE to be used after dilution and the second is the CRESYL PAE, ready to use. It is intended to be used by general public and professional users, to be applied indoor and outdoor.*

***Conclusion of the physico-chemical and technical properties***

Physical and chemical properties of each product included in ORAPI CRESYL FAMILY have been described and are considered acceptable for the intended uses.

Analytical methods are considered acceptable.

***Conclusion of Efficacy***

French competent authorities (FR CA) assessed that the products of the ORAPI CRESYL FAMILY, have shown a sufficient efficacy, for the following uses claimed:

**Meta SPC 1 – Cresyl concentré**

* For product application as a PT2 disinfectant for indoor hard surfaces, use other than in healthcare (use #1) : by mopping at 7 % v/v dilution, against bacteria and yeasts, on dirty non-porous hard surfaces, at 20°C, with a contact time of 5 minutes (bacteria) or 15 minutes (yeasts).
* For product application as a PT2 disinfectant for outdoor hard surfaces (uses #2 and #3): by brushing or spraying (with a pressure washer) at 7% v/v dilution against bacteria and yeasts, on dirty porous/non-porous hard surfaces, at 10°C, with a contact time of 45 minutes.

**Meta SPC 2 – Cresyl PAE**

* For product application as a PT2 disinfectant for indoor disinfection of small surfaces, material, equipment and furniture, use other than in healthcare (use #4): by spraying without dilution, against bacteria, yeasts and fungi, on dirty non-porous hard surfaces, at 20°C, with a contact time of 5 minutes (bacteria) or 15 minutes (yeast and fungi).
* For product application as a PT2 disinfectant for outdoor disinfection of small surfaces, material, equipment and furniture, use other than in healthcare (uses #5): by spraying without dilution, against bacteria and yeasts, on dirty porous/non-porous hard surfaces, at 10°C, with a contact time of 30 minutes (bacteria) or 45 minutes (yeasts).
* For product application as a PT3 disinfectant (backyard housing of small domestic animals) for hard surfaces (use #6): by spraying without dilution, against bacteria and yeasts, on clean porous/non-porous surfaces, at 10°C, with a contact time of 30 minutes.

The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

***Conclusion of risk characterisation for Human Health***

The **risk for professional users** is

* Acceptable for products of **Meta SPC1 for all claimed uses** with the following RMMs:
* During mixing and loading with substance/ task appropriate gloves, protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure) and chemical goggles are worn. Moreover, minimisation of splashes and spills and avoidance of contact with contaminated tools and objects should occur,
* During mopping, with gloves worn,
* During wiping (brush, wet cloth), with gloves and coated coverall worn,
* During application with a pressure cleaner, with gloves and coated coverall worn during spraying.
* Acceptable for products of **Meta SPC2** with the following RMMs:
* During spraying with a trigger spray combined to wiping, with gloves worn during wiping.

The **risk for non-professional users** is:

* Unacceptable for products of **Meta SPC1:** for non-professionals applying the product by moping/wiping (brush, wet cloth) and pressure cleaner.
* Acceptable for products of **Meta SPC2:** for non-professionals applying the product with a trigger spray (following by wiping if necessary and rinsing).

The **risk for general public** is

* acceptable for adult and children exposed to volatile residues
* acceptable for adults touching wet or dried surfaces after application
* unacceptable for toddlers crawling on wet or dried surfaces, treated with a product of meta SPC1.

Therefore the following RMM is proposed:

* Do not apply the product on surface in contact with children.
* unacceptable for toddlers crawling on wet surfaces, treated with a product of meta SPC2.

Therefore the following RMM is proposed:

* Children should not be in contact with the treated surfaces until complete drying.

**C*onclusion of risk for consumers via residues in food***

According to PT 2 intended uses, indirect or direct contact with food or feeding stuffs is not expected. No dietary exposure is expected and performed.

According to intended PT 3 non-professional uses (# use 6), some animals can be exposed to chlorocresol after use of the active substance as disinfectant of small domestic animal housing (Scenario DRA 1). Moreover, it is assumed that the chlorocresol residues can contaminate the eggs by being in contact with the treated surface (Scenario DRA 2).

For scenario Dietary Risk Assessment (DRA) 1, the instructions of use and risk mitigation measures (RMMs) to prevent animals exposure proposed by the applicant have been reviewed by eCA and are indicated in the SPC:

* Do not apply the treatment in the presence of domestic animals.
* Wait 30 minutes after the application before the re-entry of animals.
* Put new animal bedding material before re-entry of domestic animals.
* Remove or cover feed and water troughs before treatment.

Based on these RMMs, exposure of animals is expected to be negligible. There is no need to assess indirect exposure to general public via ingestion of tissues or products of animal origin.

For scenario DRA 2, the applicant proposed a scenario which was reviewed by eCA. Based on this scenario, indirect exposure via consumption of eggs was estimated and risk calculation was performed. Exceedance of ADI-ARfD for adult and child is not expected considering intended uses.

***Conclusion of risk characterisation for Environment***

**Acceptable risks** are reached for the environment for:

* **META SPC1:**
  + Use # 1 (PT2): disinfection of indoor surfaces (including floors) in private and public areas
  + Use # 2 (PT2): disinfection of outdoor surfaces (low-walls up to 50 cm height from the bottom of the wall, terrace) twice a year by brushing at an application rate not exceeding 60 mL of product/m².
* **META SPC2:**
  + Use # 4 (PT2): disinfection of indoor small surfaces material, equipment and furniture
  + Use # 5 (PT2): disinfection of outdoor small outdoor surfaces and material, equipment furniture, twice a year at an application rate of 25 mL of product/m².
  + Use # 6 (PT3): disinfection of private domestic animal housing once a week by spray and at an application rate of 25 mL of product/m², providing that treated surfaces are never rinsed after treatment when used outdoor.

**Unacceptable risks** are foreseen for the environment for:

* **META SPC1:**
  + Use # 3 (PT2): disinfection of outdoor surfaces (low-walls, terrace) twice a year by pressure washer, considering that the application rate will be higher than 0.06 L/m2 (general pressure washer devices deliver much more than 0.06 L of product/m², which is the limit to reach acceptable risks). It presents risks for soil and surface water compartments.

***ED assessment:***

An assessment of endocrine disruption (ED) properties of co-formulants in ORAPI CRESYL FAMILYhas been performed by FR CA. Four co-formulants show indications of endocrine activity (see confidential annex).

Based on available information, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case these co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

**GENERAL CONCLUSION:**

**Overall conclusions for the claimed uses**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Meta SPC** | **Uses** | **Target organism** | **Application rates** | **Use conditions** | **Acceptable/no acceptable** |
| Meta SPC 1 | Use 1 (PT2): Indoors disinfection of indoor of hard non-porous surfaces (including floors) in private and public areas, by mopping, use other than in healthcare. | Bacteria, Yeasts | 7% v/v dilution | Professional users  Surface treatment – Mopping    Contact time: 5 min for bacteria and 15 min for yeasts  Temperature: 20°C  Dirty conditions | Acceptable for non- porous surfaces |
| Use 1 (PT2): Indoors disinfection of indoor of hard surfaces (including floors) in private and public areas, by mopping | Bacteria, Yeasts | 7% v/v dilution | Non Professional users  Surface treatment – Mopping | No acceptable: human health risk |
| Use 2 (PT2): Disinfection of outdoor porous/non-porous hard surfaces surrounding households, such as terraces and low walls, in private and public areas, by brushing | Bacteria, Yeasts | 0.06 L/m²  7% v/v dilution | Professional users  Surface treatment – Brushing  Contact time: 45 minutes.  Temperature : 10°C  Dirty conditions  Frequency: 2 times/year | Acceptable |
| Use 2 (PT2): Disinfection of outdoor hard surfaces surrounding households, such as terraces and low walls, in private and public areas, by brushing | Bacteria, Yeasts | 7% v/v dilution | Non-Professional users  Surface treatment – Brushing | No acceptable: human health risk |
| Use 3 (PT2): Disinfection of outdoor non-porous hard surfaces surrounding households, such as terraces and low walls, in private and public areas, by pressure washer | Bacteria, Yeasts | 7% v/v dilution | Professional and Non-Professional users  Surface treatment – by pressure washer | No acceptable: - human health risk for non- professional users  - environment risk for soil and surface water compartments |
| Meta SPC 2 | Use 4 (PT2): disinfection of indoor small non porous hard surfaces, materials, equipments and furnitures, use other than in healthcare. | Bacteria, Yeasts,  Fungi | 100 %  Ready to use product | Professional and non-professional users  Surface treatment - Spraying  Contact time: 5 min for bacteria, 15 min for yeasts and for fungi.  Temperature: 20°C  Dirty conditions | Acceptable |
| Use 5 (PT2): disinfection of outdoor small porous/non-porous hard outdoor surfaces and materials, equipments and furnitures, use other than in healthcare. | Bacteria, Yeasts | 100 %  Ready to use product | Professional and non-professional users  Surface treatment - Spraying  Contact time: 45 min  Temperature: 10°C  Dirty conditions  Frequency: 2 times/year | Acceptable |
| Use 6 (PT3): disinfection of private domestic animal housing | Bacteria, Yeasts | 100 %  Ready to use product | Non-professional users  Surface treatment – Spraying  Contact time: 30 min  Temperature: 10°C  Clean conditions | Acceptable without rinsing when used outdoor |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| Orapi Cresyl Family | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | ORAPI GROUP |
| **Address** | 25 Rue de l’industrie  69200 Vénissieux  France |
| **Authorisation number** | FR-2020-0027 | |
| **Date of the authorisation** | 07/07/2020 | |
| **Expiry date of the authorisation** | 06/07/2030 | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | ORAPI GROUP |
| **Address of manufacturer** | 25 Rue de l’industrie  69200 Vénissieux  France |
| **Location of manufacturing sites** | Parc Industriel de la Plaine de l’Ain  225 Allée des Cèdres  01150 Saint-Vulbas  France |

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

|  |  |
| --- | --- |
| **Active substance** | Chlorocresol |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1  50569 Köln  Germany |
| **Location of manufacturing sites** | MPP-MF Alkylation Product Unit  D-47812 Krefeld-Uerdingen  Germany |

### Product (family) 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** | p-chloro-m-cresol |
| **IUPAC or EC name** | Chlorocresol |
| **EC number** | 200-431-6 |
| **CAS number** | 59-50-7 |
| **Index number in Annex VI of CLP** | 604-014-00-3 |
| **Minimum purity / content** | 99.8 % w/w |
| **Structural formula** |  |

#### Candidate(s) for substitution

Chlorocresol (CMK) does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

#### Qualitative and quantitative information on the composition of the biocidal product family2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Chlorocresol | Chlorocresol | Active substance | 59-50-7 | 200-431-6 | 0.319 | 2.9 |
| 1-methoxy-2-propanol | 1-methoxypropan-2-ol | Non-active substance | 107-98-2 | 203-539-1 | 0.6105 | 5.55 |

#### 

#### Information on technical equivalence

Not applicable

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

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, the co-formulant 1-methoxy-2-propanol has been identified as substance of concern. Please see the confidential annex for further details.

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

According to our assessment, none of the co-formulants contained in the product ORAPI CRESYL FAMILY, are regulatory identified as endocrine disruptors.

However, four co-formulants show indications of endocrine activity (see confidential annex).

Based on available information, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case these co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

#### Type of formulation

|  |
| --- |
| SL – Soluble concentrate  AL – Any other liquid |

**Part II - Second information level - meta SPC 1**

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identification** | CRESYL CONCENTRÉ |
| --- | --- |

#### Suffix to the authorisation number

| Number 1 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |

### Meta SPC 1 composition

#### Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Chlorocresol | Chlorocresol | Pure active substance | 59-50-7 | 200-431-6 | 2.89 | 2.89 |
| Technical active substance | 2.9 | 2.9 |
| 1-methoxy-2-propanol | 1-methoxy-2-propanol | Non-active substance | 107-98-2 | 203-539-1 | 5.55 | 5.55 |

#### Type(s) of formulation of the meta SPC 1

|  |
| --- |
| SL – Soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

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

| **Classification** | |
| --- | --- |
| Hazard category | Flammable liquid, category 3  Corrosive to metals, category 1  Skin irritation, category 2  Eye irritation, category 2 |
| Hazard statement | H226: Flammable liquid and vapour  H290: May be corrosive to metals  H315: Causes skin irritation  H319: Causes serious eye irritation |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H226: Flammable liquid and vapour  H290: May be corrosive to metals  H315: Causes skin irritation  H319: Causes serious eye irritation |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  P234: Keep only in original container.  P264: Wash … thoroughly after handling.  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P302+P352: IF ON SKIN: Wash with plenty of water/...  P332+P313: If skin irritation occurs: Get medical advice/attention.  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P337+P313: If eye irritation persists: Get medical advice/attention.  P362+P364: Take off contaminated clothing and wash it before reuse.  P390: Absorb spillage to prevent material damage.  P406: Store in a corrosive resistant/… container with a resistant inner liner. |
|  | |
| Note | EUH208 Contains Chlorocresol. May produce an allergic reaction. |

### Authorised use(s) of the META SPC 1

#### Use description[[1]](#footnote-2)

**Meta SPC 1 – Cresyl Concentré**

Table 1. Use # 1 – Disinfectant to be used diluted for indoor hard non-porous surfaces disinfection - Mopping

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection of indoor domestic hard non-porous surfaces, such as cellars and indoor garbage storage areas. |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Indoors disinfection of hard non-porous surfaces (including floors) in private and public areas. Use other than in healthcare. |
| **Application method(s)** | Surface treatment – Mopping |
| **Application rate(s) and frequency** | 7% v/v dilution  Contact time: 5 min for bacteria and 15 min for yeasts  Temperature: 20°C  Dirty conditions |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | 1, 5, 25 or 200 L metal packaging (varnish-free tin plate). |

##### Use-specific instructions for use[[2]](#footnote-3)

|  |
| --- |
| * Apply only on non-porous surfaces. * Do not apply at temperatures below 20 °C. * Pour 70 mL of product into 930 ml of water in a bucket. Apply the diluted product with a mop. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during application. |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

#### Use description

Table 2. Use # 2 – Disinfectant to be used diluted for outdoor hard surfaces disinfection – by brushing

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection of outdoor porous/non-porous hard surfaces surrounding households, such as terraces and low walls (up to 50 cm height from the bottom of the wall). |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Outdoors disinfection of hard surfaces (including floors) in private and public areas. |
| **Application method(s)** | Surface treatment – Brushing |
| **Application rate(s) and frequency** | 7% v/v dilution  Contact time: 45 minutes.  Temperature : 10°C  Dirty conditions  Frequency: 2 times/year |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | 1, 5, 25 or 200 L metal packaging (varnish-free tin plate). |

##### Use-specific instructions for use

|  |
| --- |
| * Do not apply at temperatures below 10 °C. * Pour 70 mL of product into 930 mL of water in a bucket. Apply the diluted product with a brush. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Make sure to wet the surface completely. Do not use more than 60 mL product/m2. * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and protective coverall at least type 6 (coverall material to be specified by the authorisation holder within the product information) during application. |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### General directions for use of the meta SPC 1

#### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect all the instructions provided * Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.) * Ensure complete wetting on the surfaces, leave for appropriate contact time. |

#### Risk mitigation measures

|  |
| --- |
| * Liquid to be poured very close to the bucket to avoid projections. * Wear substance/ task appropriate gloves, and protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure) and chemical goggle during mixing and loading of the concentrate product. * Rinse surface and material after treatment. The same PPE than those required during application have to be worn. * Do not apply the product on surface in contact with children. * Avoid any direct or indirect contact with food. |

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

|  |
| --- |
| * 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

|  |
| --- |
| * 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

|  |
| --- |
| * Shelf-life: 2 years. |

### Other information

|  |
| --- |
| * The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA). |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **Cresyl Concentré, CRESYL®, CRESYDOC, DIABLOTIN® GRESIROL, MORTIS® GRESIROL, OXI CRESOL** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Chlorocresol | Chlorocresol | Pure active substance | 59-50-7 | 200-431-6 | 2.89 |
| Technical active substance | 2.9 |
| 1-methoxy-2-propanol | 1-methoxy-2-propanol | Non-active substance | 107-98-2 | 203-539-1 | 5.55 |

**Part II - Second information level - meta SPC 2**

### Meta SPC 2 administrative information

#### Meta SPC identifier

| **Identification** | CRESYL PAE |
| --- | --- |

#### Suffix to the authorisation number

| Number 2 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2, 3 |
| --- | --- |

### Meta SPC 2 composition

#### Qualitative and quantitative information on the composition of the meta SPC 2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Chlorocresol | Chlorocresol | Pure active substance | 59-50-7 | 200-431-6 | 0.318 | 0.318 |
| Technical active substance | 0.319 | 0.319 |
| 1-methoxy-2-propanol | 1-methoxy-2-propanol | Non-active substance | 107-98-2 | 203-539-1 | 0.6105 | 0.6105 |

#### Type(s) of formulation of the meta SPC 2

|  |
| --- |
| Any other liquid (AL) |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

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

| **Classification** | |
| --- | --- |
| Hazard category | Corrosive to metals, category 1 |
| Hazard statement | H290: May be corrosive to metals |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H290: May be corrosive to metals |
| Precautionary statements | P234: Keep only in original container.  P390: Absorb spillage to prevent material damage.  P406: Store in a corrosive resistant/… container with a resistant inner liner. |
|  | |
| Note | EUH208: Contains Chlorocresol. May produce an allergic reaction. |

### Authorised use(s) of the META SPC 2

#### Use description

Table 1. Use # 1 – Ready-to-use disinfectant for small non-porous hard surfaces, material, equipment and furniture indoors disinfection.

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection of indoor domestic non-porous hard surfaces, such as small surfaces, materials, equipments and furnitures. |
| **Target organism (including development stage)** | Bacteria, yeasts, fungi |
| **Field of use** | Indoors disinfection of small non-porous hard surfaces, materials, equipments and furnitures, in private and public areas. Use other than in healthcare |
| **Application method(s)** | Surface treatment - Spraying |
| **Application rate(s) and frequency** | Ready to use product  Contact time: 5 min for bacteria, 15 min for yeasts, 15 min for fungi.  Temperature: 20°C  Dirty conditions |
| **Category(ies) of users** | Professional and non-professional. |
| **Pack sizes and packaging material** | 500 mL HDPE trigger spray |

##### Use-specific instructions for use[[3]](#footnote-4)

|  |
| --- |
| * Apply only on non-porous surfaces. * Spray uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for appropriate time, and if needed spread over the surface with a clean and wet cloth. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces and material after treatment. For professionals, wear gloves during rinsing. * Avoid any direct or indirect contact with food. |

##### 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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

#### Use description

Table 2. Use # 2 – Ready-to-use disinfectant for small hard surfaces, material, equipment and furniture outdoors disinfection.

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection of outdoor domestic surfaces, such as small surfaces, materials, equipments and furnitures. |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Outdoor disinfection of small porous/non-porous hard surfaces, materials, equipments and furnitures, in private and public areas. Use other than in healthcare. |
| **Application method(s)** | Surface treatment - Spraying |
| **Application rate(s) and frequency** | Ready to use product  Contact time: 45 min  Temperature: 10°C  Dirty conditions  Frequency: 2 times/year |
| **Category(ies) of users** | Professional and non-professional. |
| **Pack sizes and packaging material** | 500 mL HDPE trigger spray |

##### Use-specific instructions for use

|  |
| --- |
| * Do not apply at temperatures below 10 °C. * Spray uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for appropriate time, and if needed spread over the surface with a clean and wet cloth. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces and material after treatment. For professionals, wear gloves during rinsing. * Avoid any direct or indirect contact with food. |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

#### Use description

Table 3. Use # 3 – Ready-to-use disinfectant for housing of small domestic animals indoor and outdoor disinfection.

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of small domestic animal housing, such as a dog kennel, a rabbit hutch or a backyard chicken coop. |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Backyard housing of small domestic animals (porous and non-porous surfaces). Indoor and outdoor. |
| **Application method(s)** | Surface treatment - Spraying |
| **Application rate(s) and frequency** | Ready to use product  Contact time: 30 min  Temperature: 10°C  Clean conditions - Surfaces need to be cleaned prior to the disinfection. |
| **Category(ies) of users** | Non-professional. |
| **Pack sizes and packaging material** | 500 mL HDPE trigger spray |

##### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product. * Spray uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for appropriate time, and if needed spread over the surface with a clean and wet cloth. * Let the surface dry. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply the treatment in the presence of domestic animals. * Do not introduce domestic animals in housing until a total drying. * Never rinse the treated surfaces when the product is used outdoor.   For animals dedicated to human consumption:   * Do not apply the treatment in the presence of animals. * Wait 30 minutes after the application before the re-entry of animals. * Put new animal bedding material before re-entry of domestic animals. * Remove or cover feed and water troughs before treatment. |

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

|  |
| --- |
| - |

##### 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

|  |
| --- |
| - |

### General directions for use of the meta SPC 2

#### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). * Read carefully and follow all instructions. |

#### Risk mitigation measures

|  |
| --- |
| * For professionals, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during wiping. * Children should not be in contact with the treated surfaces until complete drying. |

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

|  |
| --- |
| * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and 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. * Inhalation (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. Do not give fluids or induce vomiting. * Keep the container or label available. * If medical advice is needed, have product container or label at hand. |

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

|  |
| --- |
| * 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

|  |
| --- |
| * Shelf life: 2 years. * Keep out of reach of children. |

### Other information

|  |
| --- |
| * The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA). |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **Cresyl PAE, CRESYL® PAE, OXI CRESOL PAE, CRESYDOC PAE** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Chlorocresol | Chlorocresol | Pure active substance | 59-50-7 | 200-431-6 | 0.318 |
| Technical active substance | 0.319 |
| 1-methoxy-2-propanol | 1-methoxy-2-propanol | Non-active substance | 107-98-2 | 203-539-1 | 0.6105 |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Can | 1 or 5 L | Metal (varnish-free tin plate) | PE plug with integrated pull-up spout (opaque) | Professional | Yes |
| Barrel | 25L | Metal (varnish-free tin plate) | Plastic plug with integrated pull-up spout (opaque) | Professional | Yes |
| Barrel | 200L | Metal (varnish-free tin plate) | Metal cap | Professional | Yes |
| Trigger spray | 500 mL | HDPE (opaque) | Plastic sprayer head (opaque) | Professional and Non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal product family were provided by ORAPI GROUP. Please refer to the list of reference.

*Efficacy*

New data on the product is submitted for the demonstration of the efficacy. Please refer to the list of reference.

#### Access to documentation

ORAPI GROUP has access to data on the active substance chlorocresol with a Letter of Access of Lanxess Deutschland GmbH, one applicant of the active substance 4-chloro-3-methylphenol.

### Assessment of endocrine disruption (ED) properties of the BPF

According to our assessment, none of the co-formulants contained in the product ORAPI CRESYL FAMILY, are regulatory identified as endocrine disruptors.

However, four co-formulants show indications of endocrine activity (see confidential annex).

Based on available information, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case these co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

## Assessment of the biocidal product family

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

**Meta SPC 1 – Cresyl Concentré**

Table 1. Use # 1 – Disinfectant cleaner to be used diluted for indoor surfaces and floors disinfection.

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection and cleaning of indoor domestic surfaces, such as cellars and indoor garbage storage areas. No prior cleaning of surfaces is required. |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Indoors disinfection of surfaces (including floors) in private and public areas. |
| **Application method(s)** | Pour 70 mL of product in 930 mL of water in a bucket. Apply the diluted product with a mop. Leave to act for a minimum of 5 minutes for bactericidal efficacy and 15 minutes for yeasticidal efficacy. Rinse the treated surfaces with water. |
| **Application rate(s) and frequency** | Application rate: 0.06L/m² of diluted product (7% dilution).  The product should be used once a week. |
| **Category(ies) of users** | Professional and non-professional. |
| **Pack sizes and packaging material** | 1, 5 or 25 L metal packaging for non-professional and professional users.  200 L metal packaging for professional users. |

Table 2. Use # 2 – Disinfectant cleaner to be used diluted for outdoor surfaces and floors disinfection.

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection and cleaning of outdoor surfaces surrounding households, such as terraces and low walls (up to 50cm height from the bottom of the wall). No prior cleaning of surfaces is required. |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Outdoors disinfection of surfaces (including floors) in private and public areas. |
| **Application method(s)** | Pour 70 mL of product in 930 mL of water in a bucket. Apply the diluted product with a brush. Leave to act for a minimum of 45 minutes. Rinse the treated surfaces with water. |
| **Application rate(s) and frequency** | Application rate: 0.06L/m² of diluted product (7% dilution).  The product should be used twice a year. |
| **Category(ies) of users** | Professional and non-professional. |
| **Pack sizes and packaging material** | 1, 5 or 25 L metal packaging for non-professional and professional users.  200 L metal packaging for professional users. |

Table 3. Use # 3 – Disinfectant cleaner to be used diluted for hard surfaces disinfection with a pressure washer.

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection and cleaning of outdoor surfaces surrounding households, such as terraces and low walls (up to 50cm height from the bottom of the wall). No prior cleaning of surfaces is required. |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Outdoors disinfection of hard surfaces surrounding private and public areas. |
| **Application method(s)** | Pour the product into the product bin of a pressure washer. Apply a 7% dilution of the product (70 mL per litre in water) with the pressure washer to the to-be-treated surface. Leave to act for a minimum of 45 minutes. Rinse the treated surfaces with water. |
| **Application rate(s) and frequency** | Application rate: 0.06L/m² of diluted product (7% dilution).  The product should be used twice a year. |
| **Category(ies) of users** | Professional and non-professional. |
| **Pack sizes and packaging material** | 1, 5 or 25 L metal packaging for non-professional and professional users.  200 L metal packaging for professional users. |

**Meta SPC 2 – Cresyl PAE**

Table 4. Use # 4 – Ready-to-use disinfectant cleaner for small surfaces, material, equipment and furniture indoors disinfection.

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection and cleaning of indoor domestic surfaces, such as small surfaces, material, equipment and furniture. No prior cleaning of surfaces is required. |
| **Target organism (including development stage)** | Bacteria, yeasts, fungi |
| **Field of use** | Indoors disinfection of small surfaces, material, equipment and furniture, in private and public areas. |
| **Application method(s)** | Spray the product to the to-be-treated surface. Scrub if necessary and leave to act for a minimum of 5 minutes for bactericidal efficacy and 15 minutes for yeasticidal and fungicidal efficacies. Rinse the treated surfaces with water. |
| **Application rate(s) and frequency** | Application rate: 25 mL/m².  The product should be used once a week. |
| **Category(ies) of users** | Professional and non-professional. |
| **Pack sizes and packaging material** | 500 mL HDPE packaging. |

Table 5. Use # 5 – Ready-to-use disinfectant cleaner for small surfaces, material, equipment and furniture outdoors disinfection.

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Disinfection and cleaning of outdoor domestic surfaces, such as small surfaces, material, equipment and furniture. No prior cleaning of surfaces is required. |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Outdoors disinfection of small surfaces, material, equipment and furniture, in private and public areas. |
| **Application method(s)** | Spray the product to the to-be-treated surface. Scrub if necessary and leave to act for a minimum of 45 minutes. Rinse the treated surfaces with water. |
| **Application rate(s) and frequency** | Application rate: 25 mL/m².  The product should be used twice a year. |
| **Category(ies) of users** | Professional and non-professional. |
| **Pack sizes and packaging material** | 500 mL HDPE packaging. |

Table 6. Use # 6 – Ready-to-use disinfectant for housing of small domestic animals.

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of small domestic animal housing, such as a dog kennel, a rabbit hutch or a backyard chicken coop. Surfaces need to be cleaned prior to the disinfection. |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Backyard housing of small domestic animals. |
| **Application method(s)** | Spray the product to the clean to-be-treated surface. Scrub if necessary and leave to act for a minimum of 30 minutes. Do not rinse the surfaces after application. |
| **Application rate(s) and frequency** | Application rate: 25 mL/m².  The product should be used once a week. |
| **Category(ies) of users** | Non-professional. |
| **Pack sizes and packaging material** | 500 mL HDPE packaging. |

#### Use-specific instructions for use

|  |
| --- |
| **Use # 1 – Disinfectant cleaner to be used diluted for indoor surfaces and floors disinfection**  Pour 70 mL of product in 930 mL of water in a bucket. Apply the diluted product with a mop. Leave to act for a minimum of 5 minutes for bactericidal efficacy and 15 minutes for yeasticidal efficacy. Rinse the treated surfaces with water.  **Use # 2 – Disinfectant cleaner to be used diluted for outdoor surfaces and floors disinfection**  Pour 70 mL of product in 930 mL of water in a bucket. Apply the diluted product with a brush. Leave to act for a minimum of 45 minutes. Rinse the treated surfaces with water.  **Use # 3 – Disinfectant cleaner to be used diluted for surfaces and floors disinfection with a pressure washer**  Pour the product into the product bin of a pressure washer. Apply a 7% dilution of the product (70 mL per litre in water) with the pressure washer to the to-be-treated surface. Leave to act for a minimum of 45 minutes. Rinse the treated surfaces with water.  **Use # 4 – Ready-to-use disinfectant cleaner for small surfaces, material, equipment and furniture indoors disinfection**  Spray the product to the to-be-treated surface. Scrub if necessary and leave to act for a minimum of 5 minutes for bactericidal efficacy and 15 minutes for yeasticidal and fungicidal efficacies. Rinse the treated surfaces with water.  **Use # 5 – Ready-to-use disinfectant cleaner for small surfaces, material, equipment and furniture outdoors disinfection**  Spray the product to the to-be-treated surface. Scrub if necessary and leave to act for a minimum of 45 minutes. Rinse the treated surfaces with water.  **Use # 6 – Ready-to-use disinfectant for housing of small domestic animals**  Spray the product to the clean to-be-treated surface. Scrub if necessary and leave to act for a minimum of 30 minutes. Do not rinse the surfaces after application. |

#### Use-specific risk mitigation measures

|  |
| --- |
| **Use # 1 – Disinfectant cleaner to be used diluted for indoor surfaces and floors disinfection**  For professional users, wear protecting gloves and coated coveralls (protection factor of 90%).  For non-professional users, no use-specific risk mitigation measure has been identified for the safe use of the product. Please refer to the General directions for use (point 2.1.5) for risk mitigation measures defined per Meta SPC.  **Use # 2 – Disinfectant cleaner to be used diluted for outdoor surfaces and floors disinfection**  For professional users, wear protecting gloves and coated coveralls (protection factor of 90%).  For non-profesionnal users, no use-specific risk mitigation measure has been identified for the safe use of the product. Please refer to the General directions for use (point 2.1.5) for risk mitigation measures defined per Meta SPC.  **Use # 3 – Disinfectant cleaner to be used diluted for surfaces and floors disinfection with a pressure washer**  For professional users, wear protective gloves and coated coveralls (protection factor of 90%).  For non-professional users, no use-specific risk mitigation measure has been identified for the safe use of the product. Please refer to the General directions for use (point 2.1.5) for risk mitigation measures defined per Meta SPC.  **Use # 4 – Ready-to-use disinfectant cleaner for small surfaces, material, equipment and furniture indoors disinfection**  For professional users, wear protective gloves.  For non-professional users, no use-specific risk mitigation measure has been identified for the safe use of the product. Please refer to the General directions for use (point 2.1.5) for risk mitigation measures defined per Meta SPC.  **Use # 5 – Ready-to-use disinfectant cleaner for small surfaces, material, equipment and furniture outdoors disinfection**  For professional users, wear protective gloves.  For non-profesionnal users, no use-specific risk mitigation measure has been identified for the safe use of the product. Please refer to the General directions for use (point 2.1.5) for risk mitigation measures defined per Meta SPC.  **Use # 6 – Ready-to-use disinfectant for housing of small domestic animals**  Do not rinse the treated surfaces after product application.  Do not apply the treatment in the presence of domestic animals.  No human consumption of the domestic animals.  Remove all animal bedding material and feed and water troughs before treatment and replace it before re-entry of domestic animals.  Do not disinfect feed and water troughs.  Please also refer to the General directions for use (point 2.1.5) for risk mitigation measures defined per Meta SPC. |

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

|  |
| --- |
| Please refer to general directions for use of the « Orapi Cresyl Family » biocidal product family in point 2.1.5 (same particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment for the whole meta-SPC). |

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

|  |
| --- |
| Please refer to general directions for use of the « Orapi Cresyl Family » biocidal product family in point 2.1.5 (same instructions for safe disposal of the product and its packaging for the whole meta-SPC). |

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

|  |
| --- |
| Please refer to general directions for use of the « Orapi Cresyl Family » biocidal product family in point 2.1.5 (same conditions of storage and shelf-life of the product under normal conditions of storage for the whole meta-SPC). |

### General directions for use

#### Instructions for use[[4]](#footnote-5)

|  |
| --- |
| * The material used for application of the product and rinsing should be washed with water. |

#### Risk mitigation measures

|  |
| --- |
| **Meta SPC 1 – Cresyl Concentré**   * Keep out of reach of children. * Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.   **Meta SPC 2 – Cresyl PAE**   * Keep out of reach of children. * Do not breathe mist, vapours. * Avoid release to the environment. |

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

|  |
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| **Meta SPC 1 – Cresyl Concentré**  Likely direct or indirect effects:   * Flammable liquid and vapour. * Causes skin irritation. * Causes serious eye irritation. * Contains CHLOROCRESOL. May produce an allergic reaction.   First aid instructions:   * If medical advice is needed, have product container or label at hand. * IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. * If skin irritation occurs: Get medical advice/attention.   Emergency measures to protect the environment:   * Dispose of contents and container in accordance with local regulations.   **Meta SPC 2 – Cresyl PAE**  Likely direct or indirect effects:   * Contains CHLOROCRESOL. May produce an allergic reaction.   First aid instructions:   * If medical advice is needed, have product container or label at hand. * IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.   Emergency measures to protect the environment:   * Dispose of contents and container in accordance with local regulations. |

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

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| **Meta SPC 1 – Cresyl Concentré**   * Dispose of contents and container in accordance with local regulations.   **Meta SPC 2 – Cresyl PAE**   * Dispose of contents and container in accordance with local regulations. |

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

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| The shelf-life of the products is two years under normal conditions of storage. |

### Other information

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### Physical, chemical and technical properties

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 0.319-2.9% of technical active substance chlorocresol with a minimum purity of 99.8%, corresponding to 0.318-2.89% of pure active substance. Chlorocresol contains a relevant impurity m-cresol and its content should not exceed 0.1% in the technical active substance. This impurity cannot be formed during storage so the measurement of its content after storage is not required.

The products of the family do not contain any PT6 preservative other than chlorocresol.

Meta SPC 1:

-the end-use concentrations of the product are: 7% v/v

Meta SPC 2: the products are not diluted for use (ready-to-use).

Formulation type: SL (soluble concentrates) for Meta SPC 1 and AL (any other liquids) for Meta SPC 2.

Hydrocarbon and H304 co-formulant content: <10%.

All the physical, chemical and technical properties of the product Cresyl Concentré (Meta SPC 1) presented below were assessed in the study Dr. E. Servajean, 2018, “Physical-chemical properties, stability and shelf-life of Cresyl concentré - PVE01802”. Report number 17-99-102-ES.

All the physical, chemical and technical properties of the product Cresyl PAE (Meta SPC 2) presented below were assessed in the study Dr. E. Servajean, 2018, “Physical-chemical properties, stability and shelf-life of Cresyl PAE - PVE01805”. Report number 17-99-103-ES.

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| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | Internal standardized method | Cresyl Concentré – 2.9% CMK | Liquid | Acceptable | E. Servajean, 2018,  Report number 17-99-102-ES  Report number 17-99-103-ES |
| Cresyl PAE – 0.319% CMK | Liquid |
| Colour at 20 °C and 101.3 kPa | Internal standardized method | Cresyl Concentré – 2.9% CMK | Dark brown, translucent | Acceptable | E. Servajean, 2018,  Report number 17-99-102-ES  Report number 17-99-103-ES |
| Cresyl PAE – 0.319% CMK | Light brown, translucent |
| Odour at 20 °C and 101.3 kPa | / | / | / | / | / |
| Acidity / alkalinity | CIPAC MT 75.3  CIPAC MT 191 | Cresyl Concentré – 2.9% CMK | Neat item: 8.4  1% w/v dilution: 8.3 | Acceptable | E. Servajean, 2018,  Report number 17-99-102-ES  Report number 17-99-103-ES |
| Cresyl PAE – 0.319% CMK | Neat: 8.07  1% w/v dilution: 6.6 |
| Cresyl Concentré – 2.9% CMK | 0.41% NaOH |
| Cresyl PAE – 0.319% CMK | 0.04% NaOH |
| Relative density / bulk density | OECD 109 | Cresyl Concentré – 2.9% CMK | Relative density: 0.999  Density: 0.998 g/cm³ | Acceptable | E. Servajean, 2018,  Report number 17-99-102-ES  Report number 17-99-103-ES |
| Cresyl PAE – 0.319% CMK | Relative density: 0.998  Density: 0.997 g/cm³ |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | Cresyl Concentré – 2.9% CMK  PVE01802 Batch n°: LGDP070218  Method used to quantify the AS content is validated. | Cresyl Concentré 1L metallic bottle   |  |  |  | | --- | --- | --- | |  | T0 | T=14 days at 54°C | | Appearance | Dark brown translucent liquid | No change | | AS content (g/kg) | 28 ,7 | 27,91 | | % variation | / | -2,8% | | pH neat at ambient temperature | 8,4 | 8,4 | | pH at 1%w/v at ambient temperature | 8,3 | 8,4 | | Free alkalinity | 0,41% NaOH | 0,41% NaOH | | Persistent foaming at 7% v/v | 10”: 0mL  1’: 0mL  3’: 0mL  12’: 0mL | 10”: 0mL  1’: 0mL  3’: 0mL  12’: 0mL |   Packaging:  Initial weight = 1111.62 g / Final weight = 1111.00 g (-0.06%)  The test substance still presented as a dark brown translucent liquid after ageing, and no deformation or alteration of the packaging was observed. | Acceptable  Cresyl concentré is stable 14 days at 54°C. | E. Servajean, 2018,  Report number 17-99-102-ES |
| Cresyl PAE – 0.319% CMK  PVE01805 Batch n°: VLDP130218  Method used to quantify the AS content is validated. | Cresyl PAE 0,5L HDPE sprayer bottle   |  |  |  | | --- | --- | --- | |  | T0 | T=14 days at 54°C | | Appearance | Light brown translucent liquid | No change | | AS content (g/kg) | 3,09 | 3,00 | | % variation | / | -3% | | pH neat at ambient temperature | 8,7 | 8,7 | | pH at 1%w/v at ambient temperature | 6,6 | 6,5 | | Free alkalinity | 0,04% NaOH | 0,04% NaOH |   Packaging:  Initial weight = 560.80 g / Final weight = 560.25 g (-0.10%)  The test substance still presented as a light brown translucent liquid after ageing, and no deformation or alteration of the packaging was observed.  Spray properties before storage:  - Priming: At the 4th stroke.  - Discharge rate: 0.62 g/stroke.  - Spray pattern: Ovoid circle with an empty center  - Particle size distribution: Dv (10%): 114 µm, Dv (50%): 360 µm, Dv (90%): 706 µm  Spray properties after storage:  - Priming: At the 5th stroke.  - Discharge rate: 0.63 g/stroke.  - Spray pattern: Ovoid circle with an empty center  - Particle size distribution: Dv (10%): 110 µm, Dv (50%): 362 µm, Dv (90%): 705 µm | Acceptable  Cresyl PAE is stable 14 days at 54°C. | E. Servajean, 2018,  Report number 17-99-103-ES |
| Storage stability test – **long term storage at ambient temperature** | Gifap Monography n°17 | Cresyl Concentré – 2.9% CMK  Batch n° LGDP070218  Method used to quantify the AS content is validated. | Cresyl Concentré 1L metallic bottle   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | 12 months | 24 months | | Appearance | Dark brown translucent liquid | No change | Study is still ongoing | | AS content (g/kg) | 28.7 | 29.37 (measured in another sample from the same batch) | Study is still ongoing | | % variation | / | +2.3% | Study is still ongoing | | pH neat at ambient temperature | 8.4 |  | Study is still ongoing | | pH at 1%w/v at ambient temperature | 8,3 |  | Study is still ongoing | | Free alkalinity | 0,41% NaOH |  | Study is still ongoing | | Persistent foaming at 7% v/v | 10”: 0mL  1’: 0mL  3’: 0mL  12’: 0mL |  | Study is still ongoing | | Ongoing, interim results show no significant variation.  Ongoing, interim results show no significant variation. | Servajean, E. 2019, Phytosafe Study n° 17—99-102-ES Part 2 (Interim report)  Servajean, E. 2019, Phytosafe Study n° 17—99-103-ES Part 2 (Interim report) |
| Cresyl PAE – 0.319% CMK  Batch n° VLDP130218  Method used to quantify the AS content is validated. | Cresyl PAE 0.5L HDPE sprayer   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | 12 months | 24 months | | Appearance | Light brown translucent liquid | No change | Study is still ongoing | | AS content (g/kg) | 3.09 | 3.10 | Study is still ongoing | | % variation | / | +0.3% | Study is still ongoing | | Packaging stability | / | No deformation or alteration | Study is still ongoing | | Spraying performances |  |  |  | | Priming | At 4th stroke | At 4th stroke | Study is still ongoing | | Discharge rate | 0.62 g/stroke | 0.62 g/stroke | Study is still ongoing | | Spray pattern | Round shape with empty center | Round shape with empty center | Study is still ongoing | |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | Cresyl Concentré – 2.9% CMK  PVE01802 Batch n°: LGDP070218  Method used to quantify the AS content is validated. | Cresyl Concentré 1L metallic bottle   |  |  |  | | --- | --- | --- | |  | T0 | T=7 days at 0°C | | Appearance | Dark brown translucent liquid | No change | | AS content (g/kg) | 28,7 | 28,08 | | % variation | / | -2,2% | | pH neat at ambient temperature | 8,4 | 8,4 | | pH at 1%w/v at ambient temperature | 8,3 | 8,4 | | Free alkalinity | 0,41% NaOH | 0,41% NaOH | | Persistent foaming at 7% v/v | 10”: 0mL  1’: 0mL  3’: 0mL  12’: 0mL | 10”: 0mL  1’: 0mL  3’: 0mL  12’: 0mL | | Acceptable | E. Servajean, 2018,  Report number 17-99-102-ES |
| Cresyl PAE – 0.319% CMK  PVE01805 Batch n°: VLDP130218  Method used to quantify the AS content is validated. | Cresyl PAE 0,5L HDPE sprayer bottle   |  |  |  | | --- | --- | --- | |  | T0 | T=7 days at 0°C | | Appearance | Light brown translucent liquid | No change | | AS content (g/kg) | 3,09 | 3,06 | | % variation | / | -1% | | pH neat at ambient temperature | 8,7 | 8,8 | | pH at 1%w/v at ambient temperature | 6,6 | 6,7 | | Free alkalinity | 0,04% NaOH | 0,04% NaOH | |  | E. Servajean, 2018,  Report number 17-99-103-ES |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Statement | Cresyl Concentré – 2.9% CMK | All products will be sold in opaque packaging. Light sensitivity during storage was therefore not addressed. | Acceptable. | IUCLID |
| Cresyl PAE – 0.319% CMK |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | / | Cresyl Concentré – 2.9% CMK | Effect of higher temperature than recommended storage temperature is addressed in accelerated storage. Effect of humidity is not applicable for the concerned type of formulations and packaging. | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | / |
| Cresyl PAE – 0.319% CMK |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | / | Cresyl Concentré – 2.9% CMK | Addressed by long-term storage in commercial packaging. | Ongoing | / |
| Cresyl PAE – 0.319% CMK |
| Wettability | / | / | / | Not relevant for an SL and AL formulation | / |
| Suspensibility, spontaneity and dispersion stability | / | / | / | Not relevant for an SL and AL formulation | / |
| Wet sieve analysis and dry sieve test | / | / | / | Not relevant for an SL and AL formulation | / |
| Emulsifiability, re-emulsifiability and emulsion stability | / | / | / | Not relevant for an SL and AL formulation | / |
| Disintegration time | / | / | / | Not relevant for an SL and AL formulation | / |
| Particle size distribution, content of dust/fines, attrition, friability | */* | */* | See below for spray characteristics. | Not relevant | */* |
| Persistent foaming | CIPAC MT 47.3 | Cresyl Concentré – 2.9% CMK  PVE01802 Batch n°: LGDP070218  . | Cresyl Concentré 1L metallic bottle   |  |  | | --- | --- | | Persistent foaming at 7% v/v | 10”: 0mL  1’: 0mL  3’: 0mL  12’: 0mL | | Acceptable | E. Servajean, 2018,  Report number 17-99-102-ES |
| Flowability/Pourability/Dustability | / | / | / | Not relevant for an SL and AL formulation | / |
| Burning rate — smoke generators | / | / | / | Not relevant for an SL and AL formulation | / |
| Burning completeness — smoke generators | / | / | / | Not relevant for an SL and AL formulation | / |
| Composition of smoke — smoke generators | / | / | / | Not relevant for an SL and AL formulation | / |
| Spraying pattern — aerosols | / | Cresyl PAE – 0.319% CMK  PVE01805 Batch n°: VLDP130218 | Cresyl PAE 0,5L HDPE sprayer bottle     |  |  |  | | --- | --- | --- | |  | Sprayer 1 | Sprayer 2 | | Discharges rate | 0,62g | 0,63g | | Spray pattern | Regular ovoid circle with 13-14 cm on the X axis and 13,5-16,5cm on the Y axis. The center was empty on approx. 3\*3 cm. | Distribution irregular the substance was concentrated in the upper part of the circle. Here also the center was empty |  |  |  |  | | --- | --- | --- | |  | T0 | After 14 days at 54°C | | Particle size distribution | Dv10 = 114 / Dv50 = 360 / Dv90 = 706 µm | Dv10 = 110 / Dv50 = 362 / Dv90 = 705 µm | | Acceptable | E. Servajean, 2018,  Report number 17-99-103-ES  Lienhard Mack, A. 2019, BioGenius report n° AQ063-19 |
| Physical compatibility | Statement | Cresyl Concentré – 2.9% CMK | The products are not foreseen to be used with any other product. No physical incompatibility is therefore foreseen considering normal use of the products. | Acceptable | IUCLID |
| Cresyl PAE – 0.319% CMK |
| Chemical compatibility | Statement | Cresyl Concentré – 2.9% CMK | The products are not foreseen to be used with any other product. No chemical incompatibility is therefore foreseen considering normal use of the products. | Acceptable | IUCLID |
| Cresyl PAE – 0.319% CMK |
| Degree of dissolution and dilution stability | / | / | / | Not relevant for an SL and AL formulation | / |
| Surface tension | OECD 115 | Cresyl Concentré – 2.9% CMK | 30.4 mN/m for a 7% v/v dilution in water. | Acceptable  Diluted Solutions are surface active. | E. Servajean, 2018,  Report number 17-99-102-ES  Report number 17-99-103-ES |
| Cresyl PAE – 0.319% CMK | 30.9 mN/m for the neat item. |
| Viscosity | OECD 114 | Cresyl Concentré – 2.9% CMK | At 20°C: 2.51 mm²/s  At 40°C: 1.46 mm²/s | Acceptable | E. Servajean, 2018,  Report number 17-99-102-ES  Report number 17-99-103-ES |
| Cresyl PAE – 0.319% CMK | At 20°C: 1.05 mm²/s  At 40°V: 0.73 mm²/s |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Meta SPC 1:  The product Cresyl Concentré is a SL 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 dark brown translucent liquid. 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 metal bottle packaging material (commercial packaging material). The long term storage stability study (24 months) is currently ongoing and the final report is required in post-authorization to confirm this shelf life.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an SL formulation.  Meta SPC 2:  The product Cresyl PAE is a 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 light brown translucent liquid. 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 spray bottle packaging material (commercial packaging material). The long term storage stability study (24 months) is currently ongoing and the final report is required in post-authorization to confirm this shelf life.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an AL formulation. |

### Physical hazards and respective characteristics

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| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| Explosives | Statement | Cresyl Concentré – 2.9% CMK  Cresyl PAE – 0.319% CMK | No exothermic event occurred for the sample PVE 01802 – CRESYL CONCENTRE during the DSC experiment (25°C-500°C). This indicates that the product can be regarded as not explosive and does not need to be further tested regarding its explosiveness.  An exothermic event occurred for the sample PVE 01805 – CRESYL PAE during the DSC experiment (25°C-500°C) with an onset temperature reported as the range 161.4°C to 170.2°C. As further investigation, the sample pan from Run A was subjected to a second screening run (Run C). The aim of the second screening run was to confirm that the observed exothermic event was due to decomposition; i.e. if the exotherm was not present in Run C then it is expected that the exotherm was due to decomposition. The exothermic event observed in Run A at approximately 170°C was no longer present in Run C, suggesting that the exotherm was indeed due to decomposition.  The mean heat of decomposition was only 5.285 J/g, far less than the threshold of 500 J/g above which the acceptance procedure for Class 1 explosives would have been required. This indicates that the product can be regarded as not explosive and does not need to be further tested regarding its explosiveness. | Acceptable | Neal, P. 2018, DEKRA Report n° GLP3016003156BR1V1/2018  Neal, P. 2018, DEKRA Report n° GLP3016003156AR1V1/2018 |
| Flammable gases | / | / | / | Not relevant as the product is a liquid | / |
| Flammable aerosols | / | / | / | Not relevant as the product is a liquid | / |
| Oxidising gases | / | / | / | Not relevant as the product is a liquid | / |
| Gases under pressure | / | / | / | Not relevant as the product is a liquid | / |
| Flammable liquids | EEC A9 | Cresyl Concentré – 2.9% CMK | Flash point = 57°C. Based on this result, the product meets the criteria for classification as a flammable liquid of category 3 according to the Regulation (EC) No 1272/2008 on the classification. | Acceptable  The product is classified H226 cat.3. | E. Servajean, 2018,  Report number 17-99-102-ES  Report number 17-99-103-ES |
| Cresyl PAE – 0.319% CMK | The flash point of the product is > 115°C. The product therefore does not meet the criteria for classification as a flammable liquid. | Acceptable  The product is not classified. |
| Flammable solids | / | / | / | Not relevant as the product is a liquid | / |
| Self-reactive substances and mixtures |  | Cresyl Concentré – 2.9% CMK | No exothermic event occurred for the sample PVE 01802 – CRESYL CONCENTRE during the DSC experiment (25°C-500°C). This indicates that the product should not be regarded as self-reactive and does not need to be further tested regarding its self-reactivity. | Acceptable | DEKRA Report n° GLP3016003156BR1V1/2018  DEKRA Report n° GLP3016003156AR1V1/2018 |
| Cresyl PAE – 0.319% CMK | An exothermic event occurred for the sample PVE 01805 – CRESYL PAE during the DSC experiment (25°C-500°C) with an onset temperature reported as the range 161.4°C to 170.2°C. As further investigation, the sample pan from Run A was subjected to a second screening run (Run C). The aim of the second screening run was to confirm that the observed exothermic event was due to decomposition; i.e. if the exotherm was not present in Run C then it is expected that the exotherm was due to decomposition. The exothermic event observed in Run A at approximately 170°C was no longer present in Run C, suggesting that the exotherm was indeed due to decomposition.  The mean heat of decomposition was only 5.285 J/g, far less than the threshold of 300 J/g above which the classification procedure for self-reactive substances would have been required. This indicates that the product can be regarded as not self-reactive and does not need to be further tested regarding its self-reactivity. |
| Pyrophoric liquids | Statement | Cresyl Concentré – 2.9% CMK  Cresyl PAE – 0.319% CMK | Experience in manufacture and handling shows that the liquids do not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquids are known to be stable at room temperature for prolonged periods of time (days)). Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2017, version 5.0), this classification can be excluded without further testing. | Acceptable | IUCLID |
| Pyrophoric solids | / | / | / | Not relevant as the product is a liquid | / |
| Self-heating substances and mixtures | Statement | Cresyl Concentré – 2.9% CMK  Cresyl PAE – 0.319% CMK | Substances or mixtures with a low melting point (< 160 °C) should not be considered for classification in this class. Since the products are liquid at ambient temperature, this classification can be excluded without further testing. | Acceptable | IUCLID |
| Substances and mixtures which in contact with water emit flammable gases | / | / | / | Not relevant as the product is a liquid | / |
| Oxidising liquids | Statement  CLP regulation | Cresyl Concentré – 2.9% CMK  Cresyl PAE – 0.319% CMK | The evaluated products are composed only of inert material from the perspective of oxidizing properties. None of the component is classified as oxidizing. Consequently, the products are not classified as oxidizing.  Moreover, testing is not required for products containing oxygen, fluorine or chlorine but for which these elements are linked only to carbon or hydrogen. As the products contain no fluorine and all the oxygen and chlorine atoms are linked exclusively to carbon or hydrogen, the possibility for the products to be oxidising can be excluded. We therefore consider that the products are not considered to be oxidising liquids and no further testing is foreseen. | Acceptable | IUCLID |
| Oxidising solids | / | / | / | Not relevant as the product is a liquid | / |
| Organic peroxides | Statement | Cresyl Concentré – 2.9% CMK  Cresyl PAE – 0.319% CMK | The study does not need to be conducted because the formulations do not contain organic peroxides. | Acceptable | IUCLID |
| Corrosive to metals | Statement | Cresyl Concentré – 2.9% CMK | No component of the mixtures is classified as Met. Corr. 1 (H290) in the final formulations.  Moreover, experience in handling and use shows that the mixtures are not corrosive to metals (packaging of the concentrated product is metallic).  We therefore consider that the products can be classified as non-corrosive based on this argumentation. | Not acceptable.  At least one component present in the formulations (a sequestrant) is declared by the manufacturers as potentially corrosive to metals.  No deterioration of the metallic packaging was observed, neither during the accelerated storage stability study nor during the ongoing long term stability study, however the nature of the metal is different from the ones specified by CLP regulation for testing this property.  In the absence of experimental data, it is proposed to classify both products as H290: May be corrosive to metals.  Experimental data can be provided later to demonstrate that this classification is not necessary. | IUCLID |
| Auto-ignition temperatures of products (liquids and gases) | EC A15 | Cresyl Concentré – 2.9% CMK | Autoignition temperature of PVE 01802 – CRESYL CONCENTRE has been determined to be 498 °C  Autoignition temperature of CRESYL PAE could not be determined because degradation was observed before ignition. | Acceptable | DEKRA Report n° GLP3016003156BR1V1/2018  DEKRA Report n° GLP3016003156AR1V1/2018 |
| Cresyl PAE – 0.319% CMK |
| Relative self-ignition temperature for solids | / | / | / | Not relevant as the product is a liquid | / |
| Dust explosion hazard | / | / | / | Not relevant as the product is a liquid | / |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Meta SPC 1:  The product is a flammable liquid cat.3 but not auto-flammable. It has no explosive and no oxidizing properties.  Meta SPC 2:  The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties.  Implication concerning labelling:  Cresyl Concentré:  H226 - Flammable liquid and vapour  H290 – May be corrosive to metals  Cresyl PAE :  H290 – May be corrosive to metals |

### Methods for detection and identification

**Determination of the active substance in the product**

Report: Servajean 2018. Physical-chemical properties, stability and shelf-life of Cresyl concentré PVE01802

Part 1: Physical-chemical properties upon receipt, after cold storage and after accelerated storage

Report no 17-99-102-ES

Test facilities: Phytosafe sarl

2 rue Marx Dornoy

64000 Pau

Report: Servajean 2018. Physical-chemical properties, stability and shelf-life of Cresyl PAE PVE01805

Part 1: Physical-chemical properties upon receipt, after cold storage and after accelerated storage

Report no 17-99-102-ES

Test facilities: Phytosafe sarl

2 rue Marx Dornoy

64000 Pau

Principle of the method:

The liquid formulation is dissolved in methanol and chlorocresol is analysed by HPLC-MS (SIM – at m/z = 141, 142 and 143 as parents ions, and m/z = 105 as fragment ion) by external standard calibration. Principle is the same for the two products.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

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| Specificity for the two products | To demonstrate the specificity of the method, several solution are analyzed:   * Formulation blank * Reference item of the active substance chlorocresol * Test item of the product   No interference was found: no peak appears in the formulation blank, one peak is observed at the same retention time for the reference item and test item.  All chromatograms were available. | |
| Linearity for the two products | Linearity was studied by carrying out seven levels of concentration between 0.53 to 53.0 mg/L.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Chlorocresol | log(chlorocresol) = 0.997x Log(Area) – 4.195 R2 = 0.9997  n=1 (7 levels of concentration) |
| Repeatability for Cresyl concentré | Repeatability was evaluated by analyzing twice six test item solutions at 2 levels of concentration. | |
| Compound | Repeatability (RSD) |
| Chlorocresol | RSD = 1.46% at 0.1 g test item/L |
| RSD = 1.76% at 1 g test item/L |
| Repeatability for Cresyl PAE | Repeatability was evaluated by analyzing twice six test item solutions at 2 levels of concentration. | |
| Compound | Repeatability (RSD) |
| Chlorocresol | RSD = 1.87% at 1 g test item/L |
|  | RSD = 1.95% at 10 g test item/L |
| Accuracy for Cresyl concentré | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 0.1 g item/L | 102,3;101,3;98,9; 98,4;99,8;100,2 | 100.2 | 1.46 | 6 | | 1.0 g item/L | 102,1;101,6;97,4;98,8;99,4;99,8 | 99.9 | 1.76 | 6 |   Another reconstitued sample has been analyzed:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 26.7 g chlorocresol/kg | 99.7;100.9; 98.5; 99.6 | 99.7 | 0.98 | 4 | | |
| Accuracy for Cresyl PAE | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 1.0 g item/L | 103,6;102,9;99;104,5;101,9;103,2 | 102.5 | 1.87 | 6 | | 10.0 g item/L | 99,7;98,7;94,8;96,4;97,4;99,4 | 97.7 | 1.95 | 6 |   Another reconstitued sample has been analyzed:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 3.2 g chlorocresol/kg | 99,8;100,1;99,9;100,4 | 100.1 | 0.26 | 4 | | |

The analytical method is fully validated for the determination of the active substance chlorocresol in the products Cresyl concentré and Cresyl PAE.

**Determination of the relevant impurities in the product**

Report: Servajean 2018. Physical-chemical properties, stability and shelf-life of Cresyl concentré PVE01802

Part 1: Physical-chemical properties upon receipt, after cold storage and after accelerated storage

Report no 17-99-102-ES (amendment n° 1)

Test facilities: Phytosafe sarl

2 rue Marx Dornoy

64000 Pau

Report: Servajean 2018. Physical-chemical properties, stability and shelf-life of Cresyl PAE PVE01805

Part 1: Physical-chemical properties upon receipt, after cold storage and after accelerated storage

Report no 17-99-102-ES (amendment n°1)

Test facilities: Phytosafe sarl

2 rue Marx Dornoy

64000 Pau

Principle of the method:

The liquid formulation is dissolved in methanol and m-cresol is analysed by HPLC-UV by external standard calibration. Principle is the same for the two products.

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity for the two products | To demonstrate the specificity of the method, several solution are analyzed:   * Formulation blank * Reference item of the impurity m-cresol * Test item of the product and spiked samples   No interference was found: no peak appears in the formulation blank, one peak is observed at the same retention time for the reference item and spiked test item.  Representative chromatograms were available. | |
| Linearity for the two products | Linearity was studied by carrying out seven levels of concentration between 0.50 to 49.6 mg/L.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| m-cresol | log(m-cresol) = 0.932x Log(Area) – 1.584 R2 = 0.9996  n=1 (7 levels of concentration) |
| Repeatability for the two products | Repeatability was evaluated by performing 5 replicate injections of spiked solutions at 2 levels of concentration. | |
| Compound | Repeatability (RSD) |
| m-cresol | RSD = 11.1% (0.53 mg/L) |
| RSD = 2.8% (1.49 mg/L) |
| Accuracy for Cresyl concentré | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | n | | 54.0 mg item/kg | 99.8%; 98.1% | 98.9% | 2 | | 109.4 g item/kg | 101.6%; 98.9% | 100.3% | 2 | | |
| Accuracy for Cresyl PAE | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | n | | 54.8 mg item/kg | 99.7%; 98.7% | 99.2% | 2 | | 109.5 g item/kg | 99.5%; 98.8% | 99.1% | 2 | | |
| Analysis of samples before spiking | Six distinct stock solutions were analyzed, m-cresol was not detected, ie m-cresol < 50 mg/kg in the test items. | |
| LOQ | As replicate injection showed that the measured concentrations at 0.50 mg/L deviated by more than 5% from the nominal value in several occasions, the limit of quantification was taken at 1.49 mg/L, where measured m-cresol concentration was always within 95-105% of the nominal value. | |

The analytical method can be considered validated for the determination of the relevant impurity m-cresol in the products Cresyl concentré and Cresyl PAE with a LOQ = 1.5 mg/L. As the maximum acceptable level of m-cresol in technical chlorocresol is 0.1% w/w, the maximum acceptable levels of m-cresol in Cresyl concentre and Cresyl PAE are respectively 29 mg/kg and 3.2 mg/kg. The LOQ of the method is therefore sufficient.

**Determination of the co-formulant 1-methoxy-2-propanol in the product**

Report: Servajean 2018. Physical-chemical properties, stability and shelf-life of Cresyl concentré PVE01802

Part 1: Physical-chemical properties upon receipt, after cold storage and after accelerated storage

Report no 17-99-102-ES (amendment n° 1)

Test facilities: Phytosafe sarl

2 rue Marx Dornoy

64000 Pau

Report: Servajean 2018. Physical-chemical properties, stability and shelf-life of Cresyl PAE PVE01805

Part 1: Physical-chemical properties upon receipt, after cold storage and after accelerated storage

Report no 17-99-102-ES (amendment n°1)

Test facilities: Phytosafe sarl

2 rue Marx Dornoy

64000 Pau

Principle of the method:

The liquid formulation is dissolved in methanol and 1-methoxy-2-propanol is analysed by HPLC-MS (m/z = 91.1, 108.1, 113.1 for the parent and m/z = 73.1 as a fragment ion) by external standard calibration. Principle is the same for the two products.

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity for the two products | Blank determination of the solvent used for the preparation of the working solution did not have interfering peak area at the retention time of 1-methoxy-2-propanol.  Representative chromatograms were available. | |
| Linearity for the two products | Linearity was studied by carrying out seven levels of concentration between 4.9 to 493 mg/L.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| methoxypropanol | log(methoxypropanol) = 0.948x Log(Area) – 2.860 R2 = 0.9999  n=1 (7 levels of concentration) |
| Repeatability for the two products | Repeatability was evaluated by performing 5 replicate injections of spiked solutions at 2 levels of concentration. | |
| Compound | Repeatability (RSD) |
| methoxypropanol | RSD = 9.1% (4.93 mg/L) |
| RSD = 2.3% (14.79 mg/L) |
| Accuracy for Cresyl concentré | Accuracy was determined by 6 replicate determinations of a test item.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Sample | Recovery rate | Mean recovery rate | RSD | n | | 54.4 g/kg | 99.7%; 97.6%; 98.3%; 97.4%; 98.1%; 97.3% | 98.1% | 0.90 | 6 | | |
| Accuracy for Cresyl PAE | Precision and accuracy was determined by 6 replicate determinations of a test item.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Sample | Recovery rate | Mean recovery rate | RSD | n | | 6 g/kg | 99.1%; 98.5%; 97.4%; 97.9%; 96.8%; 98.0% | 98.0% | 0.83 | 6 | | |

The analytical method is validated for the determination of the substance of concern 1-methoxy-2-propanol in the products Cresyl concentré and Cresyl PAE.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance chlorocresol, its relevant impurity m-cresol and the substance of concern 1-methoxy-2-propanol in the family products.  Analytical methods were provided at EU level for the determination of chlorocresol residue in soil, air and water with respectively LOQ = 5 µg/kg, 0.3 µg/m3 and 0.05 µg/L.  Chlorocresol is not toxic (T) nor very toxic (T+) active substance, therefore, an analytical method in biological matrices is not required.  The product is not intended to be used on surface in contact with food/feed of plant and animal origin, therefore an analytical method for the determination of chlorocresol in food/feed of plant and animal origin is not required. |

### Efficacy against target organisms

#### Function and field of use

MG 01: Disinfectants

PT2: Disinfectants and algaecides not intended for direct application to humans or animals

PT3: Veterinary hygiene

The ORAPI CRESYL Family is separated in two META-SPC:

Products of Meta-SPC 1 are soluble concentrates (2.9%) to be diluted in water before use while products of meta-SPC 2 (0.319 % CMK) are ready-to-use disinfectants.

Products of the Orapi Cresyl Family are intended for:

* PT2 disinfection of surfaces in private and public areas (use other than in healthcare): products are applied for the disinfection of:
  + indoor domestic surfaces, such as cellars and indoor garbage storage areas. (use #1, meta-SPC 1)
  + outdoor surfaces surrounding households, such as terraces, low walls (up to 50 cm height from the bottom of the wall). (uses #2 and #3, meta-SPC 1)
  + small surfaces, material, equipment and furniture indoors and outdoors (uses #4 and #5, meta-SPC 2).

Application can take place via a trigger spray, a mop, a brush or a high pressure cleaner. No prior cleaning of the surfaces is required.

* PT3 disinfection of private domestic animal housing: products are applied for the disinfection of small domestic animal housing, such as a dog kennel, a rabbit hutch or a backyard chicken coop. Application takes place via a trigger spray and surfaces need to be cleaned prior to the disinfection. This use (#6) concerns only meta-SPC 2.

Products are intended to be used by professional and non-professional users for all uses except for the PT3 use (#6) intended to be used only by non-professional users.

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

Products of ORAPI CRESYL Family are used to disinfect surfaces. They irreversibly inactivate vegetative bacteria, yeasts, and fungi.

Products are used for the purpose of the protection of humans and animals.

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

The product is able to produce a reduction in the number of viable bacterial cells (bactericidal activity), of yeast cells (yeasticidal activity) and of moulds spores (fungicidal activity), of relevant test organisms under defined conditions.

Unacceptable suffering is not applicable to the target organisms.

#### Mode of action, including time delay

“p-chloro-m-cresol as active substance of biocidal products is a multi-site bactericide and fungicide, with basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of cytoplasmic membrane. At high concentrations, CMK also has an effect on cytoplasm by general coagulation”.

(Source: Assessment Report. Chlorocresol. Product-types 1-2-3-6-9-13. April 2016 ; Revised November 2017. France)

Contact times for the different activities claimed are determined in the efficacy tests (see table below).

#### Efficacy data

Efficacy data were submitted for each of the product uses presented in the ORAPI CRESYL family. Data bridging is applied between the different products of the family: all efficacy data were generated with a concentrate product containing either 5.1% w/w CMK or 2.9% w/w CMK:

-The test item containing 2.9% w/w CMK is the reference item of the Meta SPC 1.

-The test item containing 5.1% w/w CMK is a concentrate of the products of the family, and can be diluted to obtain both the test item of the Meta SPC 1 as well as the test item of the Meta SPC 2.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Meta-SPC** | **Test substance** | **Test organism(s)** | **Test method** | **Test temperature / Exposure time / Interfering substance** | **Test results: minimum effective concentration** | **Reference** |
| **Field of use envisaged:** Disinfection of PT2 indoor non-porous hard surfaces (META-SPC1 and 2), use other than in healthcare. | | | | | | |
| 1 (uses #1, #2, #3)  2 (uses #4, #5) | L16.06.02 (5.1% CMK) | *E. hirae* ATCC10541  *E. coli* ATCC10536  *P. aeruginosa* ATCC15442  *S. aureus* ATCC6538 | EN1276 | 20°C, 5 minutes  3 g/l bovine albumin  Concentration tested :  *E. hirae, P. aeruginosa* and *S. aureus* : 1.5%, 2.0%, 2.5%, 3.0%  *E. coli* : 1.0%, 1.5%, 2.0%, 2.5% | *E. hirae*: 2.5%  *E. coli*: 2.0%  *P.aeruginosa*: 2.0%  *S. aureus*: 2.5%  => Effective concentration validated: 2.5% v/v (0.128% CMK)  ≥ 5 log unit reduction | D 2017-08.14  RI = 2 |
| EN13697 | 20°C, 5 minutes  3 g/l bovine albumin  Concentration tested :  *E. hirae, P. aeruginosa* and *E. coli* : 1.0%, 1.5%, 2.0%, 2.5%  *S. aureus* : 2.5%, 3.0%, 3.5%, 4.0% | *E. hirae*: 2.5%  *E. coli*: 2.0%  *P.aeruginosa*: 2.5%  *S. aureus*: 4.0%  => Effective concentration validated: 4% v/v (0.204 % CMK)  ≥ 4 log unit reduction | D 2016-01.8  RI = 2 |
| *C. albicans* ATCC10231 | EN1650 | 20°C, 15 minutes  3 g/l bovine albumin  Concentration tested :  2.0%, 3.0%, 4.0%, 5.0% | => Effective concentration validated:  4% v/v (0.204 % CMK)  ≥ 4 log unit reduction | D 2017-08.16  RI = 2 |
| EN13697 | 20°C, 15 minutes  3 g/l bovine albumin  Concentration tested :  1.0%, 1.5%, 2.0%, 2.5% | => Effective concentration validated: 2.5% v/v (0.128 % CMK)  ≥ 3 log unit reduction | D 2016-01.8  RI = 2 |
| 2 (use #4) | L16.06.02 (5.1% CMK) | *A. brasiliensis* ATCC16404 | EN1650 | 20°C, 15 minutes  3 g/l bovine albumin  Concentration tested :  3.0%, 4.0%, 5.0%, 6.0% | => Effective concentration validated: 6% v/v (0.306 % CMK)  ≥ 4 log unit reduction | D 2017-08.16  RI = 2 |
| EN13697 | => Effective concentration validated: 4% v/v (0.204 % CMK)  ≥ 3 log unit reduction | D 2016-01.8  RI = 2 |
| **Field of use envisaged:** Disinfection of PT2 outdoor porous hard surfaces (META-SPC1 and 2), use other than in healthcare. | | | | | | |
| 1 (use #2, #3) and 2 (use #5) | L16.06.02 bis  Cresyl Concentré (2.9% CMK) | *E. hirae* ATCC10541  *E. coli* ATCC10536  *P. aeruginosa* ATCC15442  *S. aureus* ATCC6538 | EN 13697 modified (with wood carrier : poplar) | 10°C  45 and 60 minutes  3 g/l bovine albumin  2 replicates  Concentration tested :  6%, 7%, 8% | => Effective concentration validated:  7 % v/v (0.204 % CMK) after 45 and 60 min. | 042B02-2019-02 |
| *E. hirae* ATCC10541 | 042B02-2019-02-Addendum  RI=2 |
| *C. albicans* ATCC10231 | => Effective concentration validated:  7 % v/v (0.204 % CMK) after 45 and 60 min. | 042B02-2019-02  RI = 2 |
| *E. hirae* ATCC10541  *E. coli* ATCC10536  *P. aeruginosa* ATCC15442  *S. aureus* ATCC6538 | 10°C  5, 15 and 30 minutes  3 g/l bovine albumin  2 replicates  Concentration tested :  10%, 11%, 15%, 18%, 20% | => Effective concentration validated:  5 min  : 20% v/v (0.580 % CMK)  15 min contact time : test method is not validated  30 min : 11% v/v (0.319 % CMK)  ≥ 4 log unit reduction | 042B02-2019  RI = 3 for metaSPC 1 (tested concentrations are above the claimed concentration of 0.203% cmk)  RI = 2 for meta-SPC 2 |
| *C. albicans* ATCC10231 | => Effective concentration validated:  5 min : 20% v/v (0.580 % CMK)  15 min : 18% v/v (0.522 % CMK)  30 min : 15% v/v (0.435 % CMK) but no inactive concentration tested  ≥ 3 log unit reduction | 042B02-2019  RI = 3 for metaSPC 1 and 2 (tested concentrations are above the claimed concentration) |
| **Field of use envisaged:** Disinfection of PT3 hard surfaces (META-SPC2) | | | | | | |
| 2 (use #6) | L16.06.02 (5.1% CMK) | *E. hirae* ATCC10541  *Proteus vulgaris* ATCC13315  *P. aeruginosa* ATCC15442  *S. aureus* ATCC6538 | EN1656 | 10°C  30 minutes  10 g/l bovine albumin + 10 g/l yeast extract  Concentration tested :  *E. hirae, P. aeruginosa* : 1.5%, 2.0%, 2.5%, 3.0%  *P. vulgaris*: 0.5%, 0.75%, 1.0%, 1.5%  *S. aureus* : 2.5%, 3.0%, 3.5%, 4.0% | *E. hirae*: 3.0%  *P. vulgaris*: 1.5%  *P.aeruginosa*: 2.5%  *S. aureus*: 3.0%  => Effective concentration validated: 3% v/v (0.153 % CMK) | D 2017-08.19  RI = 2 |
| EN14349 | 10°C  30 minutes  10 g/l bovine albumin + 10 g/l yeast extract  Concentration tested :  *E. hirae, P. aeruginosa, S. aureus* : 1.0%, 1.5%, 2.0%, 2.5%  *P. vulgaris*: 0.25%, 0.5%, 0.75%, 1.0% | *E. hirae*: 2.5%  *P. vulgaris*: 1.0%  *P.aeruginosa*: 2.5%  *S. aureus*: 2.5%  => Effective concentration validated: 2.5% v/v (0.128 % CMK) | D 2016-01.2  RI = 2 |
| *C. albicans* ATCC10231 | EN1657 | 10°C  30 minutes  10 g/l bovine albumin + 10 g/l yeast extract  Concentration tested :  5%, 6%, 7%, 8% | => Effective concentration validated: 6% v/v (0.306 % CMK) | D 2017-08.21  RI = 2 |
| EN16438 | 10°C  30 minutes  10 g/l bovine albumin + 10 g/l yeast extract  Concentration tested :  4%, 5%, 6%, 7% | => Effective concentration validated: 5% v/v(0.255 % CMK) | D 2017-08.26  RI = 2 |
| L16.06.02 bis (2.9% CMK) | *E. hirae* ATCC10541  *P. vulgaris* ATCC13315  *P. aeruginosa* ATCC15442  *S. aureus* ATCC6538 | EN16437 | 10°C  30 minutes  3 g/l bovine albumin  Concentration tested :  10 % 11 % 12%  2 replicates | => Effective concentration validated: 11% v/v (0.319 % CMK) | 307B25-2017  RI = 2 |

**Meta SPC 1 – Cresyl concentré**

Laboratory studies were conducted with products L16.06.02 (5.1% CMK) and L16.06.02 bis (2.9% CMK). It has to be noted that no variation of the different components (active substance and coformulants) takes place in the META-SPC 1.

* PT2: Regarding the use #1, indoor disinfection of non-porous surfaces, applied by mopping: Efficacy was demonstrated according to both phase 2 step 1 tests EN 1276, 1650 and phase 2 step 2 test EN 13697, at 0.204 % CMK corresponding to the claimed application rate of 7 % v/v biocidal product, at a temperature of 20°C, in dirty conditions (3 g/L BSA), with the claimed contact time for bacteria (5 minutes) and yeasts (15 minutes).
* PT2: Regarding the uses #2 and #3, outdoor disinfection of surfaces, applied by brushing or by pressure washer:

Same studies as for use #1 have been considered for non-porous surfaces. Furthermore, to demonstrate the efficacy on porous surfaces outdoors, studies were carried out according to phase 2 step 2 test EN 13697 modified (a poplar wood carrier is used instead of a steel carrier to prove the efficacy of the product on porous surfaces), at a temperature of 10°C, in dirty conditions (3 g/L BSA) with contact times up to 60 min.

Efficacy was demonstrated at the claimed application rate of 7% v/v biocidal product (corresponding to 0.204 % CMK), at a temperature of 10°C, in dirty conditions (3 g/L BSA), with a contact time of 45 minutes (bacteria and yeasts).

**Meta SPC 2 – Cresyl PAE**

Laboratory studies were conducted also with L16.06.02 (5.1% CMK) and L16.06.02 bis (2.9% CMK).

Indeed, the reference item of the Meta SPC 2 – Cresyl PAE is a RTU product containing 0.319% w/w CMK. No product dilution prior to use is required. Then efficient dilutions covered RTU products.

It has also to be noted that no variation of the different components (active substance and coformulants) takes place in the META-SPC 2.

* PT2: Regarding the use #4, indoor disinfection of small non-porous surfaces, material, equipment and furniture, applied by spraying: Efficacy was demonstrated according to both phase 2 step 1 tests EN 1276, 1650 and phase 2 step 2 test EN 13697, at 0.306 % CMK, at a temperature of 20°C, in dirty conditions (3 g/L BSA), with the claimed contact time for bacteria (5 minutes), yeasts and fungi (15 minutes). This concentration is in line with the product concentration of 0.319% v/v CMK of this META-SPC (RTU products).
* PT2: Regarding the use #5, outdoor disinfection of small surfaces, material, equipment and furniture, applied by spraying or by pressure washer:

Same studies as for use #1 have been considered for non-porous surfaces. Furthermore, to demonstrate the efficacy on porous surfaces outdoors, studies were carried out according to phase 2 step 2 test EN 13697 modified (a poplar wood carrier is used instead of a steel carrier), at a temperature of 10°C, in dirty conditions (3 g/L BSA) with contact times up to 60 min.

Efficacy was demonstrated according to both phase 2 step 1 tests EN 1276, 1650 and phase 2 step 2 tests EN 13697, at the claimed efficient dose as RTU product, at a temperature of 10°C, in dirty conditions (3 g/L BSA), with a contact time of 30 minutes (bacteria) or 45 minutes (yeasts).

* PT3: Regarding the use #6, indoor disinfection for housing of small domestic animals, applied by spraying: Efficacy was demonstrated according to both phase 2 step 1 tests EN 1656, 1657 and phase 2 step 2 test EN 14349, EN 16438 and EN 16437 at the claimed efficient dose as RTU product, at a temperature of 10°C, in clean (3 g/L BSA) or dirty conditions (10 g/L bovine albumin + 10 g/L yeast extract), with a contact time 30 minutes.

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| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the products of the ORAPI CRESYL FAMILY, have shown a sufficient efficacy, for the following uses claimed:  **Meta SPC 1 – Cresyl concentré**  The reference item of the Meta SPC 1 – Cresyl concentré is a concentrate product containing 2.9% w/w CMK, applied as a PT2 disinfectant only.  For product application as a PT2 disinfectant for indoor hard surfaces (use other than in healthcare) (use #1),   * By mopping at 7 % v/v dilution, against bacteria and yeasts, on dirty non-porous hard surfaces, at 20°C, with a contact time of 5 minutes (bacteria) or 15 minutes (yeasts).   For product application as a PT2 disinfectant for outdoor hard surfaces (uses #2 and #3),   * By brushing or spraying (with a pressure washer) at 7% v/v dilution against bacteria and yeasts, on dirty porous/non-porous hard surfaces, at 10°C, with a contact time of 45 minutes.   **Meta SPC 2 – Cresyl PAE**  The reference item of the Meta SPC 2 – Cresyl PAE is a RTU product containing 0.319% w/w CMK. No product dilution prior to use is required. The product of the Meta SPC 2 – Cresyl PAE is applied as both a PT2 and PT3 disinfectant.  For product application as a PT2 disinfectant for indoor disinfection of small surfaces, material, equipment and furniture (use other than in healthcare) (use #4),   * By spraying without dilution, against bacteria, yeasts and fungi, on dirty non-porous hard surfaces, at 20°C, with a contact time of 5 minutes (bacteria) or 15 minutes (yeasts and fungi).   For product application as a PT2 disinfectant for outdoor disinfection of small surfaces, material, equipment and furniture (use other than in healthcare) (uses #5),   * By spraying without dilution, against bacteria and yeasts, on dirty porous/non-porous hard surfaces, at 10°C, with a contact time of 30 minutes (bacteria) or 45 minutes (yeasts).   For product application as a PT3 disinfectant (backyard housing of small domestic animals) for hard surfaces (use #6),   * By spraying without dilution, against bacteria and yeasts, on clean porous/non-porous surfaces, at 10°C, with a contact time of 30 minutes. |

#### Occurrence of resistance and resistance management

The chlorocresol assessment report states that “The literature analysis showed that especially if the concentration of CMK is in the efficient range, no acquired resistance occurs. In addition, using bactericidal concentrations, the risk of development of cross-resistance or co-resistance is in general low, considering the multi-site activity of CMK. Since it interacts with many different targets of the bacterial cell wall, the risk of developing resistance mechanisms is minimal”.

The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

There are no known limitations to the products of the ORAPI CRESYL FAMILY.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the products of the ORAPI CRESYL FAMILY, have shown a sufficient efficacy, for the following uses claimed:

**Meta SPC 1 – Cresyl concentré**

For product application as a PT2 disinfectant for indoor hard surfaces (use other than in healthcare) (use #1),

* By mopping at 7 % v/v dilution, against bacteria and yeasts, on dirty non-porous hard surfaces, at 20°C, with a contact time of 5 minutes (bacteria) or 15 minutes (yeasts).

For product application as a PT2 disinfectant for outdoor hard surfaces (uses #2 and #3),

* By brushing or spraying (with a pressure washer) at 7 % v/v dilution, against bacteria and yeasts, on dirty porous/non-porous hard surfaces, at 10°C, with a contact time of 45 minutes.

**Meta SPC 2 – Cresyl PAE**

For product application as a PT2 disinfectant for indoor disinfection of small surfaces, material, equipment and furniture (use other than in healthcare) (use #4),

* By spraying without dilution, against bacteria, yeasts and fungi, on dirty non-porous surfaces, at 20°C, with a contact time of 5 minutes (bacteria) or 15 minutes (yeasts and fungi).

For product application as a PT2 disinfectant for outdoor disinfection of small surfaces, material, equipment and furniture (use other than in healthcare) (uses #5),

* By spraying without dilution, against bacteria and yeasts, on dirty porous/non-porous surfaces, at 10°C, with a contact time of 45 minutes.

For product application as a PT3 disinfectant (backyard housing of small domestic animals) for hard surfaces (use #6),

* By spraying without dilution, against bacteria and yeasts, on clean porous/non-porous surfaces, at 10°C, with a contact time of 30 minutes.

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

Not applicable, as the product is not intended for use with other biocidal products.

### Risk assessment for human health

#### Assessment of effects on Human Health

No study was conducted for eye and skin irritation studies and acute toxicity studies. Classification is determined by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017), based on the available data on each component.

A study is available for skin sensitisation.

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Irritation to the skin (meta SPC 1)  Not irritating to the skin (meta SPC 2) |
| Justification for the value/conclusion | Classification is made by calculation method:  Meta SPC 1: chlorocresol is classified H314 (1C) and its content is equal to 2.9%, leading to a classification of skin irritation category 2 (Generic concentration limits of ingredients to classify the product in skin irritation category 2: ≥ 1% but <5%).  Meta SPC 2: Taking into account the additivity approach with compounds classified for skin irritation, no classification is required for meta SPC 2. |
| Classification of the product according to CLP | Classification Skin irritation, category 2 - H315: Causes skin irritation is required for meta SPC 1.  No classification is required for skin corrosion and irritation to the skin for meta SPC 2. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Irritating to the eye (meta SPC 1)  Not irritating to the eye (meta SPC 2) |
| Justification for the value/conclusion | Classification is made by calculation method:  Meta SPC 1: chlorocresol is classified H314 (1C) and its content is equal to 2.9% in meta SPC 1, %, leading to a classification of eye irritation category 2 (Generic concentration limits of ingredients to classify the product in eye irritation category 2: ≥ 1% but <3%).  Meta SPC 2: Taking into account additivity approach with other coformulants classified for eye irritation, no classification is required for meta SPC 2 (Generic concentration limits of ingredients for category 2: <10%). |
| Classification of the product according to CLP | Classification Eye irritation, category 2 - H319: Causes serious eye irritation is required for meta SPC 1.  No classification for eye irritation is required for meta SPC 2. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The classification has been determined according to the CLP Regulation. According to the CAR of chlorocresol, local effects are observed during the acute toxicity studies, whatever the exposure route. From these observations, a classification STOT SE Cat. 3 H335: may cause respiratory irritation is proposed. The contents in meta SPC1 and meta SPC2 are below the concentration limit for triggering classification. |
| Classification of the product according to CLP | No classification is required for respiratory tract irritation for meta SPC 1 and meta SPC 2. |

***Skin sensitization***

| **Summary table of animal studies on skin sensitisation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline, GLP status**  **Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle,**  **Dose levels,  duration of exposure Route of exposure** | **Results** | **Remarks** | **Reference** |
| LLNA: BrdU, OECD guideline 442-B adopted 22, GLP, reliable without restriction | CBA/J (CBA/JRj) strain, female,  3 groups of 4 animals  1 group for negative control | Test substance: PVE 01802 (chlorocresol 5.1%, ethanol 10%, dowanol PM 9.75%), vehicle MEK  3 concentrations:  undiluted (100%) and 50% and 25% in methylethyl ketone (MEK)  Topical application (25 µL) to the dorsal surface of each ear for 3 consecutive days | No mortality and no signs of systemic toxicity were noted in the test and control animals during the test.  Dryness of the skin was noted in animals treated at 100% on day 6.  An increase in ear thickness (+7.9%, +5.1%, +1.4%) was noted in animals treated at 25%, 50% and 100%, respectively.  An increase in ear weight (+43.5%) was noted in animals treated at 100%.  Stimulation index (SI) was 0.77, 1.01 and 1.01 at 25%, 50% and 100%, respectively. EC1.6 cannot be determined due to the absence of SI value higher that 1.6. | The study was performed with a formulation containing more substance classified for skin sensitisation. | F. Richeux, 2018 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to the skin. |
| Justification for the value/conclusion | Study is acceptable.  Deviations from the guideline 442-B are noted: Stop solution was added to the test after 5 to 30 min, with a measurement at an absorbance of 450 nm with a reference wavelength of 690 nm, while an absorbance of 370 nm with a reference wavelength of 492 nm is proposed in the guideline without stop solution. These considerations come from ICCVAM Test method evaluation report on the Murine Local Lymph Node Assay: BrDu-ELISA, March 2010: “Measure an absorbance (ABS) at 370 nm with a reference wavelength of 492 nm. When using stop solution (1 M sulfuric acid, 25 µL/well), measure ABS at 450 nm with a reference wavelength of 690 nm.” |
| Classification of the product according to CLP | No classification for skin sensitisation is required for meta SPC 1 and meta SPC 2.  The label “EUH208 Contains Chlorocresol. May produce an allergic reaction.” is proposed for meta SPC 1 and meta SPC 2. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising to the respiratory system. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for respiratory. |
| Classification of the product according to CLP | No classification for respiratory sensitisation is required for meta SPC 1 and meta SPC 2. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via the oral route. |
| Justification for the selected value | The classification has been determined using the calculation method. Chlorocresol is classified acute toxicity (oral) cat. 4, H302.  ATEmix of 63100 is obtained (1830/2.9 x100) for meta SPC1 and 573667 for meta SPC2. |
| Classification of the product according to CLP | No classification for acute oral toxicity is required for meta SPC 1 and meta SPC 2. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via inhalation. |
| Justification for the selected value | The classification has been determined using the calculation method. None of the components is classified for acute inhalation toxicity. |
| Classification of the product according to CLP | No classification for acute inhalation toxicity is required for meta SPC 1 and meta SPC 2. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via the dermal route. |
| Justification for the selected value | The classification has been determined using the calculation method. None of the components is classified for acute dermal toxicity. |
| Classification of the product according to CLP | No classification for acute dermal toxicity is required for meta SPC 1 and meta SPC 2. |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Chlorocresol |
| Value(s)\* | The meta SPC 1 and 2 contain active substance at a concentration inferior to 5%. Therefore, a dermal absorption of 50% is used for meta SPC 1 (concentrate and diluted) and meta SPC 2. |
| Justification for the selected value(s) | Default value from EFSA guidance on dermal absorption 2017 for water-based. |

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

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, the co-formulant 1-methoxy-2-propanol has been identified as substance of concern:

| **Name and CAS**  **SOC** | **Reason(s) for identification** | **Relation to band** | **Consequences on the Human Risk assessment** | **Community workplace exposure limit** (mg/m3) [[5]](#footnote-6) |
| --- | --- | --- | --- | --- |
| **1-methoxy-2-propanol**  CAS 107-98-2 | Substances for which there are Community workplace exposure limits. | Band C | Quantitative inhalation risk assessment for the professional | 375 (long-term)  568 (short-term) |

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

No data

#### Exposure assessment

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

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

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Wiping (brush, wet cloth) and mopping application | **Primary Exposure - Dermal and inhalation routes**  The treated surfaces can be wiped (brush, wet cloth) or mopped after diluting and mixing the solution. | Professionals |
| 2. | Spray application (pressure washer) | **Primary Exposure - Dermal and inhalation routes** Product sprayed for disinfection on surfaces with a high pressure washer after diluting and mixing. | Professionals |
| 3. | Spraying application (trigger spray) | **Primary Exposure - Dermal and inhalation routes** Product sprayed for disinfection on surfaces using a RTU trigger spray. | Professionals |
| 4. | Cleaning equipment | **Primary exposure – Dermal and inhalation routes**  After application of the product by spraying with pressure washer, cleaning equipment is considered. | Professionals |
| 5. | Rinsing off | **Secondary exposure – Dermal exposure**  Rinsing off treated surface after spraying application. | Professionals |
| 6. | Loading | **Primary Exposure - Dermal and inhalation routes**  Pouring concentrate product via measuring cup or direct transfer. | Non-professionals |
| 7. | Wiping (brush, wet cloth)/mopping application | **Primary Exposure - Dermal and inhalation routes**  Application of diluted product with a mop, brush or wet cloth | Non-professionals |
| 8. | Spray application (pressure washer) | **Primary Exposure - Dermal and inhalation routes** Product sprayed for disinfection on surfaces with a high pressure washer after diluting and mixing. | Non-professionals |
| 9. | Spraying application (trigger spray) | **Primary Exposure - Dermal and inhalation routes** Product sprayed for disinfection on surfaces **(indoors and housing of animals)** using a RTU trigger spray. | Non-professionals |
| 10. | Cleaning equipment | **Primary exposure – Dermal and inhalation routes**  After application of the product by spraying with pressure washer, cleaning equipment is considered. | Non-professionals |
| 11. | Rinsing off | **Secondary exposure – Dermal exposure**  Rinsing off treated surface after spraying application. | Non-professionals |
| 12. | Volatilised residues | **Secondary exposure – Inhalation exposure**  Volatilised residues after application. | Professionals and General public |
| 13. | Exposure to treated surfaces- Adults | **Secondary exposure – Dermal exposure**  After spraying on surfaces, secondary dermal exposure may occur during the contact with the treated surfaces. | Professionals and non-professionals |
| 14. | Exposure to treated surfaces - Children | **Secondary exposure – Dermal and oral exposures**  After spraying on surfaces, secondary dermal and oral exposures may occur during the contact with the treated surfaces. | Children |

***Industrial exposure***

No exposure is foreseen.

***Professional exposure***

*Scenario [1] – Application by wiping/brushing or mopping application*

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| Application by wiping (brush, wet cloth) or moping is intended for professionals, using (meta SPC1; PT2). Exposure is assessed with the diluted product at 7% (concentrate: 2.9% w/w of chlorocresol).  The models used are *Surface disinfection model 1 and 3* (from BHHEM page 201, and in Recommendation no. 6[[6]](#footnote-7)). These models include exposure during diluting and mixing the product in water (in a bowl or a bucket) and wiping surfaces using a rung cloth or a mop. The indicative values (75th percentile) are as follows:   * Hand: 1030 mg/min (without protective gloves) and 10.3 mg/min (inside gloves); * Body (*Surface disinfection Model 3*): 87.6 mg/min; * Inhalation (*Surface disinfection Model 1*): 28.9 g/m3   Duration tasks of 220 minutes and 110 minutes are taken into consideration for wiping (brushing covered according to Recommendation no.6) and mopping respectively, following the HEADhoc recommendation no. 2[[7]](#footnote-8).  For local effects, inhalation exposure is calculated for the active substance and SoC, taking into consideration the indicative inhalation value of 28.9 mg/m3. | | | |
| Tier 1 | **Parameters** | **Value** | **References** |
| Concentration of CMK (% w/w) | 0.2% | Applicant’s data |
| Concentration of SoC (% w/w) | 0.39% | Applicant’s data |
| Indicative value - hand (mg/min) | 1030 | TNsG, 2002 |
| Indicative value - body (mg/min) | 87.6 | TNsG 2002 |
| Indicative value – inhalation (g/m3) | 28.9 | TNsG, 2002 |
| Duration task mopping (min) | 110 | Recommendation no. 2, 2014 |
| Duration task wiping (brush, wet cloth) (min) | 220 | Recommendation no. 2, 2014 |
| Inhalation absorption | 100% | Default value |
| Dermal absorption | 50% | EFSA, 2017 |
| Inhalation rate (m3/h) | 1.25 | Recommendation no. 14[[8]](#footnote-9), 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| Tier 2 | 2a: Indicative value - inside gloves (mg/min) | 10.3 | TNsG, 2002 |
| 2b: Coated coverall penetration factor | 20% | HEEG Opinion 9[[9]](#footnote-10), 2010 |

**Calculations for Scenario [1]**

| **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] mopping | 1/no PPE | 2.21E-03 | 2.05 | - | 2.05 |
| Scenario [1] mopping | 2a/gloves | 2.21E-03 | 1.79E-01 | - | 1.82E-01 |
| Scenario [1] mopping | 2b/gloves + coated coverall | 2.21E-03 | 5.10E-02 | - | 5.32E-02 |
| Scenario [1] wiping (brush, wet cloth) | 1/no PPE | 4.42E-03 | 4.10 | - | 4.10 |
| Scenario [1] wiping (brush, wet cloth) | 2a/gloves | 4.42E-03 | 3.59E-01 | - | 3.63E-01 |
| Scenario [1] wiping (brush, wet cloth) | 2b/gloves + coated coverall | 4.42E-03 | 1.02E-01 | - | 1.06E-01 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/PPE** | **Estimated inhalation** (mg/m3) |
| Scenario [1] – **CMK** | 1/ no PPE | 5.78E-02 |
| Scenario [1] – **SoC** | 1/ no PPE | 1.12E-01 |

*Scenario [2] – Spraying application by using a pressure washer*

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| Spraying by using a pressure washer is intended for professionals (meta SPC1 ; PT2). Exposure is assessed with a dilution of product at 7% (concentrate: 2.9% w/w of chlorocresol).  The model *Spraying model 2* from BHHEM page 205 is used as it includes an application at 4 to 7 bar pressure as a coarse or medium spray, indoors, overhead and downwards.  Mixing and loading liquids in reservoir for powered spray is included in the model.  For professionals, according to the Recommendation no. 6, exposure during spraying should be assessed with *Spraying model 2* considering a duration of 120 minutes. The indicative values (75th percentile) are as follows:   * Hands: 7.8 mg/min (actual), 273 mg/min (potential); * Body: 222 mg/min; * Feet: 5.4 mg/min; * Inhalation: 76 mg/m3.   For local effects, inhalation exposure is calculated for the active substance and SoC, taking into consideration the indicative inhalation value of 76 mg/m3. | | | |
| Tier 1 | **Parameters** | **Value** | **References** |
| Concentration of CMK (% w/w) | 0.2% | Applicant’s data |
| Concentration of SoC (% w/w) | 0.39% | Applicant’s data |
| Task duration (min) | 120 | Recommendation no. 6, 2017 |
| Indicative value – hand (mg/min) | 273 | TNsG, 2002 |
| Indicative value – body (mg/min) | 222 | TNsG, 2002 |
| Indicative value – inhalation (g/m3) | 76 | TNsG, 2002 |
| Inhalation absorption | 100% | Default value |
| Dermal absorption | 50% | EFSA, 2017 |
| Inhalation rate (m3/h) | 1.25 | Recommendation no. 14, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| Tier 2 | 2a: gloves | 7.8 | TNsG, 2002 |
| 2b: coated coverall penetration factor | 20% | HEEG Opinion 9, 2010 |

**Calculations for Scenario [2]**

| **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] | 1/no PPE | 6.43E-03 | 1.02 | - | 1.02 |
| Scenario [2] | 2a/gloves | 6.43E-03 | 4.77E-01 | - | 4.84E-01 |
| Scenario [2] | 2b/gloves + coverall | 6.43E-03 | 1.17E-01 | - | 1.23E-01 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/RPE** | **Estimated inhalation** (mg/m3) |
| Scenario [2] – **CMK** | 1/ no RPE | 1.54E-01 |
| Scenario [2] – **SoC** | 1/ no RPE | 2.95E-01 |

*Scenario [3] – Spraying by using a trigger spray (RTU)*

| **Description of Scenario [3]** | | | |
| --- | --- | --- | --- |
| The product is applied by indoors spraying to surfaces to disinfect it using a trigger spray (RTU), with an application rate of 25 mL/m², and wiping of treated surfaces.  For spray application with a trigger spray (3a), the *Consumer Spraying and Dusting model 2 (hand held trigger spray)* from the TNsG 2002 (part 3, p. 197) has been used according to the Recommendation 6 of HEAd Hoc[[10]](#footnote-11). The indicative exposure values from the model are as follows (75th percentile values):   * 36.1 mg/min (hand/forearm); * 9.7 mg/min (legs/feet/face); * 10.5 mg/m3 (inhalation).   For local effects, inhalation exposure is calculated for the active substance and SoC, taking into consideration the indicative inhalation value of 10.5 mg/m3.  After application by spraying a wiping can be necessary. In this context, for wiping (3b), surface disinfection model 1 considering only hand exposure is used.  The indicative exposure value from the model is as follow:   * Hand: 1030 mg/min (without protective gloves) and 10.3 mg/min (inside gloves); | | | |
| 3a- Spraying | | | |
| Tier 1 | **Parameters** | **Value** | **References** |
| Concentration of CMK in RTU product (% w/w) | 0.319% | Applicant’s data |
| Concentration of SoC in RTU product (% w/w) | 0.6105% | Applicant’s data |
| Duration task (min) | 30 | Recommendation no. 6, 2017 |
| Indicative value (hand/forearm) (mg/min) | 36.1 | TNsG, 2002 |
| Indicative value (legs/feet/face) (mg/min) | 9.7 | TNsG, 2002 |
| Indicative value (inhalation) (mg/m3) | 10.5 | TNsG, 2002 |
| Inhalation absorption | 100% | Default value |
| Dermal absorption | 50% | EFSA, 2017 |
| Inhalation rate (m3/h) | 1.25 | Recommendation no. 14, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| Tier 2 | PPE Gloves penetration factor | 10% | HEEG Opinion 9, 2010 |
| 3b - Wiping | | | |
| Tier 1 | Concentration of CMK in RTU product (% w/w) | 0.319% | Applicant’s data |
| Duration task (min) | 30 | Recommendation no. 6, 2017 |
| Indicative value - hand (mg/min) | 1030 | TNsG, 2002 |
| Dermal absorption | 50% | EFSA, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| Tier 2 | Indicative value – hand (mg/min) | 10.3 | TNsG, 2002 |

**Calculations for Scenario [3]**

| **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 [3a] – trigger spray | 1/no PPE | 3.49E-04 | 3.65E-02 | n.a. | 3.69E-02 |
| Scenario [3a] – trigger spray | 2/gloves | 3.49E-04 | 1.06E-02 | n.a. | 1.10E-02 |
| Scenario [3b] – wiping | 1/no PPE | nr | 8.21E-01 | n.a. | 8.21E-01 |
| Scenario [3b] – wiping | 2/gloves | nr | 8.21E-03 | n.a. | 8.21E-03 |
| Combined 3a and 3b | 1/no PPE | 3.49E-04 | 8.58E-01 | n.a. | 8.58E-01 |
| Combined 3a and 3b | 2/gloves | 3.49E-04 | 1.88E-02 | n.a. | 1.92E-02 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/PPE** | **Estimated inhalation** (mg/m3) |
| Scenario [3a] – **CMK** | 1/ no PPE | 3.35E-02 |
| Scenario [3a] – **SoC** | 1/ no PPE | 6.41E-02 |

*Scenario [4] – Cleaning equipment*

| **Description of Scenario [4]** | | | |
| --- | --- | --- | --- |
| Cleaning of equipment is modelled according to BEAT scenario “*Cleaning of the spray equipment*” from TNsG (2007). The task duration is 10 min. Inhalation exposure is negligible. | | | |
| Tier 1 | **Parameters** | **Value** | **References** |
| Concentration of CMK (% w/w) | 0.2% | Applicant’s data |
| Concentration of SoC (% w/w) | 0.39% | Applicant’s data |
| Duration (min) | 10 | Expert judgment |
| Dermal exposure – hand only (mg/min) | 35.87 | BEAT model and density close to 1 |
| Dermal exposure – body (mg/min) | 19.28 | BEAT model and density close to 1 |
| Dermal absorption | 50% | EFSA, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| Tier 2 | PPE Gloves penetration factor | 10% | HEEG Opinion 9, 2010 |

**Calculations for Scenario [4]**

| **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] – cleaning equipment | 1/no PPE | - | 9.33E-03 | - | 9.33E-03 |
| Scenario [4] – cleaning equipment | 1/gloves | - | 3.87E-03 | - | 3.87E-03 |

*Scenario [5] – Rinsing off treated surface after spraying*

| **Description of Scenario [5]** |
| --- |
| Professional users should rinse with water the treated surfaces after application of PT2 products only. It is considered that exposure during rinsing is covered by exposure during application. Therefore, the same PPE are required.  Meta SPC 1: Rinse surface and material after treatment. The same PPE than those required during application have to be worn.  Meta SPC2: Rinse surface and material after treatment. For professionals, wear gloves during rinsing. |

***Non-professional exposure***

*Scenario [6] - Pouring concentrate product*

| **Description of Scenario [6]** | | | |
| --- | --- | --- | --- |
| The product can be directly pouring or by using a measuring cup and pouring into a bucket. Measuring cup is considered as it could be used to determine the correct amount of product to be diluted in the bucket. The same exposure body area than during a pouring via cap (exposure at the fingertips and phalanges holding the dosing cup) is expected. Indeed, a barrel of 25L poured directly in a bucket of water seems to be more difficult to carry out in practice.  Dermal exposure is considered through spatters with direct transfer and through spills when pouring into a cap. Inhalation exposure is considered for the evaporation of the active substance when opening the bottle or barrel.  The packagings 1, 5 (can) or 25L (barrel) are intended to the non-professional user. A plastic plug with integrated pull-up spout is described in order to limit the spatters when pouring the product. A barrel of 25L is considered as a worst-case for loading and diluting the product.  According to Cleaning Products Fact Sheet (RIVM Report 2016-0179, section 4.1.2), the *inhalation–exposure to vapour–evaporation–constant release area model* and the *dermal–direct product contact–instant application loading model* are used for floor cleaner liquid during mixing and loading. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1a | Concentration of CMK (% w/w) | 2.9% | Applicant’s data |
| Molecular weight of CMK (g/mol) | 142.6 | CAR CMK |
| Vapour pressure of CMK at 20°C (Pa) | 0.0014 | CAR CMK |
| Product amount – dermal (g) **– using measuring cup** | 0.53 | RIVM Report 2016-0179 |
| Surface area (fingertips and phalanges) (cm²) **– measuring cup** | 53 | RIVM Report 2016-0179 |
| Exposure duration (min) | 0.75 | RIVM Report 2016-0179 |
| Product amount – inhalation (g) | 12500 | Half of the barrel (25 L) |
| Room volume (m3) | 1 | RIVM Report 2016-0179 |
| Ventilation rate (1/h) | 0.5 | RIVM Report 2016-0179 |
| Release area (cm²) | 25.5 | Opening of a barrel (∅ 57 mm) |
| Molecular weight matrix (g/mol) | 18 | RIVM Report 2016-0179 |
| Mass transfer coefficient (m/h) | 10 | RIVM Report 2016-0179 |
| Emission duration (min) | 0.3 | RIVM Report 2016-0179 |
| Inhalation absorption | 100% | Default value |
| Dermal absorption (concentrate) | 50% | Default value EFSA, 2017 |
| Inhalation rate (m3/h) | 1.25 | Recommendation no. 14, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| Tier 1b | Product amount – dermal (g) **– direct pouring** | 0.01 | RIVM Report 2016-0179 |
| Surface area (hand) (cm²) **– direct transfer** | 205 | Recommendation no. 14, 2017 |

**Calculations for Scenario [6]**

| **Summary table: systemic 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] – **measuring cup** | 1a | 8.1E-12 | 1.3E-01 | n.a. | 1.3E-01 |
| Scenario [6b] – **direct pouring** | 1b | 8.1E-12 | 2.4E-03 | n.a. | 2.4E-03 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/PPE** | **Estimated inhalation** (mg/m3) |
| Scenario [6] – **CMK** (event) | 1/ no PPE | 3.1E-08 |

*Scenario [7] – Application of diluted product with a mop or wet cloth*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [7]** | | | |
| The product can be applied by mopping and wiping (brush, wet cloth). No model is available for brushing. Therefore, application with a mop or wet cloth is considered to cover brushing application.  Inhalation exposure is considered for the evaporation of the active substance on the surface area which increases during application of the product. Dermal exposure to hands and forearms may occur while dipping the cloth or mop it into a bucket with diluted product and with contact between the hands and the wipe.  According to Cleaning Products Fact Sheet (RIVM Report 2016-0179, section 4.2.2.1), the *inhalation–exposure to vapour–evaporation–increasing release model* and the *dermal–direct product contact–instant application loading model* are used for surface application with cloths, mops and wet tissues.  The amount solution considered for inhalation refers to the amount of water and to the amount of floor cleaner diluted in the water that is applied on the floor.  The surface area of the floor is 22 m2.  Therefore, considering an application rate of 60 ml of solution per m2, the amount solution used is calculated as 1320g.  The dilution in number of times is calculated by dividing the amount of solution used by the product amount: 1000/70 = 14.2.    The product amount considered for dermal exposure refers to the volume of water in contact with the skin and the concentration of the floor cleaning product in the water.  The volume of water left on the skin after dipping the hands and forearms in the water is 19.5 ml (1949 cm2\*0.01 cm).  The product amount is thus calculated to be 70 ml/L \* 0.998 \* 19.5 ml = 1.36 g.  Application duration is set at 20 min according to the RIVM report. For exposure duration, it is assumed that the consumer stays in the treated room for 4 hours after the cleaning task. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1 | Concentration of CMK in concentrate product (% w/w) | 2.9% | Applicant’s data |
| Concentration of CMK in diluted product (% w/w) | 0.2% | Applicant’s data |
| Molecular weight of CMK (g/mol) | 142.6 | CAR CMK |
| Vapour pressure of CMK at 20°C (Pa) | 0.0014 | CAR CMK |
| Exposure duration (min) | 240 | Worst-case assumption |
| Product amount – dermal (g) | 1.36 | RIVM Report 2016-0179,  7% dilution |
| Exposed area (mops) – hands and forearms (cm²) | 1948.8 | Recommendation no. 14, 2017 |
| amount of solution – inhalation (g) | 1320 | RIVM Report 2016-0179,  7% dilution |
| Room volume: living room (m3) | 58 | RIVM Report 2016-0179 |
| Ventilation rate (1/h) – living room | 0.5 | RIVM Report 2016-0179 |
| Molecular weight matrix (g/mol) | 18 | RIVM Report 2016-0179 |
| Mass transfer coefficient (m/h) | 10 | RIVM Report 2016-0179 |
| Release area (m²) – living room floor | 22 | RIVM Report 2016-0179 |
| Application duration (min) | 20 | RIVM Report 2016-0179 |
| Inhalation absorption | 100% | Default value |
| Dermal absorption (dilution) | 50% | Default value EFSA, 2017 |
| Inhalation rate (m3/h) | 1.25 | Recommendation no. 14, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |

**Calculations for Scenario [7]**

| **Summary table: systemic 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] | 1 | 1.4E-06 | 3.3E-01 | n.a. | 3.3E-01 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/PPE** | **Estimated inhalation** (mg/m3) |
| Scenario [7] – **CMK** | 1/ no PPE | 1.6E-05 |

*Scenario [8] – Application by spraying with a pressure washer*

| **Description of Scenario [8]** | | | |
| --- | --- | --- | --- |
| The product is used by a pressure washer for disinfection and cleaning of outdoor surfaces surrounding households (terraces, low walls up to 50 cm height) (intended use #3). Non-professionals will use a pressure washer with downward application.  No model is available for non-professionals. Therefore, Spraying model 2 with 95th percentile is used. The indicative values (95th percentile) are:  - inhalation exposure: 2100 mg spray/m3  - dermal exposure for body: 198 mg spray/min.  A duration of 30 min by spraying is considered. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1 | Concentration of CMK in diluted product (% w/w) | 0.203% | Applicant’s data |
| Exposure time (min) | 30 | RIVM report 320104003 |
| Inhalation value (mg/m3) | 198 | TNsG 2002 |
| Dermal value - body (mg/min) | 2100 | TNsG 2002 |
| Dermal value - hand (mg/min) | 273 | TNsG 2002 |
| Inhalation absorption | 100% | Default value |
| Dermal absorption (dilution) | 50% | Default value EFSA, 2017 |
| Inhalation rate (m3/h) | 1.25 | Recommendation no. 14, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |

**Calculations for Scenario [8]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/m3) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated oral uptake** | **Estimated total uptake** (mg/kg bw/d) |
| Scenario [8] | 1 | 4.19E-03 | 1.21E+00 | n.a. | 1.21E+00 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/PPE** | **Estimated inhalation** (mg/m3) |
| Scenario [8] – **CMK** | 1/ no PPE | 4.02E-01 |

*Scenario [9] – Application by spraying with a trigger spray (RTU)*

| **Description of Scenario [9]** |
| --- |
| The RTU product is used by spraying (9a) for different purposes for non-professionals:   * disinfection of small surfaces, material, equipment and furniture, in private and public areas, Indoors (intended use #4) and Outdoors (intended use #5), * Backyard housing of small domestic animals (intended use #6).   Consumer Spraying and dusting model 2 is used. See scenario 3 for professionals without PPE.  Moreover, after application by spraying a wiping can be necessary. In this context, for wiping (9b), the dermal exposure of the following scenario 11 is considered. |

**Calculations for Scenario [9]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/m3) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated oral uptake** | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [9a] – trigger spray | 1a | 3.49E-04 | 3.65E-02 | n.a. | 3.69E-02 |
| Scenario [9b] – wiping | 1a | n.a. | 2,33E-03 | n.a. | 2,33E-03 |
| Combined 9a and 9b | 1a | 3.49E-04 | 3,89E-02 | n.a. | 3,92E-02 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/PPE** | **Estimated inhalation** (mg/m3) |
| Scenario [9] – **CMK** | 1/ no PPE | 3.35E-02 |

*Scenario [10] – Cleaning spray equipment*

| **Description of Scenario [10]** |
| --- |
| See scenario 4 for professionals without PPE. |

**Calculations for Scenario [10]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/m3) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated oral uptake** | **Estimated total uptake** (mg/kg bw/d) |
| Scenario [10] | 1 | n.a. | 9.33E-03 | n.a. | 9.33E-03 |

*Scenario [11] – Rinsing off treated surface after spraying*

| **Description of Scenario [11]** | | | |
| --- | --- | --- | --- |
| Non-professionals users should rinse with water the treated surfaces after application of PT2 products only. The applied product is removed with a wet cloth.  According to Cleaning Products Fact Sheet (RIVM Report 2016-0179, section 8.2.2), inhalation exposure during this task is already covered by the inhalation estimated from application.  Dermal exposure is estimated using *the dermal–direct product contact–instant application loading model*.  The volume of water that ends up on the inside of the hand by touching the wet cloth is calculated by multiplying a layer thickness of 0.01 cm by the exposed area of 205 cm², resulting in 2.05 ml. The total product amount is 70 g/L \* 0.00205 L = 0.14 g. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1 | Concentration of CMK - diluted (% w/w) | 0.2% | Applicant’s data |
| Product amount – dermal (g) | 0.14 |  |
| Surface area (one side hand) (cm²) | 205 | Recommendation no. 14, 2017 |
| Dermal absorption (dilution) | 50% | Default value EFSA, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |

**Calculations for Scenario [11]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/m3) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated oral uptake** | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [11] | 1 | - | 2.3E-03 | n.a. | 2.3E-03 |

***Exposure of the general public***

*Scenario [12] - Inhalation of volatilised residues after application*

| **Description of Scenario [12]** | | | |
| --- | --- | --- | --- |
| After application, inhalation exposure of volatile residues is assessed for adults, children, toddlers and infants. The assessment is done according to the HEEG opinion 13 “Assessment of inhalation exposure of volatilised biocides active substance”. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1 | Concentration of CMK - PAE (% w/w) | 0.319% | Applicant’s data |
| Inhalation absorption | 100% | Default value |
| Vapour pressure (Pa) | 1.40E-03 | CAR CMK |
| Molecular weight (g/mol) | 142.6 | CAR CMK |
| **Inhalation rate (m3/24h)** | | Recommendation no. 14, 2017 |
| Adult | 16 |
| Child (6 to <12 years old) | 12 |
| Child (2 to <6 years old) | 10.1 |
| Toddler (1 to <2 years old) | 8 |
| Infant (<1 year old) | 5.4 |
| **Body weight (kg)** | | Recommendation no. 14, 2017 |
| Adult | 60 |
| Child (6 to <12 years old) | 23.9 |
| Child (2 to <6 years old) | 15.6 |
| Toddler (1 to <2 years old) | 10 |
| Infant (<1 year old) | 8 |

**Calculations for Scenario [12]**

| **Summary table: systemic 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** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| Scenario [12] – Adults | 1 | 2.19E-02 | - | - | 2.19E-02 |
| Scenario [12] – Child (6 to <12 years old) | 1 | 4.11E-02 | - | - | 4.11E-02 |
| Scenario [12] – Child (2 to <6 years old) | 1 | 5.31E-02 | - | - | 5.31E-02 |
| Scenario [12] – Toddler (1 to <2 years old) | 1 | 6.56E-02 | - | - | 6.56E-02 |
| Scenario [12] – Infant (<1 year old) | 1 | 5.53E-02 | - | - | 5.53E-02 |

*Scenario [13] - Exposure to treated surfaces - Adults*

| **Description of Scenario [13]** | | | |
| --- | --- | --- | --- |
| After application, the secondary exposure of an adult who touches wet or dried surfaces is considered, with an exposed area of 410 cm², corresponding to the palm of two hands.  Meta SPC1 is taken into consideration for secondary exposure as a worst case. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1a | Application rate (mL/m²) | 60 | Applicant’s data |
| Concentration of CMK (% w/w) | 0.2% | Applicant’s data |
| Dislodgeable fraction from floor to skin (wet surface) | 100% | Default value |
| Surface area (palm of two hands) (cm²) | 410 | Recommendation no. 14, 2017 |
| Dermal absorption (dilution) | 50% | Default value EFSA, 2017 |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| Tier 1b | Dislodgeable fraction from floor to skin (dried surface) | 30% | TNsG, 2002 |

**Calculations for Scenario [13]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated oral uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| Scenario [13] – wet surfaces - adults | 1/no PPE | - | 4.10E-02 | - | 4.10E-02 |
| Scenario [13] – dried surfaces - adults | 1/no PPE | - | 1.23E-02 | - | 1.23E-02 |

*Scenario [14] - Exposure to treated surfaces - Children*

| **Description of Scenario [14]** | | | |
| --- | --- | --- | --- |
| After application, the secondary exposure of toddlers who crawling to wet or dried surfaces during 1 hour is considered (0.21 m2/h). A hand-to-mouth behaviour is also considered.  Inhalation of volatilised residues after application (indoors) is considered to be negligible due to the low volatile properties of the active substance. | | | |
|  | **Parameters** | **Value** | **References** |
| Meta spc 1 | Application rate (mL/m²) | 60 | Applicant’s data |
| Concentration of CMK (% w/w) | 0.2% | Applicant’s data |
| Meta spc 2 | Application rate (mL/m²) | 25 | Applicant’s data |
| Concentration of CMK (% w/w) | 0.319% | Applicant’s data |
| Tier 1a | Dislodgeable fraction from floor to skin (wet surface) | 100% | Default value |
| Transfer to the mouth | 10% |  |
| Dermal absorption (dilution) | 50% | Default value EFSA, 2017 |
| Oral absorption | 100% | CAR CMK |
| Body weight (kg) - toddlers | 10 | Recommendation no. 14, 2017 |
| Tier 1b | Dislodgeable fraction from floor to skin (dried surface) | 30% | TNsG, 2002 |

**Calculations for Scenario [14]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/m3) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated oral uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| Meta SPC 1 | | | | | |
| Scenario [14] – wet surfaces, toddlers | 1 | - | 1.13 | 2.52E-01 | 1.39 |
| Scenario [14] – dried surfaces, toddlers | 1 | - | 3.40E-01 | 7.56E-02 | 4.16E-01 |
| Meta SPC 2 | | | | | |
| Scenario [14] – wet surfaces, toddlers | 1 | - | 7.54E-01 | 1.67E-01 | 9.21E-01 |
| Scenario [14] – dried surfaces, toddlers | 1 | - | 2.26E-01 | 5.02E-02 | 2.76E-01 |

***Monitoring data***

No data

***Dietary exposure***

According to PT 2 intended uses, indirect or direct contact with food or feeding stuffs is not expected. No dietary exposure is expected and performed.

According to intended non-professional PT 3 uses, some animal species can be exposed to chlorocresol after use of the active substance as disinfectant of small domestic animal housing, such as a rabbit hutch or a backyard chicken coop.

According to the applicant, domestic animals (rabbit or chicken) are likely to be exposed to the active substance (Scenario DRA 1). The applicant proposes some instructions of use and some risk mitigation measures to prevent animal exposure:

* Do not apply the treatment in the presence of domestic animals.
* Wait 30 minutes after the application before the re-entry of animals.
* Put new animal bedding material before re-entry of domestic animals.
* Remove or cover feed and water troughs before treatment.

Therefore, the only source of exposure via food for general population is **eggs** being in contact with the treated surface (Scenario DRA 2).

Scenario proposed by the applicant have been reviewed and modified if necessary by eCA hereunder.

1-methoxy-2-propanol has been considered as a SoC (See paragraph above in human exposure part) because of its toxicity by inhalation and based on its community workplace exposure limits. According to available data this compound is not toxic by ingestion.

Therefore, considering SoCs, no further assessment is required in the frame of this dossier.

Residue definitions

As agreed at EU level for the approval of the active substance (Assessment Report of CMK; France, 2017), exposure is performed taking into account **chlorocresol only**.

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Type of use** | **Description of scenario** | **Subject of exposure** |
| DRA 1. | Disinfection of animal houses | Disinfection of rabbit hutch and backyard chicken coop with a trigger spray by non professional users only. | Poultry, rabbit |
| DRA 2 | Disinfection of hen houses | Disinfection of hen houses (backyard chicken coop) with a trigger spray by non professional users only.  Direct contamination of eggs after contact with active substance residues remaining on treated surfaces. | General population (adult) through consumption of contaminated eggs. |

*Information of non-biocidal use of the active substance*

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of usea** | **Intended use** | **Reference value(s) b** |
| 1. | Veterinary usec | Disinfectant and antiseptic | All food producing species: No MRL required |
| 2. | Phytosanitary use | Not approved as a PPP active substance d | No toxicological reference values  Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005 |

a e.g. plant protection products, veterinary use, food or feed additives

b e.g. MRLs. Use footnotes for references.

c EMEA/MRL/074/96-FINAL March 1996 : Committee for veterinary medicinal products – Summary report : Chlorocresol (4-chloro-3-methylphenol)

d <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=901>

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

No livestock exposure to CMK is foreseen with the intended uses of ORAPI CRESYL FAMILY. Indeed, the ready-to-use trigger spray is intended to be used for surface disinfection of small domestic animal housing, such as a dog kennel, a rabbit hutch or a backyard chicken coop by non-professional users. Assessment is detailed in paragraph below in “*Estimating transfer of biocidal active substances into foods as a result of non-professional use*” section.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

Not relevant.

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

Scenario [DRA-1]: Poultry and rabbit exposure after housing disinfection

According to intended uses, poultry and rabbit can be exposed to chlorocresol after use of the active substance as animal house disinfectant. None agreed European scenario is available for this non-professional use. Therefore, eCA performed an assessment for poultry and rabbit exposure taking into account applicant’s scenario proposal.

As a first tier approach, animal exposure to CMK from treated surfaces can be estimated using the **screening scenario** detailed in the EU guidance[[11]](#footnote-12) for livestock exposure estimation. For the screening step, it is assumed that the entire amount of biocidal product applied is taken up by animals. Therefore, following calculation are made for a spray treatment:

Livestock exposure = [Application rate (mg as/m2) x Area treated (m2)] / [number of animals per houses x livestock body weight (kg)]

A **realistic worst case** scenario is then performed if the trigger value of 0.004 mg/kg bw/d is exceeded15. This scenario quantifies the various possible exposure routes for animals (oral, dermal and inhalation) taking into account additional parameters for refinement or risk mitigations measures:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Exposure** | | | | | |
| **Oral** | | | **Dermal** | | **Inhalation (5)** |
| **Licking wall (1)** | **Fly ingestion (2)** | **Contaminated feed (3)** | **Rubbing (4)** | **Spray contact (4)** |
| **Poultry and rabbit** | NR | NR | NR | NR | NR | NR |

R: Relevant – NR: Not Relevant

(1) Poultry15 and rabbit are not subject to this kind of behaviour

(2) Poultry seek out dead insects intentionally. ORAPI CRESYL FAMILY is not an insecticide. Therefore, the oral exposure via insect ingestion is considered as not relevant

(3) It is assumed that poultry and rabbit houses are cleaned and emptied before treatment. Before application, all animal bedding material and troughs are removed and replaced before re-entry of animals. It is not foreseen to use the product of ORAPI CRESYL FAMILY for disinfection of feed and water troughs.

(4) Small animals such as poultry and rabbit does not engage in rubbering against walls 15. In addition, these animals are not allowed into the housing during the product application. Therefore, no dermal exposure can occur from spray hitting them during treatment. Moreover, bedding of the nest provides a separative layer between the floor and the animal.

(5) No inhalation exposure is foreseen as no animals are present during treatment and the re-entry occurs at least 30min after the application. .

Based on considerations detailed in table above for the **realistic worst case scenario**, exposure of poultry and rabbit to ORAPI CRESYL FAMILY can be considered as negligible.

| **Description of Scenario [DRA 1]** | | |
| --- | --- | --- |
| Disinfection of rabbit hutch and backyard chicken coop with a trigger spray by non-professional users only. Application rate is 25 mL/m2. Surfaces to be treated: Floor and wall without partitions. | | |
|  | Parameters | Value |
| Screening step | Maximum concentration of chlorocresol in the biocidal product | 0.319% |
| Density of the biocidal product | 1 per default |
| Application rate of working solution | 25 mL/m2 |
| Application rate of active substance | 79.75 mg/m2 |
| Area of treated houses (*applicant and eCA proposal*) | 5 m2 (1m² of floor and 4m² of walls) |
| Number of animal per chicken coop or rabbit hutch (*applicant and eCA proposal*) | 1 |
| Body weight of animalsa | 1.9 kg for chicken  2.5 kg for rabbit |
| Realistic worst case | Risk mitigations measures proposed by the applicant:   * Do not apply the treatment in the presence of domestic animals. * Wait 30 minutes after the application before the re-entry of animals. * Put new animal bedding material before re-entry of domestic animals. * Remove or cover feed and water troughs before treatment. | - |

a ECHA - Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) - 6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products. December 2017

Results of animal exposure is detailed in table below:

Scenario [DRA-1]: Results of animal exposure for housing disinfection use

| **Internal dose received by the animal (mg as/kg bw/d)** |
| --- |
| Animal exposure after disinfection of rabbit hutch and backyard chicken coop with a trigger spray by non-professional users only. Application rate is 25 mL/m2. Surfaces to be treated: Floor and wall without partitions. |
| **Screening and realistic worst case** |
| |  |  |  | | --- | --- | --- | | **Animal Species** | **Screening** | **Realistic worst case** | | Poultry | 209.9 | Not calculated (a) | | Rabbit | 159.5 | Not calculated (a) | |

a Not calculated as RMMs have been proposed by the applicant to prevent exposure.

Scenario [DRA-2]: Indirect exposure (adult and children) via consumption of eggs contaminated after direct contact with treated surfaces

There is no specific model to assess the indirect exposure to CMK residues via food (egg) that has been in contact with treated surfaces.

In the “*Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses*”[[12]](#footnote-13), a scenario is proposed for disinfectant and preserved cleaners in domestic kitchens. The applicant proposed to use this scenario. eCA agrees to use the calculation but disagrees with most of the default values used by the applicant (see explanation below).

Indirect exposure via food is therefore calculated with the following equation:

Expcons = Rsurface x Afood contact x TF x bw

Where:

Expcons: dietary exposure (mg a.s./kg bw/d)

Rsurface: biocide residues on surface (mg a.s./m2)

Afood contact: area in contact with daily food (eggs in this case) (m2)

TF: Mass transfer efficiency factor (fraction of biocide residue transferred from surface to food (eggs))

bw: human body weight (kg)

As input values, the applicant first proposed to use a default value for contaminated surface area (kitchen counter) in contact with food (that represents daily exposure of consumer) of 0.2 m2 (acute and chronic exposure). This default value is the area of food contact on a kitchen counter, taking into account the total daily food intake. In this situation, the use of this default value is not appropriate because it does not reflect the realistic case of eggs contact with treated surfaces for which the area of contact with a surface is much more smaller (see paragraph below).

Therefore in a second time, the applicant considers that the surface in contact with eggs corresponds to the entire surface of the eggs that are consumed per day. eCA agrees with it as a worst case. Based on the study made by Bonnet and Mongin[[13]](#footnote-14), the formula S= 4.69 x P2/3 (where S is the surface in cm² and P the weight in g) is used to calculate the surface of an egg. In this same study, it is indicated that the weight of an egg is situated between 55 and 75g. Therefore, if we consider that two eggs of 55g (110g in total)[[14]](#footnote-15) are consumed daily, the area in contact with food is: S= 2 x 4.69 x 552/3= 135.66 cm². As proposed by the applicant, this area in contact with food is rounded up and thus, the value taken into account for refinement is 0.02 m². This value is still conservative as the surface of the egg in contact with treated surface will be smaller than the total surface of the egg.

Moreover, considering transfer of residues from treated surfaces to eggs, eCA considers 100% of transfer as a worst case. The applicant proposed to refine exposure taking into account transfer coefficients of residues detailed “*Biocides Human Health Exposure Methodology, Vers. 1, 2015, p. 171, Table: Transfer coefficients – Dislogeable residues”*. Nevertheless, these transfer coefficients are representative of transfer from treated surfaces to human skin. As the characteristics of human skin and egg shell are not similar, eCA disagrees to use the proposed transfer coefficient. Moreover, eCA considers as a worst case a 100% transfer from the eggs shell into the egg.

| **Description of Scenario [DRA 2]** | | |
| --- | --- | --- |
| Disinfection of hen houses (backyard chicken coop) with a trigger spray by non professional users only. Application rate is 25 mL/m2. Surfaces to be treated: Floor and wall without partitions.  Eggs contaminated by direct contact with treated surfaces. | | |
|  | Parameters | Value |
|  | Maximum concentration of chlorocresol in the biocidal product | 0.319% |
| Density of the biocidal product | 1 per default |
| Application rate of working solution | 25 mL/m2 |
| Biocide residues on surface (Rsurface) | 79.75 mg/m2 |
| Treated area in contact with eggs daily consumed (100 g)[[15]](#footnote-16)(*applicant proposal reviewed by eCA*) | 0.02 m2 |
| Mass transfer efficiency factor (fraction of biocide residue transferred from surface to food) (TF) (*applicant proposal reviewed by eCA*) | 100% |
| Body weight a | 60 kg for an adult b |

1. Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) -5. Guidance on Estimating dietary risk from tranqfer of biocidal active substances into foods – Non professional uses
2. As proposed by the applicant, EMA food basket has been considered to assess eggs surfaces. EMA considers only adult chronic assessment. Therefore, only chronic indirect exposure via food for adult has been performed. Nevertheless, as other consumption data exist in PRIMo rev 3.1 for children and for acute exposure, risk calculations for both chronic and acute exposures and for both adult and children are performed in paragraph ”Risk for consumers via residues in food” below.

Chronic indirect exposure via food for adult was estimated at 0.027 mg as/kg bw/d.

**Conclusion**

Based on intended use of meta SPC as PT 3, domestic animals (rabbit or chicken) are likely to be exposed to the active substance (Scenario DRA 1). Moreover, it is assumed that the CMK residues can contaminate the eggs by being in contact with the treated surface (Scenario DRA 2).

For scenario DRA 1, the proposed instructions of use and risk mitigation measures to prevent animals exposure are indicated in the SPC:

* Do not apply the treatment in the presence of domestic animals.
* Wait 30 minutes after the application before the re-entry of animals.
* Put new animal bedding material before re-entry of domestic animals.
* Remove or cover feed and water troughs before treatment.

Based on these RMMs, exposure of animals is expected to be negligible. There is no need to assess indirect exposure to general public via ingestion of tissues or products of animal origin.

***Exposure associated with production, formulation and disposal of the biocidal product***

Not relevant.

***Aggregated exposure***

Not performed.

***Summary of exposure assessment***

***Systemic exposure***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [1] mopping | Professionals | 1/no PPE | 2,05E+00 |
| Scenario [1] mopping | Professionals | 2/gloves | 1,82E-01 |
| Scenario [1] mopping | Professionals | 2/gloves + coverall | 5,32E-02 |
| Scenario [1] wiping (brush, wet cloth) | Professionals | 1/no PPE | 4,10E+00 |
| Scenario [1] wiping (brush, wet cloth) | Professionals | 2a/gloves | 3,63E-01 |
| Scenario [1] wiping (brush, wet cloth) | Professionals | 2b/gloves + coverall | 1,06E-01 |
| Scenario [2] – pressure cleaner | Professionals | 1/no PPE | 1,02E+00 |
| Scenario [2] – pressure cleaner | Professionals | 2a/gloves | 4,84E-01 |
| Scenario [2] – pressure cleaner | Professionals | 2b/gloves + coverall | 1,23E-01 |
| Scenario [3] – trigger spray | Professionals | 1/no PPE | 3,69E-02 |
| Scenario [3] – trigger spray | Professionals | 1/gloves | 1,10E-02 |
| Scenario [3b] – wiping post spraying | Professionals | 1/no PPE | 8,21E-01 |
| Scenario [3b] – wiping post spraying | Professionals | 2/gloves | 8,21E-03 |
| Combined 3a and 3b | Professionals | 1/no PPE | 8,58E-01 |
| Combined 3a and 3b | Professionals | 2/gloves | 1,92E-02 |
| Scenario [4] - cleaning equipment | Professionals | 1/no PPE | 9.33E-03 |
| Scenario [4] - cleaning equipment | Professionals | 2/gloves | 3.87E-03 |
| Scenario [6a] - m/l measuring cup | Non-professionals | 1/no PPE | 1,30E-01 |
| Scenario [6b] - m/l direct transfer | Non-professionals | 1/no PPE | 2,40E-03 |
| Scenario [7] - mopping/wiping (brush, wet cloth) | Non-professionals | 1/no PPE | 3,30E-01 |
| Scenario [8] – pressure cleaner | Non-professionals | 1/no PPE | 1,21E+00 |
| Scenario [9] - trigger spray RTU | Non-professionals | 1/no PPE | 3,69E-02 |
| Scenario [9b] – wiping | Non-professionals | 1/no PPE | 2,33E-03 |
| Combined 9a and 9b | Non-professionals | 1/no PPE | 3,92E-02 |
| Scenario [10] – cleaning equipment | Non-professionals | 1/no PPE | 9.33E-03 |
| Scenario [11] – rinsing off | Non-professionals | 1/no PPE | 2.33E-03 |
| Scenario [12] – Adults | Professionals and general public | 1/no PPE | 2.19E-02 |
| Scenario [12] – Child (6 to <12 years old) | general public | 1/no PPE | 4.11E-02 |
| Scenario [12] – Child (2 to <6 years old) | general public | 1/no PPE | 5.31E-02 |
| Scenario [12] – Toddler (1 to <2 years old) | general public | 1/no PPE | 6.56E-02 |
| Scenario [12] – Infant (<1 year old) | general public | 1/no PPE | 5.53E-02 |
| Scenario [15] – wet surfaces - adults | Professionals and general public | 1/no PPE | 4.10E-02 |
| Scenario [15] – dried surfaces - adults | Professionals and general public | 1/no PPE | 1.23E-02 |
| Scenario [14] – wet surfaces, toddlers meta SPC1 | general public | 1/no PPE | 1.39E+00 |
| Scenario [14] – dried surfaces, toddlers meta SPC 1 | general public | 1/no PPE | 4.16E-01 |
| Scenario [14] – wet surfaces, toddlers Meta SPC 2 | general public | 1/no PPE | 9.21E-01 |
| Scenario [14] – dried surfaces, toddlers Meta SPC 2 | general public | 1/no PPE | 2.76E-01 |

***Local exposure: Chlorocresol***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [1] – wiping (brush, wet cloth) and mopping | Professionals | 1/no PPE | 5.78E-02 |
| Scenario [2] – pressure cleaner | Professionals | 1/no PPE | 1.54E-01 |
| Scenario [3] – trigger spray | Professionals | 1/no PPE | 3.35E-02 |
| Scenario [6] - Pouring | Non-professionals | 1/no PPE | 1.20E-05 |
| Scenario [7] – Mopping and wiping (brush, wet cloth) | Non-professionals | 1/no PPE | 1.80E-05 |
| Scenario [8] – pressure cleaner | Non-professionals | 1/no PPE | 4.02E-01 |
| Scenario [9] - trigger spray RTU | Non-professionals | 1/no PPE | 3.35E-02 |

***Local exposure: SoC***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [1] – wiping (brush, wet cloth) and mopping | Professionals | 1/no PPE | 1.12E-01 |
| Scenario [2] – pressure cleaner | Professionals | 1/no PPE | 2.95E-01 |
| Scenario [3] – trigger spray | Professionals | 1/no PPE | 6.41E-02 |

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL or NOAEC** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term AELmedium-term AELlong-term | rat developmental toxicity study | 30 mg/kg bw/day | 100 | 100% | 0.30 mg/kg bw/d |
| AECacute | 14-day inhalation rat study | 50 mg/m3 | 25 | - | 2 mg/m3 |
| AECmedium | 14-day inhalation rat study | 50 mg/m3 | 75 | - | 0.7 mg/m3 |
| AEClong-term | 14-day inhalation rat study | 50 mg/m3 | 150 | - | 0.3 mg/m3 |
| ARfD | rat developmental toxicity study | 30 mg/kg bw/day | 100 | 100% | 0.30 mg/kg |
| ADI | rat developmental toxicity study | 30 mg/kg bw/day | 100 | 100% | 0.30 mg/kg bw/d |

1 For AEL, ARfD, ADI values: 10 for the inter-species variations and 10 for intra-species.

For AEC values: 10 for intra-species and reduced factor of 2.5 for inter-species variations. In addition, SF added to consider longer exposure.

**Maximum residue limits or equivalent**

Chlorocresol is also used in the veterinary and phytosanitary fields. No MRLs are required as a veterinary medicine but a default MRL of 0.01 mg/kg is established under Reg (EU) n° 396/2005 as the active substance is not approved as a PPP active substance.

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| MRLs | Veterinary use[[16]](#footnote-17) | All food producing species | No MRLs needed |
| MRLs | Phytosanitary use [[17]](#footnote-18) | All food commodities | Default MRL of 0.01 mg/kg as active substance is not approved as a phytosanitary active substance |

Despite default MRLs of 0.01 mg/kg exist for phytosanitary uses (Reg EU 396/2005), MRL compliance has not been performed in this dossier as PT 3 intended use is a non-professional use.

***Risk for industrial users***

No exposure is foreseen.

***Risk for professional users***

**Systemic effects – primary exposure**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| Scenario [1] mopping | 1/no PPE | 30 | 0,3 | 2.05E+00 | **683.7%** | **No** |
| Scenario [1] mopping | 2/gloves | 30 | 0,3 | 1.82E-01 | 60.6% | Yes |
| Scenario [1] mopping | 2/gloves + coated coverall | 30 | 0,3 | 5.32E-02 | 17.7% | Yes |
| Scenario [1] wiping (brush, wet cloth) | 1/no PPE | 30 | 0,3 | 4.10E+00 | **1367.4%** | **No** |
| Scenario [1] wiping (brush, wet cloth) | 2/gloves | 30 | 0,3 | 3.63E-01 | **121.1%** | **No** |
| Scenario [1] wiping (brush, wet cloth) | 2/gloves + coated coverall | 30 | 0,3 | 1.06E-01 | 35.5% | Yes |
| Scenario [2] – pressure cleaner | 1/no PPE | 30 | 0,3 | 1.02E+00 | **340.7%** | **No** |
| Scenario [2] – pressure cleaner | 2/gloves | 30 | 0,3 | 4.84E-01 | **161.3%** | **No** |
| Scenario [2] – pressure cleaner | 2/gloves + coated coverall | 30 | 0,3 | 1.23E-01 | 41.1% | Yes |
| Scenario [3a] – trigger spray | 1/no PPE | 30 | 0,3 | 3.69E-02 | 12.3% | Yes |
| Scenario [3a] – trigger spray | 2/gloves | 30 | 0,3 | 1.10E-02 | 3.7% | Yes |
| Scenario [3b] – wiping post spraying | 1/no PPE | 30 | 0,3 | 8.21E-01 | **273.8%** | **No** |
| Scenario [3b] – wiping post spraying | 2/gloves | 30 | 0,3 | 8.21E-03 | 2.7% | yes |
| Combined 3a and 3b | 1/no PPE | 30 | 0,3 | 8.58E-01 | **286.1%** | **No** |
| Combined 3a and 3b | 2/gloves | 30 | 0,3 | 1.92E-02 | 6.4% | Yes |
| Scenario [4] - cleaning equipment | 1/no PPE | 30 | 0,3 | 9.33E-03 | 3.1% | Yes |
| Scenario [4] - cleaning equipment | 1/gloves | 30 | 0,3 | 3.87E-03 | 1.3% | Yes |

**Local effects (Chlorocresol)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated uptake**  **mg a.s./m3** | **Estimated uptake/ AEC (%)** | **Acceptable**  **(yes/no)** |
| Scenario [1] – wiping(brush, wet cloth) and mopping | 1 | 0.3 | 5.78E-02 | 19.3% | Yes |
| Scenario [2] – pressure cleaner | 1 | 0.3 | 1.54E-01 | 51.4% | Yes |
| Scenario [3] – trigger spray | 1 | 0.3 | 3.35E-02 | 11.2% | Yes |

**Local effects (SoC)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **IOEV**  **mg/m3** | **Estimated uptake**  **mg/m3** | **Estimated uptake/ IOEV (%)** | **Acceptable**  **(yes/no)** |
| Scenario [1] – wiping(brush, wet cloth) and mopping | 1 | 375 | 1.12E-01 | <0.1% | Yes |
| Scenario [2] – pressure cleaner | 1 | 375 | 2.95E-01 | 0.1% | Yes |
| Scenario [3] – trigger spray | 1 | 375 | 6.41E-02 | <0.1% | Yes |

**Conclusion**

The exposure of **professional** is inferior to AEL or AEC:

* During mopping, if gloves are worn,
* During wiping (brush, wet cloth), if gloves and coated coverall are worn,
* During spraying with a pressure cleaner, if gloves and coated coverall are worn,
* During cleaning of spray equipment,
* During spraying with a trigger spray combined to wiping, if gloves are worn during wiping.

**Systemic effects – secondary exposure**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| Scenario [12] – Adults | 1 | 30 | 0,3 | 2.19E-02 | 7.3% | Yes |
| Scenario [13] – wet surfaces - adults | 1 | 30 | 0,3 | 4.10E-02 | 13.7% | Yes |
| Scenario [13] – dried surfaces - adults | 1 | 30 | 0,3 | 1.23E-02 | 4.1% | Yes |

The professional can be exposed by primary and secondary exposure. Therefore, the assessment of combined exposure (application; exposure to volatile residues and touching a treated surface) is performed:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL** | **AEL** | **Total  Estimated uptake (mg/kg bw/d)** | **Estimated uptake/ AEL (%)** | **Acceptable YES/NO** |
| Scenarios [1+12+13] mopping + secondary exposure (wet surfaces) | 1/no PPE | 30 | 0,3 | 2.11E+00 | **704.7%** | **No** |
| Scenarios [1+12+13] mopping + secondary exposure (wet surfaces) | 2/gloves (during mopping) | 30 | 0,3 | 2.45E-01 | 81.5% | Yes |
| Scenarios [1+12+13] mopping + secondary exposure (wet surfaces) | 2/gloves + coated coverall (during mopping) | 30 | 0,3 | 1.16E-01 | 38.7% | Yes |
| Scenarios [1+12+13] wiping (brush, wet cloth) + secondary exposure (wet surfaces) | 1/no PPE | 30 | 0,3 | 4.17E+00 | **1388.4%** | **No** |
| Scenarios [1+12+13] wiping (brush, wet cloth) + secondary exposure (wet surfaces) | 2/gloves (during wiping) | 30 | 0,3 | 4.26E-01 | **142.1%** | **No** |
| Scenarios [1+12+13] wiping (brush, wet cloth) + secondary exposure (wet surfaces) | 2/gloves + coated coverall (during wiping) | 30 | 0,3 | 1.69E-01 | 56.4% | Yes |
| Scenarios [2+4+12+13] spraying + cleaning equipment + secondary exposure (wet surfaces) | 1/no PPE | 30 | 0,3 | 1.09E+00 | **364.8%** | **No** |
| Scenarios [2+4+12+13] spraying + cleaning equipment + secondary exposure (wet surfaces) | 2/gloves (during spraying) | 30 | 0,3 | 5.56E-01 | **185.4%** | **No** |
| Scenarios [2+4+12+13] spraying + cleaning equipment + secondary exposure (wet surfaces) | 2/gloves + coated coverall (during spraying) | 30 | 0,3 | 1.96E-01 | 65.2% | Yes |
| Scenarios [3ab+12+13] spraying RTU + secondary exposure (wet surfaces) | 1/no PPE | 30 | 0,3 | 9.21E-01 | **307.1%** | **No** |
| Scenarios [3ab+12+13] spraying RTU + secondary exposure (wet surfaces) | 1/gloves during wiping | 30 | 0,3 | 1.08E-01 | 36.0% | Yes |

The exposure is inferior to AEL, for **professional**:

* During mopping, if gloves are worn,
* During wiping (brush, wet cloth), if gloves and coated coverall are worn,
* During application with a pressure cleaner, if gloves and coated coverall are worn during spraying
* During spraying with a trigger spray combined to wiping, if gloves are worn during wiping.

**Local effects:** According to the guidance on the BPR for human health[[18]](#footnote-19), a qualitative local risk assessment is performed, since meta SPC1 is classified H315 and H319:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Characteristics of the product** | | | | | **Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)** | | **Relevant RMM & PPE**  **Conclusion on risk** | |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | | Potential degree of exposure | |  |
| Low | Skin Irrit.2, H315 | - | 2&3 | Professionals | mixing and loading | Dermal | More than few minutes but equal to or less than few hours per day | | |  | | --- | | Controlled exposure | | | **Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following RMM:**  **- Minimisation of splashes and spills;**  **- Avoidance of contact with contaminated tools and objects;**  **PPE**  **Wear:**  **- Substance/ task appropriate gloves**  **- Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure)**  **- Chemical goggles** |
| Low | Eye Irrit.2, H319 | - | 2&3 | Professionals | mixing and loading | Dermal | More than few minutes but equal to or less than few hours per day | | Controlled exposure | |

The risk is acceptable with the following PPE: wear gloves, coverall and googles.

After dilution, no local effects are expected.

Conclusion:

The risk is acceptable for **professionals**:

* During mixing and loading if substance/ task appropriate gloves and protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure) and chemical goggles are worn. Moreover, minimisation of splashes and spills and avoidance of contact with contaminated tools and objects should occur,
* During mopping, if gloves are worn,
* During wiping (brush, wet cloth), if gloves and coated coverall are worn,
* During application with a pressure cleaner, if gloves and coated coverall are worn during spraying
* During spraying with a trigger spray combined to wiping, if gloves are worn during wiping.

***Risk for non-professional users***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| Scenario [6a] - m/l measuring cup | 1 | 30 | 0.3 | 1.30E-01 | 43.3% | Yes |
| Scenario [6b] - m/l direct transfer | 1 | 30 | 0.3 | 2.40E-03 | 0.8% | Yes |
| Scenario [7] - mopping/wiping (brush, wet cloth) | 1 | 30 | 0.3 | 3.30E-01 | **110.0%** | **No** |
| Scenario [8] – pressure cleaner | 1 | 30 | 0.3 | 1.21E+00 | **403.7%** | **No** |
| Scenario [9a] - trigger spray RTU | *1* | *30* | *0.3* | *3.69E-02* | *12.3%* | *Yes* |
| Scenario [9b] – wiping (brush, wet cloth) | *1* | *30* | *0,3* | *2.33E-03* | *0.8%* | Yes |
| Combined 9a and 9b | 1 | 30 | 0,3 | 3.92E-02 | 13.1% | Yes |
| Scenario [10] – cleaning equipment | 1 | 30 | 0.3 | 9.33E-03 | 3.1% | Yes |
| Scenario [11] – rinsing off | 1 | 30 | 0.3 | 2.33E-03 | 0.8% | Yes |

The exposure of non-professionals is inferior to AEL during mixing and loading, application by trigger spray and rinsing. The exposure of non-professionals for the other scenarios (mopping/wiping, application by pressure cleaner) are superior to AEL.

**Local effects (Chlorocresol)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated uptake**  **(mg a.s./m3)** | **Estimated uptake/ AEC (%)** | **Acceptable**  **(yes/no)** |
| Scenario [6] - Pouring | 1 | 0.7 | 1.20E-05 | <0.1% | Yes |
| Scenario [7] - Mopping/wiping | 1 | 0.7 | 1.80E-05 | <0.1% | Yes |
| Scenario [8] – pressure cleaner | 1 | 0.7 | 4.02E-01 | 57.4% | Yes |
| Scenario [9] – trigger spray RTU | 1 | 0.7 | 3.35E-02 | 4.785% | yes |

The exposure of non-professionals is inferior to AEC for all scenario.

The non-professionals can be exposed by primary and secondary exposure. Therefore, the assessment of combined exposure (application; exposure to volatile residues and touching a treated surface) is performed for the use “application with a trigger spray”:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL** | **AEL** | **Total  Estimated uptake (mg/kg bw/d)** | **Estimated uptake/ AEL (%)** | **Acceptable YES/NO** |
| Scenarios [9ab+11+12+15] spraying RTU + rinsing off + secondary exposure (wet surfaces) | 1 | 30 | 0,3 | 1.04E-01 | 34.8% | yes |

The systemic risk for non-professionals, applying the product with a trigger spray is acceptable.

**Local effects**

According to the guidance on the BPR for human health, a qualitative local risk assessment is performed, since meta SPC1 is classified H315 and H319:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Characteristics of the product** | | | | **Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)** | **Relevant RMM & PPE**  **Conclusion on risk** |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure |  |
| Low | Skin Irrit.2, H315 | - | 2&3 | Non-professionals | mixing and loading | Dermal | Equal to or less than one hour per day | **Acceptable with the following RMM\*:**   * **Liquid to be poured very close to the bucket to avoid projections.** * **The packaging must be easy to handle and limit splashes (adding a tap, handle, spout).** |
| Low | Eye Irrit.2, H319 | - | 2&3 | Non-professionals | mixing and loading | Dermal | Equal to or less than one hour per day |

\*The mixing and loading is needed for meta SPC 1. However, all uses of meta SPC 1 are unacceptable for non professional. Therefore, the local risk assessment is presented only for completeness.

**Conclusion:**

**Only application by trigger spray (meta SPC 2) is acceptable for non-professional.**

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| Scenario [12] – Adults | 1 | 30 | 0.3 | 2.19E-02 | 7.3% | Yes |
| Scenario [12] – Child (6 to <12 years old) | 1 | 30 | 0.3 | 4.11E-02 | 13.7% | Yes |
| Scenario [12] – Child (2 to <6 years old) | 1 | 30 | 0.3 | 5.31E-02 | 17.7% | Yes |
| Scenario [12] – Toddler (1 to <2 years old) | 1 | 30 | 0.3 | 6.56E-02 | 21.9% | Yes |
| Scenario [12] – Infant (<1 year old) | 1 | 30 | 0.3 | 5.53E-02 | 18.4% | Yes |
| Scenario [13] – wet surfaces - adults | 1 | 30 | 0.3 | 4.10E-02 | 13.7% | Yes |
| Scenario [13] – dried surfaces - adults | 1 | 30 | 0.3 | 1.23E-02 | 4.1% | Yes |
| Scenario [14] – wet surfaces, toddlers meta SPC1 | 1 | 30 | 0.3 | 1.39E+00 | **462.0%** | **No** |
| Scenario [14] – dried surfaces, toddlers meta SPC 1 | 1 | 30 | 0.3 | 4.16E-01 | **138.6%** | **No** |
| Scenario [14] – wet surfaces, toddlers Meta SPC 2 | 1 | 30 | 0.3 | 9.21E-01 | **307.0%** | **No** |
| Scenario [14] – dried surfaces, toddlers Meta SPC 2 | 1 | 30 | 0.3 | 2.76E-01 | 92.1% | yes |

**Conclusion**

The risk for adult and children exposed to volatile residues is acceptable.

The risk is acceptable for adults touching wet or dried surfaces after application.

The risk is unacceptable for toddlers crawling on wet or dried surfaces, treated with a product of meta SPC1.

Therefore the following RMM is proposed:

* Do not apply the product on surface in contact with children

The risk is unacceptable for toddlers crawling on wet surfaces, treated with a product of meta SPC2.

Therefore the following RMM is proposed:

* Children should not be in contact with the treated surfaces until complete drying.

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

Scenario [DRA-1]: Animals exposure for housing disinfection use

Not relevant as exposure negligible.

Scenario [DRA-2]: Indirect exposure (adult and children) via consumption of eggs contaminated after direct contact with treated surfaces

Indirect exposure via consumption of eggs was estimated in paragraph 2.2.6.2 and risk calculation are performed here below.

Estimated human exposure is then compared to dietary toxicological reference values. Indeed, acceptable daily intake (ADI) and acute reference dose (ARfD) are established at 0.3 mg as/kg bw/day (See paragraph 2.2.6.3). Risk for consumer via food represents only 8.9% of ADI for an adult.

As proposed by the applicant, EMA food basket has been considered to assess indirect exposure via food (100 g of eggs per day). EMA considers only adult chronic assessment, and it is understood that consumption data are worst case covering also large portions (used for acute risk assessment) and intake by children.

However, PRIMo rev.3.1 gives more precise consumption data, which allows covering large portions for adults as this represents a worst case compared to the EMA food basket:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Consumption g/person / day** | **Source** | **Maximum risk** |
| **Large portion adults** | 100 | EMA food basket | 8.9 % ARfD |
| **282** | **PRIMo rev. 3.1** | **25 % ARfD** |
| **Large portion children (a)** | 100 | EMA food basket | 54 % ARfD |
| **108** | **PRIMo rev. 3.1** | **58 % ARfD** |
| **Mean consumption adults** | **100** | **EMA food basket** | **8.9 % ADI** |
| 53 | PRIMo rev. 3.1 | 4.8 % ADI |
| **Mean consumption children (a)** | **100** | **EMA food basket** | **54 % ADI** |
| 11.8 | PRIMo rev. 3.1 | 6.4 % ADI |

1. For a 10 kg child.

This worst-case scenario allows to reasonably concluding that exceedances of ADI-ARfD for adults and children are not expected considering the intended uses. Indeed,

* Estimated eggs surface in contact with treated surfaces (0.02 m2 = 200 cm2 for 2 eggs = 100 cm2 per egg ; 10 cm2 would probably be more realistic)
* 100% transfer from treated surfaces to egg shells has been considered which is highly overestimated
* 100% transfer from eggs shell to inside of eggs has been considered
* Finally, no direct or extreme limited contact of eggs with treated surfaces is expected thanks to animal bedding.

Then, the intended uses are fully supported as no risk for consumers has been identified.

***Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product***

Not applicable

### Risk assessment for animal health

Risk for animal health is considered covered by scenario [14] for secondary exposure for meta SPC2. Risk is acceptable with the following RMM:

* Do not apply the treatment in the presence of domestic animals.
* Do not introduce domestic animals in housing until a total drying.

### Risk assessment for the environment

The products of the ORAPI CRESYL FAMILY are PT2 and PT3 disinfectants containing chlorocresol that are applied for the disinfection of indoor and outdoor domestic surfaces (PT2) and for the outdoor disinfection of small domestic animal housing (PT3).

No environmental SoCs were identified for the ORAPI CRESYL FAMILY (no substances classified for the environment, no biocidal substances from other PTs with a draft final CAR available, no ED or PBT) and no metabolites are formed that would need to be addressed in a risk evaluation for the environment. The following risk assessment is therefore carried out for the active substance only.

#### Effects assessment on the environment

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

No new environmental studies have been carried out with the products of the ORAPI CRESYL FAMILY. All data pertaining to the active substance is therefore derived from the CMK assessment report as well as additional studies carried out by the active substance supplier.

***Further Ecotoxicological studies***

In addition to the data set referenced in the CMK assessment report, the active substance supplier LANXESS has also carried out additional studies on earthworms and plants, with the purpose of refining the value of PNECsoil (the details of which can be found in the ORAPI CRESYL FAMILY IUCLID dossier). These additional studies are referenced in the following table.

**Summary table - Further ecotoxicological studies**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table of further ecotoxicological studies** | | | | | | | |
| **Method, Guideline, GLP status, Reliability** | Species/  Inoculum | End point | Exposure | | Results | Remarks | Refe-rence1 |
| Design | Dura-tion | Lowest NOEC |
| OECD 222 (2004) and ISO 11268-2 (2012) | *Eisenia fetida* | Reproduction, NOEC | Laboratory study, Nominal  concentrations in artificial soil. | 56 days | 6.8 mg a.s./kg soil dwt (6.0 mg a.s./kg soil ww) | Values considering normalisation of OC | Scheffczyk, A., 2015  IUCLID 9.2 (CMK) |
| ISO 22030 guideline (2005) | *Avena sativa,*  *Brassica rapa* | Seedling emergence, NOEC | Seedling  emergence and seedling growth test: laboratory  study Nominal  concentration in natural  soil. | 35 d (Brassica rapa)/46 days (Avena sativa) | 299 mg a.s./kg soil dw (265 mg a.s./kg soil ww) | Values considering normalisation of OC | Förster, B.,2015 IUCLID  9.2 (CMK) |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Further ecotoxicological studies** | |
| Value/conclusion | The lowest NOEC was determined with the reproduction endpoint (56d) from the earthworms study. With the application of an agreed AF of 10, the new PNECsoil value is 6.0/10 = 0.60 mg a.s./kg soil ww (WGIV2019\_ENV\_7-1). |
| Justification for the value/conclusion | This value has been discussed and agreed at WG IV 2019. |

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

No data available.

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

No data available.  
 ***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No data available.

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

No data available.

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

Indirect exposure: surface water, sediment, soil and groundwater via emission to the STP.

Direct exposure:

* soil and groundwater,
* surface water and sediment.

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

No data available.

***Leaching behaviour (ADS)***

No data available.

***Testing for distribution and dissipation in soil (ADS)***No data available.

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

No data available.

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

No data 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)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study is not required. |
| Justification | Due to the intended uses with spray:   * (use 4) spray indoor, or * (use 5) spray outdoor on small surfaces, material, equipment, furniture, or * (use 6) spray outdoor in small domestic animals housing,   Direct exposition of the surface water to overspray is unlikely, therefore an overspray study is not required. |

***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)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study is not required. |
| Justification | Due to the intended uses with spray:   * (use 4) spray indoor, or * (use 5) spray outdoor on small surfaces, material, equipment, furniture outdoors disinfection, or * (use 6) spray outdoor in small domestic animals housing,   Direct exposition of the bees to overspray is unlikely, therefore an overspray study is not required. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on PNEC values** | | | | |
| **PNECSTP** | **PNECwater** | **PNECsed** | **PNECsoil initial** | **PNECoral,birds** |
| [mg CMK/l] | [mg CMK/l] | [mg CMK/kgww] | [mg CMK/kgww] | [mg CMK/kg] |
| 0.57 | 0.015 | 0.0755 | 0.60 | 0.998 |

For the terrestrial compartment, the PNECsoil initially referenced in the CMK assessment report was 0.0479 mg a.s./kg ww. This value was refined to 0.60 mg a.s./kg ww based on the additional studies provided by the active substance supplier LANXESS and approved by MS in conclusions of the WGIV2019. It was also noted that the endpoint is an initial PNEC and need to be compared in the risk assessment with an initial PEC value. These studies are included in the ORAPI CRESYL FAMILY IUCLID dossier for future reference.

No ecotoxicological data was generated for sediment dwelling organisms. The PNEC value for this compartment was therefore derived through equilibrium partitioning. Therefore, the risk assessment for the surface water covers the risk for the sediment and no PEC value is presented for this compartment.

No PNEC value can be derived for the air compartment. However, based on the information from the CMK assessment report, air is not a compartment of concern.

A PNEC value was determined for birds for quantification purposes only. Considering the low BCF values, a risk characterisation of secondary poisoning was deemed not relevant as there is no concern for bioaccumulation.

#### Exposure assessment

The products of the ORAPI CRESYL FAMILY (the concentrate Cresyl Concentré, Meta SPC 1; and the RTU Cresyl PAE, Meta SPC 2) are PT2 and PT3 biocides.

The claimed uses and the scenarios covering each of them are presented in the following table:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Claimed use | PT | Description of the use (disinfected areas) | Products used | | Covered by |
| Cresyl Concentré (2.9% CMK)  META SPC 1 | Cresyl PAE (0.319% CMK)  META SPC 2 |  |
| Use 1 | PT2 | Indoor surfaces – Mop | X |  | Scenario 1 (Disinfection in institutional areas) |
| Use 2 | Outdoor surfaces – Brush | X |  | Scenario 2 (Urban, non-separate sewer system)  Scenario 3 (Urban, separate sewer system)  Scenario 4 (Rural) |
| Use 3 | Outdoor surfaces – Pressure washer | X |  | Scenario 2 (Urban, non-separate sewer system)  Scenario 3 (Urban, separate sewer system)  Scenario 4 (Rural) |
| Use 4 | Small indoor surfaces – Spray |  | X | Scenario 1 (Disinfection in institutional areas) |
| Use 5 | Small outdoor surfaces – Spray |  | X | Scenario 2 (Urban, non-separate sewer system)  Scenario 3 (Urban, separate sewer system)  Scenario 4 (Rural) |
| Use 6 | PT3 | Private domestic animal housing – Spray |  | X | Scenario 5: private domestic animal housing outdoor |

Use 1: PT2 disinfection of indoor surfaces: The product is applied by mopping for the disinfection of indoor domestic surfaces, such as cellars and indoor garbage storage areas.

Use 2 and 3: PT2 disinfection of outdoor surfaces: The product is applied with a brush or a pressure washer for the disinfection of outdoor surfaces surrounding households, such as terraces and low walls.

Use 4: PT2 disinfection of small indoor surfaces: The product is applied with a spray for the disinfection of indoor small surfaces, material, equipment and furniture in households and in institutions.

Use 5: PT2 disinfection of small outdoor surfaces:The product is applied with a spray for the disinfection ofoutdoorsmall surfaces, material, equipment and furniture outdoors.

Use 6: PT3 disinfection of private domestic animal housing: The products are applied with a spray for the disinfection of small domestic animal housing outdoors, such as a dog kennel, a rabbit hutch or a backyard chicken coop.

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT2 |
| Assessed scenarios | Scenario 1: PT2 disinfection of indoor surfaces  Scenario 2: PT2 disinfection of outdoor surfaces, urban area, non-separate sewer system  Scenario 3: PT2 disinfection of outdoor surfaces, urban area, separate sewer system  Scenario 4: PT2 disinfection of outdoor surfaces, rural area |
| ESD(s) used | Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC Scientific and Technical reports, 2011  Adaptation of the Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses, OECD n°18, 2008  Adaptation of the Emission scenario document for biocides used as masonry preservatives, EUBEES, 2002  Assessment of direct emission to surface water in urban areas (PT 6.2/6.3 and 7-10), UBA, 2014 |
| Approach | Scenario 1: Average consumption  Scenario 2: Average consumption  Scenario 3: Average consumption  Scenario 4: Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017).  Assessment report: Chlorocresol (CMK), Product-type PT2 (private area and public health area disinfectants and other biocidal products), April 2016.  Technical Agreements for Biocides v2.0, August 2018 |
| Groundwater simulation | Yes (FOCUS PEARL v.4.4.4 simulation for groundwater) |
| Confidential Annexes | Yes (tonnage data) |
| Life cycle steps assessed | Scenario 1, 2, 3, 4:  Production: No  Formulation of products: No  Use of products: Yes  Service life: No |
| Remarks | - |

|  |  |
| --- | --- |
| Assessed PT | PT3 |
| Assessed scenarios | Scenario 5: PT3 disinfection of private domestic animal housing outdoor |
| ESD(s) used | Adaptation of the Emission scenario document for biocides used as masonry preservatives, EUBEES, 2002 |
| Approach | Scenario 5: Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017).  Assessment report: Chlorocresol (CMK), Product-type PT3 (veterinary hygiene), April 2016.  Technical Agreements for Biocides v2.0, August 2018 |
| Groundwater simulation | Yes (FOCUS PEARL v.4.4.4 simulation for groundwater) |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 5:  Production: No  Formulation of products: No  Use of products: Yes  Service life: No |
| Remarks | - |

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

###### **PT2: disinfection of indoor surfaces**

**Scenario 1: average consumption**

|  |  |  |
| --- | --- | --- |
|  | Cresyl Concentré (2.9% w/w CMK) | Cresyl PAE (0.319% w/w CMK) |
| PT2 disinfection of indoor surfaces | YES (Mop) | YES (Spray) |

When the product is used for the disinfection of indoor PT2 surfaces, it is applied either by spray (for the ready to use product) or with a mop (for the concentrate product). After the disinfection process, the treated surfaces are rinsed with water, using a sponge or a mop. The main release pathway of the product is therefore to wastewater, which will then be emitted to the sewer system and STP.

The local emission of CMK to wastewater resulting from the disinfection of indoor surfaces was calculated using the scenario “Emission scenario for calculating the releases of disinfectants used for sanitary purposes” (ESD PT2, 2011). This model includes a tonnage-based and a consumption-based scenario.

As explained in the confidential annex, based on the break-even point, the “consumption-based” model should be used as the worst-case approach.

Products of the ORAPI CRESYL FAMILY can be applied by both professional and non-professional users. The table below provides input values for calculating the local emissions.

The concentration of the RTU product (Cresyl PAE) is 0.319% w/w of CMK. The concentration of the concentrate product (Cresyl Concentré) is 2.9% w/w of CMK but it is diluted at 7% in water. Therefore, its final concentration before release into the environment is 0.203% w/w CMK (considering a density of 0.999).

Thus, the worst-case product for this use is the RTU (Cresyl PAE) and it will be considered in the risk assessment.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario 1: PT2 disinfection of indoor surfaces | | | |
| **Consumption-based model inputs** | | | |
| Number of inhabitants feeding one STP [Nlocal] | 10 000 | cap | Default value (ESD PT2, 2011) |
| Fraction released to wastewater [Fwater] | 1 | - | Default value (ESD PT2, 2011) |
| Concentration of active substance in biocidal product [Cform] | 0.00319 | kg/L | RTU product (Cresyl PAE):   * 0.319% w/w CMK (worst-case) * Density ~1 |
| Consumption per capita, general purpose [Vform] | 0.007 | L/cap.d | Default value (ESD PT2, 2011) |
| Fraction of substance disintegrated during or after application (before release to the sewer system) [Fdis] | 0 | - | Default value (ESD PT2, 2011) |
| Penetration factor of disinfectant [Fpenetr] | 0.5 | - | Default value (TAB, 2017) |
| **Output** | | | |
| **Local emission to STP [Elocalwater]** | **1.12E-01** | kg/d |  |

###### **PT2: disinfection of outdoor surfaces**

For the disinfection of outdoor PT2 surfaces, the product is applied either by spray (for the ready to use product on small surfaces) or with a brush or high-pressure cleaner (for the concentrate product on surfaces). During the application outdoors, the product can reach the environment through drift and run-off. Then, the product is rinsed off with water, with either a sponge or a water hose and emissions can also occur during this phase.

According to the ESD for PT 10 (2002), two relevant locations can be differentiated:

* In the city (urban area), the product is likely to enter paved ground during application or rinsing phase to the sewer system subsequently reaching the sewage treatment plant (STP, scenario 2) or directly the surface water via direct rainwater discharge (scenario 3). The rinsing phase also covers the leaching by rain if the product is not rinsed.
* In the countryside (rural area), the product directly reaches the soil (scenario 4) after the application and the rinsing phase/rain event.

In ESD PT2, no scenario is currently available to calculate the environmental emissions of a product applied for the disinfection of outdoor surfaces such as terraces or low walls. For this use, active substance emissions were calculated by adapting the scenario for outdoor application of insecticides (ESD for PT18, 2008) as well as scenarios for masonry preservatives (ESD for PT10, 2002) to the use of the Cresyl products.

**Scenario 2: disinfection of outdoor surfaces - urban area, STP**

|  |  |  |
| --- | --- | --- |
|  | Cresyl Concentré (2.9% CMK) | Cresyl PAE (0.319% CMK) |
| PT2 disinfection of outdoor surfaces | YES (Brush or Pressure washer) | YES (Spray) |

In urban area, the emissions are directed to the sewage treatment plant (STP). Calculations were based on certain hypotheses and input values, which are detailed in the following paragraphs:

1. Treated surfaces size:

*House:*

A default use where a user disinfects a house terrace and surrounding low walls is assessed. For the walls, it is considered that the user disinfects the lower part of the walls surrounding the house up to 50 cm height from the bottom of the wall, as it is intended in the SPC. For the terrace, the harmonised parameters from the TAB are considered.

In houses that have a terrace, it is considered that both these surfaces can be treated simultaneously during a disinfection event. In houses that do not have a terrace, low walls treatment only are considered.

As a worst-case scenario, the following hypotheses are taken:

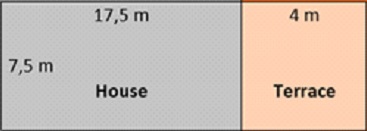
* Terrace: As a default value, it is considered that the terrace has a surface of **30 m²** (TAB v2.0, 2018). This corresponds to a 7.5 m x 4 m terrace, adjacent to the small side of the house (see Figure 1). It is assumed that the terrace is paved.
* Low walls (x4): As a worst-case value, it is considered that wall disinfection takes place all around the house, up to a height of 0.5 m. This corresponds to a treated area of 2 x (17.5 x 0.5 + 7.5 x 0.5) = **25 m²**. This surface area corresponds to the area indicated in the ESD for PT18 (2008) for outdoor application of insecticides against crawling insects.

Figure 1: Sizing of the house/terrace

* Total:

For houses with terrace: the emissions from all treated surface will reached the sewer: 25+ 30 = **55** **m²**.

For houses without terrace: the product is applied to low walls only and emissions are from **25 m²** of walls.

*Large building:*

A default use where a professional user disinfects the lower parts of a wall surrounding a larger building is assessed. For this type of building, the terrace is not considered.

* Low walls: The TAB v2.0 of 2018 indicates that the default surface for a “large building” is 609 m² (ENV 140). This corresponds to a 29 m x 21 m building. Assuming the outer walls of this building are disinfected up to 0.5 m, this corresponds to a treated area of 2 x (21 x 0.5 + 29 x 0.5) = **50 m²**.

1. Emission pathways:

As a worst case, it was considered that releases from application and rinsing arise the same day with 100% emissions at the day of application.

1. Simultaneity factor and number of building treated daily:

Simultaneity factor is a parameter that considers simultaneous emissions from several buildings and houses to a STP. It was calculated based on consumer’s behaviour. In practice, the disinfection of outer surfaces in houses and large buildings will not be performed on a regular basis, but according to the intended use, it will take place on average only once to twice a year.

Fsim = 2/365 = 0.00547 use/building or house/yr

*Houses:*

Environmental modelling considers a default city of 4000 houses, including 2500 houses possessing a terrace (TAB v2.0, ENV140, 2018). With a simultaneity factor of 0.00547, this means that 2500 x 0.00547 = ~**14** households owing a terrace can simultaneously use the product in a day. Concerning the rest of houses without a terrace, (4000-2500) x 0.00547 = ~**9** households low walls can be treated simultaneously.

*Large buildings:*

The TAB (v2.0, ENV140, 2018) indicates that the number of large buildings in a default city is 300. Based on this indication, 300 x 0.00547 = ~**2** large buildings will simultaneously emit product in a day.

As both emissions from houses and large buildings can occur simultaneously, local emissions from both these sources were summed.

1. Market penetration factor:

On the European market, products that are intended for such uses are not limited to chlorocresol-based biocides. Therefore, the consideration of a market penetration factor is relevant. For disinfectants used in private households, a default value of **0.5** can be used (TAB v2.0, ENV25, 2018) and for use in large building, this value can also be set to **0.5** as different types of building can be treated.

1. Worst-case dose and product:

The concentration of the RTU product (Cresyl PAE) is 0.319% w/w of CMK. The concentration of the concentrate product (Cresyl Concentré) is 2.9% w/w of CMK but it is diluted at 7% in water. Therefore, its final concentration before release into the environment is 0.203% w/w CMK (with a product density close to 1). Taking into account the intended application rates and the size of the treated surfaces of the respective products, the worst-case is the use of the Cresyl Concentré which covers the use of the product Cresyl PAE.

The application rate of 0.06 L product/m² claimed by the applicant is applied for the use of Crésyl Concentré by brush. However, it is not representative of a use with a pressure washer. Indeed, a simple research about devices sold on the market has shown that application of 12 L of product/m² can be applied in the case of pressure washer. Therefore, the risk assessment has been realised with both application rates.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Value** | | **Unit** | **Remarks** |
| **Brush** | **Pressure-washer** |
| Scenario 2: PT2 disinfection of outdoor surfaces, urban area | | | | |
| Quantity of active ingredient applied [Qai] | 1.22E-04 | 2.44E-02 | kg/m² | Diluted product (see 5.):   * Concentration = 0.203% w/w CMK (worst-case) * Density ~1 * Application rate :   For BRUSH = 0.06 L product/m²  For PRESSURE WASHER = 12 L product/m² |
| Disinfected surface [AREA]:  - house without a terrace (low walls)  - house with a terrace (low walls + terrace)  - large building (low walls) | 25  55  50 | | m² | See calculations of parameters above (1.) |
| Number of buildings disinfected daily [Nlocal]:  - houses without a terrace  - houses with a terrace  - large buildings | 9  14  2 | | /d | See calculations of parameters above (3.) |
| Fraction released to water [Fwater] | 1 | | - | Default value (ESD PT2, 2011) |
| Fraction of substance disintegrated during or after application, before release to the environment [Fdis] | 0 | | - | Default value (ESD PT2, 2011) |
| Market factor [Fmarket]:  -households uses  -large building (any type) | 0.5  0.5 | |  | (TAB v2.0, ENV140, 2018) |
| **Output** | | | | |
| **Houses without a terrace: Local emission to STP [Elocalwater]** | **1.37E-02** | **2.74E+00** | kg/d |  |
| **Houses with a terrace: Local emission to STP [Elocalwater]** | **4.69E-02** | **9.38E+00** | kg/d |  |
| **Large buildings: Local emission to STP [Elocalwater]** | **6.09E-03** | **1.22E+00** | kg/d |  |
|  | | | | |
| **Total (Houses without a terrace + Houses with a terrace + Large building) - Local emission to STP [Elocalwater]** | **6.67E-02** | **1.33E+01** | kg/d |  |

**Scenario 3: urban area, separate sewer system**

|  |  |  |
| --- | --- | --- |
|  | Cresyl Concentré (2.9% CMK) | Cresyl PAE (0.319% CMK) |
| PT2 disinfection of outdoor surfaces | YES (Brush or Pressure washer) | YES (Spray) |

Some cities have a separate sewer system, in which the wastewater and rainwater are collected in distinct canalisations. Wastewater is directed to a STP, while rainwater is emitted directly to surface water.

In such cities, the products that are used outside of houses will be collected by the rainwater sewer system, resulting in their direct emission to surface waters. For the PT2 outdoor surfaces disinfection use of the products of the family, the assessment of the risk to the surface water compartment in case of a separate sewer system is thus relevant.

The emitted quantity will be identical to that calculated for scenario 2 above, but it will be directed to the surface water compartment rather than to the STP.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Total (Houses without a terrace + Houses with a terrace + Large building) - Local emission to STP [Elocalwater]** | **6.67E-02** | **1.33E+01** | kg/d | See scenario 2 calculations |

**Scenario 4: rural area**

|  |  |  |
| --- | --- | --- |
|  | Cresyl Concentré (2.9% CMK) | Cresyl PAE (0.319% CMK) |
| PT2 disinfection of outdoor surfaces | YES (Brush or Pressure washer) | YES (Spray) |

In a rural area, product emissions are directed to the soil compartment.

1. Treated surfaces size:

*House:*

A default use where a user disinfects a house terrace and/or surrounding low walls is assessed. For the walls, it is considered that the user disinfects the lower part of the walls surrounding the house up to 50 cm height from the bottom of the wall as it is intended in the SPC. For the terrace, the harmonised parameters from the TAB are considered.

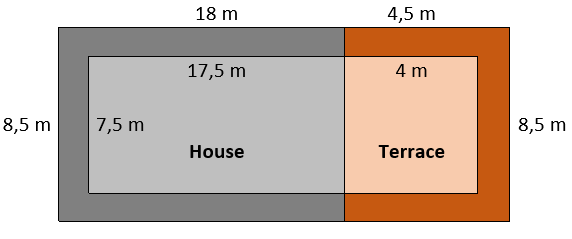
It is considered that both these surfaces can be treated simultaneously during a disinfection event. The worst-case emissions to soil are located around the terrace (at this location, the soil received the product used to treat one wall and the terrace. The receiving area of soil is represented by the brown area of the figure below).

Figure 2: Sizing of the house/terrace and of the soil area receiving the product

* Terrace: As a default value, it is considered that the terrace has a surface of **30 m²** (TAB v2.0, 2018). This corresponds to a 7.5 m x 4 m terrace, adjacent to the small side of the house. It is assumed that the terrace is paved.
* Low walls (x1): 7.5 x 0.5 = **3.75 m²**.
* Total: 3.75 + 30 = **33.75** **m²**.

*Large building:*

It is assumed that only houses are relevant for the rural area (i.e. the assessment of the houses covers large buildings, as the treated surfaces are proportional of the volume of the receiving compartment), therefore emissions of large building are assessed in urban context only.

1. Receiving compartment sizes:

Following the indications in the TAB (v2.0, ENV 153, 2018), it is considered that product emissions from the terrace will reach a 0.5 m band of soil surrounding the terrace (3 sides), and up to a 0.5 m soil depth.

* Soil surrounding a terrace (around three sides of the terrace): 8.5 (TAB v2.0, ENV154, 2018) x 0.5 = **4.25 m³**

1. Emission pathways:

The drift from façade rinsing reaches the volume of soil adjacent to the treated surface. Therefore, as a worst case, it is assumed that after the rinsing step, 100% of the product will be emitted to the soil adjacent to the treated surface during a disinfection event. No distinct assessment for application and rinsing was deemed necessary considering that only the lower parts of the walls are treated (0.5 m); therefore no Tier 2 is relevant for the application and emissions are directed to the adjacent soil only.

1. Worst-case doses and product:

The concentration of the RTU product (Cresyl PAE) is 0.319% w/w of CMK. The concentration of the concentrate product (Cresyl Concentré) is 2.9% w/w of CMK but it is diluted at 7% in water. Therefore, its final concentration before release into the environment is 0.203% w/w CMK (with a product density close to 1). Taking into account the intended application rates and the size of the treated surfaces of the respective products, the worst-case is the use of the Cresyl Concentré which covers the use of the product Cresyl PAE.

The application rate of 0.06 L product/m² claimed by the applicant is applied for the use of the Crésyl Concentré by brush. However, it is not representative of a use with a pressure washer. Indeed, a simple research about devices sold on the market has shown that application of 12L of product/m² can be applied in the case of pressure washer. Therefore, the risk assessment has been realised with both application rates.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Value** | | **Unit** | **Remarks** |
| **Brush** | **Pressure-washer** |
| Scenario 4: PT2 disinfection of outdoor surfaces, rural area | | | | |
| Quantity of active ingredient applied [Qai] | 1.22E-04 | 2.44E-02 | kg/m² | Diluted product (see 4.):   * Concentration = 0.203% w/w CMK (worst-case)   Density ~1   * Application rate :   For BRUSH = 0.06 L product/m²  For PRESSURE WASHER = 12 L product/m² |
| Area treated: [AREAwall+terrace] | 33.75 | | m² | TAB v2.0, 2018, ENV154,  ESDTP18, 2008  See calculations 1. |
| Soil volume receiving the product: [Vwall+terrace] | 4.25 | | m³ | See calculations 2. |
| Bulk density of wet soil [RHOsoil] | 1700 | | kgww/m³ | Default value (ESD PT18, 2008) |
| **Output** | | | | |
| **Local emission to soil surrounding a terrace, when terrace and walls are treated simultaneously [Elocalsoil-wall+terrace]** | **4.11E-03** | | **8.22E-01** | kg/d |

###### **PT3: disinfection of private domestic animal housing**

**Scenario 5: disinfection of private domestic dog kennel**

|  |  |  |
| --- | --- | --- |
|  | Cresyl Concentré (2.9% CMK) | Cresyl PAE (0.319% CMK) |
| PT3 disinfection of private domestic animal housing | NO | YES (Spray) |

The Cresyl products can be applied indoor or outdoor by non-professional by a ready to use spray for the disinfection of small domestic animal housing, such as a dog kennel, a rabbit hutch or a backyard chicken coop.

In a worst-case situation, the evaluated housing will be a dog kennel located outdoor in a backyard. Disinfected surfaces are the interior floor and interior walls. The application takes place on hard surfaces, and after a rinsing step, all product will therefore runoff through the kennel opening to the located soil in front of the kennel opening. Even if the treatment is realised with a spray, as it is located in the kennel, no drift phenomena is taken into account.

The use indoor is covered with PT2: disinfection of indoor surfaces, Scenario 1 average consumption.

Indeed, the PT2 emission scenario is based on average consumption data of detergents for surface cleaning collected from the population. It can thus be assumed that these data do not distinguish between the quantities of detergents/disinfectants used to clean, for example, the floor of the house or the cage of a pet.

1. Treated surface size:

For the risk assessment, a kennel of 1 x 1 x 1 meter is considered. These dimensions cover a kennel for a large dog. Surfaces to be disinfected are the kennel floor and interior walls.

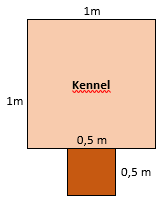


Figure 3: Sizing of a dog kennel and of the soil area receiving the product

* Kennel floor: The entire floor will be disinfected, which is a surface of 1 m².
* Kennel walls: Walls will be disinfected for a total surface of 4 m².

The total stable surface that is disinfected is **5 m²**.

1. Receiving compartment sizes:

As for scenario 4, it is considered that emissions can occur to a 0.5-meter band surrounding the emission point, and to a soil depth of 0.5 meter (considering a small scale application). It is considered that the kennel door has a width of 0.5 meters.

* Volume of the receiving compartment = (0.5\*0.5) \* 0.5 = **0.125** **m³**

Based on the previous data, environmental emissions for the scenario 5 are calculated with the following inputs.

1. Worst-case doses and product:

As only the ready to use product (Cresyl PAE) is claimed for this use, it will be assessed.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario 5: PT3 disinfection of private domestic animal housing | | | |
| Quantity of active ingredient applied [Qai] | 8.10 x 10-5 | kg/m² | RTU product (See 3.):   * Concentration = 0.319% w/w CMK * Application rate = 0.0254 L product/m² * Density ~1 |
| Area of the treated animal housing [AREA] | 5 | m² | See calculations above (1.) |
| Receiving soil volume [Vsoil] | 0.125 | m³ | See calculations above (2.) |
| Bulk density of wet soil [RHOsoil] | 1700 | kg ww/m³ | Default value (ESD PT18, 2008) |
| **Output** | | | |
| **Local emission to soil surrounding entrance [Elocalsoil-entrance]** | **4.05E-04** | kgww/d |  |

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

For indoor applications (scenario 1) and outdoor applications in urban areas where wastewater is directed to the sewer (scenario 2), the primary receiving compartment is the sewage treatment plant. After entering this compartment, a part of the active substance will be degraded. The remaining fractions of the active substance will then distribute into the environment.

For outdoor applications in urban areas having a separate sewer system (scenario 3), the primary compartment is surface water. The active substance then distributes between water and sediment.

For outdoor applications in a rural area (scenario 4 and scenario 5), the primary receiving compartment is the soil. From the soil, a fraction of the active substance can leach to the groundwater.

|  | STP | Freshwater | Air | Soil | Ground-water | Secondary poisoning |
| --- | --- | --- | --- | --- | --- | --- |
| Scenario 1: indoor surface | ++ | + | - | + | + | + |
| Scenario 2: outdoor surfaces, urban area, STP (Brush / Pressure washer) | ++ | + | - | + | + | + |
| Scenario 3: outdoor surfaces, urban area, separate sewer system (Brush / Pressure washer) | - | ++ | - | - | - | + |
| Scenario 4: outdoor surfaces, rural area (Brush / Pressure washer) | - | - | - | ++ | + | + |
| Scenario 5: outdoor surfaces, animal housing | - | - | - | ++ | + | + |

*++: direct exposure +: indirect exposure -: no exposure*

Input parameters for calculating the fate and distribution of the active substance in the environment were selected from the CMK assessment report (2017).

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 142.6 | g/mol | Revised AR of Chlorocresol (2017) |
| Vapour pressure (at 25°C) | 6 x 10-3 | Pa | Revised AR of Chlorocresol (2017) |
| Water solubility (at 20°C and pH=7) | 3.4 | g/l | Revised AR of Chlorocresol (2017) |
| Log Octanol/water partition coefficient | 2.73 | Log 10 | Updated Kow value provided by the a.s. supplier LANXESS (the initial value indicated in the CMK assessment of 2016 report was 3.02. In the revised AR of 2017, this value is 2.73) |
| Organic carbon/water partition coefficient (Koc) | 195.6 | l/kg | Revised AR of Chlorocresol (2017) |
| Henry’s Law Constant (at 12°C ) | 3.70 x 10-5 | Pa/m³/mol | The value from the revised AR of Chlorocresol (2017) is 5.87 x 10-5 Pa/m³/mol at 20°C. It has been corrected according equation 25 of the VolumeIV Part B+C (2017). |
| Biodegradability | Readily biodegradable(fulfilling the 10 day window) | - | Revised AR of Chlorocresol (2017) |
| DT50 for degradation in soil | 30 | d |  |
| k biosol | 2.31E-02 | /d | Calculations from Vol IV Part B+C (2017) |
| k volat (depth of 0.1 m\*) | 2.33E-06 | /d |
| k leach (depth of 0.1 m\*) | 7.91E-04 | /d |
| k total (depth of 0.1 m\*) | 2.39E-02 | /d |

\* For application of STP sludge on grassland

The fractioning of the actives substance between air, water, sludge and degradation is indicated in the following table.

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP** | | |
| **Compartment** | **Percentage [%]** | **Remarks** |
| Air | 1.36 x 10-5 | Simple Treat v4.0 |
| Water | 7.89 |
| Sludge | 1.78 |
| Degraded in STP | 90.32 |

***Calculated PEC values***

For the product uses leading to emissions to the station treatment plant (scenario 1 and 2) and directly to soil (scenario 4 and 5), the PECsoil initial (i.e. the concentration in soil just after the 10th annual application of sewage sludge) was calculated to take into account the fact that the PNEC value corresponds to an initial concentration in soil. Volume of soil considered are gathered in emission tables for each scenario.

Calculations were performed according to the ECHA Guidance Volume IV Part B+C (2017).

For the product uses leading to direct emissions to surface water (scenario 3), the PECwater was calculated based on the document “Assessment of direct emission to surface water in urban areas” (UBA, 2014). The PECsed was not calculated as risk for surface water compartment covers risk for sediment compartment.

For all scenarios that leads to emissions to groundwater, the resulting groundwater concentrations are higher than the threshold value of 0.1 µg/L. Thus, the FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment.

A summary of the calculated PEC values for each scenario and each environmental compartment is indicated in the following table.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated Elocal and associated PEC values** | | | | | | | | | |
|  |  | **Elocalwastewater** | **Elocalsurfacewater** | **Elocalsoil** |  | **PECSTP** | **PECwater** | **PECsoil INITIAL** | **PECGW** |
|  | [kg/d] | [kg/d] | [kg/d] | [mg/m3] | [mg/l] | [mg/kg ww] | [μg/l] |
| **INDIRECT EMISSIONS VIA STP** | | | | | | | | | |
| Scenario 1: indoor surface |  | 1.12E-01 | n.r | n.r |  | 4.40E-03 | 4.40E-04 | 3.70E-03 | **0.2** |
| Scenario 2: outdoor surfaces, urban area, STP | Brush | 6.67E-02 | n.r | n.r | 2.63E-03 | 2.63E-04 | 2.21E-03 | **0.1** |
| Pressure washer | 1.33E+01 | n.r | n.r | 5.26E-01 | 5.26E-02 | 4.42E-01 | **28.8** |
| **DIRECT EMISSIONS TO SURFACE WATER (SEPARATE SEWER SYSTEM)** | | | | | | | | | |
| Scenario 3: outdoor surfaces, urban area, separate sewer system | Brush | n.r | 6.67E-02 | n.r |  | - | 1.11E-02 | - | - |
| Pressure washer | n.r | 1.33E+01 | n.r | - | 2.22E+00 | - | - |
| **DIRECT EMISSIONS TO SOIL** | | | | | | | | | |
| Scenario 4: outdoor surfaces, rural area - Walls+terrace | Brush | n.r | n.r | 4.11E-03 |  | - | - | 5.69E-01 | **159.4** |
| Pressure washer | n.r | n.r | 8.22E-01 | - | - | 1.14E+02 | **31884.7** |
| Scenario 5: outdoor surfaces, animal housing |  | n.r | n.r | 4.05E-04 | - | - | 1.91E+00 | **534.2** |

n.r: not relevant

###### ***Primary and secondary poisoning***

Primary poisoning

Primary poisoning via the direct consumption of the product by birds and mammals is not likely to occur. For indoor applications, the product is not accessible for poisoning. In the case of the outdoor use, the Cresyl products are applied either as a spray or diluted solution, and are rinsed directly after application. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

Considering the low BCF values, a risk characterisation of secondary poisoning was deemed not relevant as there is no concern for bioaccumulation.

###### ***Groundwater***

FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment for scenario 1, 2, 4 and 5.

In scenario 1 and 2, groundwater is exposed indirectly by application of sewage sludge on grassland or agricultural land. As emissions from scenarios 1 and 2 can be aggregated, they are assessed together in a FOCUS Groundwater simulation as a worst-case.

In scenario 4 and 5, groundwater is exposed after direct releases into soil. Both of the scenarios are presented and assessed in the following tables.

For soil risk assessment of scenario 4, the emission due to the treatment of one wall and the terrace was considered in the Emission estimation section, as it is a worst case situation for the calculations of the PECsoil. For groundwater assessment, the emission due to the treatment of the entire house and the terrace is considered, as the totality of the product used can reach the groundwater compartment.

For this scenario, the Elocalsoil (4 walls+terrace) = [Qai] x [AREA4 walls+terrace]

= 1.22E-04 x 55

= 6.70E-03 kg/d/house.

|  |  |  |  |
| --- | --- | --- | --- |
| **Emissions to Groundwater : Input for refinement (FOCUS PEARL 4.4.4)** | | | |
| **Input parameters related to Active Substance** | | | |
|  | **Value** | | **Reference** |
| Molecular weight (g/mol) | 142.6 | | CAR CMK (2016) |
| Water solubility (g/l) at 20°C | 3.4 | | CAR CMK (2016) |
| Koc (L/kg) | 195.6 | | CAR CMK (2016) |
| Saturated vapour pressure (Pa) at 25°C | 6.00E-3 | | CAR CMK (2016) |
| DT50 in soil (d) at 12°C | 30 | | CAR CMK (2016) |
| Kom (=Koc/1.724) (L/kg) | 113.46 | | TAB 2.0 ENV 23 |
| 1/n | 1 | | TAB 2.0 ENV 22 |
| Plant uptake factor | 0 | | TAB 2.0 ENV 23 |
| Molar activation energy (kJ/mol) | 65.4 | | WGIV2019 |
|  | | | |
| **Input parameters related to Scenarios** | | | |
| **INDIRECT EXPOSURE – Scenario 1+2** | | | |
| Crop | Agricultural land (maize) | Grassland (alfalfa) | |
| Sewage sludge application rate (kg/ha) | 5000 kg/ha | 1000 kg/ha | |
| Number of applications/interval (d) | 1 sewage sludge application /yr | | |
| Application date | Relative application: 20 days before crop event “emergence” | Absolute application: 1st of March | |
| Incorporation depth (cm) | 20 | 10 | |
| Concentration of a.s. in dry sewage sludge, Csludge (mg/kg) | 4.02E+00 | 4.02E+00 | |
| Application rate (kg CMK/ha) | 2.01E-02 | 4.02E-03 | |
|  | | | |
| **DIRECT EXPOSURE – Scenario 4** | | | |
| Crop | Grassland (alfala) | | |
| Application date | Absolute application: 1st day of each month | | |
| Incorporation depth (cm) | Application to the soil surface | | |
| Elocalsoil (kg/d/house, considering the treatment of 4 walls and a terrace, see explanations above) | 6.70E-03 | | |
| Number of house per hectare | 16 | | |
| Number of application | 2 applications/yr | | |
| Number of house treated per month considering the number of application per year | 16 x 2 / 12 ~ 3 houses treated/month | | |
| Elocalsoil (kg/ha/month) to use in FOCUS simulation | 1.79E-02 | | |
|  | | | |
| **DIRECT EXPOSURE – Scenario 5** | | | |
| Crop | Grassland (alfalfa) | | |
| Application date | Absolute application: 1st day of each month | | |
| Incorporation depth (cm) | Application to the soil surface | | |
| Elocalsoil (kg/d/house, [see Emission scenario 5](#_Scenario_5:_disinfection)) | 4.05E-04 | | |
| Number of house per hectare | 16 | | |
| Number of application | 1 application/week | | |
| Number of house treated per month considering the number of application per week | 16 x 4 = 64 | | |
| Elocalsoil (kg/ha/month) to use in FOCUS simulation | 2.59E-02 | | |

The resulting groundwater concentrations are lower than the threshold value of 0.1 µg/L (See the Tables below).

|  |  |  |
| --- | --- | --- |
| **Emissions to Groundwater : PECgw in µg/L, (FOCUS PEARL 4.4.4)** | | |
| **Output** | | |
|  | | |
| **INDIRECT EXPOSURE – Scenario 1+2** | | |
| Crop | Agricultural land (maize) | Grassland (alfalfa) |
|  |  |  |
| CHATEAUDUN | 0.000097 | 0.0000040 |
| HAMBURG | 0.000679 | 0.0000300 |
| JOKIOINEN | n.c | 0.0000090 |
| KREMSMUENSTER | 0.000514 | 0.0000100 |
| OKEHAMPTON | 0.001652 | 0.0000310 |
| PIACENZA | 0.00035 | 0.0000210 |
| PORTO | 0.000033 | 0.0000040 |
| SEVILLA | 0.000001 | 0.0000000 |
| THIVA | 0.000004 | 0.0000000 |
|  | | |
| **DIRECT EXPOSURE – Scenario 4** | | |
| Crop | Grassland (alfalfa) | |
|  |  | |
| CHATEAUDUN | 0.000133 | |
| HAMBURG | 0.001528 | |
| JOKIOINEN | 0.000209 | |
| KREMSMUENSTER | 0.000434 | |
| OKEHAMPTON | 0.001414 | |
| PIACENZA | 0.001569 | |
| PORTO | 0.001402 | |
| SEVILLA | 0.000031 | |
| THIVA | 0.000028 | |
|  | | |
| **DIRECT EXPOSURE – Scenario 5** | | |
| Crop | Grassland (alfalfa) | |
|  |  | |
| CHATEAUDUN | 0.000192 | |
| HAMBURG | 0.002211 | |
| JOKIOINEN | 0.000302 | |
| KREMSMUENSTER | 0.000628 | |
| OKEHAMPTON | 0.002046 | |
| PIACENZA | 0.00227 | |
| PORTO | 0.002028 | |
| SEVILLA | 0.000045 | |
| THIVA | 0.000041 | |

n.c: not calculated

#### Risk characterisation

Concerning the atmosphere, no PNEC value was calculated as according to the CMK AR, it is not considered to be an environmental compartment of concern. The CMK assessment report indicates a half-life of 0.625 days in air and further states that “CMK should be rapidly degraded by photochemical processes and neither accumulation in the air nor transport over longer distances is expected”.

Thus, emissions to air from biocidal uses are not relevant*.*

A summary of the calculated PEC/PNEC values for each scenario and all other environmental compartments are indicated in the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **STP** | **Water** | **Soil** | **GW\* (µg/L)** |
| Scenario 1: indoor surfaces |  | 7.73E-03 | 2.94E-02 | 6.17E-03 | <0.1 |
| Scenario 2: outdoor surfaces, urban area, STP | Brush | 4.62E-03 | 1.75E-02 | 3.68E-03 | <0.1 |
| Pressure washer | 9.23E-01 | **3.51E+00** | 7.37E-01 | <0.1 |
| Scenario 3: outdoor surfaces, urban area, separate sewer system | Brush | n.r | 7.41E-01 | n.r | n.r |
| Pressure washer | n.r | **1.48E+02** | n.r | <0.1 |
| Scenario 4:  outdoor surfaces, rural area - Walls+terrace | Brush | n.r | n.r | 9.48E-01 | <0.1 |
| Pressure washer | n.r | n.r | **1.89E+02** | <0.1 |
| Scenario 5: outdoor surfaces, animal housing |  | n.r | n.r | **3.13E+00** | <0.1 |

n.r: not relevant

\*Concentration in groundwater calculated with FOCUS 4.4.4

Conclusions:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Claimed use | PT | Area of use | Products used | | Covered by | Acceptable risks |
| Cresyl Concentré (2.9% w/w CMK)  Meta-SPC 1 | Cresyl PAE (0.319% w/w CMK) Meta-SPC 2 |
| Use 1 | PT2 | Indoor surfaces - Mop | X |  | Scenario 1 (Disinfection in institutional areas) | YES |
| Use 2 | Outdoor surfaces - Brush | X |  | Scenario 2 (Urban, no separate sewer system)  Scenario 3 (Urban, separate sewer system)  Scenario 4 (Rural) | YES providing that a max. of 0.06 L/m2 of diluted product is applied |
| Use 3 | Outdoor surfaces - Pressure washer | X |  | Scenario 2 (Urban, no separate sewer system)  Scenario 3 (Urban, separate sewer system)  Scenario 4 (Rural) | NO (unacceptable risks for surface water and soil compartments) |
| Use 4 | Small indoor surfaces - Spray |  | X | Scenario 1 (Disinfection in institutional areas) | YES |
| Use 5 | Small outdoor surfaces - Spray |  | X | Scenario 2 (Urban, no separate sewer system)  Scenario 3 (Urban, separate sewer system)  Scenario 4 (Rural) | YES |
| Use 6 | PT3 | Private domestic animal housing - Spray |  | X | Scenario 5: private domestic animal housing outdoor | NO (unacceptable risks for soil).  YES with the proposed RMM : Never rinse the treated surfaces |

###### ***Primary and secondary poisoning***

Primary poisoning

Primary poisoning via the direct consumption of the product by birds and mammals is not likely to occur. For indoor applications, the product is not accessible for poisoning. In the case of the outdoor use, the Cresyl products are applied either as a spray or diluted solution, and are rinsed directly after application.

No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

Considering the low BCF values, a risk characterisation of secondary poisoning was deemed not relevant as there is no concern for bioaccumulation.

###### ***Groundwater***

Refined estimations of releases to groundwater (FOCUS 4.4.4, see section 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 all the uses.

***Mixture toxicity***

As no SoC was identified in the product, mixture toxicity assessment is not relevant.

***Aggregated exposure (combined for relevant emission sources)***



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

Dispersive uses leading to emissions to the station treatment plant were considered in the aggregated exposure assessment, such as use 1 (scenario 1: disinfection of indoor surfaces) and use 2 (disinfection of outdoor surfaces in urban environment – brush). As use 3 (disinfection of outdoor surfaces in urban environment – pressure washer) already presents unacceptable risks alone, it has not been considered in the aggregated exposure.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Scenarios | **ElocalSTP (kg/d)** | **ElocalSTP**  **(kg/d)** | **PEC/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsoil** | **PECGW**  **(µg/L)** |
| Scenario 1: indoor surface | 1.12E-01 | 1.78E-01 | 1.23E-02 | 4.69E-02 | 9.85E-03 | <0.1\* |
| Scenario 2: outdoor surfaces, urban area, STP (Brush) | 6.67E-02 |

\*See [Groundwater](#_Groundwater) section

Conclusion: Aggregated exposure of the use 1 (disinfection of indoor surfaces) and 2 (disinfection of outdoor surfaces in urban environment) leads to acceptable risks for the environment.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product family** |
| Acceptable risks are reached for the environment for:   * **META SPC1:**   + Use 1 (PT2): disinfection of indoor surfaces (including floors) in private and public areas   + Use 2 (PT2): disinfection of outdoor surfaces (low-walls up to 50 cm height from the bottom of the wall, terrace) twice a year by brush at an application rate not exceeding 60 mL of product/m². * **META SPC2:**   + Use 4 (PT2): disinfection of indoor small surfaces material, equipment and furniture   + Use 5 (PT2): disinfection of outdoor small outdoor surfaces and material, equipment furniture, twice a year at an application rate of 25 mL of product/m². * Use 6 (PT3): disinfection of private domestic animal housing once a week by spray and at an application rate of 25 mL of product/m², providing that treated surfaces are never rinsed after treatment when used outdoor.   Unacceptable risks are foreseen for the environment for:   * **META SPC1:**   + Use 3 (PT2): disinfection of outdoor surfaces (low-walls, terrace) twice a year by pressure washer considering that the application rate will be higher than 0.06 L/m2 (general pressure washer devices deliver around 12 L of product/m²). It presents risks for soil and surface water compartments. |

### Measures to protect man, animals and the environment

*See the SPC § 2.1*

### Assessment of a combination of biocidal products

*Non relevant*

### Comparative assessment

*Not relevant*

# Annexes[[19]](#footnote-20)

## List of studies for the biocidal product family

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Section No.** | **Author(s)** | **Year** | **Title**  **Source (laboratory)**  **Report No.**  **GLP; (un)published** | **Data protection (Yes/No)** | **Owner** |
| 3, 4 & 5 | Dr. E. Servajean | 2018 | Physical-chemical properties, stability and shelf-life of Cresyl concentré - PVE01802 Part 1 : Physical-chemical  properties upon receipt, after cold storage and after accelerated storage  PHYTOSAFE s.a.r.l.  17-99-102-ES  GLP; Unpublished | Yes | Orapi |
| 3, 4 & 5 | Dr. E. Servajean | 2018 | Physical-chemical properties, stability and shelf-life of Cresyl PAE - PVE01805  Part 1 : Physical-chemical properties upon receipt, after cold storage and after accelerated storage  PHYTOSAFE s.a.r.l.  17-99-103-ES  GLP; Unpublished | Yes | Orapi |
| 3 | Dr. Lienhard Mack | 2019 | Determination of the Particle Size Distribution and Storage Stability Tests for Cresyl PAE – PVE01805  BioGenius GmbH  AQ063-19  GLP; Unpublished | Yes | Orapi |
| 3 | Dr. E. Servajean | 2019 | Physical-chemical properties, stability and shelf-life of Cresyl PAE - PVE01805  Amendment to the final report  PHYTOSAFE s.a.r.l.  17-99-103-ES  GLP; Unpublished | Yes | Orapi |
| 3 | Dr. E. Servajean | 2019 | Physical-chemical properties, stability and shelf-life of Cresyl concentré - PVE01802  Part 2 (Interim): Shelf-life determination  PHYTOSAFE s.a.r.l.  17-99-102-ES  GLP; Unpublished | Yes | Orapi |
| 3 | Dr. E. Servajean | 2019 | Physical-chemical properties, stability and shelf-life of Cresyl PAE - PVE01805  Part 2 (Interim): Shelf-life determination  PHYTOSAFE s.a.r.l.  17-99-103-ES  GLP; Unpublished | Yes | Orapi |
| 4 | P. Neal | 2018 | Physical Hazard Analysis Testing on a Sample of PVE 01802 – CRESYL CONCENTRE  DEKRA  GLP3016003156BR1V1/2018  GLP; Unpublished | Yes | Orapi |
| 4 | P. Neal | 2018 | Physical Hazard Analysis Testing on a Sample of PVE 01805 – CRESYL PAE  DEKRA  GLP3016003156AR1V1/2018  GLP; Unpublished | Yes | Orapi |
| 4 | P. Neal | 2018 | Repeat DSC Testing on a Sample of PVE 01805 – CRESYL PAE  DEKRA  GLP3016003156A1R1V1/2018  GLP; Unpublished | Yes | Orapi |
| 5 | Dr. E Servajean | 2019 | Physical-chemical properties, stability and shelf-life of Cresyl Concentré - PVE01802  Amendment No.1 : Analytical methods for the determination of m-cresol and 1-methoxy-2-propanol in the test item  Phytosafe s.a.r.l  17-99-102-ES  GLP; Unpublished | Yes | Orapi |
| 5 | Dr. E Servajean | 2019 | Physical-chemical properties, stability and shelf-life of Cresyl PAE - PVE01805  Amendment No.1 : Analytical methods for the determination of m-cresol and 1-methoxy-2-propanol in the test item  Phytosafe s.a.r.l  17-99-103-ES  GLP; Unpublished | Yes | Orapi |
| Section 6 | M. Rech, T. Gerharz | 2017 | Determination of the bactericidal efficacy of L16.06.02 in accordance with DIN EN 1276 :2010-01 (dirty conditions)  LANXESS Deutschland GmbH  D 2017-08.14  Non GLP; Unpublished | Yes | Orapi |
| Section 6 | M. Rech, T. Gerharz | 2017 | Determination of the fungicidal efficacy of L16.06.02 in accordance with DIN EN 1650:2008 + A1:2013 (dirty conditions)  LANXESS Deutschland GmbH  D 2017-08.16  Non GLP; Unpublished | Yes | Orapi |
| Section 6 | M. Rech | 2016 | Determination of the bactericidal and fungicidal efficacy of Cresyl L16.06.02 on non-porous surfaces in accordance with DIN EN 13697:2015 (dirty conditions)  LANXESS Deutschland GmbH  D 2016-01.8  Non GLP; Unpublished | Yes | Orapi |
| Section 6 | M. Rech, T. Gerharz | 2017 | Determination of the bactericidal efficacy of L16.06.02 in accordance with DIN EN 1656:2010-03 (dirty conditions)  LANXESS Deutschland GmbH  D 2017-08.19  Non GLP; Unpublished | Yes | Orapi |
| Section 6 | M. Rech, T. Gerharz | 2017 | Determination of the fungicidal efficacy of L16.06.02 in accordance with DIN EN 1657:2016 (dirty conditions)  LANXESS Deutschland GmbH  D 2017-08.21  Non GLP; Unpublished | Yes | Orapi |
| Section 6 | M. Rech | 2016 | Determination of the bactericidal efficacy of Cresyl L16.06.02 on non-porous surfaces in accordance with DIN EN 14349:2012  LANXESS Deutschland GmbH  D 2016-01.2  Non GLP; Unpublished | Yes | Orapi |
| Section 6 | S. Morot-Bizot, G. Herbein | 2018 | Determination de l’activité bactericide du produit “CRESYL CONCENTRE” selon la norme EN 16437  Apex Bio Solutions  307B25-2017  Non GLP ; Unpublished | Yes | Orapi |
| 6 | M. Rech, T. Gerharz | 2019 | Determination of the yeasticidal efficacy of L16.06.02 on non-porous surfaces in accordance with DIN EN 16438:2014 (dirty conditions)  LANXESS Deutschland GmbH  D 2017-08.26  Non GLP; Unpublished | Yes | Orapi |
| 6 | S. Morot-Bizot | 2019 | Determination de l'activite bactericide et levuricide du produit Cresyl selon la norme EN 13697  APEX BIOSOLUTIONS  042B02-2019-02  Non GLP ; Unpublished | Yes | Orapi |
| 6 | S. Morot-Bizot | 2019 | Determination de l'activite bactericide et levuricide du produit Cresyl selon la norme EN 13697  APEX BIOSOLUTIONS  042B02-2019  Non GLP ; Unpublished | Yes | Orapi |
| 6 | S. Morot-Bizot | 2020 | Determination de l'activite bactericide et levuricide du produit Cresyl selon la norme EN 13697  APEX BIOSOLUTIONS  042B02-2019-ADDENDUM  Non GLP ; Unpublished | Yes | Orapi |
| Section 6 | F. Richeux | 2018 | Assessment of the skin sensitisation potential in the mouse using the local lymph node assay (LLNA:BrdU)  PHYCHER BIO DEVELOPPEMENT  LLNA:BrdU-PH-17/0563  GLP ; Unpublished | Yes | Orapi |

## Output tables from exposure assessment tools

## New information on the active substance

In addition to the data set referenced in the CMK assessment report, the active substance supplier LANXESS has also carried out additional studies on earthworms and plants, with the purpose of refining the value of PNECsoil (the details of which can be found in the ORAPI CRESYL FAMILY IUCLID dossier). These additional studies are referenced in the following table.

**Summary table - Further ecotoxicological studies**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table of further ecotoxicological studies** | | | | | | | |
| **Method, Guideline, GLP status, Reliability** | Species/  Inoculum | End point | Exposure | | Results | Remarks | Refe-rence1 |
| Design | Dura-tion | Lowest NOEC |
| OECD 222 (2004) and ISO 11268-2 (2012) | *Eisenia fetida* | Reproduction, NOEC | Laboratory study, Nominal  concentrations in artificial soil. | 56 days | 6.8 mg a.s./kg soil dwt (6.0 mg a.s./kg soil ww) | Values considering normalisation of OC | Scheffczyk, A., 2015  IUCLID 9.2 (CMK) |
| ISO 22030 guideline (2005) | *Avena sativa,*  *Brassica rapa* | Seedling emergence, NOEC | Seedling  emergence and seedling growth test: laboratory  study Nominal  concentration in natural  soil. | 35 d (Brassica rapa)/46 days (Avena sativa) | 299 mg a.s./kg soil dw (265 mg a.s./kg soil ww) | Values considering normalisation of OC | Förster, B.,2015 IUCLID  9.2 (CMK) |

## Summaries of the efficacy studies

Please refer to the IUCLID dossier.

## Confidential annex

Please refer to the separate confidential annex.

1. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-2)
2. 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-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. 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-5)
5. Gestis database: <http://limitvalue.ifa.dguv.de/> [↑](#footnote-ref-6)
6. Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure: Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017. [↑](#footnote-ref-7)
7. Recommendation no. 2 of the BPC Ad hoc Working Group on Human Exposure: Professional Mopping and Wiping Time Used for cleaning Hard Surfaces (PT2), March 2014. [↑](#footnote-ref-8)
8. Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products, May 2017. [↑](#footnote-ref-9)
9. HEEG opinion Default protection factors for protective clothing and gloves (agreed in TM I 2010), 2010 [↑](#footnote-ref-10)
10. Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure: Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017. [↑](#footnote-ref-11)
11. ECHA - Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) - 6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products. December 2017 [↑](#footnote-ref-12)
12. Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) -5. Guidance on Estimating dietary risk from tranqfer of biocidal active substances into foods – Non professional uses [↑](#footnote-ref-13)
13. Bonnet Y., Mongin P.Mesure de la surface de l'oeuf. 1965. Vols. Annales de ootechnie, INRA/EDP Sciences, 1965, 14 (4), pp.311-317, HAL Id: hal-00886852.

    https://hal.archives-ouvertes.fr/hal-00886852/document. [↑](#footnote-ref-14)
14. According to EMA food basket, it is assumed that the average person consumes, on a daily basis, 500 g of meat (made up of 300 g of muscle, 100 g of liver, 50 g of kidney and 50 g of fat) together with 1.5 L of milk and **100 g of eggs**. [↑](#footnote-ref-15)
15. According to EMA food basket, it is assumed that the average person consumes, on a daily basis, 500 g of meat (made up of 300 g of muscle, 100 g of liver, 50 g of kidney and 50 g of fat) together with 1.5 L of milk and **100 g of eggs**. [↑](#footnote-ref-16)
16. EMEA/MRL/074/96-FINAL March 1996 : Committeee for veterinary medicinal products – Summary report : Chlorocresol (4-chloro-3-methylphenol) [↑](#footnote-ref-17)
17. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=901> [↑](#footnote-ref-18)
18. Guidance on the Biocidal Products Regulation ,Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0 December 2017 [↑](#footnote-ref-19)
19. 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-20)