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

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

(submitted by the evaluating Competent Authority)



PHENOGEN

Product type 3

Chlorocresol and lactic acid

Case Number in R4BP: BC-DV051147-24

Evaluating Competent Authority: France

Date: 06/2022

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# CONCLUSION

France, as rMS, received an application from SYNTHESE ELEVAGE SARL for national authorisation for the biocidal product PHENOGEN.

The biocidal product contains chlorocresol and L(+) lactic acid and is intended to be used by professional users for the following uses:

* Intended Use 1 (PT3): Disinfection of livestock animal housings and equipments including hatcheries against bacteria (including *Salmonella enterica*), yeasts, fungi and virus (including Influenza virus, Porcine reproductive and respiratory syndrome virus, Duck parvovirus and African swine fever virus)
* Intended Use 2 (PT3): Disinfection of livestock animal housings and equipments against *Cryptosporidium parvum* oocystes,
* Intended Use 3 (PT3): Disinfection of animal transportation vehicles against bacteria, virus, fungi and yeasts.
* **Conclusion of the physical and chemical properties**

Physical and chemical properties of the product PHENOGEN have been described and are considered acceptable for a soluble concentrate for the intended uses.

Analytical methods are considered acceptable.

The long term storage procedure (24 months at 20 ± 2°C) in the commercial packaging is currently ongoing and the final results are required in post-authorization.

* **Conclusion of the efficacy**

The product PHENOGEN, has shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy and EN 14885:2015 standard – Assessment and Evaluation (Parts B+C) for the following uses:

* Use 1: Disinfection of livestock animal housing and equipment (including hatcheries) (PT3) with clean conditions, on porous and non-porous surfaces:
  + - Mandatory target organisms:
      * Bacteria (including *Salmonella enterica*), yeasts and fungi: 1.40% v/v, 30 min, 10 °C
    - Other target organisms:
      * Virus (including Influenza virus, Porcine reproductive and respiratory syndrome virus, Duck parvovirus and African swine fever virus): 1.40% v/v, 30 min, 10 °C
* Use 2: Disinfection of livestock animal housing and equipment (PT3) with clean conditions, on non-porous surfaces:
  + - Target organism:
      * Oocyste (*C. parvum*): 3 % v/v, 120 min, 10 °C
* Use 3: Disinfection of animal transportation vehicles (PT3) with clean conditions, on non-porous surfaces:
  + - Mandatory target organisms:
      * Bacteria, yeasts and virus: 2% v/v, 5 min, 10 °C
    - Other target organisms:
      * fungi: 2% v/v, 5 min, 10 °C
* **Substances of concern (SoCs)**

One co-formulant included in the product was identified as substance of concern for human health: propan-2-ol.

* **Conclusion on the risk for human health**

***Professional users***

For the use #1, the risk is acceptable for human health considering the wearing of gloves and coated coverall of 20% during mixing/loading and application and the following RMMs:

* Do not touch before total drying of surface,
* Only use the hatchery materials after their complete drying;
* Minimisation of manual phases.

Due to the corrosive properties of the product, a substance/task appropriate respirator and chemical goggles are required during the mixing and loading phase.

For the use #2, the risk is acceptable for human health considering the wearing of gloves, a coated coverall of 5% and a respiratory mask APF4 during mixing/loading and application and the following RMM:

* Do not touch before total drying of surface;
* Minimisation of manual phases.

Due to the corrosive properties of the product, chemical goggles are required during the mixing and loading phase.

For the use “3, the risk is acceptable for human health considering the wearing of gloves, coated coverall of 10% and a respiratory mask APF4 during mixing/loading and application and the following RMM:

* Do not touch before total drying of surface;
* Minimisation of manual phases.

Due to the corrosive properties of the product, chemical goggles are required during the mixing and loading phase.

***General public***

Exposure in transport vehicles (use 3) is considered not relevant for adults (non-professionals) and children.

For general public, for the uses #1 and #2, the risk is acceptable for adults when touching wet surfaces after spraying for animal surfaces/equipment (1.4% v/v) and dried surfaces after spraying for animal surfaces/equipment (3% v/v). The following RMM is necessary for dilution 3% v/v:

* Do not touch before total drying of surface.

The risk is not acceptable for chlorocresol for toddlers crawling on animal surfaces or touching equipments on wet or dried surfaces. Therefore the following RMM is proposed:

* Do not apply the product on surface in contact with children.
* **Conclusion on the risk for consumer under indirect exposure via food**

Regarding the intended uses on PT 3 in poultry hatcheries, no residues in food of animal origin might be expected based on instruction for use and proposed risk mitigation measures.

For the disinfection of equipment and livestock animal housing (cattle, pigs, poultry) and animal transportation vehicles, residues in food of animal origin might be expected.

Based on the endogenous production of L(+) lactic acid and the authorized uses of this active substance as food additive (E 270), significant indirect exposure via food for intended uses is not expected.

For chlorocresol, the scenarios and default values defined in European guidance document[[1]](#footnote-2) were used. Experimental studies provided in the CAR of chlorocresol to assess residue in livestock tissues were used to refine livestock exposure. Therefore, based on experimental studies and proposed risk mitigation measured, it can be reasonably concluded that residues in food of animal origin will be lower than 0.01 mg/kg and that default MRL[[2]](#footnote-3) of 0.01 mg/kg will not be exceeded. Dietary risk assessment for consumers is therefore not required.

* **Conclusion on the risk for the animal health**

For application on transport vehicles and animal surfaces, the risk is acceptable with the following RMM:

* Do not apply the treatment in the presence of animals.
* Do not introduce animals in housing/transport vehicles until a total drying.
* **Conclusion on the risk for the environment**

Acceptable risks are reached for the environment for:

* Use 1 (PT3): Disinfection of livestock animal housing and equipment including hatcheries against bacteria, yeasts, fungi and virus,
* Use 2 (PT3): Disinfection of livestock animal housing and equipment (except the ceiling) against *Cryptosporidium parvum* oocysts,
* Use 3 (PT3): Disinfection of animal transportation vehicles against bacteria, yeasts, fungi and virus.

***ED assessment:***

An assessment of endocrine disruption (ED) properties of co-formulants in PHENOGENhas been performed by FR-CA. None of the co-formulants contained in the product PHENOGEN are identified as endocrine disruptors.

**General conclusion**

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product PHENOGEN is reported in the table below, for each use:

|  |  |  |  |
| --- | --- | --- | --- |
| **Target organism** | **Application rates** | **Use conditions** | **Conclusions** |
| * Bacteria (including *Salmonella enterica*) * Yeasts * Fungi * Virus (including Influenza virus, Porcine reproductive and respiratory syndrome virus, Duck parvovirus and African swine fever virus) | 1.4 % v/v | Use 1: Disinfection of livestock animal housings and equipments including hatcheries  Spraying after dilution  Professional users | Acceptable |
| * *Cryptosporidium parvum* (oocystes) | 3 % v/v | Use 2: Disinfection of livestock animal housings (except the ceiling) and equipments  Spraying after dilution  Professional users | Acceptable |
| * Bacteria * Yeasts * Fungi * Virus | 2 % v/v | Use 3: Disinfection of animal transportation vehicles  Spraying after dilution  Professional users | Acceptable |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| PHENOGEN | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | SYNTHESE ELEVAGE SARL |
| **Address** | Rue Marie Curie, 35137 Pleumeleuc, France |
| **Authorisation number** | FR-2022-0050 | |
| **Date of the authorisation** | 20/06/2022 | |
| **Expiry date of the authorisation** | 19/06/2032 | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | HYDRACHIM |
| **Address of manufacturer** | Route de Saint Poix,  35370 Le Pertre  France |
| **Location of manufacturing sites** | Route de Saint Poix,  35370 Le Pertre  France |
|  | ZA La Pointe  35380 Plélan le Grand  France |

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

|  |  |
| --- | --- |
| **Active substance** | L-(+)-lactic acid |
| **Name of manufacturer** | Jungbunzlauer S.A. |
| **Address of manufacturer** | Z.I. et Portuaire B.P. 32,  67390 Marckolsheim  France |
| **Location of manufacturing sites** | Z.I. et Portuaire B.P. 32,  67390 Marckolsheim  France |

|  |  |
| --- | --- |
| **Active substance** | L-(+)-lactic acid |
| **Name of manufacturer** | Purac Biochem bv |
| **Address of manufacturer** | Arkelsedijk 46  4206 AC Gorinchem  The Netherlands |
| **Location of manufacturing sites** | Arkelsedijk 46  4206 AC Gorinchem  The Netherlands |

|  |  |
| --- | --- |
| **Active substance** | Chlorocresol |
| **Name of manufacturer** | Lanxess Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1,  50569 Köln  Germany |
| **Location of manufacturing sites** | Lanxess Deutschland GmbH,  47829 Krefeld  Germany |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | L(+) lactic acid |
| **IUPAC or EC name** | (S)-2-hydroxypropanoic acid |
| **EC number** | 201-196-2 |
| **CAS number** | 79-33-4 |
| **Index number in Annex VI of CLP** | - |
| **Minimum purity / content** | 95.5% w/w |
| **Structural formula** | C3H6O3  **Résultat de recherche d'images pour "acide L lactique"** |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | p-chloro-m-cresol |
| **IUPAC or EC name** | 4-Chloro-3-methylphenol |
| **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** | C7H7ClO |

#### Candidate(s) for substitution

Neither L-lactic acid nor chlorocresol are candidates for substitution.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| L(+) Lactic acid (technical, ≥95.5%) | (S)-2-hydroxypropanoic acid | Active substance | 79-33-4 | 201-196-2 | 22.00 |
| Chlorocresol (technical, ≥99.8%) | 4-chloro-3-methylphenol | Active substance | 59-50-7 | 200-431-6 | 18.50 |
| Propan-2-ol | Propan-2-ol | Solvent | 67-63-0 | 200-661-7 | 18.00 |

#### Information on technical equivalence

The source of the active substance chlorocresol from Lanxess is the same as the one evaluated for inclusion in the Union list of approved active substances.

The source of the active substance L-lactic acid from Purac Biochem is the same as the one evaluated for inclusion in the Union list of approved active substances.

The source of the active substance L-lactic acid from Jungbunzlauer S.A. is considered technically equivalent compared to the reference source (Decision number: TAP-D-1403137-31-00/F).

#### 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 propan-2-ol 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

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

However, one co-formulant show indications of endocrine activity (refer to confidential annex).

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

See the Confidential annex.

#### Type of formulation

|  |
| --- |
| SL: soluble concentrate |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Flam. Liq. 3, H226  Skin Corr. 1C, H314  Skin Sens. 1, H317  Eye Dam. 1, H318 |
| Hazard statement | H226: Flammable liquid and vapour  H314: Causes severe skin burns and eye damage.  H317: May cause an allergic skin reaction.  H318: Causes serious eye damage. |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H226: Flammable liquid and vapour  H314: Causes severe skin burns and eye damage.  H317: May cause an allergic skin reaction. |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  P260: Do not breathe vapours/spray.  P264: Wash … thoroughly after handling.  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.  P362+P364: Take off contaminated clothing and wash it before reuse.  P304 + P340: If INHALED: Remove person to fresh air and keep comfortable for breathing.  P310: Immediately call a POISON CENTER/doctor/...  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.  P403 + P235: Store in a well-ventilated place. Keep cool.  P501: Dispose of contents/container in accordance with national regulation. |
|  | |
| Note | EUH071 Corrosive to the respiratory tract. |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Disinfection of livestock animal housing and equipment

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of equipment and livestock animal housing (cattle, pigs and poultry) and disinfection of surfaces in hatcheries such as premises (rooms) and equipment (hatchers, trolleys, hatching baskets). |
| **Target organism (including development stage)** | Bacteria, including *Salmonella enterica*  Yeasts  Fungi  Virus, including Influenza virus (H1N1), porcine reproductive and respiratory syndrome virus (PRRS virus), duck parvovirus, African swine fever virus (ASFV) |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying on surfaces after dilution |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria (including *Salmonella enterica*), yeasts and fungi: 1.40% v/v, contact time 30 min, 10°C   Other target organisms:   * Virus (including Influenza virus, Porcine reproductive and respiratory syndrome virus, Duck parvovirus and African swine fever virus): 1.40% v/v, contact time 30 min, 10°C   Application rate: 100-200 mL of diluted product/m2, in hatcheries, use 100-150 mL/m².  Frequency: as needed depending on the animal species. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE Bottle, Jerrycan, Drum or IBC (1, 5, 20, 60, 220 or 1000L) |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).  * Wear a protective coverall (at least type 6) during product handling phase. * Wear appropriate respirator due to the corrosive properties of the product during mixing and loading. * For poultry hatcheries disinfection:   + Do not apply the treatment in the presence of poultry and eggs.   + Only use the hatchery materials after their complete drying.   + Always place a sheet of Kraft paper into the hatching baskets and transport crates before their reuse. |

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

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| - |

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

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| - |

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

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| --- |
| - |

#### Use description

Table 2. Use # 2 – Disinfection of livestock animal housing and equipment, against *Cryptosporidium parvum* oocysts

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of equipment and livestock animal housing (cattle, pigs and poultry), against *Cryptosporidium parvum* oocysts, all surfaces except the ceiling |
| **Target organism (including development stage)** | *Cryptosporidium parvum* oocysts |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying on non-porous surfaces after dilution |
| **Application rate(s) and frequency** | Use a 3% v/v diluted solution  Contact time: 120 minutes  Temperature: 10°C  Application rate: 200 mL of diluted product/m2  Frequency: as needed depending on the animal species. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE Bottle, Jerrycan, Drum or IBC (1, 5, 20, 60, 220 or 1000L) |

#### Use-specific instructions for use

|  |
| --- |
| * Do not apply on ceiling. * Apply only on non-porous surfaces. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Wear respiratory mask (at least APF 4) during mixing/loading and application.Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).Wear a protective coverall (at least type 4) during product handling phase. |

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

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| - |

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

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| --- |
| - |

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

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| --- |
| - |

#### Use description

Table 3. Use # 3 – Disinfection of animal transportation vehicles

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi  Virus |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying on surfaces after dilution |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeasts and virus: 2% v/v, contact time 5 min, 10°C   Other target organisms:   * fungi: 2% v/v, contact time 5 min, 10°C   Application rate: 125 mL of diluted product/m2  Frequency: as needed depending on the animal species. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE Bottle, Jerrycan, Drum or IBC (1, 5, 20, 60, 220 or 1000L) |

#### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Wear respiratory mask (at least APF 4) during mixing/loading and application.Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).Wear a protective coverall (at least type 6) during product handling phase. |

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

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| - |

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

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| --- |
| - |

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

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### General directions for use

#### Instructions for use

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| * 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.). * Clean carefully the surfaces before application of the product. |

#### Risk mitigation measures

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| Wear chemical goggles during mixing and loading.Minimisation of manual phases (concentrated product)Keep uninvolved persons away from treated surfaces/areas until dried.Avoid contact to treated surfaces/areas, in particular by children.Only use in empty animal housing.Animals should be kept away from treated areas until surfaces are dry.In treated animal housings and transport vehicles, chicks are only to be housed on litter and/or chickpaper. |

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

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| * IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. * IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. * IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with soap and water for 15 minutes. Call a POISON CENTRE or a doctor. * IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. * Keep the container or label available. |

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

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

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

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| * Always store in original packaging. * Keep the container tightly closed in a dry and well-ventilated place. * Keep away from sources of ignition, heat and direct sunlight. * Do not store near food, drink and animal feedingstuffs. * Shelf-life: 24 months. |

### Other information

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### Packaging of the biocidal product

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| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 1 L | Opaque HDPE (High density polyethylene) | HDPE | Professional | Yes (results of long term stability study will be provided when available) |
| Jerrycan | 5 L | Opaque HDPE | HDPE | Professional | Yes |
| Jerrycan | 20 L | Opaque HDPE | HDPE | Professional | Yes |
| Drum | 60 L | Opaque HDPE | HDPE | Professional | Yes |
| Drum | 220 L | Opaque HDPE | HDPE | Professional | Yes |
| IBC | 1000 L | Opaque HDPE | HDPE | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

Please refer to the list of studies in Annex 3.1 of this document

#### Access to documentation

Letters of Access of Jungbunzlauer S.A. and Purac Biochem bv have been provided for L(+) lactic acid data.

A Letter of Access of Lanxess Deutschland GmbH has been provided for chlorocresol data.

## Assessment of the biocidal product

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

**Use # 1 – Disinfection of livestock animal housing and equipment**

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| **Product Type** | PT03 Veterinary hygiene: products used to disinfect the materials and surfaces associated with the housing or transportation of animals. |
| **Where relevant, an exact description of the authorised use** | Disinfection of equipment and livestock animal housing (cattle, pigs and poultry), including poultry hatcheries |
| **Target organisms (including development stage)** | Bacteria, including *Salmonella enterica*  Yeasts and fungi  Virus, including Influenza virus H1N1, porcine reproductive and respiratory syndrome virus (PRRS virus), duck parvovirus, African swine fever virus (ASFV) |
| **Field of use** | Indoor use |
| **Application method(s)** | Spraying on surfaces after dilution |
| **Application rate(s) and frequency** | Use a 1.4% v/v diluted solution  Application rate: 100-200 mL of diluted product/m2  Frequency: as needed depending on the animal species. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please see the relevant section (paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file). |

**Use # 2 – Disinfection of livestock animal housing and equipment, against coccidiosis**

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| **Product Type** | PT03 Veterinary hygiene: products used to disinfect the materials and surfaces associated with the housing or transportation of animals. |
| **Where relevant, an exact description of the authorised use** | Disinfection of equipment and livestock animal housing (cattle, pigs and poultry), against coccidiosis |
| **Target organisms (including development stage)** | Protozoan organisms responsible of coccidiosis  *Cryptosporidium parvum* oocysts |
| **Field of use** | Indoor use |
| **Application method(s)** | Spraying on surfaces after dilution |
| **Application rate(s) and frequency** | Use a 3% v/v diluted solution  Application rate: 200 mL of diluted product/m2  Frequency: as needed depending on the animal species. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please see the relevant section (paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file). |

**Use # 3 – Disinfection of animal transportation vehicles**

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| **Product Type** | PT03 Veterinary hygiene: products used to disinfect the materials and surfaces associated with the housing or transportation of animals. |
| **Where relevant, an exact description of the authorised use** | Disinfection of animal transportation vehicles |
| **Target organisms (including development stage)** | Bacteria  Yeasts and fungi  Virus |
| **Field of use** | Indoor use |
| **Application method(s)** | Spraying on surfaces after dilution |
| **Application rate(s) and frequency** | Use of a 2% v/v diluted solution  Application rate: 125 mL of diluted product/m2  Frequency: as needed depending on the animal species.. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please see the relevant section (paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file). |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Test item** | **Results** | **Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Organoleptic and visual observations No guideline required | Product PHENOGEN Batch number: 277203 | Homogeneous slightly yellow limpid liquid with a characteristic odour, before and after an accelerated storage procedure for 14 days at 54°C or a low temperature storage procedure for 7 days at 0°C. | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-002  Demangel B. 2019 Défitraces Report n° 18-919053-003 |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa |
| Acidity / alkalinity | CIPAC MT 75.3 | Product PHENOGEN Batch number: 277203 | At initial time, the pH of the pure test item PHENOGEN was 3.27 at 19.6°C after 2 min. After 14 days at 54 ± 2°C in its commercial packaging (1L white opaque HDPE bottle), the pH of the pure test item PHENOGEN was 3.30 at 20.7°C after 2 min.  The acidity of the pure test item PHENOGEN was: 10.0% w/w as H2SO4 at 20 ± 2°C before storage and 9.51% w/w as H2SO4 at 20 ± 2°C after 14 days at 54 ± 2°C in its commercial packaging (1L white opaque HDPE bottle) | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-003 |
| Relative density / bulk density | U Method A.3, OECD Guideline No.109 (2012) (oscillating densitimeter method) | Product PHENOGEN Batch number: 277203 | The mean relative density of the test item was 1.082 ± 0.001 at 20.0°C. | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-002 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 method (storage stability)  Validated methods for the determination of AS content | Product PHENOGEN Batch number: 277203 | The test item PHENOGEN and its commercial packaging (1 L white opaque HDPE bottle) were considered to be stable after an accelerated storage procedure for 14 days at 54 ± 2°C; no significant change in the appearance of the test item and in the appearance of the commercial packaging was observed, the product became slightly cloudy after the storage. No significant change was observed in the weight of the commercial packaging (- 0.1%).   |  |  |  | | --- | --- | --- | | Parameter | Initial (T0) | After 14 days at 54 °C | | L-lactic acid content | 22.1% w/w | 22.3% w/w (+0.9%) | | Chlorocresol content | 18.5% w/w | 18.4% w/w  (-0.5%) | | pH (pure) | 3.27 (19.6 °C) | 3.30 (20.7 °C) | | Persistence of foam after dilution in Standard water D | At 1.4% v/v:  40 mL after 10 s  32 mL after 1 min  16 mL after 3 min  10 mL after 12 min    At 3% v/v:  26 mL after 10 s  24 mL after 1 min  21 mL after 3 min  17 mL after 12 min | At 1.4% v/v:  52 mL after 10 s  35 mL after 1 min  18 mL after 3 min  10 mL after 12 min    At 3% v/v:  35 mL after 10 s  29 mL after 1 min  22 mL after 3 min  18 mL after 12 min | | Dilution stability after dilution at 1.4% and 3% v/v in Standard water D | No separated material was observed after standing for 30 min at 30 ± 2°C.    Some traces of separated material were observed after standing for 24 h at 30 ± 2°C. | No separated material was observed after standing for 30 min at 30 ± 2°C.    Some traces of separated material were observed after standing for 24 h at 30 ± 2°C. | | Wet sieve test on test itemdiluted at 1.4% v/v and 3% v/v in Standard water D issued from dilution stability test | No residue of the test item solutions diluted at 1.4% v/v and 3% v/v in standard water D was held on a 75-µm sieve. | No residue of the test item solutions diluted at 1.4% v/v and 3% v/v in standard water D was held on a 75-µm sieve. | | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-003 |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife | Product PHENOGEN Batch number: 277203 | The long-term storage study (24 months at 20 ± 2°C) on the product PHENOGEN is still ongoing, however interim results were provided.  The results after 6 and 12 months of storage in its commercial packaging (1 L HDPE bottle) are the following:  The test item Phenogen and its commercial packaging (1 L white opaque HDPE bottle) were considered to be stable after 12 months at 20 ± 2°C; no significant change in the appearance of the test item and in the appearance of the commercial packaging was observed, except that the product became slightly cloudy after the storage. No significant change was observed in the weight of the commercial packaging (- 0.2%).  The L(+) lactic acid content was 22.1% w/w at initial time and 22.0% w/w after 12 months at 20 ± 2°C.  The chlorocresol content was 18.5% w/w at initial time and 18.3% w/w after 12 months at 20 ± 2°C.  With a variation of -0.5% *vs.* the value at initial time of L(+) lactic acid content and a variation of -1.1% *vs.* the value at initial time of chlorocresol content, the test item was considered to be stable after a long-term storage procedure for 12 months at 20 ± 2°C.  The results after 24 months of storage related to the appearance of the test item, the appearance and weight of the commercial packaging (1 L white opaque HDPE bottle), the analytical quantifications of the active substances, the dilution stability, the persistent foam, the pH of the pure test item and its acidity will be provided when available. | Acceptable, a signed study plan was provided and according to interim results, no significant change in a.s. content and technical properties is observed.  The final report will be required in post-authorization. | Demangel B. 2019 Défitraces Study plan n° 18-919053-004  Demangel B. 2019 Défitraces Report n° 18-919053-004 |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 method (2000) | Product PHENOGEN Batch number: 277203 | At the start of the test, the test item was a homogeneous slightly yellow limpid liquid. The appearance of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2°C, no change was observed in the appearance of the test item. | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-002 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Not required according to the Assessment Reports of L(+) lactic acid (Product Types 02, 03 and 04, June 2017) and chlorocresol (Product Type 03, April 2016; revised November 2017): L(+) lactic acid and chlorocresol do not absorb at wavelengths >290 nm which indicates that the molecules are not susceptible to breakdown by light. | Acceptable.  Moreover, the packaging is opaque. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | The test item PHENOGEN was considered to be stable after 14 days at 54 ± 2°C and after 7 days at 0 ± 2°C. The individual commercial packaging (1 L white opaque HDPE bottle) is sealed. With this closure system, the packaging is leak-tight. | Acceptable | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See the storage stability tests | Acceptable | - |
| Wettability | - | - | Not required as the product is a soluble concentrate | - | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not required as the product is a soluble concentrate | - | - |
| Wet sieve analysis and dry sieve test | CIPAC MT 185 method (2003) | Product PHENOGEN Batch number: 277203 | As some traces of separated material were observed during the dilution stability test, a wet sieve test was performed on these solutions of product PHENOGEN. Before and after the accelerated storage procedure, no residue of the PHENOGEN solutions diluted at 1.4% v/v and 3% v/v in standard water D was held on a 75-µm sieve | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-003 |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not required as the product is a soluble concentrate | - | - |
| Disintegration time | - | - | Not required as the product is a soluble concentrate | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not required as the product is a soluble concentrate | - | - |
| Persistent foaming | CIPAC MT 47.3 method (2017) | Product PHENOGEN Batch number: 277203 | At initial time, the mean volume of foam produced after several inversions of the test item diluted at 1.4% v/v and at 3% v/v in standard water D at 20 ± 2°C was respectively 32 mL and 24 mL after 1 min of standing. After an accelerated storage procedure at 54 ± 2°C for 14 days, the mean volume of foam produced after several inversions of the test item diluted at 1.4% v/v and at 3% v/v in standard water D at 20 ± 2°C was respectively 35 mL and 29 mL after 1 min of standing | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-003 |
| Flowability/Pourability/Dustability | - | - | Not required as the product is a soluble concentrate. | - | - |
| Burning rate — smoke generators | - | - | Not required as the product is a soluble concentrate. | - | - |
| Burning completeness — smoke generators | - | - | Not required as the product is a soluble concentrate. | - | - |
| Composition of smoke — smoke generators | - | - | Not required as the product is a soluble concentrate. | - | - |
| Spraying pattern — aerosols | - | - | Not required as the packaging is not an aerosol nor a spray. | - | - |
| Physical compatibility | - | - | Not applicable. The product is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of PHENOGEN with other biocidal products, chemicals or active substances is required. | Acceptable | - |
| Chemical compatibility | - | - | Not applicable. The product is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of PHENOGEN with other biocidal products, chemicals or active substances is required. | Acceptable | - |
| Degree of dissolution and dilution stability | CIPAC MT 41.1 method (1995) amended in 2011 | Product PHENOGEN Batch number: 277203 | At initial time, no separated material was observed on the test item solutions diluted at 1.4% v/v and 3.0% v/v in standard water D after standing for 30 min at 30 ± 2°C. Some traces of separated material were observed on the test item solutions diluted at 1.4% v/v and 3.0% v/v in standard water D after standing for 24 h at 30 ± 2°C.  After an accelerated storage procedure at 54 ± 2°C for 14 days, no separated material was observed on the test item solutions diluted at 1.4% v/v and 3.0% v/v in standard water D after standing for 30 min at 30 ± 2°C. Some traces of separated material were observed on the test item solutions diluted at 1.4% v/v and 3.0% v/v in standard water D after standing for 24 h at 30 ± 2°C.  As some traces of separated material were observed, a wet sieve test was performed on these solutions of product PHENOGEN. | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-003 |
| Surface tension | EU Method A.5, OECD Test Guideline115 | Product PHENOGEN Batch number: 277203 | The mean surface tension of the test item PHENOGEN diluted at 3% v/v in distilled water at a temperature of 20.2°C was 29.9 mN/m. The test item was considered as surface-active in the experimental conditions used. | Acceptable, the diluted concentrate is surface active. | Demangel B. 2019 Défitraces Report n° 18-919053-002 |
| Viscosity | OECD Test Guideline 114 ISO Standard 3219 (rotational viscometer) | Product PHENOGEN Batch number: 277203 | The mean dynamic viscosity of the product PHENOGEN was found to be 12.4 mPa\*s at 20.0 ± 0.2°C and 6.07 mPa\*s at 40.0 ± 0.2°C. The test item was considered to have newtonian properties in the experimental conditions used. | Acceptable | Demangel B. 2019 Défitraces Report n° 18-919053-002 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product PHENOGEN is a soluble concentrate (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 homogeneous slightly yellow limpid liquid with a characteristic odour. The pH of the pure product is about 3.27 at 20°C and its relative density is about 1.082 at 20.0°C.  There is no effect of high and low temperature on the stability of the formulation, since after 2 weeks at 54 °C or 7 days at 0 °C, neither the active ingredients content nor the technical properties were significantly changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging.  The long term storage procedure (24 months at 20 ± 2°C) in the commercial packaging is currently ongoing and the final results are required in post-authorization.  The technical characteristics of the product are acceptable for a SL formulation. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Test item** | **Results** | **Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | - | - | Based on the composition, the product PHENOGEN is not explosive. The product PHENOGEN contains L(+) lactic acid (CAS No.79-33-4) and chlorocresol (CAS No.59-50-7) which are not explosive according to the Assessment Reports of these active substances.  The main other constituents of the product are water (CAS No.7732-18-5) and an alcoholic solvent. These components have no chemical group associated with explosive properties and are not classified for explosive properties according to Regulation (EC) No.1272/2008. According to their chemical structure, the other components are not considered as being able to lead to a classification of the product. Therefore, the product PHENOGEN has no explosive properties and test is not required. | Acceptable, the product is not explosive | - |
| Flammable gases | - | - | The product PHENOGEN is not concerned by the physical hazard “flammable gases” as it is a liquid product. | - | - |
| Flammable aerosols | - | - | The product PHENOGEN is not concerned by the physical hazard “flammable aerosols” as it is not conditioned in aerosols. | - | - |
| Oxidising gases | - | - | The product PHENOGEN is not concerned by the physical hazard “oxidising gases” as it is a liquid product. | - | - |
| Gases under pressure | - | - | The product PHENOGEN is not concerned by the physical hazard “gases under pressure” as it is a liquid product | - | - |
| Flammable liquids | EC A.9. method (2008) (equilibrium method closed cup) ISO 3679 (March 2015) | Product PHENOGEN Batch number: L180412 | The flash point of the product PHENOGEN is 35.5°C ± 0.5°C (corrected value). Therefore, the product PHENOGEN is a flammable liquid and is classified as Flammable Liquid, Category 3, H226. | Acceptable, the product is classified as Flammable Liquid Cat. 3 | Demangel B. 2018 Défitraces Report n° 18-919053-001 |
| Flammable solids | - | - | The product PHENOGEN is not concerned by the physical hazard “flammable solid” as it is a liquid product | - | - |
| Self-reactive substances and mixtures | - | - | Based on the composition, the product PHENOGEN is not self-reactive.  The product PHENOGEN contains L(+) lactic acid (CAS No.79-33-4) and chlorocresol (CAS No.59-50-7) which are not explosive according to the Assessment Reports of these active substances.  The main other constituents of the product are water (CAS No.7732-18-5) and an alcoholic solvent. These components have no chemical group associated with self-reactive properties. According to their chemical structure, the other components are not considered as being able to lead to a classification of the product. Therefore, the product PHENOGEN is not expected to present self-reactive properties and test is not required | Acceptable | - |
| Pyrophoric liquids | - | - | Based on the composition, the product PHENOGEN is not a pyrophoric liquid. Test is not required as the product PHENOGEN does not contain any component classified as pyrophoric according to their safety data sheets. Moreover, experience in manufacture and handling shows that the product PHENOGEN does not ignite spontaneously on coming into contact with air at normal temperature | Acceptable | - |
| Pyrophoric solids | - | - | The product PHENOGEN is not concerned by the physical hazard “pyrophoric solids” as it is a liquid product | Acceptable | - |
| Self-heating substances and mixtures | - | - | The product PHENOGEN is not concerned by the physical hazard “self-heating mixtures” as it is a liquid product | Acceptable | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | Based on the composition, the product PHENOGEN does not emit flammable gases in contact with water. Test is not required as the product PHENOGEN contains around 20% w/w of water and forms a stable mixture | Acceptable | - |
| Oxidising liquids | - | - | Based on the composition, the product PHENOGEN is not oxidising.  The product PHENOGEN contains L(+) lactic acid (CAS No.79-33-4) and chlorocresol (CAS No.59-50-7) which have no oxidising properties according to the Assessment Reports of these active substances.  The main other constituents of the product are water (CAS No.7732-18-5) and an alcoholic solvent. These components have no chemical group associated with oxidising properties. According to their chemical structure, the other components are not considered as being able to lead to a classification of the product. Therefore, the product PHENOGEN has no oxidising properties and test is not required | Acceptable | - |
| Oxidising solids | - | - | The product PHENOGEN is not concerned by the physical hazard “oxidising solids” as it is a liquid product | - | - |
| Organic peroxides | - | - | The product PHENOGEN is not concerned by the physical hazard “organic peroxides” as its components are not expected to form or contains organic peroxides | Acceptable | - |
| Corrosive to metals | C.1 UN Test of UN Manual of Tests and Criteria | Product PHENOGEN Batch number: 277203 | The product PHENOGEN is not considered to be corrosive to steel and aluminium. For the steel specimen, the maximum percentage of mass loss observed after 14 days is on the specimen placed in liquid position in the reactor. It is 14.55% for a maximum allowable percentage of 26.60%. For the aluminium specimen, the maximum percentage of mass loss observed after 14 days is on the specimen immersed in the product in an intermediate position. It is 3.69% for a maximum allowable percentage of 26.20%. In addition to uniform corrosion, the maximum intrusion caused by localized corrosion (deepest hole), must not exceed 240 µm for a 14-day immersion period. The intrusion depths observed on the steel specimen placed in the intermediate position do not exceed this limit (90 µm). No intrusion was found on the aluminium specimens. | Acceptable, the product is not classified as corrosive to metals. | Aufauvre, L. 2018, DSC Report n°18-177757-11137A |
| Auto-ignition temperatures of products (liquids and gases) | EU Method A.15  NF T 20-037 | Product PHENOGEN  Batch No.: 309148 | The auto-ignition temperature of the product PHENOGEN was 518 ± 3°C (corrected temperature). | Acceptable | - |
| Relative self-ignition temperature for solids |  |  | The product PHENOGEN is not concerned by the physical hazard “relative self-ignition temperature for solids” as it is a liquid product |  |  |
| Dust explosion hazard |  |  | The product PHENOGEN is not concerned by the physical hazard “dust explosion” as it is a liquid product |  |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The flash point of the product PHENOGEN is 35.5°C (equilibrium method closed cup), therefore it is classified as Flammable Liquid, Category 3, H226. Its auto-ignition temperature is 518 ± 3°C. The product PHENOGEN is not expected to present a significant hazard for explosive properties, self-reactivity, pyrophoric properties, oxidising properties and corrosivity to metals. It does not emit flammable gases in contact with water.  Consequences on labelling:  H226: Flammable liquid and vapour. |

### Methods for detection and identification

Chlorocresol:

Ricau, H. 2019, Défitraces report n° 18-919053-005, “Validation of the analytical method for the determination of chlorocresol in the product PHENOGEN” (GLP).

L-lactic acid:

Ricau, H. 2019, Défitraces report n° 18-919053-006, “Validation of the analytical method for the determination of L(+) lactic acid in the product PHENOGEN” (GLP).

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Chlorocresol in PHENOGEN | GC-FID | 18.2% w/w (n=10)  18.0% w/w (2 blank spiked with standard) | 90.27 – 273.94 mg/L, corresponding to 50% - 150% nominal concentration  (n=5, in duplicate)  Linear regression  R=0.9987 | Specificity was studied by analysis of the solvent blank (ethyl acetate), the matrix without any active substance (blank formulation), the chlorocresol reference item (chlorocresol standard), the L(+) lactic acid reference item (L(+) lactic acid standard), and the test item PHENOGEN. The specificity was assessed by checking for any interference in GC-FID at the retention time of the peak of chlorocresol and the peak of the Internal Standard.  No interference was observed | -  100.7-101.2 | -  100.9 | 0.87%  - | Not relevant | Ricau, H. 2019, Défitraces report n° 18-919053-005 |
| L-lactic acid in PHENOGEN | HPLC-UV | 21.9% w/w (n=10)  22.0% w/w (2 blank spiked with standard) | 3.83 – 11.51 g/L, corresponding to 50% - 150% nominal concentration  (n=5, in duplicate)  Linear regression  R=1.0000 | Specificity was studied by analysis of the solvent blank (sulphuric acid 1N solution), the matrix without any active substance (blank formulation), the chlorocresol reference item (chlorocresol standard), the L(+) lactic acid reference item (L(+) lactic acid standard), and the test item PHENOGEN. The specificity was assessed by checking for any interference in HPLC-UV at the retention time of the peak of L(+) lactic acid.  No interference was observed. | -  100.1-100.1 | -  100.1 | 0.70%  - | Not relevant | Ricau, H. 2019, Défitraces report n° 18-919053-006 |

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| **Conclusion on the methods for detection and identificationof the product** |
| The chlorocresol content in the product PHENOGEN is determined using a gas chromatography method with flame ionisation detector (GC-FID).  The L(+) lactic acid content in the product PHENOGEN is determined using Liquid Chromatography with UV detection.  Quantification are performed using external standard calibration.  These two analytical methods for the determination of chlorocresol and L(+) lactic acid contents in the product PHENOGEN were validated according to SANCO/3030/99 rev.4.  No analytical method for the determination of m-cresol (relevant impurity of chlorocresol) was provided.  Analytical methods for the determination of chlorocresol residues in soil, water and air are available in the Assessment Report chlorocresol (CMK) Product-type PT03 (Veterinary hygiene), April 2016, revised November 2017, with LOQs which are respectively 5 µg/kg, 0.05 µg/L and 0.3 µg/m3. A Letter of Access from Lanxess was provided.  As the active substance chlorocresol is not classified as toxic or very toxic, an analytical method for the determination of chlorocresol residue in human body fluids and tissues is not necessary.  The product PHENOGEN is intended to be used on surfaces in contact with food/feed of plant and animal origins. However; as no MRL has been set, analytical methods for the determination of chlorocresol residues in food/feed of plant and animal origins are not necessary.  As specified in the Assessment Report L(+) lactic acid PTP02, 03 and 04 (Disinfectants and algaecides not intended for direct application to humans or animals, Veterinary Hygiene and Disinfectants in food and feed areas), June 2017, no residues are expected in soil, air, drinking and surface water, therefore analytical methods for the determination of L(+) lactic acid residue in in soil, air, drinking and surface water are unnecessary. Letters of Access from Jungbunzlauer S.A. and Purac Biochem bv were provided.  As the active substance L(+) lactic acid is not classified as toxic or very toxic, an analytical method for the determination of L(+) lactic acid residue in human body fluids and tissues is not necessary.  The product PHENOGEN is intended to be used on surfaces in contact with food/feed of plant and animal origins. However; as specified in the Assessment Report L(+) lactic acid PT02, 03 and 04 (Disinfectants and algaecides not intended for direct application to humans or animals, Veterinary Hygiene and Disinfectants in food and feed areas), June 2017, no residues are expected in food/feed of plant and animal origins. Therefore analytical methods for the determination of L(+) lactic acid residue in food/feed of plant and animal origins are not necessary. |

### Efficacy against target organisms

#### Function and field of use

Main Group 1: Disinfectants

Product Type 03: Veterinary hygiene. Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

The product PHENOGEN is a soluble concentrate disinfectant. It is used for the disinfection of equipment and livestock animal housings (cattle, pigs, poultry), including poultry hatcheries, by spraying on surfaces (PT03). It is also used for the disinfection of animal transportation vehicles by spraying (PT03).

The product is used after dilution in water and by professional users only.

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

The organisms to be controlled are bacteria (including *Salmonella*), oocysts responsible for cryptosporisiosis (*Cryptosporidium parvum*), yeasts, fungi and viruses (including Influenza virus H1N1, porcine reproductive and respiratory syndrome virus (PRRS virus), duck parvovirus and African swine fever virus (ASFV)) depending on the claimed uses.

The organisms to be protected are animals (cattle, pigs and poultry) and humans and the objects to be protected are PT3 surfaces in field veterinary.

#### 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), of moulds spores (fungicidal activity) and of oocyste cells (oocydal activity) of relevant test organisms under defined conditions.

#### Mode of action, including time delay

According to the chlorocresol Assessment Report (April 2016), this active substance has a multi-site mode of action, with basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of cytoplasmic membrane. At high concentrations, it also has an effect on cytoplasm by general coagulation.

Concerning L(+) lactic acid (Assessment Report, June 2017), this acid exists in solution in a pH-dependent equilibrium between the non-dissociated and dissociated form. Only in its non-dissociated state, the acid is able to go through the cell membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the L(+) lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot go through the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited.

Further effects are also reported, such as decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed.

PHENOGEN is effective after a contact time varying between 5 minutes and at least 2 hours, depending on the application rate used and the target organism.

#### Efficacy data

Laboratory studies were conducted with the product PHENOGEN in accordance with the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C). The results are summarized in Section 6.7 of the IUCLID file and the main efficacy data are summarized in the table below.

Regarding the potential activity of co-formulants, which may impact the efficacy of the product, the applicant provided an additional test with the co-formulant only. Details of this test and conclusions are presented in the confidential part of the PAR.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test product** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Bacteria  *Pseudomonas aeruginosa*  *Enterococcus hirae*  *Staphylococcus aureus*  *Proteus vulgaris* | EN 1656: 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 1.25%, 1.30% and 1.40% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 1.30% v/v. | S6.7\_01  Morot-Bizot S. and Herbein G., 2018  Efficacy report No 106D11-2018-05  R.I.: 1 |
| Bactericide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch 309148 | Bacteria  *Salmonella enterica* serovar *enteridis* | EN 1656: 2019 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.50%, 0.80% and 1.00% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.80% v/v. | S6.7\_01bis  Morot-Bizot S., 2020  Efficacy report No 034D03-2020-04  R.I.: 1 |
| Bactericide | Indoor  Livestock animal housing and equipment.  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Bacteria  *Pseudomonas aeruginosa*  *Enterococcus hirae*  *Staphylococcus aureus*  *Proteus vulgaris* | EN 14349: 2012 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.75%, 0.80% and 1.00% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Surface: stainless steel  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 0.80% v/v. | S6.7\_02  Morot-Bizot S. and Herbein G., 2018  Efficacy report No 106D11-2018-01  R.I.: 1 |
| Bactericide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Bacteria  *Salmonella enterica* subsp. *enteritidis*  *Salmonella enterica* subsp. *typhimurium* | EN 14349: 2012 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.50%, 0.70% and 0.75% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Surface: stainless steel  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 0.70% v/v. | S6.7\_03  Morot-Bizot S. and Herbein G., 2018  Efficacy report No 144D15-2018-02  R.I.: 1 |
| Bactericide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch 277202 | Bacteria  *Pseudomonas aeruginosa*  *Enterococcus hirae*  *Staphylococcus aureus*  *Proteus vulgaris* | EN 16437: 2014 | Phase 2 step 2 test (porous surface test)  Concentration tested: 0.10%, 1.00% and 10.00% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Surface: poplar sheet  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1 % v/v. | S6.7\_05  Morot-Bizot S. and Herbein G., 2018  Efficacy report No 255B27-2018  R.I.: 1 |
| Bactericide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch 309148 | Bacteria  *Salmonella enterica* serovar *enteridis* | EN 16437: 2019 | Phase 2 step 2 test (porous surface test)  Concentration tested: 0.10%, 1.00% and 10.00% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Surface: poplar sheet  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1 % v/v. | S6.7\_05bis  Morot-Bizot S., 2020  Efficacy report No 034D03-2020  R.I.: 1 |
| Fungicide  Yeasticide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Yeasts  *Candida albicans*  Fungi  *Aspergillus brasiliensis* | EN 1657: 2016 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.60%, 0.75% and 1.00% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 4 log reduction | Fungicidal and yeasticidal activity demonstrated at 0.75 % v/v. | S6.7\_06  Morot-Bizot S. and Herbein G., 2018  Efficacy report No 106D11-2018-04  R.I.: 1 |
| Fungicide Yeasticide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Yeasts  *Candida albicans*  Fungi  *Aspergillus brasiliensis* | EN 16438: 2014 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 1.30%, 1.40% and 1.50% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Surface: stainless steel  Criteria: at least a 3 log reduction | Fungicidal and yeasticidal activity demonstrated at 1.4 % v/v. | S6.7\_07  Morot-Bizot S. and Herbein G., 2018  Efficacy report No 106D11-2018-02  R.I.: 1 |
| Virucide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Virus  Bovine enterovirus type 1 | EN 14675: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.90%, 1.00% and 1.10% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 1 % v/v. | S6.7\_09  Morot-Bizot S. and Herbein G., 2018  Efficacy report No 106D11-2018-03  R.I.: 1 |
| Virucide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Virus  Influenza virus, H1N1 | EN 14675: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.75%, 0.90% and 1.00% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 0.90 % v/v. | S6.7\_11  Morot-Bizot S. and Herbein G., 2018  Efficacy report No 144D15-2018-04  R.I.: 1 |
| Virucide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Virus  Porcine reproductive and respiratory syndrome virus, PRRS virus | EN 14675: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.75%, 1.10% and 1.20% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 1.10 % v/v. | S6.7\_12  Morot-Bizot S., 2018  Efficacy report No 144D15-2018-06  R.I.: 1 |
| Virucide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Virus  Duck parvovirus | EN 14675: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.75%, 1.10% and 1.20% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 1.10 % v/v. | S6.7\_13  Morot-Bizot S., 2018  Efficacy report No 144D15-2018-08  R.I.: 1 |
| Virucide | Indoor  Livestock animal housing and equipment  **Use #1** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch L180412 | Virus  African swine fever virus, ASFV | EN 14675: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.75%, 1.10% and 1.20% v/v  Contact time: 30 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 1.10 % v/v. | S6.7\_14  Morot-Bizot S., 2018  Efficacy report No 144D15-2018-10  R.I.: 1 |
| Coccidiocide | Indoor  Livestock animal housing and equipment  **Use #2** | PHENOGEN | *Cryptosporidium parvum,* oocysts | DVG Protocol | **Quantitative suspension test.**  Quantitative PCR for quantification (hsp70 gene) of the pathogen (after inoculation of the oocysts on host cell cultures and incubation).  Concentration tested: 2.00%, 3.00% and 4.00% v/v  Contact time: 120 minutes  Temperature: 10°C  Soiling: no soiling  2 independent repetitions | Effective concentration (reduction of DNA copies > 95%):  *C. parvum*: 3.00% v/v  Thus, the product PHENOGEN is effective against *C. parvum* oocysts in suspension from a concentration of 3.00% v/v, with a contact time of 120 min. | S6.7\_15\_16  Daugschies A. and Renteria Z., 2018  R.I.: 1 |
| Coccidiocide | Indoor  Livestock animal housing and equipment  **Use #2** | PHENOGEN | *Cryptosporidium parvum,* oocysts | Protocol of the 66th meeting of the disinfection commission of the DVG (German Veterinary Society), 2015 | **Quantitative test on surface.**  Quantitative PCR for quantification (hsp70 gene) of the pathogen (after inoculation of the oocysts on host cell cultures and incubation).  Concentration tested: 2.00%, 3.00% and 4.00% v/v  Contact time: 120 minutes  Temperature: 10°C  Soiling: no soiling  Surface: metal  2 independent repetitions | Effective concentration (reduction of DNA copies > 95%):  *C. parvum*: 3.00% v/v  Thus, the product PHENOGEN is effective against *C. parvum* oocysts on non-porous surfaces from a concentration of 3.00% v/v, with a contact time of 120 min. | S6.7\_15\_16  Daugschies A. and Renteria Z., 2018  R.I.: 1 |
| Bactericide | Indoor  Livestock animal transportation vehicles  **Use #3** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch 309148 | Bacteria  *Pseudomonas aeruginosa*  *Enterococcus hirae*  *Staphylococcus aureus*  *Proteus hauserii* (ex *vulgaris*) | EN 1656: 2019 | Phase 2 step 1 test (suspension test)  Concentration tested: 1.00%, 1.40% and 1.50% v/v  Contact time: 5 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 1.40 % v/v. | S6.7\_01ter  Morot-Bizot S. and Herbein G., 2020  Efficacy report No 034D03-2020-03  R.I.: 1 |
| Bactericide | Indoor  Livestock animal transportation vehicles  **Use #3** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch 277203 | Bacteria  *Pseudomonas aeruginosa*  *Enterococcus hirae*  *Staphylococcus aureus*  *Proteus vulgaris* | EN 14349: 2012 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 1.20%, 1.50% and 2.00% v/v  Contact time: 5 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Surface: stainless steel    Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1.50 % v/v. | S6.7\_04  Morot-Bizot S. and Herbein G., 2019  Efficacy report No 327D29-2018-04  R.I.: 1 |
| Fungicide  Yeasticide | Indoor  Livestock animal transportation vehicles  **Use #3** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch 309148 | Yeasts  *Candida albicans*  Fungi  *Aspergillus brasiliensis* | EN 1657: 2016 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.50%, 0.80% and 1.00% v/v  Contact time: 5 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 4 log reduction | Fungicidal activity demonstrated at 1 % v/v.  Yeasticidal activity demonstrated at 0.80 % v/v. | S6.7\_06bis  Morot-Bizot S., 2020  Efficacy report No 034D03-2020-02  R.I.: 1 |
| Fungicide  Yeasticide | Indoor  Livestock animal transportation vehicles  **Use #3** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch 277203 | Yeasts  *Candida albicans*  Fungi  *Aspergillus brasiliensis* | EN 16438: 2014 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 1.50%, 2.00% and 2.50% v/v  Contact time: 5 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Surface: stainless steel  Criteria: at least a 3 log reduction | Fungicidal and yeasticidal activity demonstrated at 2 % v/v. | S6.7\_08  Morot-Bizot S. and Herbein G., 2019  Efficacy report No 327D29-2018-02  R.I.: 1 |
| Virucide | Indoor  Livestock animal transportation vehicles  **Use #3** | PHENOGEN  chlorocresol 18.5% w/w and lactic acid 22% w/w  Batch 277203 | Virus  Bovine enterovirus type 1 | EN 14675: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 1.50%, 1.80% and 2.00% v/v  Contact time: 5 minutes  Temperature: 10°C  Soiling: low level conditions (bovine albumin 3 g/L)  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 1.80 % v/v. | S6.7\_10  Morot-Bizot S. and Herbein G., 2019  Efficacy report No 327D29-2018-03  R.I.: 1 |

**For PT3 use #1 “disinfection of livestock animal housing and equipment (including hatcheries)”:**

* Bactericidal activity (including *Salmonella enterica)* is demonstrated both in phase 2, steps 1 and 2 tests (EN 1656 and EN 14349/EN 16437), at 10°C, with a contact time of 30 minutes, in clean conditions (3.0 g/L BSA) on porous and non-porous surfaces. In these conditions, bactericidal activity is shown at the in-use concentration of 1.30 % v/v for non-porous/porous surfaces.
* Yeasticidal/fungicidal activities are demonstrated both in phase 2, steps 1 and 2 tests (EN 1657 and EN 16438), at 10°C, with a contact time of 30 minutes, in clean conditions (3.0 g/L BSA). In these conditions, yeasticidal/fungicidal activities are shown at the in-use concentration of 1.40 % v/v for non-porous surfaces (there is currently no phase 2, step 2 standard method available for yeasticidal/fungicidal efficacy on porous surfaces).
* virucidal activity (including Influenza virus, Porcine reproductive and respiratory syndrome virus, Duck parvovirus and African swine fever virus) is demonstrated in phase 2, step 1 test (EN 14675) - (no surface test exist until now for the veterinary area), at 10°C, with a contact time of 30 minutes, in clean conditions (3.0 g/L BSA). In these conditions, virucidal activity is shown at the in-use concentration of 1.10 % v/v.

**For PT3 use #2 “disinfection of livestock animal housing and equipment against *Cryptosporidium parvum* oocysts”:**

* Efficacy against *C. parvum* oocysts in demonstrated in both suspension and surface tests, at 10°C, with a contact time of 120 minutes, on non-porous surfaces. In these conditions, efficacy is shown at the in-use concentration of 3 % v/v for non-porous surface.

It has to be noted that there is currently no EN standard relating to efficacy of disinfectant against *Cryptosporidium parvum*. The activity against *Cryptosporidium parvum* oocysts has been validated by two efficacy tests (suspension and surface tests), done according to protocols validated at the German national level (DVG, German Veterinary Society), and published (Shahiduzzaman et al., 2010, Dresely et al., 2015, and Delling et al., 2017).

The existing *Eimeria tenella* model, although very suitable and reproducible, includes animal experimentation which is of increasing public and ethical concern. Therefore, replacement by an *in vitro* model such as *C. parvum* in HCT-8 cells appears highly desirable, and germ carriers and suspensions assays where oocyst suspensions are exposed to disinfectants have been developed. Germ carriers are generally applied in testing of antimicrobial disinfection to model contamination of surface by pathogens and are considered indispensable to properly reflect in practical situations.

Standardised *in vitro* assays according to methods reported in Dresely et al. (2015), are suitable for the assessment of infectivity/inactivation of apicomplexan oocysts and may replace animal experimentation.

**For PT3 use #3 “disinfection of animal transportation vehicles”:**

* Bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1656 and EN 14349), at 10°C, with a contact time of 5 minutes, in clean conditions (3.0 g/L BSA) on non-porous surfaces. In these conditions, bactericidal activity is shown at the in-use concentration of 1.50 % v/v for non-porous surfaces.
* Yeasticidal/fungicidal activity are demonstrated both in phase 2, steps 1 and 2 tests (EN 1657 and EN 16438), at 10°C, with a contact time of 5 minutes, in clean conditions (3.0 g/L BSA). In these conditions, yeasticidal/fungicidal activity are shown at the in-use concentration of 2 % v/v for non-porous surfaces.
* Virucidal activity is demonstrated in phase 2, step 1 test (EN 14675) - (no surface test exist until now for the veterinary area), at 10°C, with a contact time of 5 minutes, in clean conditions (3.0 g/L BSA). In these conditions, virucidal activity is shown at the in-use concentration of 1.80 % v/v.

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| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product PHENOGEN, has shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C) and EN 14885:2015 standard for the following uses:   * Use 1: Disinfection of livestock animal housing and equipment (including hatcheries) (PT3) with clean conditions, on porous and non-porous surfaces:   + - Mandatory target organisms:       * Bacteria (including *Salmonella enterica*), yeasts and fungi: 1.40% v/v, 30 min, 10°C     - Other target organisms:       * Virus (including Influenza virus, Porcine reproductive and respiratory syndrome virus, Duck parvovirus and African swine fever virus): 1.40% v/v, 30 min, 10°C * Use 2: Disinfection of livestock animal housing and equipment (PT3) with clean conditions on non-porous surfaces:   + - Target organism:       * Oocyste (*C. parvum*): 3 % v/v, 120 min, 10°C * Use 3: Disinfection of animal transportation vehicles (PT3) with clean conditions, on non-porous surfaces:   + - Mandatory target organisms:       * Bacteria, yeasts and virus: 2% v/v, 5 min, 10°C     - Other target organisms:       * fungi: 2% v/v, 5 min, 10°C |

#### Occurrence of resistance and resistance management

According to the Assessment Reports of chlorocresol (April 2016) and L(+) lactic acid (June 2017), resistance is unlikely to develop.

For chlorocresol, the literature analysis clearly showed that especially if the concentration of this active substance is in the efficient range no acquired resistance occur. 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 chlorocresol. Since it interacts with many different targets of bacterial cell walls, 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

None.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product PHENOGEN has shown a sufficient efficacy in accordance with the requirement of the Efficacy guidance Vol II Part B/C and EN 14885:2015 standard:

* Use 1: Disinfection of livestock animal housing and equipment (including hatcheries) (PT3) with clean conditions, on porous and non-porous surfaces:
  + - Mandatory target organisms:
      * Bacteria (including *Salmonella enterica*), yeasts and fungi: 1.40% v/v, 30 min, 10°C
    - Other target organisms:
      * Virus (including Influenza virus, Porcine reproductive and respiratory syndrome virus, Duck parvovirus and African swine fever virus): 1.40% v/v, 30 min, 10°C
* Use 2: Disinfection of livestock animal housing and equipment (PT3) with clean conditions on non-porous surfaces:
  + - Target organism:
      * Oocyste (*C. parvum*): 3 % v/v, 120 min, 10°C
* Use 3: Disinfection of animal transportation vehicles (PT3) with clean conditions, on non-porous surfaces:
  + - Mandatory target organisms:
      * Bacteria, yeasts and virus: 2% v/v, 5 min, 10°C
    - Other target organisms:
      * fungi: 2% v/v, 5 min, 10°C

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

#### The product PHENOGEN is not intended to be used with another biocidal product.

### Risk assessment for human health

In order to avoid unnecessary animal experiment, no study was conducted for skin and eye irritation, sensitisation and acute toxicity effects. Classification is determined 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.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Corrosive to the skin |
| Justification for the value/conclusion | The active substance chlorocresol is classified skin corrosive 1C (H314). As the content is superior to 5%, this leads to a classification for skin corrosion category 1C of the product. |
| Classification of the product according to CLP | Skin corr. 1C; H314. |

***Eye irritation***

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| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Corrosive to the eyes |
| Justification for the value/conclusion | Classification as skin corrosive 1C is proposed for PHENOGEN; therefore serious eye damages are expected and a classification is required. |
| Classification of the product according to CLP | Eye Dam. 1; H318. |

***Respiratory tract irritation***

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| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | According to the CAR on 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, was proposed for the active substance.  As chlorocresol is at a content <20% and no other co-formulants or active substances are classified as irritating to the respiratory tract, therefore no classification is required.  However, PHENOGEN contains 22.00% w/w of L(+) lactic acid, for which the CLP additional hazard statement EUH071 is applicable according to the RAC Opinion (adopted on 9 March 2018). |
| Classification of the product according to CLP | EUH071: Corrosive to the respiratory tract. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Sensitizing to the skin |
| Justification for the value/conclusion | Chlorocresol is classified skin sensitive 1B (H317) and is present at a content ≥1%; therefore a classification is required. |
| Classification of the product according to CLP | Skin Sensitisation, category 1; H317 |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising to the respiratory system. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product PHENOGEN, no classification is required for respiratory sensitization. |
| Classification of the product according to CLP | Not classified. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not toxic via oral route |
| Justification for the selected value | According to the additivity approach, PHENOGEN is not classified for acute oral toxicity (ATEmix = 5687). |
| Classification of the product according to CLP | Not classified. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not toxic via inhalation |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product, classification is not required. |
| Classification of the product according to CLP | Not classified. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not toxic via dermal route. |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product, classification is not required. |
| Classification of the product according to CLP | Not classified. |

***Information on dermal absorption***

The product contains the co-formulant propan-2-ol which is a biocidal active substance, at a content superior to 0.1%. According to the ECHA guidance volume III part B/C, this substance is consequently considered as substance of concerns (SoC) and a quantitative risk assessment is needed. Please see paragraph on SoC below. Therefore, dermal absorption values for these substances are needed.

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substances | Chlorocresol, Propan-2-ol |
| Value(s) | * 100% for concentrated formulation (the concentration > 5% are corrosive); * 50% for diluted formulation (concentration < 5% non corrosive). |
| Justification for the selected value(s) | Default value from EFSA guidance on dermal absorption 2017 for water-based product/dilution, respectively and BPC-WG-III-2016 (TAB version 2.0, 2018) for corrosive concentration. |

***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 following co-formulant has been identified as a substance of concern:

| **Name and CAS**  **SOC** | **Reason(s) for identification** | **Relation to band** | **Consequences on the Human Risk assessment** | **TRVs** |
| --- | --- | --- | --- | --- |
| Propan-2-ol  CAS: 67-63-0 | Biocidal active substance at a concentration > 0.1% | Band C | Quantitative risk assessment for the professional and non-professional when TRVs available | See RA section |

***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 | n.a. | n.a. | Yes | Yes | n.a. |
| Dermal | n.a. | Yes | n.a. | n.a. | Yes | Yes | n.a. |
| Oral | n.a. | no | n.a. | n.a. | No | Yes | Yes |

PHENOGEN is a soluble concentrate disinfectant applied by spraying on surfaces.

It is used for the disinfection of livestock animal housing and equipment, and of poultry hatchery premises, equipment and materials. It is also used for the disinfection of animal transport vehicles.

The intended uses are as follows:

* Use #1: Disinfection of equipment and livestock animal housing (cattle, pigs and poultry), including poultry hatcheries:
  + Use a 1.4% v/v diluted solution;
  + Application rate: 100-200 mL of diluted product/m2 (in hatcheries, use 100-150 mL/m²).
* Use #2: Disinfection of equipment and livestock animal housing (cattle, pigs and poultry), against *C. parvum*:
  + Use a 3% v/v diluted solution;
  + Application rate: 200 mL of diluted product/m2.
* Use #3: Disinfection of animal transportation vehicles:
  + Use of a 2% v/v diluted solution;
  + Application rate: 125 mL of diluted product/m2.

The product is used by professionals only, after dilution in water.

***List of scenarios***

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |
| **Primary exposure** | | |
| **Scenario 1** | **Spraying application on animal housing surfaces and equipment (dilution 3% and 1.4% v/v)** | |
| Task 1 | **Manual spray application on animal surfaces and equipment** Mixing/loading of the concentrated product to be used by spraying. | Professionals |
| Task 2 | **Manual spray application on animal surfaces and equipment**  The product is manually sprayed on animal surfaces and equipment. | Professionals |
| Task 3 | **Post-application: Cleaning of equipment**  After application of the product by spraying, the cleaning of the equipment is considered. | Professionals |
| **Scenario 2** | **Spraying application on animal transport vehicles (dilution 2% v/v)** | |
| Task 1 | **Manual spray application on animal transport vehicles**  Mixing/loading of the concentrated product to be used by spraying. | Professionals |
| Task 2 | **Manual spray application on animal transport vehicles**  The product is manually sprayed on animal transport vehicles. | Professionals |
| Task 3 | **Post-application: Cleaning of equipment**  After application of the product by spraying, the cleaning of the equipment is considered. | Professionals |
| **Secondary exposure** | | |
| **Scenario 3** | **Inhalation of volatilised residues after spraying on animal surfaces and equipment (dilution 3% and 1.4% v/v)**  Volatilised residues after application on animal surfaces and equipment. | Professionals and general public |
| **Scenario 4** | **Inhalation of volatilised residues after spraying on animal transport vehicles (dilution 2% v/v)**  Volatilised residues after application on animal transport vehicles. | Professionals |
| **Scenario 5** | **Exposure to treated surfaces (animal surfaces and equipment) - Adults and toddlers**  After spraying on animal surfaces/equipment, secondary dermal exposure may occur during the contact with the treated surfaces for adults and toddlers. In addition, oral exposure may occur during the contact with the treated surfaces for toddlers (crawling). | Professionals and general public |
| **Scenario 6** | **Exposure to treated surfaces (transport vehicles) – Adults**  After spraying on animal surfaces/equipment, secondary dermal exposure may occur during the contact with the treated surfaces for adults. | Professionals |

***Industrial exposure***

No exposure is foreseen.

***Professional exposure***

***Scenario [1] – Task 1 & 2:******Manual spraying on animal surfaces and equipment (dilution 3% and 1.4% v/v)***

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| The product PHENOGEN contains:   * 18.5% w/w chlorocresol; * 22% w/w L(+) lactic acid and ; * 18% w/w Propan-2-ol.   The product is applied by manual spraying on animal surfaces/equipment after being diluted in water at 3% v/v and 1.4% v/v.  Taking into account a relative density value of 1.082 at 20°C for the product PHENOGEN and a density value of 1 for the dilution (mainly water), concentrations of active substances and SoC in the diluted product are calculated as follows:  *Diluted product 3% v/v*   * Chlorocresol: 0.6% v/v; * L(+) lactic acid: 0.71% v/v; * Propan-2-ol: 0.58% v/v.   *Diluted product 1.4% v/v*:   * Chlorocresol: 0.28% v/v; * L(+) lactic acid: 0.33% v/v; * Propan-2-ol: 0.27% v/v.   During manual spray application, dermal and inhalation exposure can occur.  The *Spraying model 2* from the BHHEM is used to estimate exposure during application.  Due to the intended uses claimed by the applicant (surface disinfection in animal housing and equipment), the exposure model for powered spray application at 4 to 7 bar pressure (as a coarse or medium spray) has been considered relevant.  The mixing and loading phase is already included in the model.  The indicative values from the model (75th percentile) are as follows:  - Hands: 7.8 mg/min (actual);  - Hands: 273 mg/min (potential);  - Body: 222 mg/min;- Inhalation: 76 mg/m3.  In addition, due to the high volatility of the identified SoC Propan-2-ol, the exposure to vapour during the **mixing/loading (Task 1)** and **spray application (Task 2)** has to be considered using the scenario *inhalation–exposure to vapour–evaporation–constant release area* from ConsExpo according to the Cleaning Products Fact Sheet 2018.  Task 1:  *Exposure duration/Emission duration*  According to ECHA Recommendation no.6, 2017, exposure duration of 10 minutes is considered during manual mixing and loading. The same value is considered for emission duration.  *Product amount – inhalation*  According to ConsExpo recommendation, this parameter does not correspond to the product amount but half of the bottle content. Manual loading is considered from 1L bottle to 20L jerrycan.  Considering a 20L jerrycan, an amount of product of 10L with a density of 1.082, 10 820 g is considered.  *Room volume and ventilation rate*  According to RIVM report, ‘Room volume’ is interpreted here as ‘personal volume’: a small area of 1 m3 around the user. A small area around the user is relevant for the inhalation exposure of the user, for the short use duration in which the treatment takes place, as it enables the evaporation of the active substance from the concentrate to be described.  The ventilation rate of 0.6 hours-1 is taken (unspecified room).  *Release area*  The opening of the bottle is considered to be the release area for substances evaporating from a bottle, which is by default set at 20 cm².  Task 2:  For animal surfaces, estimated inhalation has been done for all species and available in the Annex 3.2.  The laying hens (litter floor, free range) is chosen as a worst-case for exposure of animal surfaces. For more information, ConsExpo sheets are available in the Annex 3.2.  *Exposure duration/Emission duration*  A duration of 120 minutes is taken into consideration for spraying. The same value is considered for emission duration.  *Room volume/release area*  - For animal surfaces, a surface of 1430 m² is taken (laying hens, litter floor, free range) and a room volume of 5360 m3. These values is chosen as a ‘worst-case’ for animal surfaces since the estimated inhalation (evaporation) made in ConsExpo for (laying hens (litter floor, free range) is the maximum value modelled.   * For equipment, a surface of 10 m2 and a volume of 50 m3are taken (small room as a worst-case).   *Ventilation rate*  - For animal surfaces, the ventilation rate for laying hens (litter floor, free range) housing is between 1.3 (min. winter) and 14.2 h-1 (max. summer), depending on the season. A ventilation rate of 1.3 h-1 s taken as a worst-case.  - For equipment, the ventilation rate of 0.6 hours-1 is taken (unspecified room).  *Product amount – inhalation*  The application rate is 200 mL/m² for animal surfaces/equipment:  - Considering a surface of 1430 m² for surfaces (laying hens (litter floor, free range), the amount of product deposited on the treated surface is 286000 g.  - Considering a surface of 10 m2 for equipment (worst-case, no available value), the amount of product deposited on the treated surface is 2000 g. | | | |
| Tier 1 | Parameters | Value | References |
| Concentration of Chlorocresol (% w/w) (animal surfaces/equipment) (dilution 3% v/v) | 0.601% | See calculation above |
| Concentration of L (+) lactic acid (% w/w) (animal surfaces/equipment) (dilution 3% v/v) | 0.714% | See calculation above |
| Concentration of Propan-2-ol (% w/w) (animal surfaces/equipment) (dilution 3% v/v) | 0.584% | See calculation above |
| Concentration of Chlorocresol (% w/w) (animal surfaces/equipment) (dilution 1.4% v/v) | 0.280% | See calculation above |
| Concentration of L (+) lactic acid (% w/w) (animal surfaces/equipment) (dilution 1.4% v/v) | 0.333% | See calculation above |
| Concentration of Propan-2-ol (% w/w) (animal surfaces/equipment) (dilution 1.4% v/v) | 0.273% | See calculation above |
| Molecular weight of Propan-2-ol (g/mol) | 60.09 | CAR Propan-2-ol |
| Vapour pressure of Propan-2-ol at 25°C (Pa) | 5780 | CAR Propan-2-ol |
| ***Task 1 – mixing loading (evaporation)*** | | |
| Product amount (g) – inhalation | 10820 | See calculation above |
| Exposure duration/Emission duration (min) | 10 | HEAd hoc Recommendation no. 6, 2017 |
| Room volume (m3) | 1 | Cleaning Products Fact Sheet, 2018 |
| Ventilation rate (1/hour) (unspecified room) | 0.6 | General Fact Sheet, 2014 |
| Mass transfer coefficient (m/h) | 10 | Default value from Consexpo |
| Realease area (cm2) | 20 | Cleaning Products Fact Sheet, 2018 |
| ***Task 2 – spray application (evaporation)*** | | |
| Product amount (g) – inhalation (animal surfaces) | 286000 | See calculation above |
| Product amount (g) – inhalation (equipment) | 2000 | See calculation above |
| Exposure duration/Emission duration (min) | 120 | HEAd hoc Recommendation no. 6, 2017 |
| Molecular weight matrix (g/mol) | 18 | Cleaning Products Fact Sheet, 2018 |
| Room volume (m3) (animal surfaces) | 5360 | See calculation above |
| Room volume (m3) (equipment) | 50 | Default value |
| Ventilation rate (1/hour) (animal surfaces) | 1.3 | BPR Guidance, 2015 (laying hens) |
| Ventilation rate (1/hour) (unspecified room) | 0.6 | General Fact Sheet, 2014 |
| Mass transfer coefficient (m/h) | 10 | Default value from Consexpo |
| Release area (m²) (animal surfaces) | 1430 | BPR Guidance, 2015 (laying hens) |
| Release area (m2) (equipment) | 10 | Default value from Consexpo |
| Task duration (min) | 120 | HEAd hoc Recommendation no. 6, 2017 |
| Inhalation absorption – all substances | 100% | Default value |
| Inhalation rate (m3/h) | 1.25 | HEAd hoc Recommendation no. 14, 2017 |
| Dermal absorption (diluted) – all substances | 50% | EFSA, 2017 (water-based) |
| Body weight (kg) | 60 | HEAd hoc Recommendation no. 14, 2017 |
| Tier 2 | PPE Indicative value – gloves (mg/min) | 7.80 | TNsG, 2002 |
| PPE Coated coverall penetration factor | 20%,  10%  5% | HEEG Opinion 9, 2010 |
| RPE factor | 4 | Overview of “Assigned Protection Factors” for filtering devices, BHHEM (2015), p. 154. |

**Calculations for Scenario [1] – Chlorocresol**

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Animal surfaces/equipment (dilution 3% v/v)** | | | | |
| Scenario [1] – Task 1 & 2– spraying | 1/ no PPE | 1.90E-02 | 2.97 | 2.99 |
| 2a/gloves | 1.90E-02 | 1.38 | 1.40 |
| 2/gloves, coverall 20%, mask PF4 | 4.75E-03 | 3.13E-01 | 3.32E-01 |
| 2/gloves, coverall 10%, mask PF4 | 4.75E-03 | 1.80E-01 | 1.85E-01 |
| 2/gloves, coverall 5% mask PF4 | 4.75E-03 | 1.13E-01 | 1.18E-01 |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | |
| Scenario [1] – Task 1 & 2 – spraying | 1/ no PPE | 8.87E-03 | 1.39 | 1.40 |
| 2a/gloves | 8.87E-03 | 0.64 | 6.53E-01 |
| 2/gloves, coverall 20%, | 8.87E-03 | 1.46E-01 | 1.55E-01 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/RPE** | **Estimated inhalation** (mg/m3) |
| Scenario [1] – Task 1 & 2 – Chlorocresol (animal surfaces/equipment) **(dilution 3% v/v)** | 1/ no RPE | 4.56E-01 |
| Scenario [1] – Task 1 & 2 – Chlorocresol (animal surfaces/equipment) **(dilution 3% v/v)** | 1/ RPE (APF4) | 1.14E-02 |
| Scenario [1] ] – Task 1 & 2 – Chlorocresol (animal surfaces/equipment) **(dilution 1.4% v/v)** | 1/ no RPE | 2.13E-01 |

**Calculations for Scenario [1] - Propan-2-ol**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (evaporation) uptake** (mg/kg bw/d) | **Estimated inhalation uptake**  **(aerosols)** (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| Scenario [1] – Task 1 – mix/loading | 1/ no PPE | 7.84E-01 | - | - | 7.84E-01 |
| **Animal surfaces (dilution 3% v/v)** | | | | | |
| Scenario [1] – Task 2 – spraying (animal surfaces) | 1/ no PPE | 3.2 | 1.85E-02 | 2.89 | 5.98 |
| **Equipment (dilution 3% v/v)** | | | | | |
| Scenario [1] – Task 2 – spraying (equipment) | 1/ no PPE | 3.3 | 1.85E-02 | 2.89 | 5.83 |
| **Animal surfaces (dilution 1.4% v/v)** | | | | | |
| Scenario [1] – Task 2 – spraying (animal surfaces) | 1/ no PPE | 1.59 | 8.63E-03 | 1.35 | 2.95 |
| **Equipment (dilution 1.4% v/v)** | | | | | |
| Scenario [1] – Task 2 – spraying (equipment) | 1/ no PPE | 1.36 | 8.63E-03 | 1.35 | 2.72 |

***Scenario [1] – Task 3: Cleaning spray equipment***

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| 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.  The indicative values from the model (75th percentile) are as follows (taking into account a density of 1 as the product is diluted in water):   * Dermal exposure – hand only: 35.87 mg/min * Dermal exposure – body: 19.28 mg/min | | | |
| Tier 1 | Parameters | Value | References |
| Concentration of Chlorocresol (% w/w) (animal surfaces) (dilution 3% v/v) | 0.601% | See calculation in Scenario 1 Task 1&2 |
| Concentration of L (+) lactic acid (% w/w) (animal surfaces) (dilution 3% v/v) | 0.714% | See calculation in Scenario 1 Task 1&2 |
| Concentration of Propan-2-ol (% w/w) (animal surfaces) (dilution 3% v/v) | 0.584% | See calculation in Scenario 1 Task 1&2 |
| Concentration of Chlorocresol (% w/w) (animal surfaces/equipment) (dilution 1.4% v/v) | 0.280% | See calculation in Scenario 1 Task 1&2 |
| Concentration of L (+) lactic acid (% w/w) (animal surfaces/equipment) (dilution 1.4% v/v) | 0.333% | See calculation in Scenario 1 Task 1&2 |
| Concentration of Propan-2-ol (% w/w) (animal surfaces/equipment) (dilution 1.4% v/v) | 0.273% | See calculation in Scenario 1 Task 1&2 |
| Duration (min) | 10 | Expert judgment |
| Dermal absorption (diluted) – all substances | 50% | EFSA, 2017 |
| Body weight (kg) | 60 | HEAd hoc Recommendation no. 14, 2017 |
| Tier 2 | PPE Gloves penetration factor | 10% | HEEG Opinion 9, 2010 |

**Calculations for Scenario [1] – Chlorocresol**

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Animal surfaces/equipment (dilution 3% v/v)** | | | | |
| Scenario [1] **-** Task 3 | 1/no PPE | - | 2.76E-02 | 2.76E-02 |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | |
| Scenario [1] **-** Task 3 | 1/no PPE | - | 1.29E-02 | 1.29E-02 |

**Calculations for Scenario [1] – Propan-2-ol**

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Animal surfaces/equipment (dilution 3% v/v)** | | | | |
| Scenario [1] **-** Task 3 | 1/no PPE | - | 2.69E-02 | 2.69E-02 |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | |
| Scenario [1] **-** Task 3 | 1/no PPE | - | 1.25E-02 | 1.25E-02 |

***Scenario [2] – Task 1&2: Manual spraying animal transport vehicles (dilution 2% v/v)***

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| The product PHENOGEN contains:   * 18.5% w/w chlorocresol; * 22% w/w L(+) lactic acid and ; * 18% w/w Propan-2-ol.   The product is applied by manual spraying on animal transport vehicles after being diluted in water at 2% v/v.  Taking into account a relative density value of 1.082 at 20°C for the product PHENOGEN and a density value of 1 for the dilution (mainly water), concentrations of active substances and SoC in the diluted product are calculated as follows:  *Diluted product 2% v/v*:   * Chlorocresol: 0.4% v/v; * L(+) lactic acid: 0.48% v/v; * Propan-2-ol: 0.39% v/v.   During manual spray application, dermal and inhalation exposure can occur. The same parameters from Scenario [1] are taken for manual spray application, with a dilution of 2% v/v.  In addition, due to the high volatility of the identified SoC Propan-2-ol, the exposure to vapour during the **mixing/loading (Task 1)** and **spray application (Task 2)** has to be considered using the scenario *inhalation–exposure to vapour–evaporation–constant release area* from ConsExpo, according to the Cleaning Products Fact Sheet 2018.  Task 1: see scenario [1] above.  Task 2:  *Exposure duration/Emission duration*  A duration of 120 minutes is taken into consideration for spraying. The same value is considered for emission duration.  *Room volume/release area*- For transport vehicles, a surface of 18 m² (default truck of 7.0 m x 2.5 m) is taken according to Guidance on the BPR 2017. A room volume of 53 m3 are taken, assuming a minimum height of 3 m by default.  *Ventilation rate*  - For transport vehicles, according to EC Regulation 1/2005, “The ventilation system must be capable of ensuring even distribution throughout with a minimum airflow of nominal capacity of 60 m3/h/KN of payload”. It is therefore assumed that 1 time of air changes per hour is done for a volume of 58 m3, leading to a ventilation rate of 1 h-1.  *Product amount – inhalation*  The application rate is 125 mL/m² for transport vehicles:  - Considering a surface of 18 m² for transport vehicles, the amount of product deposited on the treated surface is 2250 g. | | | |
| Tier 1 | Parameters | Value | References |
| Concentration of Chlorocresol (% w/w) (transport vehicles) (dilution 2% v/v) | 0.400% | See calculation above |
| Concentration of L (+) lactic acid (% w/w) (transport vehicles) (dilution 2% v/v) | 0.476% | See calculation above |
| Concentration of Propan-2-ol (% w/w) (transport vehicles) (dilution 2% v/v) | 0.390% | See calculation above |
| Molecular weight of Propan-2-ol (g/mol) | 60.09 | CAR Propan-2-ol |
| Vapour pressure of Propan-2-ol at 25°C (Pa) | 5780 | CAR Propan-2-ol |
| Product amount (g) – inhalation (transport vehicles) | 2250 | See calculation above |
| Exposure duration/Emission duration (min) | 120 | HEAd hoc Recommendation no. 6, 2017 |
| Molecular weight matrix (g/mol) | 18 | Cleaning Products Fact Sheet, 2018 |
| Room volume (m3) (transport vehicles) | 53 | See calculation above |
| Ventilation rate (1/hour) (transport vehicles) | 1 | Expert judgment (see above) |
| Mass transfer coefficient (m/h) | 10 | Default value from Consexpo |
| Release area (m²) (transport vehicles) | 18 | See calculation above |
| Task duration (min) | 120 | HEAd hoc Recommendation no. 6, 2017 |
| Inhalation absorption – all substances | 100% | Default value |
| Inhalation rate (m3/h) | 1.25 | HEAd hoc Recommendation no. 14, 2017 |
| Dermal absorption (diluted) – all substances | 50% | EFSA, 2017 (water-based) |
| Body weight (kg) | 60 | HEAd hoc Recommendation no. 14, 2017 |
| Tier 2 | PPE Indicative value – gloves (mg/min) | 7.80 | TNsG, 2002 |
| PPE Coated coverall penetration factor | 20%,  10% | HEEG Opinion 9, 2010 |
| RPE factor | 4 | Overview of “Assigned Protection Factors” for filtering devices, BHHEM (2015), p. 154. |

**Calculations for Scenario [2] – Chlorocresol**

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Transport vehicles (dilution 2% v/v)** | | | | |
| Scenario [2] – Task 2 – spraying | 1/ no PPE | 1.27E-02 | 1.98 | 1.99 |
|  | 2a/gloves | 1.27E-02 | 0.92 | 0.93 |
| 2b/ gloves, coverall 20% | 3.17E-03 | 2.09E-01 | 0.21 |
|  | 2/gloves, coverall 20%, mask PF4 | 1.27E-02 | 1.98 | 1.99 |

|  |  |  |
| --- | --- | --- |
| **Local exposure** | **Tier/RPE** | **Estimated inhalation** (mg/m3) |
| Scenario [2] – Task 1 & 2 – Chlorocresol (transport vehicles) | 1/ no RPE | 3.04E-01 |
| Scenario [2] – Task 1 & 2 – Chlorocresol (transport vehicles) | 1/ RPE (APF4) | 7.61E-02 |

**Calculations for Scenario [2] - Propan-2-ol**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (evaporation) uptake** (mg/kg bw/d) | **Estimated inhalation uptake**  **(aerosols)** (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Transport vehicles (dilution 2% v/v)** | | | | | |
| Scenario [2] – Task 1 - mix/loading | 1/ no PPE | 1.7.8E-01 | - | - | 7.8E-01 |
| Scenario [2] – Task 2 - spraying (transport vehicles) | 1/ no PPE | 1.97 | 1.23E-02 | 1.93 | 3.91 |

***Scenario [2] – Task 3: Cleaning spray equipment***

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| Same parameters are taken from Scenario [1] with a dilution of 2% v/v. | | | |
| Tier 1 | Parameters | Value | References |
| Concentration of Chlorocresol (% w/w) (transport vehicles) (dilution 2% v/v) | 0.400% | See calculation in Scenario 2 Task 1&2 |
| Concentration of L (+) lactic acid (% w/w) (transport vehicles) (dilution 2% v/v) | 0.476% | See calculation in Scenario 2 Task 1&2 |
| Concentration of Propan-2-ol (% w/w) (transport vehicles) (dilution 2% v/v) | 0.390% | See calculation in Scenario 2 Task 1&2 |
| Duration (min) | 10 | Expert judgment |
| Dermal absorption (diluted) – all substances | 50% | EFSA, 2017 |
| Body weight (kg) | 60 | HEAd hoc Recommendation no. 14, 2017 |
| Tier 2 | PPE Gloves penetration factor | 10% | HEEG Opinion 9, 2010 |

**Calculations for Scenario [2] – Chlorocresol**

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Transport vehicles (dilution 2% v/v)** | | | | |
| Scenario [2] – Task 3 | 1/no PPE | - | 1.84E-02 | 1.84E-02 |

**Calculations for Scenario [2] – Propan-2-ol**

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Transport vehicles (dilution 2% v/v)** | | | | |
| Scenario [2] – Task 3 | 1/no PPE | - | 1.79E-02 | 1.79E-02 |

***Non-professional exposure***

No exposure is foreseen.

***Exposure of the general public***

*Scenario [3] - Inhalation of volatilised residues after spraying on animal surfaces and equipment – Adults & children*

| **Description of Scenario [3]** | | | |
| --- | --- | --- | --- |
| After application on surfaces and equipment, adults, children, toddlers and infants can be exposed by inhalation exposure to volatile residues.  The Human Exposure Expert Group (HEEG) opinion 13 on the assessment of inhalation exposure to volatilised biocides is applied in order to estimate if it is considered negligible or not.  The risk from inhalation exposure of volatilised residues is considered negligible if:    Where *mw* and *vp* denote the molecular weight (in g/mol) and the vapour pressure (in Pa), for a toddler (based on an inhalation rate of 8 m3/24 hour and bw of 10 kg) and using an AEL expressed in mg a.s./kg bw/d.  The calculation is performed for toddler since it is considered a ‘worst case’ scenario.  Chlorocresol has a molecular weight of 142.6 g/mol and a vapour pressure of 1.40E-03 at 20°C. The AEL (long term) is 0.3 mg/kg bw/d. Therefore applying the above equation: 0.328\*((142.6\*0.0014)/0.3) = 0.22  The value is <1 therefore the risk from inhalation exposure to Chlorocresol is considered negligible.  L (+) lactic acid has a molecular weight of 90.08 g/mol and a vapour pressure of 0.4 at 20°C. The AEL (long term) is 1667 mg/kg bw/d (endogenous production).  The value is <1 therefore the risk from inhalation exposure to L (+) lactic acid is considered negligible.  For Propan-2-ol, exposure to general public to volatile residues can occur. The exposure to volatile residues after spraying application is considered using the scenario *inhalation–exposure to vapour–evaporation–constant release area* from ConsExpo according to the Cleaning Products Fact Sheet 2018. Exposure to 24h is determined for general public (very conservative assessment considering the uses). Exposure to 8h is determined for professionals (this duration corresponds to a day of working). The parameters for product amounts, release areas, room volumes, ventilation rates and emission durations are the same used in Scenarios [1] for professionals and general public. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1 | Concentration of Propan-2-ol (% w/w) (animal surfaces/equipment) (dilution 3% v/v) | 0.584% | See calculation in Scenario 1 Task 1&2 |
| Concentration of Propan-2-ol (% w/w) (animal surfaces/equipment) (dilution 1.4% v/v) | 0.273% | See calculation in Scenario 1 Task 1&2 |
| Molecular weight of Propan-2-ol (g/mol) | 60.09 | CAR Propan-2-ol |
| Vapour pressure of Propan-2-ol at 25°C (Pa) | 5780 | CAR Propan-2-ol |
| Inhalation absorption | 100% | Default value |
| **Inhalation rate (m3/24h)** | | HEAd hoc 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)** | | HEAd hoc 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 [3] – Propan-2-ol**

|  |  |  |
| --- | --- | --- |
|  | **General public** | **Professional** |
| **Mean event concentration**  (spraying, animal surfaces) **(dilution 3% v/v)** | 7.2 mg/m3 | 22 mg/m3 |
| **Mean event concentration**  (spraying, equipment) **(dilution 3% v/v)** | 10.9 mg/m3 | 32.6 mg/m3 |
| **Mean event concentration**  (spraying, animal surfaces) **(dilution 1.4% v/v)** | 3.4 mg/m3 | 10.3 mg/m3 |
| **Mean event concentration**  (spraying, equipment) **(dilution 1.4% v/v)** | 5.5 mg/m3 | 16.3 mg/m3 |

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Animal surfaces (dilution 3% v/v)** | | | | |
| Scenario [3] – Adults (24h) | 1 | 1.93 | - | 1.93 |
| Scenario [3] – Child (6 to <12 years old) | 1 | 3.63 | - | 3.63 |
| Scenario [3] – Child (2 to <6 years old) | 1 | 4.68 | - | 4.68 |
| Scenario [3] – Toddler (1 to <2 years old) | 1 | 5.78 | - | 5.78 |
| Scenario [3] – Infant (<1 year old) | 1 | 4.88 | - | 4.88 |
| Scenario [3] – Professionals (8h) | 1 | 3.67 | - | 3.67 |
| **Equipment (dilution 3% v/v)** | | | | |
| Scenario [3] – Adults (24h) | 1 | 2.91 | - | 2.91 |
| Scenario [3] – Child (6 to <12 years old) | 1 | 5.47 | - | 5.47 |
| Scenario [3] – Child (2 to <6 years old) | 1 | 7.06 | - | 7.06 |
| Scenario [3] – Toddler (1 to <2 years old) | 1 | 8.72 | - | 8.72 |
| Scenario [3] – Infant (<1 year old) | 1 | 7.36 | - | 7.36 |
| Scenario [3] – Professionals (8h) | 1 | 5.43 | - | 5.43 |
| **Animal surfaces (dilution 1.4% v/v)** | | | | |
| Scenario [3] – Adults (24h) | 1 | 0.90 | - | 0.90 |
| Scenario [3] – Child (6 to <12 years old) | 1 | 1.70 | - | 1.70 |
| Scenario [3] – Child (2 to <6 years old) | 1 | 2.19 | - | 2.19 |
| Scenario [3] – Toddler (1 to <2 years old) | 1 | 2.70 | - | 2.70 |
| Scenario [3] – Infant (<1 year old) | 1 | 2.28 | - | 2.28 |
| Scenario [3] – Professionals (8h) | 1 | 1.72 | - | 1.72 |
| **Equipment (dilution 1.4% v/v)** | | | | |
| Scenario [3] – Adults (24h) | 1 | 1.46 | - | 1.46 |
| Scenario [3] – Child (6 to <12 years old) | 1 | 2.74 | - | 2.74 |
| Scenario [3] – Child (2 to <6 years old) | 1 | 3.54 | - | 3.54 |
| Scenario [3] – Toddler (1 to <2 years old) | 1 | 4.37 | - | 4.37 |
| Scenario [3] – Infant (<1 year old) | 1 | 3.69 | - | 3.69 |
| Scenario [3] – Professionals (8h) | 1 | 2.72 | - | 2.72 |

*Scenario [4] - Inhalation of volatilised residues after spraying on animal transport vehicles (dilution 2% v/v) – Professionals*

| **Description of Scenario [4]** | | | |
| --- | --- | --- | --- |
| Exposure in transport vehicles after spraying is considered not relevant for adults (non-professionals) and children. Same parameters are taken from Scenario [3] with a dilution of 2% v/v, in case if professionals may enter after spraying application. | | | |
|  | **Parameters** | **Value** | **References** |
|  | Concentration of Propan-2-ol (% w/w) (transport vehicles) (dilution 2% v/v) | 0.390% | See calculation in Scenario 2 Task 1&2 |
|  | Molecular weight of Propan-2-ol (g/mol) | 60.09 | CAR Propan-2-ol |
| Vapour pressure of Propan-2-ol at 25°C (Pa) | 5780 | CAR Propan-2-ol |
| Inhalation absorption | 100% | Default value |
| **Inhalation rate (m3/24h)** | | HEAd hoc 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)** | | HEAd hoc 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 [4] – Propan-2-ol**

|  |  |  |
| --- | --- | --- |
|  | **General public** | **Professional** |
| **Mean event concentration**  (spraying, transport vehicles) | Not relevant | 15.8 mg/m3 |

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Transport vehicles (dilution 2% v/v)** | | | | |
| Scenario [4] – Professionals (8h) | 1 | 2.63 | - | 2.63 |

*Scenario [5] - Exposure to treated surfaces (animal surfaces and equipment) - Adults and toddlers*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [5]** | | | |
| After application, the secondary exposure of an adult touching wet or dried surfaces is considered for treatment on animal surfaces and equipment, with an exposed area of 410 cm², corresponding to the palm of two hands. Secondary exposure is also considered for toddlers when crawling by touching or mouthing dried or wet surfaces.  For Chlorocresol, a dislodgeable fraction of 100% from wet surface to skin is considered as a worst-case. A dislodgeable fraction of 30% from dried surface to skin is considered, based on transfer coefficients for dislodgeable residues reported in the TNsG Human exposure 2002 part 2 (cotton, knitwear, plastic, wood on wet hands).  For Chlorocresol and L (+) lactic acid, 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.  For Propan-2-ol, the dermal exposure is considered negligible because of the high volatility of containing in the product; no residue will remains on surfaces.  A refinement is proposed as Tier 2 following Recommendation no.5 (2015): 40% of the maximum palm area of both hands is in contact with dried surfaces. This leads to a surface of 164 cm². | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1a | Application rate (mL/m²) (animal surfaces) | 200 | Applicant’s data |
| Concentration of Chlorocresol (% w/w) (animal surfaces) (dilution 3% v/v) | 0.601% | See calculation in Scenario 1 Task 1&2 |
| Concentration of L (+) lactic acid (% w/w) (animal surfaces) (dilution 3% v/v) | 0.714% | See calculation in Scenario 1 Task 1&2 |
| Concentration of Chlorocresol (% w/w) (animal surfaces) (dilution 1.4% v/v) | 0.280% | See calculation in Scenario 1 Task 1&2 |
| Dislodgeable fraction from floor to skin (wet surface) (adults and toddlers) | 100% | Default value |
| Surface area (palm of two hands) (cm²) (adults) | 410 | HEAd hoc Recommendation no. 14, 2017 |
| Transfer to the mouth (toddlers) | 10% | TNsG, 2002 |
| Transfer coefficient for a toddler (m²/h) | 0.21 | HEAd hoc Recommendation no. 12, 2016 |
| Dermal absorption (dilution) | 50% | Default value EFSA, 2017 |
| Oral absorption | 100% | CAR Chlorocresol |
| Body weight (kg) – adults | 60 | HEAd hoc Recommendation no. 14, 2017 |
| Body weight (kg) – toddlers | 10 | HEAd hoc Recommendation no. 14, 2017 |
| Tier 1b | Dislodgeable fraction from floor to skin (dried surface) (adults and toddlers) | 30% | TNsG, 2002 |
| Tier 2 | Surface area (palm of two hands) (cm²) (adults) | 164 | Recommendation no.5, 2015 |

**Calculations for Scenario [5] – Chlorocresol**

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Animal surfaces/equipment (dilution 3% v/v)** | | | | |
| Scenario [5] – wet surfaces, adults | 1a | **-** | 4.44E-01 | 4.44E-01 |
| Scenario [5] – dried surfaces, adults | 1b | **-** | 1.33E-01 | 1.33E-01 |
| Scenario [5] – dried surfaces, adults | 2 |  | 5.33E-02 | 5.33E-02 |
| Scenario [5] – wet surfaces, toddlers (crawling) | 1a | - | 1.88E+01 | 1.88E+01 |
| Scenario [5] – dried surfaces, toddlers (crawling) | 1b | - | 5.63 | 5.63 |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | |
| Scenario [5] – wet surfaces, adults | 1a | **-** | 2.07E-01 | 2.07E-01 |
| Scenario [5] – dried surfaces, adults | 1b | **-** | 6.22E-02 | 6.22E-02 |
| Scenario [5] – dried surfaces, adults | 2 |  | 2.49E-02 | 2.49E-02 |
| Scenario [5] – wet surfaces, toddlers (crawling) | 1a | **-** | 8.76 | 8.76 |
| Scenario [5] – dried surfaces, toddlers (crawling) | 1b | **-** | 2.63 | 2.63 |

*Scenario [6] - Exposure to treated surfaces (transport vehicles) - Adults*

| **Description of Scenario [6]** | | | |
| --- | --- | --- | --- |
| For transport vehicles, adults are considered to be only professionals as this use is not relevant for general public. Same parameters from Scenario [5] are taken into account, with an application rate of 125 mL/m² and a dilution of 2% v/v.  Exposure in transport vehicles is considered not relevant for toddlers. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1a | Application rate (mL/m²) (transport vehicles) | 125 | Applicant’s data |
| Concentration of Chlorocresol (% w/w) (transport vehicles) (dilution 2% v/v) | 0.400% | See calculation in Scenario 2 Task 1&2 |
| Concentration of L (+) lactic acid (% w/w) (transport vehicles) (dilution 2% v/v) | 0.476% | See calculation in Scenario 2 Task 1&2 |
| Dislodgeable fraction from floor to skin (wet surface) | 100% | Default value |
| Surface area (palm of two hands) (cm²) | 410 | HEAd hoc Recommendation no. 14, 2017 |
| Dermal absorption (dilution) | 50% | Default value EFSA, 2017 |
| Body weight (kg) | 60 | HEAd hoc Recommendation no. 14, 2017 |
| Tier 1b | Dislodgeable fraction from floor to skin (dried surface) | 30% | TNsG, 2002 |
| Tier 2 | Surface area (palm of two hands) (cm²) (adults) | 164 | Recommendation no.5, 2015 |

**Calculations for Scenario [6] – Chlorocresol**

| **Summary table: systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated total uptake** (mg/kg bw/d) |
| **Transport vehicles (dilution 2% v/v)** | | | | |
| Scenario [6] – wet surfaces, adults | 1a | **-** | 1.85E-01 | 1.85E-01 |
| Scenario [6] – dried surfaces, adults | 1b | **-** | 5.55E-02 | 5.55E-02 |
| Scenario [6] – dried surfaces, adults | 2 | **-** | 2.22E-02 | 2.22E-02 |

*Combined scenarios*

*Combined scenarios (primary exposure and secondary exposure)*

* Systemic effects (professionals)

For professionals, spraying and cleaning equipment are considered the same day when spraying on animal surfaces and equipment and on animal transport vehicles.

In addition, inhalation of volatilised residues after spraying is considered for propan-2-ol and exposure to treated surfaces is considered for chlorocresol for all uses. Further information are available in the human exposure sheet for PPE. The results below with selected PPE are used for cumulative riks assessment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenarios combined** | **Active substance** | **PPE** | **Estimated uptake**  **mg/kg bw/d** |
| **Spray application on animal surfaces (dilution 3% v/v)** | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 5%, respiratory mask PF4 during application, dried surfaces (tier 2) | 1.99E-01 |
|  | Propan-2-ol | 4.30 |
| **Spray application on equipment (dilution 3% v/v)** | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 5%, respiratory mask PF10 during application, gloves during cleaning, dried surfaces | 1.99E-01 |
|  | Propan-2-ol | 4.77 |
| **Spray application on animal surfaces (dilution 1.4% v/v)** | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 20% during m/l and application, dried surfaces | 1.93E-01 |
| Propan-2-ol | 4.02 |
| **Spray application on equipment (dilution 1.4% v/v)** | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 20% during m/l and application, dried surfaces | 1.93E-01 |
| Propan-2-ol | 3.44 |
| **Spray application on animal transport vehicles (dilution 2% v/v)** | | | |
| Scenario 2 (task 1, 2, 3) + 4 + 6 (dried surfaces) | Chlorocresol | gloves, coverall 10%, mask PF4 during m/l and application, dried surfaces (tier 2) | 1.64E-01 |
| Propan-2-ol | 4.94 |

* Systemic effects (non-professionals, adults)

Inhalation of volatilised residues after spraying is considered for propan-2-ol and exposure to treated surfaces is considered for chlorocresol for animal surfaces and equipment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenarios combined** | **Active substance** | **Tier** | **Estimated uptake**  **mg/kg bw/d** |
| **Scenario 1: spray application on animal surfaces and equipment (dilution 3% v/v)** | | | |
| Scenario 3 + 5 | Chlorocresol | Dried surfaces – tier 1b | 1.33E-01 |
| Propan-2-ol | 1 – animal surfaces | 1.93 |
| 1 – equipment | 2.91 |
| **Scenario 1: spray application on animal surfaces and equipment (dilution 1.4% v/v)** | | | |
| Scenario 3 + 5 | Chlorocresol | Wet surfaces – tier 1a | 2.07E-01 |
| Propan-2-ol | 1 – animal surfaces | 0.90 |
| 1 – equipment | 1.46 |

* Systemic effects (toddlers)

Inhalation of volatilised residues after spraying is considered for propan-2-ol and exposure to treated surfaces is considered for chlorocresol for animal surfaces and equipment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenarios combined** | **Active substance** | **Tier** | **Estimated uptake**  **mg/kg bw/d** |
| **Scenario 1: spray application on animal surfaces (dilution 3% v/v)** | | | |
| Scenario 3 + 5 | Chlorocresol | Dried surfaces | 5.63 |
| Propan-2-ol | 1 – animal surfaces | 5.78 |
| 1 – equipment | 8.72 |
| **Scenario 1: spray application on animal surfaces (dilution 1.4% v/v)** | | | |
| Scenario 3 + 5 | Chlorocresol | Dried surfaces | 2.63 |
| Propan-2-ol | 1 – animal surfaces | 2.70 |
| 1 – equipment | 4.37 |

***Monitoring data***

None.

***Dietary exposure***

Regarding the intended uses on PT 3 in poultry hatcheries, poultry exposure and eggs contamination can occur. Nevertheless, the applicant proposed following risk mitigation measures:

* Do not apply the treatment in the presence of poultry and eggs.
* Only use the hatchery materials after their complete drying.
* Always place a sheet of Kraft paper into the hatching baskets and transport crates before their reuse.

Therefore, after disinfection of poultry hatcheries, no poultry and eggs contamination can occur. No residues in food of animal origin is expected based on proposed risk mitigation measures and no dietary exposure assessment for consumers is therefore necessary.

According to intended uses in animal housing and transport vehicles, livestock can be exposed directly or indirectly to active substances. Therefore, livestock exposure has to be further assessed and estimated:

* Based on the low concentration of L(+) lactic acid, its endogenous production and the authorized uses of this active substance as food additive (E 270), significant indirect exposure via food for intended uses is not expected.
* For chlorocresol, livestock exposure might occur via intended uses and is therefore further assessed and estimated here below.

For this dossier, one substance of concern (SoC) is identified (See paragraph above in human exposure part): propan-2-ol. Propan-2-ol is an approved active substance in EU Biocidal Regulation n°528/2012. Exposure and risk calculations via food are not necessary considering specific properties of propan-2-ol. Indeed:

“*Due to its high vapour pressure, the active substance evaporates completely within the time of application of the biocidal product, so that no transfer from treated surfaces to food should occur.”* (AR (DE, 2017))

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, livestock exposure is performed taking into account **chlorocresol only**.

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Type of usea** | **Description of scenario** | **Subject of exposureb** |
| DRA - 1. | Animal husbandry | Disinfection of equipment and livestock animal housing (cattle, pigs and poultry), | Poultry, pigs and cattle |
| DRA - 2. | Animal husbandry | Disinfection of animal transportation vehicles | Poultry, pigs and cattle |

1 e.g. animal husbandry, food industry, professional use, residential use.

2 e.g. chicken, milk, beer

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

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use a** | **Intended use** | **Reference value(s) b** |
| **Lactic acid** | | | |
| 1. | Food | Lactic Acid (E 270) – Food additive | Quantum satis (Regulation (EU) 1129/2011) |
| 2. | Veterinary | Lactic Acid - All food producing species | No MRL required (Regulation (EC) No 37/2010) |
| 3. | Cosmetic | Lactic Acid – Used as buffering humectant or skin conditioning | Up to a maximum level of 2.5% and a pH ≥ 5 (SCCBFP, 2000) |
| **Chlorocresol** | | | |
| 1. | Veterinaryc | Disinfectant and antiseptic | All food producing species: No MRL required |
| 2. | Phytosanitary | Not approved as a PPP active substance d (Commission Decision 2004/129/EC) | 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 : Committeee 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*

According to intended uses, livestock can be exposed directly or indirectly to chlorocresol after use of BP as animal houses and transport vehicles disinfection. The scenarios and default values defined in European guidance document[[3]](#footnote-4) were used for animal houses and transport vehicles disinfection uses. The calculator developed by BfR based on scenarios detailed in this guidance has been used to estimate livestock exposure.

* Animal housings disinfection

Animals may also be exposed when re-entering animal facilities where surfaces were treated by PHENOGEN. Indeed, application of PHENOGEN is performed in absence of livestock. Exposure is estimated taking in account:

* Oral exposure by licking surfaces, by uptake of feed contaminated in trough
* Dermal exposure by rubbing against surfaces
* Inhalation with saturated vapour concentration model SVC
* Transport vehicles:

Animals may also be exposed when entering vehicles for transport where surfaces were treated with PHENOGEN. Indeed, application of PHENOGEN is performed in absence of livestock. Exposure is estimated taking in account:

* Oral exposure by licking surfaces
* Dermal exposure by rubbing against surfaces
* Inhalation with saturated vapour concentration model SVC

For all scenarios (animal housing and transport vehicle), an exposure is estimated per animal in mg of chlorocresol/kg body weight per day.

Exposure is first compared to the trigger value of 0.004 mg/kg bw/d. If this trigger value is exceeded, a Tier 2 is performed taking into account a dermal absorption.

Finally, to estimate residues in livestock tissues, empirical transfer factors (TF) based on the Octanol–Water Partition Coefficient (log P\_O/W) have been applied (see Leeman et al. 2007[[4]](#footnote-5)). These transfer factors allow to estimate the maximum transfer of an external oral dose to livestock edible tissues.

Log Octanol/water partition coefficient for chlorocresol is 2.73 (revised AR of CMK (2017)). From the study Leeman et al., transfer factors for a substance with a Log Octanol/water partition coefficient between 2 and 3 are detailed in the table below:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Transfer factors (TF)** | | | | | |
| **Log Octanol/water partition coefficient** | **Eggs** | **Milk** | **Muscle** | **Fat** | **Liver** | **Kidney** |
| 2-3 | 0.13 | 0.01 | 0.02 | 0.02 | 0.04 | 0.04 |

Residues in livestock tissues are estimated following calculation detailed below:

Residues in livestock tissue X = Sum Oral exposure \* TF for tissue X + Sum Dermal and Inhalative exposures

Parameters, default values and results for these two scenarios are presented in the table below.

Scenario [DRA-1] - Animal housing disinfection

| **Description of Scenario [DRA-1]** | | |
| --- | --- | --- |
| Disinfection for surfaces and equipment in veterinary field for poultry, pig and cattle houses. Application rate is 200 mL/m2. Surfaces to be treated: Floor and wall without partitions | | |
|  | Parameters | Value |
| **Tier 1** | Maximum concentration of chlorocresol in the biocidal product | 18.50 % (w/w) |
| Maximum dilution | 3% (v/v) |
| Density of the biocidal product | 1.08 |
| In use concentration of chlorocresol | 0.599 % |
| Application rate of working solution | 200 mL/m2 |
| Application rate of active substance | 1200 mg/m2 |
| Vapour Pressure | 1.40x10-3 Pa |
| Molecular weight | 142.6 g/mol |
| Emission factor for sprayinga:  - oral exposure through licking of surface and dermal exposure through rubbing against surfaces (fraction emitted to the treated surface during surface treatment by spraying)  - oral exposure through uptake of contaminated feed (fraction emitted to the floor during surface treatment by spraying) | 0.85  0.11 |
| Body weight of animals, number of animal per stable  Gas constant  Temperature | See guidancea |
| **Tier 2** | Dermal absorption (See value proposed in the Human health section) | 50 % |

a 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

Scenario [DRA - 2] – Transport vehicles disinfection

| **Description of Scenario [DRA-2]** | | |
| --- | --- | --- |
| Disinfection for surfaces and equipment in veterinary field for poultry, pig and cattle transport vehicle. Application rate is 125 mL/m2. Surfaces to be treated: Floor and wall without partitions | | |
|  | Parameters | Value |
| **Tier 1** | Maximum concentration of chlorocresol in the biocidal product | 18.50 % (w/w) |
| Maximum dilution | 2% (v/v) |
| Density of the biocidal product | 1.08 |
| In use concentration of chlorocresol | 0.40 % |
| Application rate of working solution | 125 mL/m2 |
| Application rate of active substance | 500 mg/m2 |
| Vapour Pressure | 1.40x10-3 Pa |
| Molecular weight | 142.6 g/mol |
| Emission factor for sprayinga:  - oral exposure through licking of surface and dermal exposure through rubbing against surfaces (fraction emitted to the treated surface during surface treatment by spraying)  - oral exposure through uptake of contaminated feed (fraction emitted to the floor during surface treatment by spraying) | 0.85  0.11 |
| Body weight of animals, number of animals per transport vehicles,  Gas constant, Temperature | See guidancea |
| **Tier 2** | Dermal absorption (See value proposed in the Human health section) | 50 % |

a 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

**Calculations for estimating livestock exposure for Scenario [DRA-1 and DRA-2]**

For scenario DRA-1 and DRA-2, a screening step is first performed. Results are available for all animal intended species for which default values for the chosen scenario are available in the guidance. As the trigger value of 0.004 mg as/kg bw/day is exceeded, a refined assessment is necessary. In both scenario DRA-1 and DRA-2, a Tier 2 (dermal absorption of 50%) is performed. Finally, to estimate residues in livestock tissues, empirical transfer factors (TF) based on the Octanol–Water Partition Coefficient (log P\_O/W) (see Leeman et al. 2007) have been applied.

Scenario [DRA-1] – animal housing disinfection

| **Internal dose received by the animal (mg as/kg bw/d)** |
| --- |
| 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. BfR calculator |
| **Screening, realistic worst case (Tier 1 and Tier 2)** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Animal Species |  | Screening | Tier 1 | Tier 2 | | Beef cattle |  | 19.18 | 3.29 | 1.82 | | Dairy cattle |  | 30.80 | 3.36 | 2.04 | | Calf |  | 24.73 | 5.18 | 2.96 | | Fattening pig |  | 29.07 | 5.94 | 3.65 | | Breeding pig |  | - | 3.62 | 1.97 | | Breeding pig | individual housing | 31.79 | 1.93 | 1.93 | | Breeding pig | group housing | 40.52 | 2.29 | 2.29 | | Sheep |  | - | 1.10 | 1.10 | | Lamb |  | - | 2.05 | 2.05 | | Slaughter goat  (= goat kids) |  | - | 18.05 | 12.17 | | Lactating goat |  | - | 7.73 | 4.45 | | Broilers |  | - | 0.01 | 0.01 | | Broilers | free range. litter floor | 56.41 | - | - | | Broilers | parent broilers. free range (grating floor) | 60.44 | - | - | | Broilers | parent broilers in rearing. free range (grating floor) | 58.76 | - | - | | Laying hen |  | - | 0.70 | 0.70 | | Laying hen | battery | 33.05 | - | - | | Laying hen | free range (litter floor) | 128.08 | - | - | | Laying hen | free range (grating floor) | 57.48 | - | - | | Turkey |  | - | 0.01 | 0.01 | | Horse |  | - | 4.14 | 2.07 | | Rabbit |  | 80.56 | 0.03 | 0.03 | |

Scenario [DRA-1] – animal housing disinfection – residues in livestock tissues

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Residues in livestock tissues** | | | | | |
| **Animal Species** |  | **Sum Oral Exposure** | **Sum Dermal and Inhalative Exposure** | **Eggs** | **Milk** | **Muscle** | **Fat** | **Liver** | **Kidney** |
| Beef cattle | - | 0.348 | 1.476 |  |  | 1.48 | 1.48 | 1.49 | 1.49 |
| Dairy cattle | - | 0.714 | 1.325 |  | 1.33 | 1.34 | 1.34 | 1.35 | 1.35 |
| Calf | - | 0.737 | 2.227 |  |  | 2.24 | 2.24 | 2.26 | 2.26 |
| Fattening pig | - | 1.343 | 2.304 |  |  | 2.33 | 2.33 | 2.36 | 2.36 |
| Breeding pig | - | 0.314 | 1.656 |  |  | 1.66 | 1.66 | 1.67 | 1.67 |
| Breeding pig | individual housing | 1.934 | 0.000 |  |  | 0.04 | 0.04 | 0.08 | 0.08 |
| Breeding pig | group housing | 2.286 | 0.000 |  |  | 0.05 | 0.05 | 0.09 | 0.09 |
| Sheep | - | 1.087 | 0.013 |  | 0.02 | 0.03 | 0.03 | 0.06 | 0.06 |
| Lamb | - | 2.038 | 0.014 |  |  | 0.06 | 0.06 | 0.10 | 0.10 |
| Slaughter goat | - | 6.271 | 5.898 |  |  | 6.02 | 6.02 | 6.15 | 6.15 |
| Lactating goat | - | 1.165 | 3.288 |  | 3.30 | 3.31 | 3.31 | 3.33 | 3.33 |
| Broilers | - | 0.000 | 0.010 |  |  | 0.01 | 0.01 | 0.01 | 0.01 |
| Broilers | free range, litter floor |  |  |  |  |  |  |  |  |
| Broilers | parent broilers, free range (grating floor) |  |  |  |  |  |  |  |  |
| Broilers | parent broilers in rearing, free range (grating floor) |  |  |  |  |  |  |  |  |
| Laying hen | - | 0.694 | 0.009 | 0.099 |  | 0.02 | 0.02 | 0.04 | 0.04 |
| Laying hen | battery |  |  | 0 |  |  |  |  |  |
| Laying hen | free range (litter floor) |  |  | 0 |  |  |  |  |  |
| Laying hen | free range (grating floor) |  |  | 0 |  |  |  |  |  |
| Turkey | - | 0.000 | 0.007 |  |  | 0.01 | 0.01 | 0.01 | 0.01 |
| Horse | - | 0.000 | 2.072 |  |  | 2.07 | 2.07 | 2.07 | 2.07 |
| Rabbit | - | 0.000 | 0.030 |  |  | 0.03 | 0.03 | 0.03 | 0.03 |
|  |  |  | **Maximum** | **0.099** | **3.30** | **6.02** | **6.02** | **6.15** | **6.15** |

Scenario [DRA-2] – Transport vehicles disinfection

| **Internal dose received by the animal (mg as/kg bw/d)** |
| --- |
| 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. BfR calculator |
| **Screening, realistic worst case (Tier 1 and Tier 2)** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Animal Species |  | Screening | Tier 1 | Tier 2 | | Beef cattle |  | 8.00 | 1.30 | 0.69 | | Dairy cattle |  | 12.85 | 1.16 | 0.61 | | Calf |  | 10.31 | 2.03 | 1.10 | | Fattening pig |  | 12.13 | 2.26 | 1.31 | | Breeding pig |  | - | 1.51 | 0.83 | | Breeding pig | individual housing | 13.26 | - | - | | Breeding pig | group housing | 16.90 | - | - | | Sheep |  | - | 0.47 | 0.47 | | Lamb |  | - | 0.86 | 0.86 | | Slaughter goat  (= goat kids) |  | - | 7.54 | 5.09 | | Lactating goat |  | - | 3.23 | 1.86 | | Broilers |  |  | 0.01 | 0.01 | | Broilers | free range. litter floor | 23.53 | - | - | | Broilers | parent broilers. free range (grating floor) | 25.21 | - | - | | Broilers | parent broilers in rearing. free range (grating floor) | 24.51 | - | - | | Laying hen |  |  | 0.01 | 0.01 | | Laying hen | battery | 13.78 | - | - | | Laying hen | free range (litter floor) | 53.42 | - | - | | Laying hen | free range (grating floor) | 23.97 | - | - | | Turkey |  | - | 0.01 | 0.01 | | Horse |  | - | 1.73 | 0.87 | | Rabbit |  | 33.60 | 0.03 | 0.03 | |

Scenario [DRA-2] – Transport vehicles disinfection -residues in livestock tissues

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Residues in livestock tissues** | | | | | |
| **Animal Species** |  | **Sum Oral Exposure** | **Sum Dermal and Inhalative Exposure** | **Eggs** | **Milk** | **Muscle** | **Fat** | **Liver** | **Kidney** |
| Beef cattle | - | 0.068 | 0.620 |  |  | 0.622 | 0.622 | 0.623 | 0.623 |
| Dairy cattle | - | 0.052 | 0.557 |  | 0.558 | 0.558 | 0.558 | 0.559 | 0.559 |
| Calf | - | 0.170 | 0.935 |  |  | 0.938 | 0.938 | 0.941 | 0.941 |
| Fattening pig | - | 0.340 | 0.968 |  |  | 0.975 | 0.975 | 0.981 | 0.981 |
| Breeding pig | - | 0.131 | 0.696 |  |  | 0.699 | 0.699 | 0.701 | 0.701 |
| Breeding pig | individual housing |  |  |  |  |  |  |  |  |
| Breeding pig | group housing |  |  |  |  |  |  |  |  |
| Sheep | - | 0.453 | 0.013 |  | 0.018 | 0.022 | 0.022 | 0.031 | 0.031 |
| Lamb | - | 0.850 | 0.014 |  |  | 0.031 | 0.031 | 0.048 | 0.048 |
| Slaughter goat | - | 2.615 | 2.471 |  |  | 2.523 | 2.523 | 2.575 | 2.575 |
| Lactating goat | - | 0.486 | 1.379 |  | 1.384 | 1.389 | 1.389 | 1.398 | 1.398 |
| Broilers | - | 0.000 | 0.010 |  |  | 0.010 | 0.010 | 0.010 | 0.010 |
| Broilers | free range, litter floor |  |  |  |  |  |  |  |  |
| Broilers | parent broilers, free range (grating floor) |  |  |  |  |  |  |  |  |
| Broilers | parent broilers in rearing, free range (grating floor) |  |  |  |  |  |  |  |  |
| Laying hen | - | 0.000 | 0.009 | 0.009 |  | 0.009 | 0.009 | 0.009 | 0.009 |
| Laying hen | battery |  |  |  |  |  |  |  |  |
| Laying hen | free range (litter floor) |  |  |  |  |  |  |  |  |
| Laying hen | free range (grating floor) |  |  |  |  |  |  |  |  |
| Turkey | - | 0.000 | 0.007 |  |  | 0.007 | 0.007 | 0.007 | 0.007 |
| Horse | - | 0.000 | 0.869 |  |  | 0.869 | 0.869 | 0.869 | 0.869 |
| Rabbit | - | 0.000 | 0.030 |  |  | 0.030 | 0.030 | 0.030 | 0.030 |
|  |  |  | **Maximum** | **0.009** | **1.38** | **2.52** | **2.52** | **2.58** | **2.58** |

**Experimental data**

SYNTHESE ELEVAGE has access to data on the active substance chlorocresol with a Letter of Access from one applicant of the active substance 4-chloro-3-methylphenol. Therefore, experimental studies provided in the CAR to assess residue in livestock tissues can be used to refine the assessment.

Experimental studies deal with disinfection of animal housing. The objective of the 3 experimental studies was to investigate the magnitude of chlorocresol residue in the edible parts of fattening pigs (meat, fat, liver, kidney, skin) and broiler chickens (meat, live, skin and fat) after one single application in the shed (except for the third study in which a disinfection occurred before each pen transfer, ie 4 disinfections). In all studies, the shed was disinfected with a ready-to-use solution containing chlorocresol. After drying, pigs or chickens were introduced and fed. In the three studies, in all tissues, all residue levels were below the limit of quantification of 0.01 mg/kg or 0.1 mg/kg (kidney and liver in the last study).

The test conditions of the three experimental studies are representative of the conditions of use of PHENOGEN in animal housing and transport vehicle. Indeed, application rate in experimental studies are worst case (around 200-2900 mg chlorocresol/m2 instead of 500-1200 mg/m2 intended). Nevertheless, it has to be noted that, in the experimental studies, only pigs and chickens were exposed.

As proposed by the applicant, re-entry of the animals in the housing/vehicle is not authorised before total drying of surfaces.

Therefore, based on experimental studies and on proposed RMM by the applicant (total drying before re-entry), it can be reasonably concluded that, after disinfection of animal housing and transport vehicle by PHENOGEN, **residue in animal tissues are below 0.01 mg/kg.** **Therefore, dietary risk assessment for consumers is not required. Hence, the dietary exposure via ingestion of products and tissues from animals that have been reared in facilities disinfected with CMK is expected to be negligible.**

**Conclusion about livestock exposure assessment**

**For animal housing and transport vehicle disinfection,** even if the trigger value of 0.004 mg/kg bw/day is exceeded with default scenarios, it can be reasonably concluded that residue in animal tissues are below 0.01 mg/kg based on experimental studies.

*Estimating transfer of biocidal active substances into foods of animal origin as a result of professional and/or industrial application(s) and indirect exposure via food*

Not relevant.

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

Not relevant.

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

Not applicable

***Aggregated exposure***

Not performed

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation:

* **Chlorocresol**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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% | 0.3 mg/kg bw/d |
| AECacute | 14-day inhalation rat study | 50 mg/m3 | 25 | - | 2 mg/m3 |
| AEcmedium-term | 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% | 0.3 mg/kg/d |
| ADI | rat developmental toxicity study | 30 mg/kg bw/day | 100 | 100% | 0.3 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.

* **L(+) lactic acid**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term | Not allocated – not necessary\* | | | | |
| AELmedium-term |
| AELlong-term |
| ARfD |
| ADI |

\* because of very low systemic toxicity of L ( + ) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary, however, the exposure estimates are compared with endogenous production of L ( +) lactic acid: 1667 mg/kg bw/day.

* **Propan-2-ol**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Reference** |  | **Study** | **NOAEL NOAEC** | **AF3** | **Correction for oral absorption** | **Value** |
| AELshort-term, AELmedium-term, AELlong-term | General population | Human volunteer study (neurological effects) | 200 ppm | 6.4 | 100% | 10.7 mg/kg bw/d |
| Professional workers | 3.8 | 100% | 17.9 mg/kg bw/d |
| AECshort-term, AECmedium-term, AEClong-term | General population | 6.4 | - | 31.25 ppm (8h) |
| Professional workers | 3.8 | - | 52.6 ppm (8h) |
| ARfD, ADI | Not necessary, no residues in food expected | | | | | |

3 AF of 3.8 for intraspecies variability within the population (from 5 to 75 years of age). AF of 6.4 for intraspecies variability within the general population (from birth to 75 years of age).

**Maximum residue limits or equivalent**

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| **Chlorocresol** | | | |
| MRLs | Veterinary use[[5]](#footnote-6) | All food producing species | No MRLs needed |
| MRLs | Phytosanitary use [[6]](#footnote-7) | All food commodities | Default MRL of 0.01 mg/kg as active substance is not approved as a phytosanitary active substance |
| **Lactic acid** | Not relevant | | |

**For animal housing and transport vehicle disinfection,** based on experimental studies, it can be reasonably concluded that default MRL of 0.01 mg/kg in food of animal origin for chlorocresol will not be exceeded.

***Risk for professional users***

*Primary exposure*

Systemic effects - **Chlorocresol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **Transport vehicle (dilution 2% v/v)** | | | | |
| Scenario [2] – Task 1&2 – spraying | 1/no PPE | 0.3 | 1.99 | **665%** |
| Scenario [2] – Task 1&2 – spraying | 2a/gloves | 0.3 | 9.33E-01 | **311%** |
| Scenario [2] – Task 1&2 – spraying | 2b/gloves, coverall 20%, mask PF4 | 0.3 | 2.12E-01 | 70.7% |
| Scenario [2] – Task 3 – cleaning equipment | 1/no PPE | 0.3 | 1.84E-02 | 0.2% |
| **Animal surfaces/equipment (dilution 3% v/v)** | | | | |
| Scenario [1] – Task 1&2 – spraying | 1/no PPE | 0.3 | 2.99 | **997%** |
| Scenario [1] – Task 1&2 – spraying | 2a/gloves | 0.3 | 1.40 | **466%** |
| Scenario [1] – Task 1&2 – spraying | 2b/gloves, coverall 20%, mask PF4 | 0.3 | 3.18E-01 | **106%** |
| Scenario [1] – Task 1&2 – spraying | 2b/gloves, coverall 10%, mask PF4 | 0.3 | 1.85E-01 | 61.6% |
| Scenario [1] – Task 3 – cleaning equipment | 1/no PPE | 0.3 | 2.76E-02 | 9.2% |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | |
| Scenario [1] – Task 1&2 – spraying | 1/no PPE | 0.3 | 1.40 | **465%** |
| Scenario [1] – Task 1&2 – spraying | 2a/gloves | 0.3 | 6.53E-01 | **218%** |
| Scenario [1] – Task 1&2 – spraying | 2b/gloves, coverall 20% | 0.3 | 1.55E-01 | 52% |
| Scenario [1] – Task 3 – cleaning equipment | 1/no PPE | 0.3 | 1.29E-02 | 4.3% |

Systemic effects – **Propan-2-ol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **Transport vehicles (dilution 2% v/v)** | | | | |
| Scenario [2] – Task 1 – m/l | 1/no PPE | 17.9 | 7.8E-01 | 4.4% |
| Scenario [2] – Task 2 – spraying | 1/no PPE | 17.9 | 3.91 | 21.8% |
| Scenario [2] – Task 3 – cleaning equipment | 1/no PPE | 17.9 | 1.79E-02 | 0.2% |
| **Animal surfaces (dilution 3% v/v)** | | | | |
| Scenario [1] – Task 1 – m/l | 1/no PPE | 17.9 | 7.83E-01 | 4.4% |
| Scenario [1] – Task 2 – spraying | 1/no PPE | 17.9 | 5.83 | 32.6% |
| Scenario [1] – Task 3 – cleaning equipment | 1/no PPE | 17.9 | 2.69E-02 | 0.2% |
| **Equipment (dilution 3% v/v)** | | | | |
| Scenario [1] – Task 1 – m/l | 1/no PPE | 17.9 | 7.84E-01 | 4.4% |
| Scenario [1] – Task 2 – spraying | 1/no PPE | 17.9 | 5.98 | 33.4% |
| Scenario [1] – Task 3 – cleaning equipment | 1/no PPE | 17.9 | 2.69E-02 | 0.2% |
| **Animal surfaces (dilution 1.4% v/v)** | | | | |
| Scenario [1] – Task 1 – m/l | 1/no PPE | 17.9 | 7.84E-01 | 4.4% |
| Scenario [1] – Task 2 – spraying | 1/no PPE | 17.9 | 2.72 | 15.2% |
| Scenario [1] – Task 3 – cleaning equipment | 1/no PPE | 17.9 | 1.25E-02 | 0.1% |
| **Equipment (dilution 1.4% v/v)** | | | | |
| Scenario [1] – Task 1 – m/l | 1/no PPE | 17.9 | 7.84E-01 | 4.4% |
| Scenario [1] – Task 2 – spraying | 1/no PPE | 17.9 | 2.95 | 16.5% |
| Scenario [1] – Task 3 – cleaning equipment | 1/no PPE | 17.9 | 5.20E-03 | < 0.1% |

*Secondary exposure*

Systemic effects – **Chlorocresol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **Transport vehicles (dilution 2% v/v)** | | | | |
| Scenario [6] – wet surfaces, professionals | 1a | 0.3 | 1.85E-01 | 61.7% |
| Scenario [6] – dried surfaces, professionals | 1b | 0.3 | 5.55E-02 | 18.5% |
| Scenario [6] – dried surfaces, professionals | 2 | 0.3 | 2.22E-02 | 7.4% |
| **Animal surfaces/equipment (dilution 3% v/v)** | | | | |
| Scenario [5] – wet surfaces, professionals | 1a | 0.3 | 4.44E-01 | **148%** |
| Scenario [5] – dried surfaces, professionals | 1b | 0.3 | 1.33E-01 | 44.4% |
| Scenario [5] – dried surfaces, professionals | 2 | 0.3 | 5.33E-02 | 17.8% |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | |
| Scenario [5] – wet surfaces, professionals | 1a | 0.3 | 2.07E-01 | 69.1% |
| Scenario [5] – dried surfaces, professionals | 1b | 0.3 | 6.22E-02 | 20.7% |
| Scenario [5] – dried surfaces, professionals | 2 | 0.3 | 2.49E-02 | 8.3% |

Systemic effects – **Propan-2-ol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **Transport vehicles (dilution 2% v/v)** | | | | |
| Scenario [4] – Professionals (8h) | 1 | 17.9 | 2.63 | 14.7% |
| **Animal surfaces (dilution 3% v/v)** | | | | |
| Scenario [3] – Professionals (8h) | 1 | 17.9 | 3.67 | 20.5% |
| **Equipment (dilution 3% v/v)** | | | | |
| Scenario [3] – Professionals (8h) | 1 | 17.9 | 5.43 | 30.4% |
| **Animal surfaces (dilution 1.4% v/v)** | | | | |
| Scenario [3] – Professionals (8h) | 1 | 17.9 | 1.72 | 9.6% |
| **Equipment (dilution 1.4% v/v)** | | | | |
| Scenario [3] – Professionals (8h) | 1 | 17.9 | 2.72 | 15.2% |

***Combined scenarios***

The professionals can be exposed by primary and secondary exposure. Therefore, the assessment of combined exposure is performed:

Combined scenarios – **Professionals**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Active substance** | **PPE** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEC (%)** |
| **Spray application on animal surfaces (dilution 3% v/v)** | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 5%, respiratory mask PF4 during application, dried surfaces (tier 2) | 1.99E-01 | 66.4% |
| Propan-2-ol | 3.03 | 16.9% |
| **Spray application on equipment (dilution 3% v/v)** | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 5%, respiratory mask PF4 during application, dried surfaces (tier 2) | 1.99E-01 | 66.4% |
| Propan-2-ol | 4.30 | 24.0% |
| **Spray application on animal surfaces (dilution 1.4% v/v)** | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 10% during application, dried surfaces | 1.93E-01 | 64.3% |
| Propan-2-ol | 4.02 | 22.5% |
| **Spray application on equipment (dilution 1.4% v/v)** | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 10% during application, dried surfaces | 1.93E-01 | 64.3% |
| Propan-2-ol | 4.25 | 23.8% |
| **Spray application on animal transport vehicles (dilution 2% v/v)** | | | | |
| Scenario 2 (task 1, 2, 3) + 4 + 6 (dried surfaces) | Chlorocresol | gloves, coverall 10%, mask PF4 during m/l and application, dried surfaces (tier 2) | 1.64E-01 | 54.6% |
| Propan-2-ol | 4.94 | 27.6% |

Further information are available in the human exposure sheet for PPE. The results above with selected PPE are used for cumulative risk assessment (see below).

**Local effects**

**Quantitative risk assessment for Chlorocresol**

Local effects – **Chlorocresol**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC mg/m3** | **Estimated uptake**  **mg/m3** | **Estimated uptake/ AEC (%)** | **Acceptable**  **(yes/no)** |
| Scenario [1] – Chlorocresol (transport vehicles) 2% v/v | 1/ no RPE | 0.3 | 3.04E-01 | **101%** | **No** |
| Scenario [1] – Chlorocresol (transport vehicles) 2% v/v | 1/ RPE PF4 | 0.3 | 7.61E-02 | 25.4% | Yes |
| Scenario [1] – Chlorocresol (animal surfaces/equipment) 3% v/v | 1/ no RPE | 0.3 | 4.56E-01 | **152%** | **No** |
| Scenario [1] – Chlorocresol (animal surfaces/equipment) 3% v/v | 1/ RPE PF4 | 0.3 | 1.14E-01 | 38.0% | Yes |
| Scenario [1] – Chlorocresol (animal surfaces/equipment) 1.4% v/v | 1/ no RPE | 0.3 | 2.13E-01 | 70.9% | Yes |

**Qualitative risk assessment for professional users**

According to the guidance on the BPR for human health[[7]](#footnote-8), a qualitative local risk assessment is performed, since the product PHENOGEN is classified H314, H318 and H317.

This assessment is also required due to the presence of L(+) lactic acid as active substance in the product for which only a qualitative RA is necessary.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | **Considering that the product will be applied by a professional, technic and organizational RMM are followed.** | **PPE** |
| Very high | H314, 1C | Professionals | mixing and loading | Dermal and inhalation | More than few minutes but equal to or less than few hours per day | Controlled exposure | **The risk is acceptable considering the following RMM:**  - Containment as appropriate;  - Segregation of the emitting process;  - Effective contaminant extraction;  - Good standard of general ventilation;  - Minimisation of manual phases;  - Regular cleaning of equipment and work area;  - Avoidance of contact with contaminated tools and objects; | **PPE**  - Substance/task appropriate gloves  - Protection coverall (according to pattern of exposure)  - Substance/task appropriate respirator;  - Chemical goggles |
| Very high | H318 | Professionals | mixing and loading | Dermal and inhalation | More than few minutes but equal to or less than few hours per day | Controlled exposure | **PPE**  - Chemical goggles |
| Medium | H317 | Professionals | mixing and loading | Dermal and inhalation | More than few minutes but equal to or less than few hours per day | Controlled exposure | **PPE**  - Substance/task appropriate gloves  - Protection coverall (according to pattern of exposure) |

The risk is acceptable with the following PPE:

* Wear gloves, coverall, respiratory mask and goggles during the mixing and loading step.

After dilutions (1.4%, 2% and 3% v/v), no local effects are expected.

**Conclusion regarding local effects for professional users**

The following RMMs are proposed:

- Minimisation of manual phases;

- Regular cleaning of equipment and work area;

- Avoidance of contact with contaminated tools and objects;

And the following PPE are required:

- Substance/task appropriate gloves

- Protection coverall (according to pattern of exposure)

- Substance/task appropriate respirator;

- Chemical goggles.

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

Combined exposure is estimated for actives substances and a substance of concern: Chlorocresol and Propan-2-ol.

**TIER 1**: risk assessment is performed for each substance, with or without PPE. When the risk is > 100% AEL for one substance, no further refinement can be done.

**TIER 2**: additivity is performed by combining hazard quotients (HQs) for all substances to derive a hazard index (HI). If HI < 1, the risk related to use of the mixture is acceptable and not further refinement is done. If HI > 1, the risk related to use of the mixture is unacceptable and refinement is needed in Tier 3.

For Tier 3, it is necessary to find information in the CAR of each active substance and/or data available for SoC.

**TIER 3A**: risk assessment is performed by combining HQs for all substances with common target organ/system, with the non-refined AEL of each substance.

As a first step, target organ(s)/mode of action(s) for each substance are listed.

Substances are then grouped related to their common target organ(s)/mode of action(s). For each group of target organ, HQto are summarized for each substance and approx. HIto calculated. All adjusted HIto values must be ≤1 to consider the risk as acceptable.

If one or more HIto >1, risk is considered unacceptable and Tier 3B could be envisaged. When a target organ or mode of action is observed for only one substance, there is no need to perform a Tier 3A.

**Tier 3B**: risk assessment is performed by combining exposure assessment with specific AEL by target organ/mode of action. Tier 3B considerations apply only for target organs for which a risk was identified in Tier 3A.

For this case, no Tier 3B is necessary.

**Tier 3C**: risk assessment is performed by combining exposure assessment by considering mechanism of action (if available).

For this case, no Tier 3C is necessary.

***Professional users***

**Tier 1 – acceptability of each substance**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Active substance** | **PPE** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEC (%)** |
| **Spray application on animal surfaces (dilution 3% v/v)** | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 5%, respiratory mask PF4 during m/l and application, dried surfaces | 1.99E-01 | 66.4% |
| Propan-2-ol | 4.30 | 24.0% |
| **Spray application on equipment (dilution 3% v/v)** | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 5%, respiratory mask PF4 during m/l and application, dried surfaces | 1.99E-01 | 66.4% |
| Propan-2-ol | 4.77 | 26.7% |
| **Spray application on animal surfaces (dilution 1.4% v/v)** | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 20% during m/l and application, dried surfaces | 1.93E-01 | 64.3% |
| Propan-2-ol | 4.02 | 22.5% |
| **Spray application on equipment (dilution 1.4% v/v)** | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | Chlorocresol | gloves, coverall 20% during ml/ and application, dried surfaces | 1.93E-01 | 64.3% |
| Propan-2-ol | 4.25 | 23.8% |
| **Spray application on transport vehicles (dilution 2% v/v)** | | | | |
| Scenario 2 (task 1, 2, 3) + 4 + 6 (dried surfaces) | Chlorocresol | gloves, coverall 10%, respiratory mask PF4 during m/l and application, dried surfaces | 1.64E-01 | 54.6% |
| Propan-2-ol | 4.94 | 27.6% |

**Tier 2 – additivity**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **PPE** | Chlorocresol | Propan-2-ol | **HI** | **Acceptable**  **(yes/no)** |
| **Spray application on animal surfaces (dilution 3% v/v)** | | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | gloves, coverall 5%, respiratory mask PF4 during m/l and application, dried surfaces | 0.66 | 0.24 | 0.90 | Yes |
| **Spray application on equipment (dilution 3% v/v)** | | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | gloves, coverall 5%, respiratory mask PF4 during m/l and application, dried surfaces | 0.66 | 0.27 | 0.93 | Yes |
| **Spray application on animal surfaces (dilution 1.4% v/v)** | | | | | |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | gloves, coverall 20% during m/l and application, dried surfaces | 0.64 | 0.22 | 0.87 | Yes |
| **Spray application on equipment (dilution 1.4% v/v)** | | |  |  |  |
| Scenario 1 (task 1, 2, 3) + 3 + 5 (dried surfaces) | gloves, coverall 10% during m/l and application, dried surfaces | 0.64 | 0.24 | 0.88 | Yes |
| **Spray application on transport vehicles (dilution 2% v/v)** | | | | | |
| Scenario 2 (task 1, 2, 3) + 4 + 6 (dried surfaces) | gloves, coverall 10%, respiratory mask PF4 during m/l and application, dried surfaces | 0.55 | 0.28 | 0.82 | Yes |

The risk is acceptable (HI < 1) for animal surfaces and for equipment (dilution 3% v/v and 1.4% v/v).

The risk is acceptable (HI < 1) for transport vehicles (dilution 2% v/v).

For the disinfection of animal surfaces and for equipment (dilution 3% v/v and 1.4% v/v) (use #1 & 2), the risk is acceptable (HI < 1) considering gloves, coverall 5% during the mixing and loading and application phases. A respiratory mask (APF at least 4) is required during mixing/loading and application for animal surfaces/equipment (dilution 3% v/v).

For the disinfection of transport vehicles (dilution 2% v/v) (use #3), the risk is acceptable (HI < 1) considering gloves, coverall 5% and a respiratory mask (APF at least 4) during the mixing and loading and application phases.

Moreover, for the three uses, a direct contact with dried treated surfaces has been taken into account.

***Risk for the general public***

Systemic effects – **Chlorocresol**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Animal surfaces/equipment (dilution 3% v/v)** | | | | | |
| Scenario [5] – wet surfaces, adults | 1a | 0.3 | 4.44E-01 | **148%** | **No** |
| Scenario [5] – dried surfaces, adults | 1b | 0.3 | 1.33E-01 | 44.4% | Yes |
| **Animal surfaces/equipment (dilution 3% v/v)** | | | | | |
| Scenario [5] – wet surfaces, toddlers (crawling) | 1a | 0.3 | 1.88E+01 | **6254%** | **No** |
| Scenario [5] – dried surfaces, toddlers (crawling) | 1b | 0.3 | 5.63 | **1876%** | **No** |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | | |
| Scenario [5] – wet surfaces, adults | 1a | 0.3 | 2.07E-01 | 69.1% | Yes |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | | |
| Scenario [5] – wet surfaces, toddlers (crawling) | 1a | 0.3 | 8.76 | **2918%** | **No** |
| Scenario [5] – dried surfaces, toddlers (crawling) | 1b | 0.3 | 2.63 | **876%** | **No** |

Systemic effects – **Propan-2-ol**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Animal surfaces (dilution 3% v/v)** | | | | | |
| Scenario [3] – Adults (24h) | 1 | 10.7 | 1.93 | 18.0% | Yes |
| Scenario [3] – Child (6 to <12 years old) | 1 | 10.7 | 3.63 | 33.9% | Yes |
| Scenario [3] – Child (2 to <6 years old) | 1 | 10.7 | 4.68 | 43.7% | Yes |
| Scenario [3] – Toddler (1 to <2 years old) | 1 | 10.7 | 5.78 | 54.1% | Yes |
| Scenario [3] – Infant (<1 year old) | 1 | 10.7 | 4.88 | 45.6% | Yes |
| **Equipment (dilution 3% v/v)** | | | | | |
| Scenario [3] – Adults (24h) | 1 | 10.7 | 2.91 | 27.2% | Yes |
| Scenario [3] – Child (6 to <12 years old) | 1 | 10.7 | 5.47 | 51.1% | Yes |
| Scenario [3] – Child (2 to <6 years old) | 1 | 10.7 | 7.06 | 66.0% | Yes |
| Scenario [3] – Toddler (1 to <2 years old) | 1 | 10.7 | 8.72 | 81.5% | Yes |
| Scenario [3] – Infant (<1 year old) | 1 | 10.7 | 7.36 | 68.8% | Yes |
| **Animal surfaces (dilution 1.4% v/v)** | | | | | |
| Scenario [3] – Adults (24h) | 1 | 10.7 | 0.90 | 8.4% | Yes |
| Scenario [3] – Child (6 to <12 years old) | 1 | 10.7 | 1.70 | 15.9% | Yes |
| Scenario [3] – Child (2 to <6 years old) | 1 | 10.7 | 2.19 | 20.5% | Yes |
| Scenario [3] – Toddler (1 to <2 years old) | 1 | 10.7 | 2.70 | 25.3% | Yes |
| Scenario [3] – Infant (<1 year old) | 1 | 10.7 | 2.28 | 21.3% | Yes |
| **Equipment (dilution 1.4% v/v)** | | | | | |
| Scenario [3] – Adults (24h) | 1 | 10.7 | 1.46 | 13.6% | Yes |
| Scenario [3] – Child (6 to <12 years old) | 1 | 10.7 | 2.74 | 25.6% | Yes |
| Scenario [3] – Child (2 to <6 years old) | 1 | 10.7 | 3.54 | 33.0% | Yes |
| Scenario [3] – Toddler (1 to <2 years old) | 1 | 10.7 | 4.37 | 40.8% | Yes |
| Scenario [3] – Infant (<1 year old) | 1 | 10.7 | 3.69 | 34.4% | Yes |

**Local effects**

After dilutions (1.4%, 2% and 3% v/v), no local effects are expected for secondary exposure for general public.

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

**Tier 1 – acceptability of each substance**

Cumulative risk assessment is done for **animal surfaces and equipment for adults only (secondary exposure),** since the risk is not acceptable for children for Chlorocresol:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | | **Tier** | **Active substances** | | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL (%)** |
| **Animal surfaces (dilution 3% v/v)** | | | | | | |
| Scenarios [3+5] secondary exposure | dried surfaces | | Chlorocresol |  | 1.33E-01 | 44.4% |
| Propan-2-ol |  | 1.93 | 18.0% |
| **Equipment (dilution 3% v/v)** | | | | | | |
| Scenarios [3+5] secondary exposure | dried surfaces | | Chlorocresol |  | 1.33E-01 | 44.4% |
| Propan-2-ol |  | 2.91 | 27.2% |
| **Animal surfaces (dilution 1.4% v/v)** | | | | | | |
| Scenarios [3+5] secondary exposure | wet surfaces | | Chlorocresol |  | 2.07E-01 | 69.1% |
| Propan-2-ol |  | 0.90 | 8.4% |
| **Equipment (dilution 1.4% v/v)** | | | | | | |
| Scenarios [3+5] secondary exposure | Wet surfaces | | Chlorocresol |  | 2.07E-01 | 69.1% |
| Propan-2-ol |  | 1.46 | 13.6% |

**Tier 2 – additivity**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Chlorocresol** | **Propan-2-ol** | **HI** | **Acceptable (yes/no)** |
| **Animal surfaces (dilution 3% v/v)** | | | | | |
| Scenarios [3+5] secondary exposure | dried surfaces | 0.44 | 0.18 | 0.63 | Yes |
| **Equipment (dilution 3% v/v)** | | | | | |
| Scenarios [3+5] secondary exposure | dried surfaces | 0.44 | 0.27 | 0.71 | Yes |
| **Animal surfaces/equipment (dilution 1.4% v/v)** | | | | | |
| Scenarios [3+5] secondary exposure | wet surfaces | 0.69 | 0.08 | 0.77 | Yes |
| **Equipment (dilution 1.4% v/v)** | | | | | |
| Scenarios [3+5] secondary exposure | wet surfaces | 0.69 | 0.13 | 0.82 | Yes |

The risk is acceptable (HI < 1) for adults.

**Conclusion**

For animal surfaces and equipment disinfection with a dilution 3% v/v, the risk is deemed acceptable for professionals with gloves, impermeable coverall and respiratory mask (APF4) during mixing/loading and application phases.

For animal surfaces and equipment disinfection with a dilution 1.4% v/v, the risk is deemed acceptable for professionals with gloves and coated coverall during mixing/loading and application phases.

For transport vehicles disinfection with a dilution 2% v/v, the risk is deemed acceptable for professionals with gloves, coated coverall and respiratory mask (APF4) during mixing/loading and application phases.

Concerning secondary exposure of professionals and general public, the risk is deemed acceptable only when considering a direct dermal contact with dried surfaces or equipment. Therefore, the following RMMs are proposed:

* Do not touch treated surfaces before complete drying;
* Only use the hatchery materials after their complete drying.

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

**For animal housing and transport vehicle disinfection,** residue in animal tissues are expected to be below 0.01 mg/kg. **Therefore, risk assessment for consumers via residues in food is not required.**

### Risk assessment for animal health

For application on transport vehicles and animal surfaces, the animal exposure is considered.

***Approach used for animal risk assessment (systemic effects)***

No guidance document is available to perform an animal risk assessment.

According to the CAR, the AEL (short-term, medium-term and long-term) of chlorocresol is based on the lowest NOAEL of 30 mg/kg bw/day observed in the rat developmental toxicity study (considering 100% oral absorption).

Moreover, an inhalation AEC is set considering the NOAEC of 50 mg/m3 from the 14-day inhalation rat study.

Without any available guidance, eCA proposes to apply a margin of exposure (MOE) representing a direct comparison between exposure and toxicity.

The MOE approach is not intended to provide a health-based limit-value but serves primarily as an instrument for risk characterisation.

The MOE is calculated as follows: systemic NOAEL (or NOAEC)/ systemic Exposure[[8]](#footnote-9).

Considering that lifespans of livestock species are much shorter than natural life expectancies, the NOAEL used for AEL is considered to cover animal risk assessment, taking into account estimating livestock exposure in Tier 2 in Scenarios [DRA-1] and [DRA-2] (see Dietary exposure section):

Animal housing disinfection

|  |  |  |  |
| --- | --- | --- | --- |
| Animal Species | Tier 2  Exposure value to Chlorocresol (mg/kg bw/d) | NOAEL Chlorocresol (mg/kg bw/d) | Margin of exposure (MOE) |
| Beef cattle | 1.82 | 30 | 16.5 |
| Dairy cattle | 2.04 | 30 | 14.7 |
| Calf | 2.96 | 30 | 10.1 |
| Fattening pig | 3.65 | 30 | 8.2 |
| Breeding pig | 1.97 | 30 | 15.2 |
| Breeding pig (individual housing) | 1.93 | 30 | 15.5 |
| Breeding pig (group housing) | 2.29 | 30 | 13.1 |
| Sheep | 1.1 | 30 | 27.3 |
| Lamb | 2.05 | 30 | 14.6 |
| Slaughter goat (goat kids) | 12.17 | 30 | 2.5 |
| Lactating goat | 4.45 | 30 | 6.7 |
| Broilers | 0.01 | 30 | 3000.0 |
| Laying hen | 0.7 | 30 | 42.9 |
| Turkey | 0.01 | 30 | 3000.0 |
| Horse | 2.07 | 30 | 14.5 |

Transport vehicles disinfection

|  |  |  |  |
| --- | --- | --- | --- |
| Animal Species | Tier 2  Exposure value to Chlorocresol (mg/kg bw/d) | NOAEL Chlorocresol (mg/kg bw/d) | Margin of exposure (MOE) |
| Beef cattle | 0.69 | 30 | 43.5 |
| Dairy cattle | 0.61 | 30 | 49.2 |
| Calf | 1.1 | 30 | 27.3 |
| Fattening pig | 1.31 | 30 | 22.9 |
| Breeding pig | 0.83 | 30 | 36.1 |
| Sheep | 0.47 | 30 | 63.8 |
| Lamb | 0.86 | 30 | 34.9 |
| Slaughter goat (goat kids) | 5.09 | 30 | 5.9 |
| Lactating goat | 1.86 | 30 | 16.1 |
| Broilers | 0.01 | 30 | 3000.0 |
| Laying hen | 0.01 | 30 | 3000.0 |
| Turkey | 0.01 | 30 | 3000.0 |
| Horse | 0.87 | 30 | 34.5 |

The systemic risk can be considered acceptable when MOE > 10.

For several species, such as Fattening pig (animal housing disinfection only), Slaughter goat and Lactating goat, the estimated MOE is inferior to 10, therefore the risk cannot be considered acceptable.

The Tier 2 exposure evaluation to chlorocresol has been performed taking into account 50% dermal absorption and wet surfaces (100% transfer residues). Both parameters represent a worst case assumption, however no specific assessment can be performed yet. In order to avoid animal exposure, it is recommended by applicant to not authorized the re-entry in treated areas (animal housing and transport vehicles) before complete drying of surfaces.

Following this RMM (in line with the good breeding practices) the risk can be reasonably considered acceptable for all species.

***Exposure to volatilized residues***

**Systemic effects**

|  |
| --- |
| The Human Exposure Expert Group (HEEG) opinion 13 on the assessment of inhalation exposure to volatilised biocides provides whether inhalation exposure can be considered negligible:  Where *mw* and *vp* denote the molecular weight (in g/mol) and the vapour pressure (in Pa), for a toddler (based on an inhalation rate of 8 m3/24 hr and bw of 10 kg) and using an AEL expressed in mg a.s./kg bw/d, if    Then the risk from inhalation exposure is considered negligible. The assessment assumes that the individual is exposed to the saturated vapour concentration of the active substance for 24 hours a day and therefore reflects a ‘worst-case’ scenario. The calculation of toddler inhalation exposure represents a ‘worst case’ scenario and as such forms the risk envelope for the assessment of an infant, child and/or adult.  The active substance Chlorocresol has a molecular weight of 142.6 g/mol and a vapour pressure of 1.40E-03 at 20°C. The AEL (long term) is 0.3 mg/kg bw/d.  Therefore applying the above equation: 0.328\*((142.6\*0.0014)/0.3) = 0.22  Same reasoning is applied with NOAEL of 30 mg/kg bw/d.  The value is <1 therefore the risk from inhalation exposure to Chlorocresol is considered negligible.  L (+) lactic acid has a molecular weight of 90.08 g/mol and a vapour pressure of 0.4 at 20°C. The AEL (long term) is 1667 mg/kg bw/d (endogenous production).  The value is <1 therefore the risk from inhalation exposure to L (+) lactic acid is considered negligible. |

**Local effects**

*Quantitative exposure*

|  |
| --- |
| The Human Exposure Expert Group (HEEG) opinion 13 on the assessment of inhalation exposure to volatilised biocides provides whether inhalation exposure can be considered negligible:  Where *mw* and *vp* denote the molecular weight (in g/mol) and the vapour pressure (in Pa), for a toddler (based on an inhalation rate of 8 m3/24 hr and bw of 10 kg) and using an AEL expressed in mg a.s./kg bw/d, if  Then the risk from inhalation exposure is considered negligible. The assessment assumes that the individual is exposed to the saturated vapour concentration of the active substance for 24 hours a day and therefore reflects a ‘worst-case’ scenario. The calculation of toddler inhalation exposure represents a ‘worst case’ scenario and as such forms the risk envelope for the assessment of an infant, child and/or adult.  The active substance Chlorocresol has a molecular weight of 142.6 g/mol and a vapour pressure of 1.40E-03 at 20°C. The AEC (long term) is 0.3 mg/kg bw/d.  Therefore applying the above equation: 0.410\*((142.6\*0.0014)/0.3) = 0.27  Same reasoning is applied with the NOAEC of 50 mg/m3.  The value is <1 therefore the risk from inhalation exposure to Chlorocresol is considered negligible. |

**Conclusion**

For application in transport vehicles and animal housing, the risk is acceptable with the following RMM:

* Do not apply the disinfection treatment in the presence of animals.
* Do not introduce animals in treated housing/vehicles until a complete drying.

### Risk assessment for the environment

The product PHENOGEN is a PT3 soluble concentrate disinfectant containing L(+) lactic-acid (CAS No.79-33-4, 22.00% w/w technical value) and chlorocresol (CAS No.59-50-7, 18.50% w/w technical value) as active substances. It is applied for the disinfection of equipment and livestock animal housing (cattle, pigs, and poultry) including poultry hatcheries, by spraying on surfaces. It is also used for the disinfection of animal transportation vehicles by spraying.

*Substances of Concern and Metabolites:*

No Substance of Concern is identified (see Confidential Annex) 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 two active substances only.

#### Effects assessment on the environment

No new environmental studies have been carried out with the product PHENOGEN. All data pertaining to the active substances are therefore derived from the revised CMK assessment report (2017) and L(+) lactic-acid assessment report (2017).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on PNEC values** | | | | | |
|  | **PNECSTP** | **PNECwater** | **PNECsed**  **(EPM)** | **PNECsoil** | **PNECoral,birds** |
|  | [mg/L] | [mg/L] | [mg/kgww] | [mg/kgww] | [mg/kg] |
| L(+) lactic acid | 10 | 3.90 | 4.80 | 1.90 | - |
| CMK | 0.57 | 0.015 | 0.0755 | 0.60\* | 0.998 |

\*initial

*Air:*

No PNEC value can be derived for the air compartment. Moreover, according to the information from the CMK and L(+) lactic acid assessment reports:

* L(+) lactic acid: The vapour pressure of L(+) lactic acid is 0.4 Pa at 20°C and the Henry’s law constant is 3.6E-05 Pa m3/mol at 20°C.
* CMK: The vapour pressure is 6.0E-03 Pa at 25°C and the Henry's law constant of 5.87E-05 Pa.m3.mol-1.

Therefore, for both substances, direct evaporation is not expected and a low volatility from water is foreseen. Therefore, exposure to air is expected to be insignificant and no PEC value is presented for this compartment.

*Sediments:*

For both substances, no ecotoxicological data was generated for sediment dwelling organisms. The PNEC values for this compartment were 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.

*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 additional studies approved by MS in conclusions of the WG-IV-2019.

For CMK, the endpoint is an initial PNEC and it needs to be compared with an initial PEC value in the risk assessment. As a worst case, initial PEC are also calculated for L(+) lactic acid

*Secondary poisoning:*

For chlorocresol, a PNEC value was determined for birds for quantification purposes only. Considering the low BCF values for both substances (between 0.048 and 41.7 L/kgww), a risk characterisation of secondary poisoning is deemed not relevant as there is no concern for bioaccumulation and therefore, no PEC value is presented for this compartment.

***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***

According to the CAR of the active substances:

- L(+) lactic acid is not classified for the environment,

- Chlorocresol (18.5%) is classified H400/H412,

- One co-formulant (50% maximum of a mixture contained at 9.5% in the product) is classified H412.

The product should be classified Chronic 3 H412 if:

* ∑ (% substances H410 x 100 x facteur M) + (10 x % substance H411) + % substance H412 ≥ 25%

For the product PHENOGEN, this calculation is:

* 18.5% + 9.5%\*50% = 23.25%

By calculation, the product PHENOGEN is therefore not classified for the environment according to Regulation (EC) No.1272/2008 (CLP).

***Further Ecotoxicological studies***

No new ecotoxicological studies have been carried out with the product PHENOGEN.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk. |
| Justification | Available ecotoxicity data on the active substances and the co-formulant are considered sufficient to assess the toxicity of the product.  In addition, as explained in section 2.2.8 of the PAR, there is no direct exposure of the environment as the product is only used indoor.   * + - * + Based on this assessment, no additional ecotoxicological study with the product was conducted to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. It is not relevant for the product PHENOGEN used as indoor spray.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. It is not relevant for the product PHENOGEN used as indoor spray.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on secondary ecological effect. |
| Justification | As the product is for indoor use only, it is not intended to be applied directly in a specific habitat such as water body, wetland, forest or field. No large proportion of specific habitat type will be treated with the product PHENOGEN and it can be concluded that no secondary ecological effect is expected when using the product PHENOGEN according to the label recommendations.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

According to the intended uses, two types of direct releases are taken into account:

* Releases *via* the Sewage Treatment Plant (STP) relevant for:
  + some animal sub-category of the indoor “animal housing” scenario,
  + the indoor disinfection of surfaces in the “poultry hatcheries” scenario,
  + the disinfection of surfaces in animal transport vehicles.

The final environmental receiving compartments are surface water, including sediment (through STP effluent), the soil and the groundwater (from sludge application).

* Releases to soil by spreading of the treated manure/slurry, after the treatment of "animal housing”.

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

A new experimental study is available for L(+) Lactic acid biodegradability at the product authorisation stage and shows that the substance is readily biodegradable fulfilling the 10 days window. In the exposure assessment, it allows to refine the DT50 in soil to 30 days and the Fwater calculated with Simple Treat 4.0.

As:

* In the AR (2017), DT50soil has already been reduced to 30 days with expert judgement,
* The modification of the Fwater has no impact on the conclusions of this dossier,

The study is not proposed to be discussed at European level for this particular case. However, it has been assessed by the eCA and add support to the final conclusion of the dossier (see overall conclusion).

The results are presented in the following table and the reports are included in IUCLID file in section S10\_2 (L+) lactic acid active substance dataset:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline / Test Method** | **Test type** | **Test parameter** | **Inoculum** | | | **Additional substrate** | **TS conc.** | **Degradation** | | **Ref.** |
| **Type** | **Conc.** | **Adaptation.** | **Incubation period** | **Degree [%]** |
| OECD 301D | ThOD | Oxygen demand | Activated sludge (microorganisms from a domestic waste water treatment plant) was supplied by sewage plant Rossdorf, Germany | 2.5 mL of the filtered inoculum were added to 5L of aqueous test medium | No | No | 5.06 mg/L | 28 days | 7 days: 61%  12 days: 72%  28 days: 79% | Ready Biodegradability of Lactic acid 80% food grade in a Closed Bottle Test  Dr. Ute Hammesfahr (2018- Project 80031161). IUCLID available section 13 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment** | |
| Value/conclusion | L-(+) lactic acid is readily biodegradable, fulfilling the 10-days window.  Considering this and its Kpsoil value (0.4L/kg), DT50soil is 30 days (Vol IV Part B+C, 2017). |
| Justification for the value/conclusion | Under the OECD 301D test conditions the percentage biodegradation of L(+) Lactic acid 80% food grade reached in the mean 51% after 3 days of incubation and continuously increased to 61% at 7d, 71% after 14 days and 79% after 28 days. The percentage biodegradation did exceed 60% within the 10-day window. All the validity criteria are fulfilled and no deviations from the OCDE guidance is observed. |

***Leaching behaviour (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Leaching behaviour |
| Justification | The product is used indoors and is not intended to be used for the treatment of surfaces exposed to weathering.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in soil. |
| Justification | The soil is not expected to be directly contaminated as the product is only used indoor.  Moreover, several environmental data are available on chlorocresol and L(+) lactic acid. These data are considered sufficient to assess the product behaviour.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in water and sediment. |
| Justification | The aquatic compartment (water and sediment) is not expected to be directly contaminated as the product is only used indoor.  Moreover, several environmental data are available on chlorocresol and L(+) lactic acid. These data are considered sufficient to assess the product behaviour.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in air. |
| Justification | Based on the indoor application of the product, it is likely that the emissions to the atmosphere will be limited in time and restricted to local scale.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

***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 to assess risks to aquatic organisms or plants under field conditions. |
| Justification | The product PHENOGEN is intended to be used indoor by professionals for direct surface treatment. This product is not used close to or on surface water. Thus no further data is needed.   * + - * + Based on this assessment, no additional study with the product was conducted to address this point. |

***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 to assess risks to bees and non-target arthropods under field conditions. |
| Justification | The product PHENOGEN is intended to be used indoor by professionals for direct surface treatment.  The product is not intended to be sprayed in the outdoor environment and it has no potential for large scale formation of dust. Therefore there is no risk of exposure of honeybees and non-target arthropods.   * + - * + Based on this assessment, no additional study with the product was conducted to address this point. |

#### Exposure assessment

The product PHENOGEN is a soluble concentrate intended to be used indoor by professionals by spray:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Claimed Uses** | **Area of use** | **Details on treated surfaces** | **Targets** | **Application rate (mL of diluted product/m2)** | **Dilution of the product** | **Covered by scenarios (see exposure assessment)** |
| 1 | Disinfection of surfaces of livestock animal housing and equipment (cattle, pigs and poultry) | All housing surfaces | Bacteria, yeast, fungi and some virus | 200 | 1.4% v/v | Scenario 1 |
| Disinfection of surfaces in poultry hatcheries | - | 100-150 | 1.4% v/v | Scenario 2 |
| 2 | Disinfection of surfaces of livestock animal housing and equipment (cattle, pigs and poultry) | Housing surfaces except the ceiling | *C. parvum* | 200 | 3% v/v | Scenario 1 |
| 3 | Disinfection of surfaces of animal transport vehicles | - | Bacteria, yeast, fungi and some virus | 125 | 2% v/v | Scenario 3 |

General information

|  |  |
| --- | --- |
| Assessed PT | PT 3 |
| Assessed scenarios | Scenario 1: Disinfection of surfaces of livestock animal housing and equipment   * Scenario 1-a: Emission to the STP via wastewater * Scenario 1-b: Emission to soil via manure/slurry   Scenario 2: Disinfection of surfaces in poultry hatcheries  Scenario 3: Disinfection of vehicles used for animal transport |
| ESD(s) used | Emission scenario document for PT03 – Veterinary hygiene biocidal products (2011).  Technical Agreements for Biocides v2.1, December 2019. |
| Approach | Scenario 1: Average consumption  Scenario 2: Average consumption  Scenario 3: Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017).  Assessment report: Chlorocresol (CMK), PT2 (private area and public health area disinfectants and other biocidal products), April 2016, revised in November 2017.  Assessment report: L(+) lactic acid, PT2 (private area and public health area disinfectants and other biocidal products), June 2017. |
| Groundwater simulation | Yes (FOCUS PEARL v.4.4.4 simulation for groundwater). |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1/2/3:  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | - |

#### **Emission estimation**

##### **Scenario 1 - Disinfection of surfaces of livestock animal housings and equipments:**

The local emissions of chlorocresol and L(+) lactic acid are calculated using the scenario “Emission scenario for calculating the release of disinfectants used for disinfection of animal housing” (ESD PT3, 2011) considering updates from the TAB v2.1 of December 2019.

*Animal Subcategory:*

The main emission path is the soil via the slurry/manure system (scenario 1-b). In the case of some housing types for poultry, releases to waste water can take place, they will then be emitted to the sewer system and STP (scenario 1-a).

For an easier reading of the PAR, only worst-case situations are presented:

* For emissions to soil via slurry: **veal calves** emissions,
* For emissions to wastewater: **turkey’s** emissions.

WG discussions (I-2021) took place after the drafting of this PAR and agreed on refinements of the emissions for the housing scenario (1-a, 1-b). As the calculations proposed in this PAR are worst-cases, they were left as they were.

*AREAtreated:*

It is acceptable as second tier to take label information on reduced treatment areas in an animal housing into account (TAB v2.1 of 2019, ENV54). However, in the ESD for PT3, no individual value for the ceiling surface is available. In a worst-case, it is considered that the ceiling is flat and that its area is equal to the floor area.

Therefore, the surface of the entire housing excluding the ceiling in:

* Veal calves accommodations is 650-160 = **490** **m²**,
* Turkeys accommodations is 8040-3330 = **4710** **m²**.

*Worst-case dilution:*

Considering these AREAtreated values, the use of a **3% v/v** diluted solution on all the housing surfaces except the ceiling (490 m2) is a worst case compared to the use of a 1.4% v/v diluted solution on the entire housing surfaces (650 m2), considering that the application rates are the same for both use (200 mL/m2). Therefore, it is presented alone to ensure the clarity of the PAR.

###### **Scenario 1-a – Emissions to the stp via wastewater**

| **Scenario 1-a: Emissions to the STP via wastewater** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value** | | **Unit** | **S/D/O** |
|  |  | **Chlorocresol** | **L(+) lactic-acid** |  | **Remarks** |
| **Input** | | | | | |
| Type of House | cat-subcat (i1) | Turkey in free range – litter floor | | [-] | Worst case for releases to the STP |
| Type of biocide | bioctype (i2) | Disinfectant | | [-] | D |
| Type of application | appway (i3) | Spraying | |  | - |
| Relevant emission stream | stream (i4) | Wastewater | | [-] | - |
| Area of the housing for application (entire housing excluding the ceiling) | AREAi1 | 4710 | | [m2] | S – All surfaces except ceiling |
| Content of active ingredient in formulation (product) | Fbioc | 185 | 220 |  | S – Considering a product density around 1\* |
| Amount of product prescribed to be used per m² | Vprodi1,i2,i3 | 0.2 | | [L/m²] | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | Fdil | 0.03 | | [-] | S – Worst case covering dilution of 0.014 |
| Fraction of a.s released to wastewater | Fww | 0.2 | |  | D |
| **Intermediate calculations** | | | | | |
| Amount of active ingredient to be used for one  application | Qai-prescri1,i2,i3 | 5.23E+00 | 6.22E+00 | [kg] | O  Qai-prescri1,i2,i3 = 10-3• Fbioc • Vprodi1,i2,i3 • Fdil • AREAi1 |
| **Output** | | | | | |
| Emission from one application to a standard STP | Elocalww = Qai-stpi1,i2,i3,i4 | 1.05E+00 | 1.24E+00 | [kg/d] | O  Elocalww = Fstp• Qai-prescr i1,i2,i3 |

\*According to ENV189 (2019), the exact product density (1.082) could be added as an input. As it has no impact in the risk assessment, the calculations were left as they were, considering an approximate density of 1 instead of the exact density of 1.082.

###### **Scenario 1-b – Emissions to soil via slurry**

| **Scenario 1-b: Emission to soil via slurry** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value** | | **Unit** | **S/D/O** |
|  |  | **Chlorocresol** | **L(+) lactic-acid** |  |  |
| **Input** | | | | | |
| Type of House | cat-subcat (i1) | Veal calves | | [-] | Worst case for releases to slurry/manure |
| Type of biocide | bioctype (i2) | Disinfectant | | [-] | D |
| Type of application | appway (i3) | Spraying | |  | - |
| Relevant emission stream | stream (i4) | Slurry | | [-] | - |
| Area of the housing for application (entire housing excluding the ceiling) | AREAi1 | 490 | | [m2] | S – All surfaces except ceiling |
| Content of active ingredient in formulation (product) | Fbioc | 185 | 220 | [g/L] | S – Considering a product density of 1\* |
| Amount of product prescribed to be used per m² | Vprodi1,i2,i3 | 0.2 | | [L/m²] | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | Fdil | 0.03 | | [-] | S – Worst case covering dilution of 0.014 |
| Fraction of a.s released to slurry | Fslurry | 0.5 | | [-] | D |
| Number of disinfectant applications in one year | Napp-bioc | 4 | | [-] | D |
| Biocide application interval | Tbioc-int | 91 | | [d] | D |
| Number of manure applications for grassland | Nlapp-grass | 4 | | [-] | D  TAB 2019, ENV 62 |
| Number of manure applications for arable land | Nlapp-arab | 1 | | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | | [d] | D |
| Manure application time interval for arable land | Tar-int | 212 | | [d] | D |
| Land application interval for manure application on arable land | Tar-int,10 | 365 | | [d] | D |
| Number of animal in housing | Nanimali1 | 80 | | [-] | D |
| Amount of nitrogen per animal | Qnitrogi1 | 0.02382 | | [kg/d] | D |
| ***If nitrogen emission applied*** | | | | | |
| Nitrogen immission standard for one year on grassland | QN, grassland | 170 | | [kg/ha] | D  TAB 2019, ENV 160 |
| Nitrogen immission standard for one year on arable land | QN, arable land | 170 | | [kg/ha] | D  TAB 2019, ENV 160 |
| Mixing depth with soil, grassland | DEPTH,grassland | 0.05 | | [m] | D |
| Mixing depth with soil, arable land | DEPTH,arable land | 0.2 | | [m] | D |
| Density of wet bulk soil | RHOsoilwet | 1700 | | [kg/m3] | D |
|  | | | | | |
| **Intermediate calculations** | | | | |  |
| Number of biocides applications during storage period for application on grassland | Napp-manuregr | 1 | | [-] | O |
| Number of biocides applications during storage period for application on arable land | Napp-manurear | 2.3 | | [-] | O |
| Amount of active ingredient to be used for one  application | Qai-prescri1,i2,i3 | 5.44E-01 | 6.47E-01 | [kg] | O  Qai-prescri1,i2,i3 = 10-3• Fbioc • Vprodi1,i2,i3 • Fdil • AREAi1 |
| Amount of active ingredient in relevant stream i4 after one application | Qai i1,i2,i3,i4 (manure/slurry) | 2.72E-01 | 3.23E-01 | [kg] | O  Qai i1,i2,i3,i4 = slurry/manure i1,i2,i3,i4 • Qai-prescr i1,i2,i3 |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland | Qai-grassi1,i2,i3,i4 (manure/slurry) | 2.72E-01 | 3.23E-01 | [kg] | O  Qai-grassi1,i2,i3,i4 = Qai i1,i2,i3,i4 • Napp-manuregr |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land | Qai-arabi1,i2,i3,i4 (manure/slurry) | 6.25E-01 | 7.44E-01 | [kg] | O  Qai-arabi1,i2,i3,i4 = Qai i1,i2,i3,i4 • Napp-manurear |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | Qnitrog-grassi1,i4 | 1.01E+02 | | [kg] | O  Qnitrog-grassi1,i4 = Nanimali1 • Qnitrogi1 • Tgr-inti2 |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land | Qnitrog-arab i1,i4 | 4.04E+02 | | [kg] | O  Qnitrog-arab1,i4 = Nanimali1 • Qnitrogi1 • Tar-inti2 |
|  | | | | | |
| **End calculations** | | | | | |
| ***SOIL*** | | | | | |
| Concentration of the a.s in soil based on the nitrogen immission standard for grassland | PIECgrs4- Ni1,i2,i3,i4 | 1.35E-01\*\* | 1.60E-01 | [mg/kgwwt] | O  PIECgrs4- Ni1,i2,i3,i4 =100 • Qai-grassi1,i2,i3,i4 • QN, grassland / Qnitrog-grassi1,i4 • Nlapp-grass • DEPTHgrassland • RHOsoilwet |
| Concentration of the a.s. in soil based on the nitrogen immission standard for grassland after four manure application events | PIECgrs4- NTotal | 1.83E-01 | 1.89E-01 | [mg/kgwwt] | O  PIECgrs4- NTotal = PIECgrs4-Ni1,i2,i3,i4 • Napppresc / Napp-manuregr x Nlapp-grass  TAB 2019, ENV 162 |
| Initial concentration in grassland soil (after the last of four manure applications per year), after 10 years of manure application | PIECgrs10\_DEG–Ni1,i2,i3,i4 | 1.84E-01 | 1.89E-01 | [mg/kgwwt] | O  PIECgrs10\_DEG–Ni1,i2,i3,i4 = PIECgrs4 DEG-Ni1,i2,i3,i4 • (1+SommeFsoilgrs2n) |
| Concentration of the active ingredient in soil based on the nitrogen immission standard for arable land | PIECars- Ni1,i2,i3,i4 | 7.74E-02\*\* | 9.21E-02 | [mg/kgwwt] | O  PIECars- Ni1,i2,i3,i4 =100 • Qai-arabi1,i2,i3,i4 • QN, arable-land / Qnitrog-arabi1,i4 • Nlapp-arab• DEPTHarable-land• RHOsoilwet |
| Initial concentration in soil of arable land after 10 years of manure application | PIECars 10 DEG-Ni1,i2,i3,i4 | 7.74E-02 | 9.21E-02 | [mg/kgwwt] | O  PIECars 10 DEG-Ni1,i2,i3,i4 =Fsoilars\_10 • PIECars- Ni1,i2,i3,i4 |
| ***GROUNDWATER*** | | | | | |
| Initial concentration in groundwater (after the last of four manure applications per year) after 10 years of manure application on grassland | PIECgrs10\_DEG–GW–Ni1,i2,i3,i4 | 5.14E+01 | n.c | [µg.L-1] | O  PIECgrs10\_DEG–GW–Ni1,i2,i3,i4 = PIECgrs10\_DEG–Ni1,i2,i3,i4 • RHOsoil / Ksoil\_water • 1000 • 1000 |
| Initial concentration in groundwater after 10 years of manure application on arable land | PIECars10\_DEG-GW - Ni1,i2,i3,i4 | 2.17E+01 | n.c | [µg.L-1] | O  PIECars10\_DEG-GW - Ni1,i2,i3,i4 = PIECars 10 DEG-Ni1,i2,i3,i4 • RHOsoil / Ksoil\_water • 1000 • 1000 |
| ***SURFACE WATER*** | | | | | |
| Initial concentration in surface water (after the last of four manure applications per year) after 10 years of manure application on grassland | PIECgrs10\_DEG–SURFACE WATER–Ni1,i2,i3,i4 | 5.14E-03 | 4.03E-02 | [mg.L-1] | O  PIECgrs10\_DEG–SURFACE WATER–Ni1,i2,i3,i4 = PIECgrs10\_DEG–GW–Ni1,i2,i3,i4 /10 |
| Initial concentration in surface water after 10 years of manure application on arable land | PIECars10\_ DEG-SURFACE WATER - Ni1,i2,i3,i4 | 2.17E-03 | 1.96E-02 | [mg.L-1] | O  PIECars10\_DEG-SURFACE WATER - Ni1,i2,i3,i4 = PIECars 10 DEG-GW - Ni1,i2,i3,i4/10 |

n.c: not calculated, see the justification for the waiving of the L(+) lactic acid the assessment in the section “Calculated PEC values”.

\*\*According to ENV189 (2019), the exact product density (1.082) could be added as an input. As it has no impact in the risk assessment, the calculations were left as they were, considering an approximate density of 1 instead of the exact density of 1.082.

\*\*PECsoil values used in FOCUS Pearl for groundwater refinement.

##### **Scenario 2 - Disinfection of surfaces in poultry hatcheries:**

The local emissions of CMK and L(+) lactic acid are calculated using the scenario “Emission scenario for disinfection in hatcheries” (ESD PT3, 2011).

*Elocalww equation:*

The product PHENOGEN is intended to be used to disinfect premises (rooms) and equipment (hatchers, trolleys, hatching baskets) but not directly the eggs. It corresponds only to the “stage 3” of the scenario, therefore the Elocalwastewater equation is adapted accordingly (see the table below).

*Dose:*

In the ESDTP3 scenario, the application rate of a product for a use in hatcheries is a default value (Qa.iappl) set to 7 g/m3. The product PHENOGEN is applied by spray and its application rate is expressed as an amount per square meter (150 mL/m² at 1.4%%). In the ESD, the surface of a hatcher (or a settler) can be calculated, however, this calculation does not take into account the tray surfaces in the hatcher, and no data is available on this subject.

Therefore, the dose of 7 g of combined active substances/m3 of the ESD is considered. Considering the percentages of the two active substances in the product (18.5% for CMK and 22% for L(+) lactic acid), 3.20 g CMK (18.5/18.5+22)\*7 and 3.80 g of L(+) lactic acid (22/18.5+22)\*7 are used per m3 in the calculations.

The following inputs are considered:

1. HARMONISED APPLICATION RATE: 3.20 g of CMK and 3.80 g of L(+) lactic acid per m3. With a density of approximately 1\*, it corresponds to 3.20 mL for CMK and 3.80 mL for L(+) lactic acid per m3.
2. PRODUCT CONCENTRATION: 18.5\*1.4%\*10 = 2.59 mL / L of CMK and 22\*1.4%\*10 = 3.08 mL / L of L(+) lactic acid in the working solution.
3. VOLUME HATCHER: 9.73 m3.

By a reverse calculation:

For CMK (it applies the same way to L(+) lactic acid), applying 3.20 mL of CMK/m3 would correspond to use 3.20 / (2.59/1000) = 1234.57 mL of product / m3 or 12012 mL / hatcher. Considering an application rate of 150 mL of product / m², 12012 mL would be sufficient to treat at least 80 m² for one hatcher. Thus, this calculation largely covers, as a worst case, the application claimed by the applicant for the product.

According to ENV189 (2019), the exact product density (1.082) could be considered as an input. As it has no impact in the risk assessment, the calculations were left as they were, considering an approximate density of 1 instead of the exact density of 1.082.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario 2: Emissions to STP via wastewater** | | | | | |
| **Parameters** | **Symbol** | **Value** | | **Unit** | **S/D/O** |
|  |  | **Chlorocresol** | **L(+) Lactic acid** |  |  |
| **Input** | | | | | |
| Quantity of active ingredient used per cubic meter | Qa,i,appl | 3.20 | 3.80 | [g/m3] | S  Calculated from the application rate of the applicant |
| Volume of the setter | Vsetter | 9.73 | | [m3] | D |
| Number of setters | Nsetter | 162 | | [-] | D |
| Number of disinfection events (single-stage setter) | Napplsetter | 0.06 | | [/d] |
| Volume of the hatcher | Vhatcher | 9.73 | | [m3] | D |
| Number of hatchers | Nhatcher | 27 | | [-] | D |
| Number of disinfection events | Napplhatcher | 0.57 | | [/d] |
| Fraction released to air after aerosol or fogging treatment | Fair\_fog | 0.1 | | [-] |
| Fraction released to waste water | Fwater | 0.9 | | [-] | O  Fwater = (1 - Fair) |
| **Output** | | | | | |
| Local emission rate to water for each active substance (on the day of hatching) | Elocalwater | 7.04E-01 | 8.36E-01 | [kg/d] | O  Elocalww = Qa,i,appl\*0.001\*Fwater\*((Vsetter\*Nsetter\*Naplsetter)+(Vhatcher\*Nhatcher\*Napplhatcher)) |

##### **Scenario 3 - Disinfection of vehicles used for animal transport:**

The local emissions of CMK and L(+) lactic acid are calculated using the scenario “Emission scenario for disinfection of vehicles used for animal transport” (ESD PT3, 2011). The main emission path is the STP via wastewater, direct emissions to soil are not considered as the treatments of vehicle are usually done on hard standing (TAB 2019, ENV57).

| **Emissions to STP via wastewater: disinfection of vehicles used for animal transport** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Parameters** | **Symbol** | **Value** | | | **Unit** | | **Remarks** | |
|  |  | **Chlorocresol** | | **L(+) Lactic acid** |  | |  | |
| **Input** | | | | | | | | |
| Area of trucks (mammal transports) | AREAmam | 4546 | | | [m2 ] | | D | |
| Area of trucks (poultry transports) | AREApoul | 1120 | | | [m2 ] | |
| Area of containers (poultry transports) | AREAcont | 3355 | | | [m2 ] | |
| Content of active ingredient in formulation (product) | Fbioc | 185 | | 220 | [g/L] | | S | |
| Amount of (diluted) product prescribed to be used per m2 | Vprodi2,i3 | 0.125 | | | [L/m2] | | S | |
| Dilution factor (for preparation of the working solution from the formulation (product)) | Fdil | 0.02 | | | [-] | | S | |
| Fraction released to air | Fair i2,i3,i4 | 0.1 | | | [-] | | D | |
| Fraction released to waste water | Fstp i2,i3,i4 | 0.9 | | | [-] | | S | |
| Number of disinfectant applications in one year | Napp-bioc | 365 | | | [-] | | D | |
| **Output** | | | | | | | |
| **Intermediate calculations** | | | | | | | |
| Amount of a.i to be used for one application (mammal) | Qai-prescri2,i3mammal | 2.10 | 2.50 | | [kg] | O  Qai-prescri2,i3 = 10-3 • Fbioc • Vprodi2,i3 • Fdil • AREAmam | |
| Amount of a.i to be used for one application (poultry) | Qai-prescri2,i3, poultry | 2.07 | 2.46 | | [kg] | O  Qai-prescri2,i3 = 10-3 • Fbioc • Vprodi2,i3 • Fdil • (AREApoul + AREAcont) | |
| **Emissions** | | | | | | | |
| Mammals transport: Emission from one application to a standard STP or an on-site waste water treatment plant | Elocalww, mammal | 1.89 | 2.25 | | [kg/d] | O  Elocalww, mammals= Fstp i2,i3,i4 • Qai-prescri2,i3mammals | |
| Poultry transport: Emission from one application to a standard STP or an on-site waste water treatment plant | Elocalww, poultry | 1.86 | 2.22 | | [kg/d] | O  Elocalww, poultry= Fstp i2,i3,i4 • Qai-prescri2,i3poultry | |

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | | **Freshwater** | **Freshwater sediment** | **STP** | **Air** | **Soil** | **GW** |
| Scenario 1 – Disinfection of animal housing | Scenario 1-a Turkey emissions Via STP | + | + | ++ | - | + | + |
| Scenario 1-b Veal calves emissions via slurry | + | - | - | - | ++ | + |
| Scenario 2 – Disinfection of surfaces in hatcheries | | + | + | ++ | - | + | + |
| Scenario 3 – Disinfection of vehicles used for animal transport | | + | + | ++ | - | + | + |

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

Input parameters for calculating the fate and distribution of the active substances in the environment are selected from the CMK (2017) and L(+) lactic acid assessment reports (2017) and gathered in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the fate and distribution in the environment** | | | | |
| **Input** | **Value** | | **Unit** | **Remarks** |
|  | **Chlorocresol** | **L(+) lactic-acid** |  |  |
| Molecular weight | 142.6 | 90.08 | g/mol | Revised AR of CMK (2017)  and  AR of L(+) lactic acid (2017) |
| Vapour pressure | 6E-03 (at 25°C) | 4E-01 (at 20°C) | Pa |
| Water solubility | 3.4 (at 20°C) | 1E+06 (at 12°C) | mg/L |
| Log Octanol/water partition coefficient | 2.73 | -0.74 | Log 10 |
| Organic carbon/water partition coefficient (Koc) | 195.6 | 20 | L/kg |
| Biodegradability | Readily biodegradable (fulfilling the 10 day window) | Readily biodegradable (failing the 10 day window) | - | Revised AR of CMK (2017)  and  AR of L(+) lactic acid (2017) |
| DT50 for degradation in soil | 30 | 30 | d | CMK: Default value for readily biodegradable substance fulfilling the 10 days windows with a kp,soil < 100 L/kg, Vol IV Part B+C  L(+) lactic acid: 30d as refinement for 90d value in AR (2017) |
| k biosol | 2.31E-02 | 2.31E-02 | /d | Calculations from Vol IV Part B+C (2017) |
| k volat (depth of 0.2 m\*) | 1.17E-06 | 4.84E-06 | /d |
| k leach (depth of 0.2 m\*) | 3.96E-04 | 3.00E-03 | /d |
| k total (depth of 0.2 m\*) | 2.35E-02 | 2.61E-02 | /d |
| k volat (depth of 0.05 m\*\*) | 4.67E-06 | 1.94E-05 | /d |
| k leach (depth of 0.05 m\*\*) | 1.58E-03 | 1.20E-02 | /d |
| k total (depth of 0.05 m\*\*) | 2.47E-02 | 3.51E-02 | /d |
| BCF fish | 7.28E+00 | 4.80E-02 | L/kg | AR of L(+) lactic acid (2017)  and  Calculated with the new value of Log Kow of the revised AR of CMK (2017) |
| BCF earthworms | 4.17E+01 | 6.78E+00 | L/kg |

\*For application of STP sludge on arable land  
\*\*For application of manure/slurry on grassland

In the STP, the fractioning of the active substances between air, water, sludge and degradation is indicated in the following table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP** | | | |
| Compartment | Percentage [%] | | Remarks |
| Chlorocresol | L(+) lactic acid |
| Air | 1.36E-05 | 2.50E-05 | Simple Treat v4.0, considering a concentration suspended solids effluents (Css) of 30 mg/L or 0.03 kg/m3 (TAB 2019, ENV9) |
| Water | 7.89 | 22.5 |
| Sludge | 1.78 | 0.20 |
| Degraded in STP | 90.32 | 77.3 |

#### **Calculated PEC values**

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 used for the risk assessment** | | | | | | |
|  | Scenario 1 – disinfection of animal housing (turkey, worst-case) | | Scenario 2 – Disinfection of surfaces in hatcheries | | Scenario 3 – Disinfection of vehicles used for animal transport (mammal, worst-case) | |
|  | Chlorocresol | Lactic acid | Chlorocresol | Lactic acid | Chlorocresol | Lactic acid |
| **EMISSIONS VIA THE STP** | | | | | | |
| **Elocalww** **[kg/d]** | 1.05E+00 | 1.24E+00 | 7.04E-01 | 8.36E-01 | 1.89E+00 | 2.25E+00 |
|  | | | | | | |
| **PECSTP** [mg/m3] | 4.12E-02 | 1.40E-01 | 2.78E-02 | 9.40E-02 | 7.47E-02 | 2.53E-01 |
| **PECwater** [mg/L] | 4.12E-03 | 1.40E-02 | 2.78E-03 | 9.40E-03 | 7.46E-03 | 2.53E-02 |
| **PECsoil INITIAL** [mg/kg ww] | 3.46E-02 | 4.63E-03 | 2.33E-02 | 3.11E-03 | 6.27E-02 | 8.38E-03 |
| **PECGW** [μg/L] | **2.26E+00** | n.c | **1.52E+00** | n.c | **4.09E+00** | n.c |
|  | | | | | | |
| **EMISSIONS VIA SLURRY** | | | Not relevant | | | |
|  | Scenario 1 – disinfection of animal housing (veal calves, worst-case) | |
|  | Chlorocresol | Lactic acid |
| **PECsoil INITIAL** [mg/kg ww]**:** | | |
| PIECgrs10\_DEG–Ni1,i2,i3,i4 | 1.84E-01 | 1.89E-01 |
| PIECars10\_DEG-Ni1,i2,i3,i4 | 7.74E-02 | 9.21E-02 |
| **PECGW** [μg/l]**:** | | |
| PIECgrs10\_DEG–GW–Ni1,i2,i3,i4 | **5.14E+01** | n.c |
| PIECars10\_DEG-GW - Ni1,i2,i3,i4 | **2.17E+01** | n.c |
| **PECwater** [mg/L]**:** | | |
| PIECgrs10\_DEG–SURFACE WATER–Ni1,i2,i3,i4 | 5.14E-03 | 4.03E-02 |
| PIECars10\_DEG-SURFACE WATER - Ni1,i2,i3,i4 | 2.17E-03 | 1.96E-02 |

n.c: not calculated, see the justification for the waiving of the groundwater/surface water assessment below.

*PECSediments:*

For both substances, no ecotoxicological data was generated for sediment dwelling organisms and the PNEC values for this compartment were 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.

*PECsoil:*

For the product uses leading to emissions to the sewage treatment plant (scenario 1 via the wastewater and scenarios 2 and 3) or directly to soil (scenario 1 via slurry):

1. the initial PECsoil is calculated to take into account the fact that the PNECsoil value for CMK corresponds to initial concentrations in soil,
2. the initial PECsoil is calculated as well for L(+) lactic acid in a worst-case, even if the PNECsoil value is not considered as an initial one.

*PECGW:*

In the case of Chlorocresol emissions, for scenarios that leads to emissions to groundwater and for which the resulting groundwater concentrations are higher than the threshold value of 0.1 µg/L, the FOCUS groundwater model PEARL (version 4.4.4) is used as a refinement and output are presented below.

For L(+) Lactic acid, it was decided during the WG-II-2020 (ENV, item 7.4) that only arguments to support a qualitative assessment without further calculations should be provided. The harmonized justification is presented below:

*“Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier 1). Modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic.*

*For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater and no further calculations are needed.”*

***Primary and secondary poisoning***

Primary poisoning

It is not believed that liquid is a form that could be sufficiently appetent to bird or mammals so they would be at risk. Therefore, no primary poisoning is expected.

Secondary poisoning

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

***Groundwater concentrations refinements for Chlorocresol***

- In scenario 1 (emissions from STP - turkey), 2, and 3, groundwater are exposed indirectly via the STP by application of sewage sludge on grassland or agricultural land. As emissions from these scenarios can be aggregated, they are assessed together in a FOCUS Pearl simulation (version 4.4.4) as a worst-case.

- In scenario 1 (emission from slurry/manure - veal calves), groundwater are exposed after direct releases of slurry into soil and concentrations are estimated with FOCUSPearl version 4.4.4.

*Input related to the active substance and scenarios:*

According to the TAB 2.1, ENV165 (2019), PIECars/PIECgrs after one application are used in the different simulations.

***Groundwater (FOCUSGW, version 4.4.4)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Emissions to Groundwater : Input for refinement (FOCUS PEARL 4.4.4) for CMK** | | | | | |
| **Input parameters related to the Active Substance** | | | | | |
|  | **Value** | **Reference** | | | |
| Molecular weight (g/mol) | 142.6 | CAR CMK (2017) | | | |
| Water solubility (g/l) at 20°C | 3.4 |
| Koc (L/kg) | 195.6 |
| Saturated vapour pressure (Pa) at 25°C | 6.00E-3 |
| DT50 in soil (d) at 12°C | 30 |
| Kom (=Koc/1.724) (L/kg) | 113.46 | TAB 2.1 ENV 23 | | | |
| 1/n | 1 | TAB 2.1 ENV 22 | | | |
| Plant uptake factor | 0 | TAB 2.1 ENV 23 | | | |
| Molar activation energy (kJ/mol) | 65.4 | WG-IV-2019 | | | |
|  | | | | | |
| **Input parameters related to the Scenarios** | | | | | |
| **EXPOSURE VIA THE STP – Scenario 1 (turkey emissions via the STP)+2+3** | | | | **Reference** | |
| Crop | Agricultural land (maize) | Grassland (alfalfa) | | TAB 2.1 ENV165 | |
| Sewage sludge application rate (kg/ha) | 5000 | 1000 | |
| Number of sewage sludge applications (/y) | 1 | | |
| Application date | Relative application: 20 days before crop event “emergence” | Absolute application: 1st of March 1901 | |
| Incorporation depth (cm) | 20 | 10 | |
| Concentration of a.s. in dry sewage sludge, Csludge (mg/kg) | 8.20E+01 | 8.20E+01 | |
| Application rate (kg CMK/ha) | 4.10E-01 | 8.20E-02 | |
|  | | | | | |
| **EXPOSURE VIA SLURRY – Scenario 1 (veal calves emissions via slurry/manure)** | | | | | |
| Crop | Agricultural land (maize) | Agricultural land (winter cereals) | Grassland (alfalfa) | | TAB 2.1 ENV165 | |
| Number of manure applications (/y) | 1 | 2 with different application rates (autumn/spring) | 4 with the same application rate | |
| Application rate (kg CMK/ha/application) | PIECars- Ni1,i2,i3,i4 (1 application) x 3.4  = 2.63E-01 | Spring:  PIECars- Ni1,i2,i3,i4 (1 application) x 1.8 =  1.39E-01  Autumn:  PIECars- Ni1,i2,i3,i4 (1 application) x 1.6 =  1.24E-01 | PIECgrs4- Ni1,i2,i3,i4 (1 application) x 0.85  = 1.14E-01 | |
| Application date | Relative application: 20 days before crop event “emergence” | Absolute applications in 1901:  - 15th of March  - 3rd of October | Absolute applications in 1901:   * 1st of March * 23rd of April * 15th of June * 7th of August | |
| Incorporation depth (cm) | 20 | 20 | 5 | |

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 CMK/L, (FOCUS PEARL 4.4.4)** | | | | |
| **Output** | | | | |
|  | | | | |
| **EXPOSURE VIA THE STP – Scenario 1 (turkey emissions via the STP)+2+3** | | | | |
| Crop | Agricultural land (maize) | | Grassland (alfalfa) | |
|  |  | |  | |
| CHATEAUDUN | 0.002562 | | 0.003055 | |
| HAMBURG | 0.024371 | | 0.022154 | |
| JOKIOINEN | 0.0218 | | 0.022297 | |
| KREMSMUENSTER | 0.054961 | | 0.016652 | |
| OKEHAMPTON | 0.025592 | | 0.041592 | |
| PIACENZA | 0.00967 | | 0.023725 | |
| PORTO | 0.000225 | | 0.010025 | |
| SEVILLA | 0.000331 | | 0.000484 | |
| THIVA | 0.002562 | | 0.000699 | |
|  | | | | |
| **EXPOSURE VIA SLURRY – Scenario 1 (veal calves emissions via slurry/manure)** | | | | |
| Crop | Agricultural land (maize) | Agricultural land (winter cereals) | | Grassland (alfalfa) |
|  |  |  | |  |
| CHATEAUDUN | 0.001277 | 0.001023 | | 0.000237 |
| HAMBURG | 0.008931 | 0.025925 | | 0.003044 |
| JOKIOINEN | n.c | 0.014891 | | 0.000655 |
| KREMSMUENSTER | 0.006754 | 0.024667 | | 0.001389 |
| OKEHAMPTON | 0.021726 | 0.055749 | | 0.002099 |
| PIACENZA | 0.004602 | 0.01924 | | 0.001766 |
| PORTO | 0.000431 | 0.008824 | | 0.000651 |
| SEVILLA | 0.000015 | 0.000041 | | 0.000025 |
| THIVA | 0.000058 | 0.000098 | | 0.000052 |

n.c: not calculated

#### Risk characterisation

*Atmosphere:*Concerning the atmosphere, no PNEC values were calculated as according to the ARs, it is not considered to be an environmental compartment of concern. Indeed, 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”. The L(+) lactic acid has a half-life of 2.71 days in air, the assessment report indicates that “exposure to air is expected to be insignificant” and “lactic acid has no global-warming potential”.

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

*Sediments:*For both substances, no ecotoxicological data was generated for sediment dwelling organisms. The PNEC values for this compartment were therefore derived through equilibrium partitioning. Therefore, the risk assessment for the surface water covers the risk assessment for the sediment and no RCR value are presented for this compartment.

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated RCR values** | | | | | | |
|  | Scenario 1 – disinfection of animal housing (turkey, worst-case) | | Scenario 2 – Disinfection of surfaces in hatcheries | | Scenario 3 – Disinfection of vehicles used for animal transport (mammal, worst-case) | |
|  | Chlorocresol | Lactic acid | Chlorocresol | Lactic acid | Chlorocresol | Lactic acid |
| **EMISSIONS VIA THE STP** | | | | | | |
| **RCRSTP** | 7.24E-02 | 1.40E-02 | 4.87E-02 | 9.40E-03 | 1.31E-01 | 2.53E-02 |
| **RCRwater** | 2.75E-01 | 3.59E-03 | 1.85E-01 | 2.41E-03 | 4.98E-01 | 6.49E-03 |
| **RCRsoil INITIAL:** | 5.77E-02 | 2.44E-03 | 3.89E-02 | 1.64E-03 | 1.05E-01 | 4.41E-03 |
| **PECGW** [μg/l] | < 0.1\* | n.c | < 0.1\* | n.c | < 0.1\* | n.c |
|  | | | | | | |
| **EMISSIONS VIA SLURRY** | | | Not relevant | | | |
|  | Scenario 1 – disinfection of animal housing (veal calves, worst-case) | |
|  | Chlorocresol | Lactic acid |
| **RCRsoil INITIAL:** | | |
| PIECgrs10\_DEG–Ni1,i2,i3,i4 | 3.06E-01 | 9.97E-02 |
| PIECars10\_DEG-Ni1,i2,i3,i4 | 1.29E-01 | 4.85E-02 |
| **PECGW** [μg/l]**:** | | |
| PIECgrs10\_DEG–GW–Ni1,i2,i3,i4 | < 0.1\* | n.c |
| PIECars10\_DEG-GW - Ni1,i2,i3,i4 | < 0.1\* | n.c |
| **RCRwater:** | | |
| PIECgrs10\_DEG–SURFACE WATER–Ni1,i2,i3,i4 | 3.54E-01 | 1.03E-02 |
| PIECars10\_DEG-SURFACE WATER - Ni1,i2,i3,i4 | 1.72E-01 | 5.02E-03 |

n.c: not calculated, see the justification for the waiving of the groundwater assessment in section “Calculated PEC values”

\*ouput of FOCUS Groundwater v4.4.4 simulation

***Aquatic compartment (including the STP)***

All the uses lead to acceptable risks for the STP microorganisms and the aquatic compartment.

***Terrestrial compartment***

All the uses lead to acceptable risks for the terrestrial compartment.

***Groundwater***

For chlorocresol emissions, refined estimations of releases to groundwater (FOCUS 4.4.4, see section Groundwater) are lower than the threshold value of 0.1 µg/L. Moreover, a justification provided section “Calculated PEC values” demonstrates that groundwater is not at risk for product containing for L(+) lactic acid.

Thus, requirements for acceptable risk to groundwater according to the Guidance for BPR are met for all the uses.

***Primary and secondary poisoning***

Primary poisoning

It is not believed that liquid is a form that could be sufficiently appetent to bird or mammals so they would be at risk. Therefore, no primary poisoning is expected.

Secondary poisoning

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

***Conclusions***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Claimed Uses | Are of use | Details on treated surfaces | Targets | Application rate (mL of diluted product/m2) | Dilution of the product | Covered by scenarios (see exposure assessment) | Acceptable risks for the environment |
| 1 | Disinfection of surfaces of livestock animal housing and equipment (cattle, pigs and poultry) | All housing surfaces | bacteria, yeast, fungi and some virus | 200 | 1.4% v/v | Scenario 1 | **YES** |
| Disinfection of surfaces in poultry hatcheries | - | 100-150 | 1.4% v/v | Scenario 2 | **YES** |
| 2 | Disinfection of surfaces of livestock animal housing and equipment (cattle, pigs and poultry) | Housing surfaces except the ceiling | *C. parvum* | 200 | 3% v/v | Scenario 1 | **YES** |
| 3 | Disinfection of surfaces of animal transport vehicles | - | bacteria, yeast, fungi and some virus | 125 | 2% v/v | Scenario 3 | **YES** |

To conclude, the three uses claimed for the product PHENOGEN lead to acceptable risks for the environment.

***Mixture toxicity***

Please refer to the aggregated risk assessment for a complete view of the conclusions for all the uses including the mixture toxicity of chlorocresol and L(+) lactic acid.

***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 same STP are considered in the aggregated exposure assessment, such as in scenario 1 (turkey emissions via the STP), scenario 2 and 3. For scenario 1 in case of releases via slurry/manure, no aggregated risk assessment is needed. Only the mixture toxicity has been proposed in this case for soil (the only relevant compartment for lactic acid).

Risk ratios of chlorocresol and L(+) lactic acid are cumulated for every relevant compartments in the following table:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenarios | **PEC/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsoil** | **PECGW (µg/L)** |
| 1 - Disinfection of animal housing (turkey emissions via the STP) | 3.01E-01 | 9.70E-01 | 2.10E-01 | < 0.1\* |
| 2 – Disinfection of poultry hatcheries |
| 3 – Disinfection of vehicles used for animal transport |
| 1 - Disinfection of animal housing (veal calf emissions via slurry/manure) | not relevant | not relevant | 4.06E-01 (grassland as a worst case) | not relevant |

\*See Groundwater section, FOCUS simulation v 4.4.4

Conclusion: Aggregated exposure combined to mixture toxicity of the use 1, 2 and 3 leads to acceptable risks for the environment.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Acceptable risks are reached for the environment for:   * + Use 1 (PT3): Disinfection of livestock animal housing and equipment including hatcheries against bacteria, yeasts, fungi and virus,   + Use 2 (PT3): Disinfection of livestock animal housing and equipment (except ceiling) against *C. parvum*,   + Use 3 (PT3): Disinfection of animal transportation vehicles against bacteria, yeasts, fungi and virus. |

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

*Please refer to summary of the product assessment and to the relevant sections of the assessment report.*

### Assessment of a combination of biocidal products

*Not relevant*

### Comparative assessment

*Not relevant*

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité bactéricide du produit Phenogen selon la norme EN 1656  Report No 106D11-2018-05 | Yes | Synthese Elevage |
| Morot-Bizot S. | 2020 | Determination of the bactericidal activity of the Phenogen product according to the EN 1656 standard. Salmonella  Report No 034D03-2020-03 | Yes | Synthese Elevage |
| Morot-Bizot S. | 2020 | Determination of the bactericidal activity of the Phenogen product according to the EN 1656 standard. 5 minutes.  Report No 034D03-2020-04 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité bactéricide du produit Phenogen selon la norme EN 14349  Report No 106D11-2018-01 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité bactéricide du produit Phenogen selon la norme EN 14349. *Salmonella*  Report No 144D15-2018-02 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2019 | Détermination de l’activité bactéricide du produit Phenogen selon la norme EN 14349 (5 min)  Report No 327D29-2018-04 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité bactéricide du produit Phenogen selon la norme EN 16437  Report No 255B27-2018 | Yes | Synthese Elevage |
| Morot-Bizot S. | 2020 | Determination of the bactericidal activity of the Phenogen product according to the EN 16437 standard. *Salmonella enterica.*  Report No 034D03-2020 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité fongicide du produit Phenogen selon la norme EN 1657  Report No 106D11-2018-04 | Yes | Synthese Elevage |
| Morot-Bizot S. | 2020 | Determination of the fungicidal activity of the Phenogen product according to the EN 1657 standard. 5 minutes.  Report No 034D03-2020-02 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité fongicide du produit Phenogen selon la norme EN 16438  Report No 106D11-2018-02 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2019 | Détermination de l’activité fongicide du produit Phenogen selon la norme EN 16438 (5 min)  Report No 327D29-2018-02 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité virucide vis-à-vis de l’enterovirus bovin de type 1 (ECBO) du produit Phenogen.  Report No 106D11-2018-03 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2019 | Détermination de l’activité virucide du produit Phenogen selon la norme EN 14675 (5 min).  Report No 327D29-2018-03 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité virucide vis-à-vis du virus grippal de type H1N1 du produit Phenogen.  Report No 144D15-2018-04 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité virucide vis-à-vis du virus porcin responsable du syndrome respiratoire et dysgenesique (PRRS) du produit Phenogen.  Report No 144D15-2018-06 | Yes | Synthese Elevage |
| Morot-Bizot S. and Herbein G. | 2018 | Détermination de l’activité virucide vis-à-vis du parvovirus de canard du produit Phenogen.  Report No 144D15-2018-08 | Yes | Synthese Elevage |
| Morot-Bizot S. | 2018 | Détermination de l’activité virucide vis-à-vis du virus de la fièvre africaine porcine (ASFV) du produit Phenogen.  Report No 144D15-2018-10 | Yes | Synthese Elevage |
| Daugschies A. and Renteria Z. | 2018 | Assessment of the disinfectant efficacy of Phenogen. | Yes | Synthese Elevage |
| Shahiduzzaman M. et al. | 2010 | Combination of cell culture and quantitative PCR (cc–qPCR) to assess disinfectants efficacy on Cryptosporidium oocysts under standardized conditions. | No |  |
| Dresely I. et al. | 2015 | Establishment of a germ carrier assay to assess disinfectant efficacy against oocysts of coccidian parasites | No |  |
| Delling C. et al. | 2017 | Improvement of in vitro evaluation of chemical disinfectants for efficacy on Cryptosporidium parvum oocysts | No |  |
| Morot-Bizot S. and Herbein G. | 2019 | Détermination de l’activité bactéricide d’une solution d’isopropanol selon la norme EN 1656  Report No 327D29-2018-05 | Yes | Synthese Elevage |

## Output tables from exposure assessment tools

For each species for cattle, pigs and poultry according to the following parameters (Guidance on the BPR: Volume III Parts B+C, Appendix 6-1: Default Value Working Tables, Table 53: Animal Housing):

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **category** | **floor area (m²)** | **housing volume per stable (m3)** | **product amount inhalation (g)** | **ventilation rate  (h-1) (winter worst-case)** | **estimated inhalation (evaporation) uptake (mg/kg bw/d)** |
|  |  |  |
| **Cattle** |  | | dairy cattle | 1170 | 9630 | 234000 | 0.9 | 2.10E+00 |
| beef cattle | 370 | 3063 | 74000 | 2 | 1.30E+00 |
| veal calves | 160 | 590 | 32000 | 4.1 | 1.60E+00 |
| **Pigs** | individual | | sows | 560 | 1960 | 112000 | 3.5 | 1.80E+00 |
| group | | sows | 710 | 2480 | 142000 | 2.8 | 2.10E+00 |
| fattening pigs | 600 | 2110 | 120000 | 1.9 | 2.70E+00 |
| **Poultry** | battery | all | laying hens | 750 | 2810 | 150000 | 5.2 | 1.20E+00 |
| free range | litter floor | laying hens | 1430 | 5360 | 286000 | 1.3 | **3.20E+00** |
| litter floor | broilers | 1110 | 4170 | 222000 | 4.3 | 1.40E+00 |
| grating floor | laying hens | 1270 | 4780 | 254000 | 2.9 | 1.90E+00 |
| grating floor | parent broilers | 390 | 1458 | 78000 | 4.3 | 1.40E+00 |
| litter floor | parent broilers in rearing | 500 | 1880 | 100000 | 4.3 | 1.40E+00 |
| litter floor | turkey | 3330 | ND | 666000 | ND | **-** |
| litter floor | ducks | 2000 | ND | 400000 | ND | **-** |
| litter floor | geese | 2500 | ND | 500000 | ND | **-** |

## New information on the active substance

*Not relevant*

## Residue behaviour

*Not relevant*

## Summaries of the efficacy studies (B.5.10.1-xx)

*Please refer to IUCLID dossier*

## Confidential annex

*Please refer to the confidential document annex.*

1. 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 [↑](#footnote-ref-2)
2. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=901> [↑](#footnote-ref-3)
3. 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 [↑](#footnote-ref-4)
4. EMA guideline on risk characterisation and assessment of maximum residue limits (MRL) for biocides, EMA/CVMP/90250/2010, 2015 [↑](#footnote-ref-5)
5. EMEA/MRL/074/96-FINAL March 1996 : Committeee for veterinary medicinal products – Summary report : Chlorocresol (4-chloro-3-methylphenol) [↑](#footnote-ref-6)
6. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=901> [↑](#footnote-ref-7)
7. Guidance on the Biocidal Products Regulation ,Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0 December 2017 [↑](#footnote-ref-8)
8. TNsG on Annex I Inclusion, Revision of Chapter 4.1: Quantitative Human Health Risk Characterisation, 2009. <https://echa.europa.eu/documents/10162/16960215/revision_tnsg_annex_i_inclusion_chapter_4.1_2009_en.pdf> [↑](#footnote-ref-9)