

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

CHLOROCRESOL BASED PRODUCTS – CID LINES NV

ECHA/BPC/362/2022

16 September 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of CHLOROCRESOL BASED PRODUCTS – CID LINES NV

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product family:	CHLOROCRESOL BASED PRODUCTS – CID LINES NV
Authorisation holder:	CID LINES NV
Active substances common name:	chlorocresol (CAS number 59-50-7)
Product types:	2 and 3

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 25 July 2018, recorded in R4BP3 under case number BC-RF039183-42, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 7 January 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-43) and its Working Groups (WG I 2022). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the Union authorisation of the biocidal product family was reached on 16 September 2022.

The BPC opinion was adopted by simple majority. The opinion and the minority position including its grounds are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(1)(s).

The biocidal product family meets the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of CHLOROCRESOL BASED PRODUCT – CID LINES NV referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family split into five sub-paragraphs.

General

The biocidal product family CHLOROCRESOL BASED PRODUCTS – CID LINES NV consists of products containing 0.49 to 24.9% of the active substance chlorocresol. Products are intended to be used for the disinfection of surfaces, equipments or animal skin in PT2 and PT3 uses.

The biocidal product family (BPF) is composed of 8 meta SPCs. The structuring of the BPF into meta SPCs is based on the intended uses, the formulation and the mode of application of the products.

The following non-active substances are identified as substances of concern (SoC):

- propan-1-ol, propan-2-ol and salicylic acid as they are approved biocidal active substances in concentrations above 0.1 %.
- Propionic acid, Acetone, Dimethylether, Formic acid and Phosphoric acid as they contribute to the classification for human health hazards. Acetone, Dimethylether and Formic acid also have EU Occupational Exposure Limits (OELs).
- Hydroterpene processing by-products (CAS 68956-56-9) contained in Pine oil (CAS 94266-48-5) at 36%, which is classified H411 for the environment.

The following intended claims were assessed:

Users	Meta-SPC	Uses
Professionals	Meta SPC 1	Use #1.1: Concentrated surface and equipment disinfectants in veterinary field (PT3) by spraying. Products of Meta SPC 1 are soluble concentrates containing 24.0 % v/v chlorocresol.

Users	Meta-SPC	Uses
Professionals	Meta SPC 2	<p>Use #2.1: Concentrated surface and equipment disinfectants in veterinary field (PT3) by spraying.</p> <p>Use #2.2: Concentrated surface disinfectants in transport vehicles (PT3) by spraying.</p> <p>Products of Meta SPC 2 are soluble concentrate containing 24.9 % v/v chlorocresol.</p>
Professionals	Meta SPC 3	<p>Use #3.1: Concentrated surface and equipment disinfectants in veterinary field (PT3) by spraying.</p> <p>Use #3.2: Concentrated surface disinfectants in transport vehicles (PT3) by spraying.</p> <p>Products of Meta SPC 3 are soluble concentrates containing 24.9 % v/v chlorocresol.</p>
Professionals	Meta SPC 4	<p>Use #4.1: Concentrated surface and equipment disinfectants in veterinary field (PT3) by spraying.</p> <p>Use #4.2: Concentrated surface disinfectants in transport vehicles (PT3) by spraying.</p> <p>Products of Meta SPC 4 are soluble concentrates containing 24.9 % v/v chlorocresol.</p>
Professionals	Meta SPC 5	<p>Use #5.1: Ready to use animal skin disinfectants (PT3) by spraying.</p> <p>Products of Meta SPC 5 are ready-to-use solutions containing 1.5 % v/v chlorocresol.</p>
Professionals	Meta SPC 6	<p>Use#6.1: Ready to use animal skin disinfectants (PT3) by spraying.</p> <p>Products of Meta SPC 6 are ready-to-use solutions containing 0.49 % v/v chlorocresol.</p>
Professionals and non professionals	Meta SPC 7	<p>Use#7.1: Concentrated general surface disinfectants in the house (PT2) by wiping.</p> <p>Use#7.2: Concentrated disinfectants for toilet bowls (PT2) by pouring.</p> <p>Use#7.3: Concentrated hard surface disinfectants (including disinfection of animal cages by veterinarians or their assistants) (PT3) by spraying.</p>
Professionals		<p>Use#7.4: Concentrated disinfectants for use on instruments/equipment by veterinarians (PT2) by spraying or immersion.</p>
Professionals and non professionals		<p>Use#7.5: Concentrated disinfectants for use on areas where pets live (PT3) by spraying.</p>
Professionals		<p>Use#7.6: Concentrated disinfectants for surfaces for examination and treatment of animals (PT2) by spraying.</p> <p>Use#7.7: Concentrated animal skin disinfectants (PT3) by spraying.</p>

Users	Meta-SPC	Uses
		<p>Use#7.8: Concentrated disinfectants for use on areas where pets live (PT3) by immersion.</p> <p>Use#7.9: Concentrated hard surface disinfectants (including disinfection of animal cages by veterinarians or their assistants) (PT3) by immersion.</p> <p>Products of Meta SPC 7 are soluble concentrates containing 4.5 % v/v chlorocresol.</p>
Professionals and non professionals	Meta SPC 8	<p>Use#8.1: Concentrated general surface disinfectants in the house (PT2) by wiping.</p> <p>Use#8.2: Concentrated disinfectants for toilet bowls (PT2) by pouring.</p> <p>Products of Meta SPC 8 are soluble concentrates containing 2.9 % v/v chlorocresol.</p>

Conclusions of the assessments of each section are given here below:

Physico-chemical properties

Meta SPC 1, 2, 3, 4, 7 and 8 are soluble concentrates (SL) containing 2.9 to 24.9% of technical chlorocresol, intended to be diluted in water before application. Concentrates are clear liquids whereas after dilution, they appear as milky solutions.

Meta SPC 5 and 6 are ready-to-use solutions containing 0.49 to 1.5% of technical chlorocresol, packaged under pressure in aluminium can aerosols. As these products contain 50% of a propellant which is gaseous at ambient pressure, once sprayed the liquid is twice more concentrated (0.98 to 3% chlorocresol).

A shelf life of 2 years can be granted for all meta SPCs, except for the Meta SPC 1 where stability has been sufficiently demonstrated for 3 years when stored in HDPE.

All relevant physical, chemical and technical properties of each product included in the biocidal product family CHLOROCRESOL BASED PRODUCTS – CID LINES NV have been described and are considered acceptable for the intended uses.

Analytical methods are considered acceptable.

Meta SPC 1 is classified as H225 - Highly flammable liquid and vapour;

Meta SPC 2 and 3 are classified as H226 – Flammable liquid and vapour and H290 – May be corrosive to metals;

Meta SPC 4 is classified as H225 - Highly flammable liquid and vapour and H290 – May be corrosive to metals;

Meta SPC 5 and 6 are classified as H222 – Extremely flammable aerosol, H229 – Pressurised container: May burst if heated and H290 – May be corrosive to metals;

Meta SPC 7 and 8 are not classified for physical hazards.

Efficacy

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), Version 3.0, April 2018 and EN 14885:2015 standard has been demonstrated for the following uses:

META-SPC 1

- Use 1.1: Disinfection of non-porous surface and equipments by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 1% v/v, 60 min, 10 °C
 - Other target organisms:
 - Fungi: 2% v/v, 60 min, 10°C
 - Virus: 1% v/v, 60 min, 10 °C
 - Endoparasites: parasitic protozoa: 4 % v/v, 120 min, 10 °C
 - Endoparasites: helminth eggs: 2 % v/v, 120 min, 10 °C

META-SPC 2

- Use 2.1: Concentrated surface and equipment disinfectants (non porous surface) – by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 1.5% v/v, 30 min, 10 °C
 - Other target organisms:
 - Virus: 3.5% v/v, 30 min, 10 °C
 - Endoparasites: parasitic protozoa: 4 % v/v, 120 min, 10 °C
 - Eggs of *A. suum*: 2 % v/v, 120 min, 10 °C
- Use 2.2: Concentrated non-porous surface disinfectants for animal transport vehicles (non porous surfaces) – by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria, yeasts and virus: 3.5% v/v, 5 min, 10 °C

META-SPC 3

- Use 3.1: Concentrated surface and equipment disinfectants (non porous surface) – by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 1% v/v, 30 min, 10 °C

- Other target organisms:
 - Virus: 3.5% v/v, 30 min, 10 °C
 - Endoparasites: parasitic protozoa: 4 % v/v, 120 min, 10 °C
 - Endoparasites: helminth eggs: 2 % v/v, 120 min, 10 °C
- Use 3.2: Concentrated surface disinfectants for animal transport vehicles (non porous surface) – by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria, yeasts and: virus 3.5% v/v, 5 min, 10 °C

META-SPC 4

- Use 4.1: Concentrated surface and equipment disinfectants (non porous surface) – by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.75% v/v, 30 min, 10 °C
 - Other target organisms:
 - Fungi: 2% v/v, 30 min, 10 °C
 - Virus: 3.5% v/v, 30 min, 10 °C
 - Endoparasites: parasitic protozoa: 4% v/v, 120 min, 10 °C
 - Endoparasites: helminth eggs: 2% v/v, 120 min, 10 °C
- Use 4.2: Concentrated surface disinfectants for animal transport vehicles (non porous surface) – by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria, yeasts and virus: 3.5% v/v, 5 min, 10 °C
 - Other target organisms:
 - Fungi: 3% v/v, 5 min, 10 °C

META-SPC 5 (NOT PROPOSED FOR AUTHORISATION regarding animal health and indirect exposure via food)

- Use 5.1: Ready to use animal's skin disinfectants – by spraying (PT3) with dirty conditions:
- Disinfection of hoof skin:
 - Mandatory target organisms:
 - Bacteria: 100% v/v, 5 min, 10 °C

- Other target organisms:
 - Yeasts: 100% v/v, 5 min, 10 °C
- Disinfection of animal's skin except feet:
 - Mandatory target organisms:
 - Bacteria and yeasts: 100% v/v, 5 min, 30 °C
 - Other target organisms:
 - Fungi: 100% v/v, 5 min, 30°C
 - Virus: 100% v/v, 5 min, 30 °C

META-SPC 6 (NOT PROPOSED FOR AUTHORISATION regarding indirect exposure via food)

- Use 6.1: Ready to use animal's skin disinfectants – by spraying (PT3) with dirty conditions:
- Disinfection of hoof skin:
 - Mandatory target organisms:
 - Bacteria: 100% v/v, 5 min, 10 °C
 - Other target organisms:
 - Yeasts: 100% v/v, 5 min, 10 °C
- Disinfection of animal's skin except feet:
 - Mandatory target organisms:
 - Bacteria and yeasts: 100% v/v, 5 min, 30 °C
 - Other target organisms:
 - Fungi: 100% v/v, 5 min, 30°C
 - Virus: 100% v/v, 5 min, 30 °C

META-SPC 7

- Use 7.1: Concentrated surface disinfectants for surfaces in the house (non porous surface) –with a mop/towel (without mechanical action) (PT2) with dirty conditions:
 - Mandatory target organisms:
 - Bacteria: 2,5% v/v, 15 min, 20 °C
 - Other target organisms:
 - Yeasts: 2.5% v/v, 15 min, 20 °C
- Use 7.2: Concentrated disinfectants for toilet bowls (non porous surface) – by pouring (PT2) with dirty conditions:

- Mandatory target organisms:
 - Bacteria: 100% v/v, 15 min, 20 °C
 - Other target organisms:
 - Yeasts: 100% v/v, 15 min, 20 °C
- Use 7.3: Concentrated disinfectants, including disinfection of animal cages by veterinarians or their assistants (non-porous surface) – by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 5% v/v, 15 min, 10 °C
 - Other target organisms:
 - Virus: 19% v/v, 15 min, 10 °C
- Use 7.4: Concentrated disinfectants for use on instruments / equipment (non porous surface) by veterinarians – by spraying or immersion (PT2) with clean conditions:
 - Mandatory target organisms:
 - Bacteria, yeasts and virus: 19%v/v, 5 min, 20 °C
- Use 7.5: Concentrated disinfectants for areas where pets live (non porous surface) – by spraying (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 5% v/v, 15 min, 10 °C

It has to be noted that applicant claimed an application rate of 2.5% against bacteria and yeasts.

 - Other target organisms:
 - Virus: 19% v/v, 15 min, 10 °C
- Use 7.6: Concentrated disinfectants surfaces for examination and treatment of animals (non porous surface) – by spraying (PT2) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 5% v/v, 5 min, 20 °C
- Use 7.7: Ready to use animal's skin disinfectants – by spraying (PT3):
 - Disinfection of hoof skin with dirty conditions:
 - Mandatory target organisms:
 - Bacteria: 8% v/v, 5 min, 10 °C
 - Other target organisms:

- Yeasts: 8% v/v, 5 min, 10 °C
- Disinfection of animal's skin except feet with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 8% v/v, 15 min, 30 °C
- Use 7.8: Concentrated disinfectants for areas where pets live (non porous surface) – by immersion (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 5% v/v, 15 min, 10 °C

It has to be noted that applicant has claimed an application rate of 2.5% against bacteria and yeasts.

- Other target organisms:
 - Virus: 19% v/v, 15 min, 10 °C
- Use 7.9: Concentrated disinfectants for materials and non porous surfaces associated with the housing of animals, including disinfection of animal cages by veterinarians or their assistants (non porous surface) – by immersion (PT3) with clean conditions:
 - Mandatory target organisms:
 - Bacteria and yeasts: 5% v/v, 15 min, 10 °C
 - Other target organisms:
 - Virus: 19% v/v, 15 min, 10 °C

META-SPC 8

- Use 8.1: Concentrated surface disinfectants for surfaces in the house (non porous surface) with a mop or towel (without mechanical action) (PT2) with dirty conditions:
 - Mandatory target organisms:
 - Bacteria: 4% v/v, 15 min, 20 °C
 - Other target organisms:
 - Yeasts: 4% v/v, 15 min, 20 °C
- Use 8.2: Concentrated disinfectants for toilet bowls (non porous surface) – by pouring (PT2) with dirty conditions:
 - Mandatory target organisms:
 - Bacteria: 100% v/v, 15 min, 20 °C
 - Other target organisms:
 - Yeasts: 100% v/v, 15 min, 20 °C

Human health

Classification is summarised in the following table:

Meta SPC	Classification	Labelling specification/other information
meta SPC 1	H314 1C, (H318), H317 1, H335	Contains chlorocresol
meta SPC 2	H314 1B, (H318), H317 1, H335, H302	Contains chlorocresol
meta SPC 3	H314 1C, (H318), H317 1, H335, H336, H361d	Contains chlorocresol
meta SPC 4	H314 1B, (H318), H317 1, H335, H336	Contains chlorocresol and hydrocarbons terpene.
meta SPC 5 (aerosol)	H318, H315, H317 1, H336	Contains chlorocresol.
meta SPC 6 (aerosol)	H319, H336, EUH208	EUH208 Contains Chlorocresol. May produce an allergic reaction.
meta SPC 7	H315, H318, H317 1	Contains chlorocresol and hydrocarbons terpene.
meta SPC 8	H315, H319, H317 1	Contains chlorocresol and hydrocarbons terpene.

The risk assessment is performed considering the risk for active substance, substances of concern and cumulative risk.

- **Meta SPC 1, 2, 3, 4**

Professionals

- *Manual spraying*

For meta SPC 1, 2, 3 and 4, the risk is not acceptable during manual spraying with dilutions covering all target organisms.

For Meta SPC 1, the risk is acceptable considering cumulative risk assessment with manual sprayer when gloves, coverall 5% and mask (at least APF4) are worn during mixing and loading and spraying with a dilution of max 2% v/v.

For Meta SPC 2, the risk is acceptable when gloves, coverall and mask (at least APF10) are worn during mixing and loading and spraying with manual sprayer with a dilution of max 2 % v/v.

For Meta SPC 3, the risk is acceptable considering cumulative risk assessment with manual sprayer when gloves and coverall 5% are worn during mixing and loading and spraying with dilution max 1%.

For Meta SPC 4, the risk is acceptable considering cumulative risk assessment with manual sprayer when gloves, coverall 5% and mask (at least APF4) are worn during mixing and loading and spraying with dilution max 2% v/v.

For Meta SPC 1, 2, 3 and 4 the following RMM is to be considered for manual spraying:

- Do not touch or manipulate before total drying of surface.

Due to high volatility of SoC, a re-entry period is assessed for person staying 8 hours in the room without respiratory protective equipment (RPE).

For meta SPC 2, the following re-entry period is needed:

- 100 minutes after the end of application on equipment
- 40 minutes after the end of application on surface

For meta SPC 4, the following re-entry period is needed:

- 120 minutes after the end of application on equipment
- 45 minutes after the end of application on surface

- Automated spraying

For Meta SPC 1, 3 and 4, the risk is acceptable considering cumulative risk assessment with automated system with maximum dilution 4% v/v (uses 1.1, 3.1 and 4.1 against all target organisms).

For Meta SPC 2, the risk is acceptable with maximum dilution 4% v/v (use 2.1) when gloves are worn during loading.

For Meta SPC 1, 2, 3 and 4 the following RMMs have to be considered for automatic system:

- Do not touch or manipulate before total drying of surface.
- The professional must not stay in the room during the application.

For Meta SPC 4 the following RMM is to be considered for manual sprayer:

- Do not touch or manipulate before total drying of surface.

For Meta SPC 1, 2, 3 and 4, the following RMMs have to be considered regarding local effects:

- Minimisation of manual phases;
- Regular cleaning of equipment and work area;
- Avoidance of contact with contaminated tools and objects;
- In addition, the following PPE is required for Meta SPC 1, 2, 3 and 4:
- Substance/task appropriate gloves;
- Protection overall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);
- Substance/task appropriate respirator;
- Chemical goggles.

Due to high volatility of SoC, a re-entry period is assessed for person staying 8 hours in the room without RPE.

For meta SPC 1, the following re-entry period is needed:

- 1h after the end of application on equipment;
- 20 minutes after the end of application on surface;

- 30 minutes after the end of application on transport vehicle.

For meta SPC 2, the following re-entry period is needed:

- 160 minutes after the end of application on equipment;
- 70 minutes after the end of application on surface;
- 110 minutes after the end of application on transport vehicle.

For meta SPC 3, the following re-entry period is needed:

- 1h after the end of application on equipment;
- 20 minutes after the end of application on surface;
- 30 minutes after the end of application on transport vehicle.

For meta SPC 4, the following re-entry period is needed:

- 190 minutes after the end of application on equipment;
- 80 minutes after the end of application on surface;
- 120 minutes after the end of application on transport vehicle.

General public

The risk is not acceptable for toddlers crawling on wet or dried surfaces, treated with a product of Meta SPC 1, 2, 3 and 4. Therefore the following RMM is to be considered:

- Do not apply the product on surface in contact with children.

- **Meta SPC 5**

Professionals

The risk is acceptable when gloves and coated coverall are worn during application (use 5.1).

The following RMMs have to be considered regarding local effects:

- Regular cleaning of equipment and work area;
- Minimisation of manual phases;
- Avoidance of contact with contaminated tools and objects.

In addition, the following PPE is required:

- Substance/task appropriate gloves;
- Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);
- Chemical goggles.

- **Meta SPC 6**

Professionals

The risk is acceptable when gloves and coated coverall are worn during application (use 6.1).

The following risk management measures (RMMs) have to be considered regarding local effects:

- Minimisation of manual phases/work tasks;
- Minimisation of splashes and spills;
- Avoidance of contact with contaminated tools and objects.

- **Meta SPC 7**

Professionals

- *Mopping/wiping*

The risk is acceptable considering cumulative risk assessment during mopping and wiping using a mop/towel with gloves and coverall, when wet surfaces for mopping and dried surfaces for wiping are considered for secondary exposure, respectively (use 7.1). Therefore, the following RMM is to be considered:

- Do not touch before total drying of surface.

- *Pouring*

The risk is unacceptable considering cumulative risk assessment when pouring the product into toilet bowl with PPE (use 7.2).

- *Spraying*

The risk is not acceptable considering cumulative risk assessment during spraying on surfaces and cages (use 7.3), on instruments/equipment (use 7.4) and on areas where pets live with a dilution of 19% v/v (use 7.5 against all target organisms).

The risk is acceptable during spraying on surfaces and cages and on areas where pets live with a dilution of 5% v/v (use 7.3 and 7.5 against mandatory target organisms only) and during spraying on instruments/equipment with the dilution of 2.5% v/v (use 7.4 against mandatory target organisms only). The risk is acceptable during spraying on tables for examination (use 7.6) without PPE and considering contact with wet surfaces for secondary exposure and on animal skin (use 7.7) without PPE.

For all uses, the following RMMs have to be considered regarding local effects:

- Minimisation of manual phases;
- Regular cleaning of equipment and work area;
- Avoidance of contact with contaminated tools and objects;

In addition, the following PPE is required:

- Substance/task appropriate gloves;

- Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);
- Chemical goggles.

- o Immersion

The risk is acceptable considering cumulative risk assessment with gloves during mixing and loading and gloves and coverall during immersion step (uses 7.4).

Non professionals

The risk is not acceptable during wiping and mopping following cumulative risk assessment (use 7.1). The risk is acceptable when pouring the product into toilet bowl (use 7.2) following cumulative risk assessment. The risk is not acceptable considering the exposure to chlorocresol when the product is sprayed with a trigger spray on hard surfaces and on areas where pets live with a dilution of 19% v/v (uses 7.3 and 7.5 against all target organisms). The risk is acceptable considering cumulative risk assessment with a trigger spray for non-professionals with a dilution of 5% v/v (uses 7.3 and 7.5 against mandatory target organisms only).

General public

The risk is not acceptable for chlorocresol for toddlers crawling on wet or dried surfaces, treated with a product of Meta SPC 7. Moreover, the exposure to volatile residues after application after application by trigger spray or by mopping/wiping leads to an unacceptable risk due to propan-2-ol for children populations. Therefore, no cumulative risk is considered.

Therefore, the following RMM is to be considered:

- Use only in areas inaccessible for children.
- **Meta SPC 8**

Professionals

- o Mopping/wiping

The risk is acceptable considering cumulative risk assessment during mopping and wiping with gloves and coverall when wet surfaces for mopping and dried surfaces for wiping are considered for secondary exposure, respectively (use 8.1). Therefore, the following RMM is to be considered:

- Do not touch before total drying of surface.

- o Pouring

The risk is unacceptable considering cumulative risk assessment when pouring the product into toilet bowl with PPE (use 8.2).

For both uses of the Meta SPC 8, the following RMMs have to be considered:

- Minimisation of manual phases;
- Regular cleaning of equipment and work area;
- Avoidance of contact with contaminated tools and objects;

In addition, the following PPE is required:

- Substance/task appropriate gloves;
- Protection overall (EN 13034, 13962, 14605 or 943 according to pattern of exposure).

Non Professionals

The risk is not acceptable considering cumulative risk assessment during wiping and mopping (use 8.1). The risk is acceptable considering cumulative risk assessment when pouring the product into toilet bowl for non-professionals (use 8.2).

General public

The risk is not acceptable for chlorocresol for toddlers crawling on wet or dried surfaces, treated with a product of meta SPC 8. Moreover, the exposure to volatile residues after application by mopping/wiping leads to an unacceptable risk for propan-2-ol for children. Therefore, no cumulative risk is considered.

Therefore, the following RMM is to be considered:

- Use only in areas inaccessible for children.

Animal health

• Meta SPC 1, 2, 3, 4

For application on transport vehicles, surfaces and cages, instruments/equipment, areas where pets live, equipment and tables for examination, the risk is considered covered by secondary exposure estimated in the human health section. The risk is acceptable with the following RMMs:

- Do not apply the treatment in the presence of domestic animals;
- Do not introduce domestic animals in housing until a total drying;
- Do not use instruments/equipment on animals until a total drying.

Moreover:

- for very small piglets, which stay the whole time near the ground, a higher exposure levels cannot be excluded. Therefore, animal housings for piglets should be fitted with strew, mats or other suitable materials. In this context, the following RMM is proposed: "For pig breeding: For use only in animal housings, where lying areas of suckling piglets are covered with mats, strew or any other suitable material."
- the assessment of exposure of young chick (presented in the annex of the PAR) leads to the necessity to add the following RMM: Do not use in breeding stations or other breeding areas for chicks.

• Meta SPC 5

For application on animal skin by spraying, the systemic risk is acceptable with a minimum MOE of 13.4 for pigs (fattening pig).

Due to the classification of meta SPC 5 for local effects (H317, H315 and 318), considering

the application frequency, the areas to be treated and because the product is left to dry on skin, the local risk is not acceptable for animal health.

- **Meta SPC 6**

For application on animal skin by spraying, the systemic risk is acceptable with a minimum MOE of 41.0 for pigs (fattening pig). Considering classification of meta SPC 6 and dilution rate, the local risk for animals is acceptable.

- **Meta SPC 7**

For application on animal skin by spraying, the systemic risk is acceptable with a minimum MOE of 42.6 for pigs (fattening pig). Considering the classification of meta 7 and the dilution rate, the local risk is acceptable.

Indirect exposure via food

Surface treatment in veterinary field

For animal housing and transport vehicle disinfection, the scenarios and default values defined in the relevant guidance document¹ were used. Experimental studies provided in the Competent Authority Report (CAR) of the active substance to assess residue in livestock tissues were used to refine livestock exposure. Moreover, a rinsing step is performed after CHLOROCRESOL BASED PRODUCT – CID LINES NV application which is demonstrated to be effective (see rinsing efficiency study). Therefore, based on experimental studies and on the rinsing efficiency study, it can be reasonably concluded that after disinfection of animal housing and transport vehicles with CHOROCRESOL BASED PRODUCT– CID LINES NV, residues in animal tissues are below 0.01 mg/kg. Therefore, a dietary risk assessment for consumers is not required.

Animal skin disinfection

For livestock skin disinfection use a exposure scenario was proposed by the applicant which has been reviewed. According to this scenario the chronic consumer exposure is below 100% of the ADI in Tier 1 and in Tier 2 for meta SPC 7 while in Tier 2 only for meta SPC 6. Regarding children and adult acute exposures, risk calculation is below 100% ARfD only in meta SPC 7 Tier 2.

In the phytopharmaceutical regulation², default MRLs on food of animal origin for chlorocresol were established of 0.01 mg/kg. Livestock exposure calculation shows that the default MRL of 0.01 mg/kg in food of animal origin is exceeded.

Therefore, based on available data and default exposure scenario:

- For meta SPC 5 and 6, a dietary risk cannot be excluded;
- For meta SPC 5, 6 and 7, the default MRLs could be exceeded.

In conclusion, uses for meta SPC 5 and meta SPC 6 are therefore considered not acceptable.

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

² <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=901>

No conclusion on acceptability for use 7.7 can be reached. The reason for this is an on-going discussion at regulatory level about the consequences of an exceedance of the default MRL for chlorocresol³.

Environment

The META-SPCs 1, 2, 3, 4, 7 and 8 are classified as Aquatic Chronic 3, H412: Harmful to aquatic life with long lasting effects.

The META-SPCs 5 and 6 are not classified for the environment.

An assessment on the combined risks for Chlorocresol and HTPBP (considered as an SoC for the environment) for each individual use has been performed with the following conclusions:

Acceptable risks are reached for the environment for:

- META-SPC 1, 2, 3 and 4:

Intended uses 1.1, 2.1, 3.1 and 4.1: Concentrated surface disinfectant for surfaces and equipment in veterinary field for poultry, pig and cattle houses,

- except for the treatment of duck housings as unacceptable levels of chlorocresol have been demonstrated in groundwater,
- for the disinfection of all the surfaces except the ceiling,
- considering the following risk mitigation measure: "Do not use in animal housings where exposure to a STP or direct emission to surface water cannot be prevented".

- META-SPC 5, 6 and 7:

Intended uses 5.1, 6.1, and 7.7: Disinfection of animal's skin

- META-SPC 7 and 8:

Intended uses 7.1 and 8.1: Concentrated disinfectant for surfaces use in and around the house,

- provided that products are restricted to indoor use only as risks are foreseen for the aquatic and terrestrial compartments for a use outdoor.

- META-SPC 7:

Intended use 7.3: Concentrated hard surface disinfectant (including disinfection of animal cages by veterinarians or their assistants) by spray

Intended use 7.4: Concentrated disinfectant for use on instruments/equipment by veterinarians

Intended use 7.5: Concentrated disinfectant for use on areas where pets live by spraying

Intended use 7.6: Concentrated disinfectants for surfaces for examination and treatment of animals

³ See CA meeting of March 2022, agenda item 7.2 (document on "Questions regarding the MRL for the active substance chlorocresol" CA-Dec21-Doc.7.3).

All these uses are considered acceptable if products are restricted to a spray application only, as risks are foreseen for the aquatic and terrestrial compartment for application via immersion.

- META-SPC 8:

Intended uses 8.2: Concentrated disinfectant for toilet bowls.

Unacceptable risks are foreseen for:

- META-SPC 1, 2, 3 and 4:

Intended uses 1.1, 2.1, 3.1 and 4.1: Concentrated surface disinfectant for surfaces and equipment in veterinary field for poultry, pig and cattle houses

- for the treatment of duck housings as unacceptable levels of chlorocresol have been demonstrated in groundwater.

- META-SPC 2, 3 and 4:

Intended uses 2.2, 3.2 and 4.2: Concentrated surface disinfectant of transport vehicles in veterinary field for poultry, pig and cattle as risks are foreseen for the aquatic compartment.

- META-SPC 7 and 8:

Intended uses 7.1 and 8.1: Concentrated disinfectant for surfaces use in and around the house,

- for outdoor applications as risks are foreseen for the aquatic and terrestrial compartments for use outdoor.

- META-SPC 7:

Intended uses 7.2: Concentrated disinfectant for toilet bowls as risks are foreseen for groundwater.

When the following uses are applied by immersion, unacceptable risks are foreseen for the terrestrial compartment:

Intended uses 7.4: Concentrated disinfectant for use on instruments/equipment by veterinarians

Intended use 7.6: Concentrated disinfectants for surfaces for examination and treatment of animals

Intended uses 7.8: Concentrated disinfectant for use on areas where pets live by immersion

Intended uses 7.9: Concentrated hard surface disinfectant (including disinfection of animal cages by veterinarians or their assistants)

An aggregated risk assessment has also been performed, to cover the potential risks of the combinaison of the different uses leading to acceptable risks alone:

Acceptable risks are foreseen for the manure pathway when combining the disinfection of animal housings and animal's skin.

Acceptable risks are foreseen for the STP pathway when combining the uses leading to acceptable risks in Meta-SPC 7 (PT2- Scenario 1b, 6).

Unacceptable risks are foreseen for the STP pathway when combining the uses leading to acceptable risks in Meta-SPC 8 (PT2- Scenario 1b, 5, 6). However, as there is no guidance available on the regulatory consequences of an aggregated exposure assessment this has no impact on the conclusion for this meta-SPC.

Overall conclusion

According to the assessment performed for the biocidal product family CHLOROCRESOL BASED PRODUCTS– CID LINES NV, conclusions are given for the following uses considering the appropriate instruction of uses and risk mitigation measures, as indicated in the Summary of Product Characteristics. Lines highlighted in grey correspond to uses not proposed for authorisation. Use 7.7 is also highlighted, however as indicated above no conclusion can be drawn due to an on-going regulatory discussion.

META SPC	Uses		Physical hazard properties	Efficacy	Human health	Animal health	Indirect exposure via food	Environment
1	1.1	<p>Concentrated surface and equipment disinfectants in veterinary field (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> 2 to 13 times per year</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 1% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Fungi: 2% v/v • Virus: 1% v/v <ul style="list-style-type: none"> • Endoparasites: parasitic protozoa: 4% v/v • Endoparasites: helminth eggs o: 2% v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Automatic spraying • Manual spraying with a dilution of 2% v/v and less 	Acceptable	Acceptable	<p>Acceptable</p> <ul style="list-style-type: none"> • Disinfection of all the surfaces except the ceiling • Except duck housings • No release to STP
2	2.1	<p>Concentrated surface and equipment disinfectants in veterinary field (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> 2 to 13 times per year</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 1.5% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Virus: 3.5% v/v <ul style="list-style-type: none"> • Endoparasites: parasitic protozoa: 4% v/v • Endoparasites: helminth eggs: 2% v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Automatic spraying • Manual spraying with a dilution of 2% v/v and less 	Acceptable	Acceptable	<p>Acceptable</p> <ul style="list-style-type: none"> • Disinfection of all the surfaces except the ceiling • Except duck housings • No release to STP

	2.2	<p>Concentrated surface disinfectants in transport vehicles (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> 2 to 13 times per year</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria yeasts and virus: 3.5% v/v 	<p>NON acceptable</p> <p>Due to an unacceptable risk with a dilution at 3.5% v/v</p>	Acceptable	Acceptable	<p>NON acceptable</p> <p>Due to the risk for the aquatic compartment</p>
3	3.1	<p>Concentrated surface and equipment disinfectants in veterinary field (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> 2 to 13 times per year</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 1% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Virus: 3.5% v/v <ul style="list-style-type: none"> • Endoparasites: parasitic protozoa: 4% v/v • Endoparasites: helminth eggs: 2% v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Automatic spraying • Manual spraying with a dilution of 1% v/v only 	Acceptable	Acceptable	<p>Acceptable</p> <ul style="list-style-type: none"> • Disinfection of all the surfaces except the ceiling • Except duck housings • No release to STP
	3.2	<p>Concentrated surface disinfectants in transport vehicles (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> 2 to 13 times per year</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria, yeasts and virus: 3.5% v/v 	<p>NON acceptable</p> <p>Due to an unacceptable risk with a dilution at 3.5% v/v</p>	Acceptable	Acceptable	<p>NON acceptable</p> <p>Due to the risk for the aquatic compartment</p>

4	4.1	<p>Concentrated surface and equipment disinfectants in veterinary field (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> 2 to 13 times per year</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 0.75% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Fungi: 2% v/v • Virus: 3.5% v/v <ul style="list-style-type: none"> • Endoparasites: parasitic protozoa: 4% v/v • Endoparasites: helminth eggs: 2 % v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Automatic spraying • Manual spraying with a dilution of 2% v/v and less 	Acceptable	Acceptable	<p>Acceptable</p> <ul style="list-style-type: none"> • Disinfection of all the surfaces except the ceiling • Except duck housings • No release to STP
	4.2	<p>Concentrated surface disinfectants in transport vehicles (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> 2 to 13 times per year</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria yeasts: and virus: 3.5% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Fungi: 3% v/v 	<p>NON acceptable</p> <p>Due to an unacceptable risk with a dilution at 3.5% v/v</p>	Acceptable	Acceptable	<p>NON acceptable</p> <p>Due to the risk for the aquatic compartment</p>
5	5.1	<p>Ready to use animal skin disinfectants (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> in order to cover the area to be disinfected</p> <p><u>Frequency:</u> once a week for cattle (dairy, beef, calves) and once every 4 days for pigs</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria: 100% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Yeasts: 100% v/v • Fungi: 100% v/v • Virus: 100% v/v 	<p>Acceptable</p>	<p>NON acceptable</p> <p>Due to local effects for animals</p>	<p>NON acceptable</p> <p>Due to possible dietary risk</p>	<p>Acceptable</p>

6	6.1	<p>Ready to use animal skin disinfectants (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate:</u> in order to cover the area to be disinfected</p> <p><u>Frequency:</u> once a week for cattle (dairy, beef, calves) and once every 4 days for pigs</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria: 100% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Yeasts: 100% v/v • Fungi: 100% v/v • Virus: 100% v/v 	Acceptable	Acceptable	<p>NON acceptable</p> <p>Due to possible dietary risk</p>	Acceptable
7	7.1	<p>Concentrated general surface disinfectants in and around the house (PT2)</p> <p>Mopping by professional or non professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> daily</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria: 2.5% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Yeasts: 2.5% v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Professional users only 	/	/	<p>Acceptable</p> <ul style="list-style-type: none"> • Indoor use only
	7.2	<p>Concentrated disinfectants for toilet bowls (PT2)</p> <p>Pouring by professional or non professional users</p> <p><u>Application rate:</u> Maximum 30 mL of pure product</p> <p><u>Frequency:</u> daily</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria: 100% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Yeast : 100% v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Non professional users only 	/	/	<p>NON acceptable</p> <p>Due to the risk for the groundwater due to the presence of substance of concern</p>

	<p>7.3 Concentrated hard surface disinfectants (including disinfection of animal cages by veterinarians or their assistants) (PT3)</p> <p>Spraying by professional or non professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> daily</p>	<p>Acceptable</p>	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 5% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Virus: 19% v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Spraying with a dilution of 5% v/v only 	<p>/</p>	<p>Acceptable</p>	<p>Acceptable</p> <ul style="list-style-type: none"> • By spraying only (trigger spray)
	<p>7.4 Concentrated disinfectants for use on instruments/equipment by veterinarians (PT2)</p> <p>Spraying or immersion by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> daily</p>	<p>Acceptable</p>	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria, yeasts and virus: 19% v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Immersing with a dilution of 19% v/v or less • Spraying with a dilution of 2.5% v/v only 	<p>/</p>	<p>/</p>	<p>Acceptable</p> <ul style="list-style-type: none"> • By spraying only (trigger spray)
	<p>7.5 Concentrated disinfectants for use on areas where pets live (PT3)</p> <p>Spraying by professional or non professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> daily ²</p>	<p>Acceptable</p>	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 5% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Virus: 19% v/v 	<p>Acceptable</p> <ul style="list-style-type: none"> • Spraying with a dilution of 5% v/v or less 	<p>/</p>	<p>Acceptable</p>	<p>Acceptable</p> <ul style="list-style-type: none"> • By spraying only (trigger spray)
	<p>7.6 Concentrated disinfectants for</p>	<p>Acceptable</p>	<p>Acceptable</p>	<p>Acceptable</p>	<p>/</p>	<p>/</p>	<p>Acceptable</p>

		<p>surfaces for examination and treatment of animals (PT2)</p> <p>Spraying by professional users</p> <p><u>Application rate</u>: 250 mL of diluted product/m²</p> <p><u>Frequency</u>: daily</p>		<p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 5% v/v 				<ul style="list-style-type: none"> • By spraying only (trigger spray)
7.7		<p>Concentrated animal skin disinfectants (PT3)</p> <p>Spraying by professional users</p> <p><u>Application rate</u>: in order to cover the area to be disinfected</p> <p><u>Frequency</u>: once a week for cattle (dairy, beef, calves) and once every 4 days for pigs</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria: 8% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Yeasts: 8% v/v 	Acceptable	Acceptable	<p>No conclusion possible</p> <p>about MRL exceedance</p>	Acceptable
7.8		<p>Concentrated disinfectants for use on areas where pets live (PT3)</p> <p>Immersion by professional users</p> <p><u>Application rate</u>: 250 mL of diluted product/m²</p> <p><u>Frequency</u>: daily</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 5% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Virus: 19% v/v 	Acceptable	/	Acceptable	<p>NON acceptable</p> <p>Due to the risk for the terrestrial compartment</p>

	7.9	<p>Concentrated hard surface disinfectants (including disinfection of animal cages by veterinarians or their assistants) (PT3)</p> <p>Immersion by professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> daily</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria and yeasts: 5% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Virus: 19% v/v 	Acceptable	/	Acceptable	<p>NON acceptable</p> <p>Due to the risk for the terrestrial compartment</p>
8	8.1	<p>Concentrated general surface disinfectants in and around the house (PT2)</p> <p>Mopping by professional or non professional users</p> <p><u>Application rate:</u> 250 mL of diluted product/m²</p> <p><u>Frequency:</u> daily</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria: 4% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Yeasts: 4% v/v 	Acceptable	/	/	<p>Acceptable</p> <ul style="list-style-type: none"> • Indoor use only
	8.2	<p>Concentrated disinfectants for toilet bowls (PT2)</p> <p>Pouring by professional or non professional users</p> <p><u>Application rate:</u> Maximum 30 mL of pure product</p> <p><u>Frequency:</u> daily</p>	Acceptable	<p>Acceptable</p> <p>Mandatory target organisms:</p> <ul style="list-style-type: none"> • Bacteria: 100% v/v <p>Other target organisms:</p> <ul style="list-style-type: none"> • Yeasts: 100% v/v 	Acceptable	/	/	Acceptable

b) Presentation of the biocidal product family including classification and labelling

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance chlorocresol contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product family is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use(s) of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance(s) in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,

- the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the use(s) described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised⁴, for the use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC. For use 7.7 no conclusion is drawn due to an on-going discussion at regulatory level on the impact of an exceedance of the default MRL for chlorocresol.

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⁴ This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.