HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 2 juni 2021 is van

Huvepharma SA
Rue Jean Monnet 34 Zone industrielle d'Etriché
FR-49500 SEGRÉ-EN-ANJOU BLEU
France

een aanvraag voor een toelating van de biocide op basis van niet geplaatste stoffen (overgangsrecht) ontvangen voor het middel

Prophyl S

op basis van de werkzame stoffen chloorcresol en glycolzuur.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:
- Bijlage I voor details van de aanvraag en toelating;
- Bijlage II voor de etikettering;
- Bijlage III voor wettelijk gebruik;
- Bijlage IV voor de onderbouwing.

Dit besluit treedt in werking op de dag van bekendmaking in de Staatscourant.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage III bij dit besluit is voorgeschreven.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen op de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het toelatingsnummer.
- De etikettering zoals opgenomen in bijlage II bij dit besluit, deze moet volgens de voorschriften op de verpakking worden vermeld.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III, onder A.
- De gebruiksaanwijzing, hetzij letterlijk, hetzij naar zakelijke inhoud, zoals opgenomen in bijlage III, onder B. De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

2 WETTELIJKE GRONDSLAG

Besluit	artikel 89, tweede lid van EU 528/2012 jo art 130a, vierde lid Wet gewasbeschermingsmiddelen en biociden (Wgb) jo art 4, tweede lid Wgb (oud) jo art 121 Wgb (oud) jo art 44 Wgb (oud) .
Classificatie en etikettering	artikel 89, tweede lid, Verordening 528/2012, jo. artikel 130a, vierde lid, WBB, jo. artikel 50 WGB oud
Gebruikt toetsingskader	RGB (Hoofdstuk 10)

3 BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden.

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Bezwaarmogelijkheid

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE of post@ctgb.nl.

Ede, 3 april 2024

Het college voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Drs. R.J.T. van Lint

16671 N

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BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20210866 TB
Type aanvraag:	toelating van de biocide op basis van niet geplaatste stoffen (overgangsrecht)
Middelnaam:	Prophyl S
Formele registratiedatum: *	5 augustus 2021

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2 Stofinformatie

Werkzame stof	Gehalte
chloorcresol	17,0 %w/w
glycolzuur	4,9 %w/w

De werkzame stof chloorkresol is opgenomen in het review programma en is per 01/05/2018 voor het aangevraagde PT03 geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

De werkzame stof glycolzuur is opgenomen in het reviewprogramma maar nog niet geplaatst voor het aangevraagde PT03 op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

3 Toelatingsinformatie

Toelatingsnummer:	16671 N
Expiratiedatum:	1 maart 2034
Afgeleide of parallel:	n.v.t. (nieuw middel)
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Met water mengbaar concentraat

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BIJLAGE II Etikettering van het middel Prophyl S

Professioneel	
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: chloorkresol	
Pictogram	GHS05 GHS07
Signaalwoord	Gevaar
Gevarenaanduidingen	H314 Veroorzaakt ernstige brandwonden en oogletsel. H317 Kan een allergische huidreactie veroorzaken. H412 Schadelijk voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P260 Stof/rook/gas/nevel/damp/spuitnevel niet inademen. P280 Draag beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming/gehoorbescherming/... P301 + P330 + P331 NA INSLIKKEN: de mond spoelen - GEEN braken opwekken. P303 + P361 + P353 BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken. Huid met water afspoelen/afdouchen. P305 + P351 + P338 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. P310 Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P333 + P313 Bij huidirritatie of uitslag: een arts raadplegen. P501 Inhoud/verpakking afvoeren naar ....
Aanvullende etiketelementen	-

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BIJLAGE III WG/GA van het middel Prophyl S

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van:
- bacteriën (exclusief bacteriesporen), mycobacteriën, gisten, schimmels, virussen* en parasitaire protozoa op harde oppervlakken in dierverblijfplaatsen en bijbehorende ruimten, met uitzondering van transportvoertuigen voor dieren;
- bacteriën (exclusief mycobacteriën en bacteriesporen) en gisten in ontsmettingsbaden voor schoeisel.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.
Het middel is uitsluitend bestemd voor professioneel gebruik.

**Een volledige virusclaim is gedefinieerd in EN14885. Tegen welke virussen dit middel werkzaam is, is te vinden op www.ctgb.nl onder 'uitleg virusclaim'.*

B.
GEBRUIKSAANWIJZING

Harde oppervlakken in dierverblijfplaatsen en bijbehorende ruimten
Oppervlakken vooraf grondig reinigen met een geschikt reinigingsmiddel en vervolgens afspoelen met schoon water. Overtollig water verwijderen. Verdun Prophyl S in water al naargelang het gewenste effect. Desinfecteer door de oplossing bij lage druk te spuiten met een dosering van 100 ml/m^2, totdat de vloeistof van de oppervlakken loopt. Laat inwerken volgens de gespecificeerde inwerktijd.

Algemene veiligheidsinstructie:
Bij mengen en laden van het product handschoenen, beschermende kleding en oog/gelaatbescherming dragen. Niet toepassen op oppervlakken die in aanraking komen met etenswaren of voer. Reinig de toepassingsapparatuur met water.
Ruimtes niet opnieuw betreden voordat het product opgedroogd is.
Behandelde oppervlakten die in contact kunnen komen met dieren naspoelen met water.

Bacteriën en gisten
Dosering: 0,6% v/v (6 ml product aanvullen met water tot 1 liter)
Inwerktijd: 120 minuten
Bescherming bij toepassen: handschoenen en beschermende kleding.

Mycobacteriën en schimmels
Dosering: 1,5% v/v (15 ml product aanvullen met water tot 1 liter)
Inwerktijd: 120 minuten
Bescherming bij toepassen: handschoenen en beschermende kleding.

Virussen
Dosering: 4% v/v (40 ml product aanvullen met water tot 1 liter)
Inwerktijd: 120 minuten
Bescherming bij toepassen: handschoenen, beschermende kleding en adembescherming (beschermingsfactor 4).

Parasitaire protozoa
Dosering: 5% v/v (50 ml product aanvullen met water tot 1 liter)
Inwerktijd: 120 minuten
Bescherming bij toepassen: handschoenen, beschermende kleding en adembescherming (beschermingsfactor 4).

Ontsmetting van schoeisel
Zorg dat de capaciteit van de ontsmettingsbaden voor schoeisel ongeveer 10 tot 15 l bedraagt, met een minimumhoogte van 10 cm. Vul de ontsmettingsbaden voor schoeisel met Prophyl S-gebruiksoplossing en plaats ze bij de ingang van elk gebouw op een plaats die beschut is tegen slechte weersomstandigheden. Dompel de eerder gereinigde (geborstelde) schoenzolen in het voetontsmettingsbad. Laat de oplossing 1 minuut inwerken bij ten minste 10°C. Vervang de oplossing na 100 paar schoenen of wanneer er zichtbare verontreiniging is. Vanwege milieurisico mag er niet vaker dan 1x per week gebruiksoplossing voor een ontsmettingsbad voor schoeisel worden aangemaakt.

Algemene veiligheidsinstructie:
Bij mengen en laden van het product handschoenen, beschermende kleding en oog/gelaatbescherming dragen.

Bacteriën en gisten
Dosering: 2% (20 ml product aanvullen met water tot 1 liter)
Inwerktijd: 1 minuut
Bescherming bij toepassen: geen specifieke eisen.

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BIJLAGE IV RISKMANAGEMENT

Contents

1 Introduction

1.1 Applicant

Huvepharma SA
Rue Jean Monnet 34 Zone industrielle d'Etriché
FR-49500 SEGRÉ-EN-ANJOU BLEU
France

1.2 Active substance

Chlorocresol and glycolic acid

1.3 Product

Prophyl S

1.4 Function

Prophyl S is a disinfectant (PT03).

1.5 Background to the application

This concerns an application for authorisation of a new biocidal product.

1.6 Intended uses

The proposed field of use of Prophyl S is the control of:

- bacteria (excluding bacterial spores), mycobacteria, yeasts, fungi, viruses and parasitic protozoans on hard surfaces of livestock farming buildings, with the exception of animal transport vehicles;
- bacteria (excluding bacterial spores and mycobacteria), yeasts and viruses for bootdips.

The product is intended for professional use.

1.7 Packaging details

	Material	Size / content	Other information
Professional use	HDPE	1, 5, 20, 200 or 1000 L	Cans or barrels

2 Identity

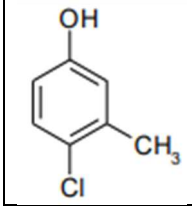
2.1 A Identity of the active substance

Common name	Chlorocresol (CMK)
Name in Dutch	chlorocresol
Chemical name	4-Chloro-3-methylphenol
CAS no	59-50-7
EC no	200-431-6

The active substance chlorocresol is included in the Union list of approved substances of EU Regulation 528/2012. An AR is available (April 2016 ; Revised November 2017 RMS FR) for PT 1, 2, 3, 6, 9, 13.

The list of endpoints presented below is taken from the AR of PT 3 (April 2016 ; Revised November 2017 RMS FR).

Chemical name (IUPAC)	4-Chloro-3-methylphenol
Chemical name (CA)	Phenol, 4-Chloro-3-methyl-

CAS No	59-50-7
EC No	200-431-6
Other substance No.	Not allocated
Minimum purity of the active substance as manufactured (g/kg or g/l)	≥ 99.8%
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	m-cresol<0.1 %
Molecular formula	C_7H_7ClO
Molecular mass	142.6 g/mol
Structural formula	

2.1 B Identity of the active substance

Common name	Glycolic acid
Name in Dutch	Glycolzuur
Chemical name	Glycolic acid
CAS no	79-14-1
EC no	201-180-5

The active substance Glycolic acid is not included in the Union list of approved substances of EU Regulation 528/2012. A CAR is available (RMS NL) for PT 2, 3, 4.

The list of endpoints presented below is taken from the CAR of PT 2 (August 2021 RMS NL).

Chemical name (IUPAC)	Glycolic acid
Chemical name (CA)	Acetic acid, 2-hydroxy-
CAS No	79-14-1
EC No	201-180-5
Other substance No.	no
Minimum purity of the active substance as manufactured (g/kg)	990
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Formic acid ≤0.076 Methoxyacetic acid ≤0.26 Formaldehyde ≤0.0076
Molecular formula	$C_2H_4O_3$
Molecular mass	76.05
Structural formula	

2.2 Identity of the biocidal product

Name	Prophyl S
Formulation type	SL – soluble concentrate
Content active substance	Chlorocresol: 17%w/w Glycolic acid: 4.9%w/w

Packaging information:

	Material	Size / content	Other information
Professional use	HDPE	1, 5, 20, 200 or 1000 L	Cans or barrels

2.3 Overall conclusions identity

The identity of the active substances and the biocidal product is sufficiently described.

Data requirements

None.

3 Physical and chemical properties

3.1 Physical and chemical properties of the biocidal product

Appearance	Blue liquid
Explosive properties	Not explosive; there are no chemical groups available associated with explosive properties.
Oxidative properties	Not an oxidizer; all available oxygen and chlorine are chemically bonded to carbon or hydrogen.
Autoflammability	Not auto-flammable
Flammability	Not flammable; no flammable components available.
pH 1% solution	pH: 2.3 pH (1% solution): 3.5
Particle size distribution	Not applicable
Surface tension	Not applicable
Viscosity	Not applicable
Relative density	1.1
Storage stability/Shelf life/Packaging	Shelf-life claim: 36 months The product was tested for 36 months at 30°C and at room temperature in HDPE. In addition the product was tested at 54°C for 3 weeks. The following parameters were addressed: colour of the product, pH, pH 1% solution, density, dilution stability, persistent foaming, chlorocresol (CMK) content, Glycolic acid content, weight change, visual aspect of containers. All parameters remain within acceptable limits during storage. A shelf-life of 36 months is supported in HDPE for Prophyl S.
Technical properties	**Dilution stability** Dilution stability was performed using Saint-Etienne tap water and hard water. No separation observed after standing for 30 minutes or 18 hours. **Persistent foaming** Persistent foaming was determined at 0.80% dilution: t = 10s: 127 - 256 ml t = 1 min: 113 - 216 ml t = 3 min: 111 - 210 ml

	t = 12 min: 95 – 158 ml Persistent foaming was determined at 2% dilution: t = 10s: 237 - 270 ml t = 1 min: 207 - 228 ml t = 3 min: 175 - 222 ml t = 12 min: 55 – 120 ml Risk mitigation measures are required because the volume of foam is > 60 mL after 12 min.
Physical and chemical compatibility	Not applicable. Product is not intended to be used in combination with other products.

3.2 Overall conclusions physical and chemical properties

The physical and chemical properties of the active substances and the biocidal product are sufficiently described by the available information.

A shelf-life of 36 months is supported in HDPE for Prophyl S.

Data requirements

None.

4 Analytical methods for detection and identification

4.1 Analytical methods for analysis of the biocidal product

Preparation (principle of method)	Chlorocresol: HPLC-UV Glycolic acid: colorimetric titration

4.2 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements

None.

5 Efficacy

5.1 Function

Prophyl S is a disinfectant based on chlorocresol (17% w/w) and glycolic acid (4.9% w/w).

5.2 Field of use envisaged

The proposed field of use of Prophyl S is the control of:

- bacteria (excluding bacterial spores), mycobacteria, yeasts, fungi, viruses and parasitic protozoans on hard surfaces of livestock farming buildings, with the exception of animal transport vehicles;
- bacteria (excluding bacterial spores and mycobacteria), yeasts and viruses for bootdips.

These uses are included in PT03.

The product is intended for professional use.

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

29 studies were provided of which 29studies were used in this assessment. These are summarised in Table 1.

Table 1. Summary of studies assessed

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Bacteria (excluding mycobacteria and bacterial spores)			
EN 1656 (2010) 2, 1	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Proteus vulgaris*	**Concentration (%):** 0.5%, 1%, 2% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 1 and 5 minutes **Test temperature:** 10°C	**log R>5.12** 2 % Clean 1 min 10°C
EN 1656 (2010) 2, 1	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Proteus vulgaris*	**Concentration (%):** 0.8%, 1%, 1.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>5.12** 1 % Clean 30 min 10°C
EN 1656 (2010) 2, 1	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Proteus vulgaris*	**Concentration (%):** 0.05, 0.1, 0.2, 0.3, 0.4, 0.6% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 60 and 120 minutes **Test temperature:** 10°C	**log R>5.24** 0.4 % Clean 120 min 10°C
EN 14349 (2012) 2, 2	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Proteus vulgaris*	**Concentration (%):** 1%, 2%, 3% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 1 and 5 minutes **Test temperature:** 10°C	**log R>4.31** 2 % Clean 1 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 14349 (2012) 2, 2	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Proteus vulgaris*	**Concentration (%):** 0.5%, 0.8%, 1% **Interfering substances:** 10 g/L bovine albumin + 10 g/L yeast extract **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>4.29** 1 % Dirty 30 min 10°C
EN 14349 (2012) 2, 2	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Proteus vulgaris*	**Concentration (%):** 0.05, 0.1, 0.2, 0.3, 0.4, 0.6% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 60 and 120 minutes **Test temperature:** 10°C	**log R>5.02** 0.4 % Clean 120 min 10°C
Capacity test for footbaths Adapted EN1656 Simulated use test	*Enterococcus hirae* *Pseudomonas aeruginosa*	**Concentration (%):** 2% **Interfering substances:** Each inoculation representing the soiling of 25 pairs of boots: 3 g/L bovine albumin+ $1*10^9$ CFU/mL bacteria **Contact time:** 1 minute per inoculation **Test temperature:** 10°C	**log R>6.98** 2 % Clean 1 min 10°C Efficacy is proven for 100 passages of boot pairs (4 inoculations)
Mycobacteria			
EN 14204 (2012) 2, 1	*Mycobacterium avium*	**Concentration (%):** 0.8%, 1%, 1.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 60 minutes **Test temperature:** 10°C	**log R>5.69:** 1.5 % Clean 60 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Endoparasites			
DVG Methods for the testing of chemical disinfectants for lifestock farming (2019) 2, 1	*Cryptosporidium parvum*	**Concentration (%):** 0.5%, 2%, 2.5%, 3% **Interfering substances:** No soiling **Contact time:** 2 hours **Test temperature:** 10°C	**98.9% reduction:** 2 % Clean 2 hours 10°C **Not valid** **No carrier test**
DVG Methods for the testing of chemical disinfectants for lifestock farming (2019) 2, 1	*Cryptosporidium parvum*	**Test conditions:** - 2%, 6 hours, 10°C - 2.5%, 4 hours, 10°C - 2%, 3 hours, 20°C **Interfering substances:** No soiling	**100% reduction:** 2 % Clean 6 hours 10°C **100% reduction:** 2.5 % Clean 4 hours 10°C **100% reduction:** 2 % Clean 3 hours 20°C **Not valid** **No carrier test**
DVG Methods for the testing of chemical disinfectants for lifestock farming (2019) 2, 1 & 2,2	*Cryptosporidium parvum*	**Test conditions:** Suspension test 1,5, 2, 2.5%, 1 hours, 10°C Carrier test 2, 3, 4%, 2 hours, 10°C **Interfering substances:** 3 g/l BSA in carrier test	**Suspension test >98% reduction:** 4 % Clean 2 hours 10°C **Carrier test >98% reduction:** 5 % Clean 2 hours 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Yeasts			
EN 1657 (2016) 2, 1	*Candida albicans*	**Concentration (%):** 1%, 2%, 3% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 1 and 5 minutes **Test temperature:** 10°C	**log R>4.11** 2 % Clean 1 min 10°C
EN 1657 (2016) 2, 1	*Candida albicans*	**Concentration (%):** 0.5%, 0.8%, 1% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>4.14** 1 % Clean 30 min 10°C
EN 1657 (2016) 2, 1	*Candida albicans*	**Concentration (%):** 0.4, 0.4, 0.8. 1% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 60 and 120 minutes **Test temperature:** 10°C	**log R>4.03** 0.6 % Clean 120 min 10°C
EN 16438 (2014) 2, 2	*Candida albicans*	**Concentration (%):** 1%, 2%, 3% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 1 and 5 minutes **Test temperature:** 10°C	**log R>3.95** 2 % Clean 1 min 10°C
EN 16438 (2014) 2, 2	*Candida albicans*	**Concentration (%):** 0.5%, 0.8%, 1% **Interfering substances:** 10 g/L bovine albumin + 10 g/L yeast extract **Contact time:** 60 minutes **Test temperature:** 10°C	**log R>3.98** 1 % Dirty 60 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 16438 (2014) 2, 2	*Candida albicans*	**Concentration (%):** 0.4, 0.6, 0.8, 1% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 60 and 120 minutes **Test temperature:** 10°C	**log R>4.05** 0.6 % Clean 120 min 10°C
Fungi			
EN 1657 (2016) 2, 1	*Aspergillus brasiliensis*	**Concentration (%):** 1%, 1.5%, 2% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>4.14:** 2 % Clean 30 min 10°C
EN 1657 (2016) 2, 1	*Aspergillus brasiliensis*	**Concentration (%):** 0.5, 1, 1.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 60 and 120 minutes **Test temperature:** 10°C	**log R>4.06:** 1.5% Clean 60 min 10°C
EN 16438 (2014) 2, 2	*Aspergillus brasiliensis*	**Concentration (%):** 1%, 1.5%, 2% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 60 minutes **Test temperature:** 10°C	**log R>3.42:** 1.5 % Clean 60 min 10°C
EN 16438 (2014) 2, 2	*Aspergillus brasiliensis*	**Concentration (%):** 0.5, 1, 1.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 60 and 120 minutes **Test temperature:** 10°C	**log R>3.28:** 1.5 % Clean 60 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Viruses / Bacteriophages			
EN 14675 (2015) 2, 1	*Bovine viral diarrhea virus*	**Concentration (%):** 0.8%, 1%, 1.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 5 minutes **Test temperature:** 10°C	**log R=5:** 1.5 % Clean 5 min 10°C
EN 14675 (2015) 2, 1	*Influenza A virus subtype H1N1*	**Concentration (%):** 0.8%, 1%, 1.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 5 minutes **Test temperature:** 10°C	**log R=5:** 1 % Clean 5 min 10°C
EN 14675 (2015) 2, 1	*Bovine enterovirus (ECBO)*	**Concentration (%):** 1.5%, 2%, 2.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 30 and 60 minutes **Test temperature:** 10°C	**log R>5:** 2 % Clean 30 min 10°C **Not valid**
EN 14675 (2015) 2, 1	*Bovine viral diarrhea virus*	**Concentration (%):** 0.8%, 1%, 1.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>5:** 1 % Clean 30 min 10°C
EN 14675 (2015) 2, 1	*Influenza A virus subtype H1N1*	**Concentration (%):** 0.8%, 1%, 1.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>6:** 1 % Clean 30 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 14675 (2015) 2, 1	*Bovine parvovirus*	**Concentration (%):** 1.5%, 2%, 2.5% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>5:** 2 % Clean 30 min 10°C
EN 14675 (2015) 2, 1	*Newcastle disease virus*	**Concentration (%):** 0.05%, 0.1%, 0.2%, 0.4% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 30 and 60 minutes **Test temperature:** 10°C	**log R>5.25:** 0.2 % Clean 30 min 10°C
EN 14675 (2015) 2, 1	*Bovine enterovirus (ECBO)*	**Concentration (%):** 2, 3, 4% **Interfering substances:** 3 g/L bovine albumin **Contact time:** 5 minutes **Test temperature:** 10°C	**log R>5.25:** 4 % Clean 5 min 10°C

* The most challenging test conditions resulting in the required lg reduction should be given.

The available information was sufficient to evaluate the efficacy of Prophyl S for control of bacteria (excluding bacterial spores), mycobacteria, yeasts, fungi, viruses and parasitic protozoans, considering evaluation is done under article 121 of the WGB.
The studies show that Prophyl S complies with the criteria for log reduction for the key species of the target organisms, when used in accordance with the instructions described on the WG/GA for disinfection hard surfaces of livestock farming building.

The studies show that Prophyl S complies with the criteria for log reduction for the bacteria (excluding bacterial spores and mycobacteria) and yeasts, when used in accordance with the instructions described on the WG/GA for bootdips. The studies show that Prophyl S **does not** comply with the criteria for log reduction for viruses, when used in accordance with the instructions described on the WG/GA for bootdips. There is no valid efficacy test available for the contact time claimed.

5.3.2 Evaluation of the label (WG/GA)

The applicant has provided a WG/GA in Dutch. This has been adapted to our standards.

5.4 Mode of action

The inhibitory activity of glycolic acid is caused by acidification of the cell cytoplasm, disturbance of the plasma membrane, inhibition of cell functions and enzyme systems. The proton motive force will

be targeted leading to depletion of energy. Acid will induce leakage of intracellular components. Further, inhibition of the active uptake of amino and oxo acids has been described.

Chlorocrysol (CMK) as active substance of biocidal products is a multi-site bactericide and fungicidal, with basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of cytoplasmic membrane. At high concentrations, CMK also has an effect on cytoplasm by general coagulation.

5.5 Limitations on efficacy including resistance

5.5.1 General limitations
No limitations are mentioned.

5.5.2 Resistance
Resistance against glycolic acid is not reported. As glycolic acid is not specific for one cellular target and will acidify the cell cytoplasm, interferes with membrane integrity, inhibits the cell functions and enzyme systems and leads to energy depletion, the development of true resistance is not to be expected.

For CMK, the literature analysis showed that especially if the concentration of CMK is in the efficient range, no acquired resistance occurs. In addition, using bactericidal concentrations, the risk of development of cross-resistance or co-resistance is in general low, considering the multi-site activity of CMK. Since it interacts with many different targets of the bacterial cell wall, the risk of developing resistance mechanisms is minimal. Few authors described insufficient sporicidal effects of CMK and explained this by development of resistance. However, CMK is not efficacious against microbial spores and such well-known lack of sporicidal efficacy cannot be interpreted as result of resistance development.

5.5.3 Resistance management strategies
No management strategy is necessary.

5.6 Overall conclusions of efficacy
Based on the data submitted and considering that the evaluation is done under article 121 of the WGB, it can be concluded that Prophyl S, when used in accordance with the proposed label (WG/GA), is effective in controlling:

- bacteria (excluding bacterial spores and mycobacteria) and yeasts for bootdips;
- bacteria (excluding bacterial spores), mycobacteria, yeasts, fungi, viruses and parasitic protozoans on hard surfaces of livestock farming buildings, with the exception of animal transport vehicles.

Based on the data submitted and considering that the evaluation is done under article 121 of the WGB, it can be concluded that Prophyl S, when used in accordance with the proposed label (WG/GA), is **not** effective in controlling viruses for bootdips.

6 Human toxicology

Human health effects assessment active substance

Chlorocresol
Chlorocresol is an approved active substance for uses in PT1, 2, 3, 6 and 9 for which France was the RMS. The List of Endpoints presented below is taken from the Assessment report on Chlorocresol (d.d. November 2017). Where relevant, some additional remarks/information are given in italics.

List of Endpoints
Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Assumed to be complete: 100% (from study: 85%)
Rate and extent of dermal absorption* :	Default values from EFSA guidance (2012): 25% will be used for concentrated products (> 5% a.s.) and 75% will be used for diluted products (< 5% a.s.).
Distribution:	
Potential for accumulation:	None
Rate and extent of excretion:	Within 24 hours after administration, 85.21% and 84.30% of the administered dose was excreted in urine of male and female rats, respectively
Toxicologically significant metabolite(s)	None

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD50 oral	1830 mg/kg bw (♂), H302
Rat LD50 dermal	> 2000 mg/kg bw (♀), > 5000 mg/kg bw (♂)
Rat LD50 inhalation	> 2871 mg/m³ (♂ +♀)
Skin corrosion/irritation	Skin corr. 1C H314 Causes severe skin burns and eye damage
Eye irritation	Eye Dam 1 H318 Causes serious eye damage
Respiratory tract irritation	Stot SE 3 H335 May cause respiratory irritation.
Skin sensitisation (test method used and result)	Sensitising (GPMT, LLNA), Skin Sens; 1B H317 May cause an allergic skin reaction.
Respiratory sensitisation (test method used and result)	

Repeated dose toxicity

Short term

Species / target / critical effect	
Relevant oral NOAEL / LOAEL	3-month rat feeding study: NOEL = 1500 ppm ≅ 120/170 mg/kg/day (♂/♀) based on no effect combined chronic/carcinogenicity study : 105-week rat feeding study: NOAEL = 2000 ppm ≅ 103.1/134.3 mg/kg/day (♂/♀) based on delayed bw gain, poor general condition (♀), water intake↑, kidney weight↑, nephrotoxicity (♂), at terminal sacrifice: reduced spermatozoa in the epididymides and increased degeneration of seminiferous tubules (♂).

	No carcinogenic effects
Relevant dermal NOAEL / LOAEL	21 days study in rabbit: LOAEC = 10 mg/kg/d 13-week rat dermal study: NOEL = 500 mg/kg/day (♂/♀) No adverse effect
Relevant inhalation NOAEL / LOAEL	14days rat (7 days/week): systemic: 50 mg/m3 based on thymus effects local : 50 mg/m3 based on respiratory effects

Subchronic

Species / target / critical effect	
Relevant oral NOAEL / LOAEL	
Relevant dermal NOAEL / LOAEL	
Relevant inhalation NOAEL / LOAEL	

Long term

Species / target / critical effect	
Relevant oral NOAEL / LOAEL	
Relevant dermal NOAEL / LOAEL	
Relevant inhalation NOAEL / LOAEL	

Genotoxicity	Negative (in vitro + in vivo)

Carcinogenicity

Species / type of tumour	Rat: Slightly increased incidence of benign Leydig cell tumours of the testes in males as well as adenomas of the pars distalis of the pituitary glands in both sexes, were within the historical control range. Conclusion: CMK is not considered as having carcinogenic effects and none classification for carcinogenicity is deemed justified.
Relevant NOAEL / LOAEL	

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	Rat: reduced foetal weight, increased resorption rate, reduced foetus number. No malformations
Relevant maternal NOAEL	30 mg/kg bw/day
Relevant developmental NOAEL	100 mg/kg bw/day

Fertility

Species/critical effect	Rat: no reproductive effects
Relevant parental NOAEL	parental NOAEL = 750 ppm (90 mg/kg bw/day) based on effects on liver and kidneys and a statistical significant decrease in body weight gain (equivalent to 365 mg/kg/day)
Relevant offspring NOAEL	NOAEL for offspring toxicity = 750 ppm (corresponding to 47 mg/kg bw/day – F1) based on pup weight ↓ (♀) at 3000 ppm (F2b).

Relevant fertility NOAEL	No effects on fertility parameters; NOAEL for toxicity on fertility = 3000 ppm (corresponding to 288 mg/kg bw/day) based on the increased weights of the seminal vesicles effects at 12 000 ppm. In addition, at 12 000 ppm, ovarian atrophy, increased metoestrus, decreased dioestrus and atrophy of the vaginal epithelium appear in F0 and F1 females.

Neurotoxicity

Species/ target / critical effect	Rat: no neurotoxicity observed in subchronic or acute neurotoxicity testing

Developmental Neurotoxicity

Species/ target / critical effect	

Immunotoxicity

Species/ target / critical effect	

Developmental Immunotoxicity

Species/ target / critical effect	

Other toxicological studies

No indications for special concern.

Medical data

Some reports of poisoning with CMK-containing disinfectants with homicidal intent.
Corrosive damage to oesophagus/stomach was evident.
Several reports of contact hypersensitivity to CMK-containing products.

Summary

	Value	Study	Safety factor
$AEL_{long-term}$	0.3 mg/kg bw/d	Rat developmental study	100
$AEL_{medium-term}$	0.3 mg/kg bw/d	Rat developmental study	100
$AEL_{short-term}$	0.3 mg/kg bw/d	Rat developmental study	100
ADI[13]	0.3 mg/kg bw/d	Rat developmental study	100
ARfD[8]	0.3 mg/kg bw	Rat developmental study	100

[13] If residues in food or feed.
**Furthermore, concerning local effects for the inhalation route the following AEC are set :*
An acute respiratory AEC of 2 mg/m3.
A medium-term respiratory AEC of 0.7 mg/m3 .
A long-term respiratory AEC of 0.3 mg/m3 .

MRLs

Relevant commodities	Not required based on experimental data. For products that may lead to residues in food or feed, the need to set or amend MRLs shall be verified.

Local effects

Chlorocresol produces local effects after a single exposure as observed in the acute toxicity studies (oral, dermal and inhalation). Moreover, chloroscresol was found to be corrosive to skin and eyes and sensitising to skin. Based on the available studies, classification as Stot SE Cat 3 H335 (may cause respiratory irritation), Skin Corr Cat 1C H314 (cause severe skin burns and eye damage), Eye Dam. Cat 1 H318 (causes serious eye damage) and Skin Sens Cat 1B H317 (may cause an allergic skin reaction)

is proposed. Local effects on the skin and respiratory tract were also observed following repeated exposure to chlorocresol. These local effects are covered in the risk assessment/management by means of assignment of H- and P-phrases. Furthermore, an AEC inhalation is set, for which a risk assessment will be performed.

Glycolic acid

Glycolic acid is an existing active substance, not yet included in the Union list of approved substances of EU Regulation 528/2012. An application for inclusion is submitted (RMS = the Netherlands). A draft CAR is not available and the summary dossier is not discussed in the EU yet.
Therefore, the current evaluation is based on publicly available data (among others US-EPA and EFSA reports) and data provided by the applicant. As the evaluation of this substance as biocidal active substance has not yet been finalized, the LoEP should be regarded as provisional. Where relevant, additional comments are presented below in italics.

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption and distribution :	The metabolism of [1-14C] glycolic and [1-14C] glyoxylic acids was investigated in orally dosed female rhesus monkeys. Dose levels were 500 mg glycolate/kg and 60 or 500 mg glyoxylate/kg. Faecal excretion of 14C following administration of 500 mg glyoxylate/kg was approximately 1% and 3% for 500 mg glycolate/kg. Urinary excretion after 96 hours was 37-52% of the glycolate dose and 34-69% of the glyoxylate dose. Analysis of the individual acids showed that for glycolate 34- 44% of the glycolate was excreted unchanged, 0.3 – 2.2% excreted as the glyoxylate, 0.3% as hippurate and 0.3 – 1.3% as oxalate. (6% of urinary 14C was unaccounted for in terms of the various acids). For the 500 mg glyoxylate dose 24-59% was excreted unchanged, 0.1% was hippurate, 3% as oxalate and approximately 2% as glycolate. (6.5 to 16% of urinary 14C was unaccounted for in terms of the various acids). Some of the unaccounted radioactivity was present as labelled unconjugated glycine. At the lower concentration, 60 mg glyoxylate/kg, the metabolism and distribution was dramatically altered. Only 20% of 14C appeared in urine within 96 hours and only 1-1.5% of the dose was unchanged parent. 70% of the total 14C was oxalic acid with labelled hippurate forming a very minor metabolite. In the monkey the plasma half-life for ethylene glycol after oral administration of a 1 ml/kg dose was about 3 hours.

Following intravenous administration of 0.125 ml/kg of radiolabelled ethylene glycol, excretion of 14CO2 began almost immediately and within 4 hours circa 5% of administered dose had been excreted by this route. At four hours, 90% of the
administered dose was present in the soft tissues.
Liver and kidney contained larger amounts of 14C than blood, heart, lungs, spleen, brain or adrenals.
The 24 hour urinary excretion of unchanged ethylene glycol was 22% but the total 14C excreted in this period was 45%, indicating approximately half the urinary radioisotope was present in forms other than the parent. At 4 hours the total soft tissue concentrations accounted for circa 80% of administered dose. The distribution suggested that ethylene glycol was uniformly occupying all of the available water space. The most important excretory product in the urine of both rat and monkey (after the unchanged parent ethylene glycol) was glycolic acid – recovered at approximately 12% of a 1 ml/kg dose. The proposed metabolic pathway for ethylene glycol contains both glycolic acid and the minor metabolites oxalte and hippurate. It can be presumed that glycolic acid metabolism would proceed along the same pathway and at a rate consistent with this scheme.

The method used for determining glycolic acid did not distinguish between radiolabelled and non labelled forms. Following oral administration of radiolabelled glycolic acid, the amounts appearing in the urine were so great that practically all glycolate in urine must have carried the 14C label. The situation was less clearcut following administration of the glyoxylic acid since mammalian enzymatic action catalyses the reduction of glyoxylate to glycolate and therefore some of the radioactivity found in urine but not accounted for as glyoxylic, hippuric
or oxalic acid in the 0-24 hour period may have derived from glycolate but it appears unlikely that there was any in later intervals. An estimate of 2.5% of administered dose was postulated for the amount of glyoxylate excreted as glycolic acid.

Urinary radioactivity showed that the 96 hour

	excretion of 14C-glycolic acid was 51% of administered dose and for 14C-glyoxylic acid the value was 44%. Faecal radioactivity resulting from oral administration of 500 mg/kg doses of glycolic or glyoxylic acids was low indicating poor absorption.

Acute toxicity

Rat LD50 oral	LD50 (male and female rates combined) – 2040 mg/kg). (95% confidence limits of 1443-2469 mg/kg)	H302
Rat LD50 dermal	The conduct of an acute study with rats or rabbits to determine the likely acute dermal effects of topical application of glycolic acid is not considered justifiable in the light of extensive human exposure without adverse effect.	
Rat LD50 inhalation	For nose only exposure: female 4 hour LC50 = >5.2 mg/l male 4 hour LC50 = 3.6 mg/l (95% confidence limits of 2.4 – 8.9 mg/l)	H332
Skin corrosion/irritation	Corrosive	H314
Eye irritation	Ocular effects were severe and irreversible.	H318
Skin sensitisation	Negative (Buehler)	

Repeated dose toxicity

Target / critical effect	90 day gavage study (dosed 150,300 or 600 mg/kg bw/day), rat kidney effects (chemistry changes included a mild decrease in glomerular filtration rate (increased serum urea nitrogen, creatinine and phosphorus), kidneys weights (absolute and relative), oxalate crystal nephropathy). Increased neutrophils (among rats with indications of renal insufficiency) Reduced body weight gain, effects on food consumption or conversion efficiency (only seen at 300 and 600 mg/kg bw/day) Local effects; Pulmonary irritation (aspiration of small amounts of the gavage administered dose, with the acidic test material causing inflammation of upper airways/lungs in a dose related manner that correlated with lower pH) Three rats from the subchronic study subset died during the treatment phase, one male and two females. The high dose male died on day 46. The cause of death was determined from histopathology to be oxalate crystal nephropathy. One female dosed at 300 mg/kg bw/day died of

	renal hydronephrosis. The other female death was considered not to be treatment-related. One female dosed at 600 mg/kg bw/day was sacrificed in extremis on day 78 with oesophageal perforation following a gavage accident. A 14-day repeated exposure study via the inhalation route gave a NOAEC of 0.23 mg/L air. Very mild hepatocellular degeneration was apparent in one rat. This effect was more marked at higher dose levels (0.72 or 2.0 mg/L).
Relevant oral NOAEL / LOAEL	LOAEL 300 mg/kg bw/day NOAEL 150 mg/kg bw/day
Relevant dermal NOAEL / LOAEL	No data available
Relevant inhalation NOAEL / LOAEL	NOAEC: 230 mg/m³

Genotoxicity	Not genotoxic

Carcinogenicity

Target / critical effect	No data available
Relevant NOAEL / LOAEL	-
Target / critical effect	Based on human epidemiological data considered not carcinogenic

Reproductive toxicity

Reproduction target / critical effect	Rat, developmental toxicity The no observed effect level for maternal and development toxicity in this study was 150 mg/kg bw/day based on clinical signs apparent for dams dosed at 300 mg/kg bw/day and the minor skeletal effects among foetuses of the same dose group.
Relevant reproduction NOAEL	LO(A)EL maternal toxic effects 300 mg/kg bw/day NO(A)EL maternal toxic effects 150 mg/kg bw/day LO(A)EL embryotoxic / teratogenic effects 300 mg/kg bw/day NO(A)EL embryotoxic / teratogenic effects 150 mg/kg bw/day

Developmental toxicity

Developmental target / critical effect	A 90-day gavage study in rat was performed, including one-generation reproduction. No developmental effects were observed at the highest dose tested.
Relevant developmental NOAEL	LO(A)EL - Not established – greater than 600 mg/kg bw/day (the highest dose tested) NO(A)EL - 600 mg/kg bw/day Parents - 600 mg/kg bw/day Offspring - 600 mg/kg bw/day

Neurotoxicity

Neurotoxic effect	A 90-day gavage study in rat was performed, including a neurotoxicity subset. No neurotoxic effects were observed at the highest dose tested. Six of the rats in the neurotoxicity subset died during the course of the study. All had pulmonary lesions consistent with maladministration (i.e. gavage fluid administered into the lungs).
Relevant neurotoxic NOAEL	The NOEL for neurobehavioural effects was 600 mg/kg bw/day.

Other toxicological studies

The EFSA Panel (EFSA Journal 2010;8(12):1927), noted that glycolic acid is a major metabolite of ethylene glycol (Ref. No. 16990) that is authorized for the manufacture of plastics in contact with food with a restriction of 30 mg/kg food (EC, 2002).

Setting of the AEL

Based on the toxicological information the following limit values are derived:

	Value	**Study**	**Safety factor**
$AEL_{short/medium-term}$	1.5 mg/kg bw/d	90-day rat	100
$AEL_{long-term}$	0.75 mg/kg bw/d	90-day rat	200 (100 and an additional factor of 2 to compensate for duration)

Local effects

Glycolic is irritating to skin, eye and induces pulmonary irritation (aspiration of small amounts of the gavage administered dose, with the acidic test material causing inflammation of upper airways/lungs in a dose related manner that correlated with lower pH) and has no sensitizing properties. As the pulmonary irritation is not seen at 150 mg/kg bw/d in the 90 day rat study, which is the point of departure for deriving the AEL, it is considered that this AEL derived for systemic effects will also cover the local effects. The effects on skin and eye irritation are covered in the risk assessment/management by means of assignment of H- and P-statements.

6.1 Human exposure assessment active substance

6.1.1 General aspects

Prophyl S is a soluble liquid concentrate, that contains 17% chlorocresol and 4.9% glycolic acid as active substances. It is to be used as disinfectant on non-porous livestock farming buildings surfaces and disinfection of footwear (PT3).

Depending on the target organism, Prophyl S is used in a range from 0.6-5% (6-50 ml of Prophyl S in 1 Liter of water) the maximum dosage of a 5% dilution contains 0.85% w/w chlorocresol and 0.245% glycolic acid.

The formulation Prophyl S is for professional use only.

6.1.2 Identification of main paths of professional exposure towards active substance from its use in biocidal product

The professional user can be dermally and respiratory exposed to chlorocresol and glycolic acid during mixing and loading and application via spraying and dipping (foot bath) using Prophyl S. As Prophyl S is intended for professional use only, oral exposure is considered negligible.

Inhalation exposure is expected to be negligible for chlorocresol during mixing and loading in view of the low vapour pressure (1.4×10^{-3} Pa at 20°C). However, during spraying application inhalation to aerosols could still occur for chlorocresol. Glycolic acid is mildly volatile with a vapour pressure of 0.05 Pa at 20°C. Exposure to inhalation by vapour can thus occur during mixing, loading and application and in addition exposure to aerosols can occur during spray application.

6.1.3 Identification of main paths of non-professional exposure towards active substance from its use in biocidal product

The formulation Prophyl S is to be used by professionals only.

6.1.4 Indirect exposure as a result of use of the active substance in biocidal product

Based on the mildly volatile vapour pressure of glycolic acid, bystander exposure via inhalation in the near surroundings cannot be excluded. This is also applicable to the exposure via inhalation by animals when re-entering the room.
According to the WG/GA the equipment need to be rinsed with water after application. However, surfaces are not included in these instructions. Therefore, secondary dermal exposure of the general public including children visiting a farm by touching treated surfaces. Although direct exposure to animals is excluded, as the WG/GA stated that animals should not be present while spraying takes place, secondary exposure of animals by licking or touching treated surfaces should be taken into account. Actually, after spraying, animals re-enter the stable and might be exposed to chlorocresol and glycolic acid residues. These residues might end up in the meat and could be consumed by the general public, thus dietary exposure should be taken into account.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

No studies with Prophyl S have been submitted and the classification and labelling of the formulation has been prepared based on the calculation method described in Annex I of Regulation 1272/2008/EC.

6.3 Risk characterisation for human health

6.3.1 Professional users

The Technical Agreements for Biocides (TAB, 9 November 2018) and WG-III-2016 states that systemic dermal and oral route is not necessary for exposure to corrosive concentrations as exposure will be negligible as appropriate PPE and RMM will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances.
The undiluted product of Prophyl S is classified with H314, and as such can cause local effects after dermal and eye exposure. Therefore, the use of personal protective equipment (gloves, protective cloths, eye/face protection) is prescribed during mixing and loading for the professional user and the systemic dermal or oral route will not have to be assessed. However, systemic inhalation route should be performed if inhalation exposure is possible.

The in-use dilution of 5% of Prophyl S is not considered corrosive to skin and eye according to CLP principles, therefore the systemic dermal exposure route should be assessed. No dermal absorption study with the biocidal product is available, therefore a default dermal absorption value will be used in the risk assessment according to EFSA GD 2017, which is 50% for the in-use dilution for a water based/dispersed formulation.

<u>Mixing, loading and spraying application</u>

To estimate systemic dermal and inhalation exposure to chlorocresol and glycolic acid during the application of Prophyl S by spraying, Spraying Model 2 (User Guidance v.1, 2002, p.30) is considered to be applicable. Using Spraying Model 2 is in accordance with the final CAR for chlorocresol for the mixing, loading and application of a formulation containing chlorocresol when used as a veterinary hygiene product (PT3) and is also included in the HEAd hoc recommendation 6. This model also includes mixing and loading step; therefore no separate assessment of mixing and loading is performed. The concentration chlorocresol and glycolic acid in the maximum in-use solution of 5% is 0.85% and 0.245%, respectively. The indicative exposure values are 273 mg/min for hand exposure without protective gloves, 7.8 mg/min for hand exposure inside protective gloves, 222 mg/min for body exposure and 76 mg product/m^3 for inhalation exposure, and a default value of 2 hours for duration for spray application in animal house scenarios, according to the Technical Agreements on Biocides on TOX (TOX-TAB, Version of 9 August 2021).

Table T.1 Internal professional operator exposure to chlorocresol and risk assessment for the use of Prophyl S during mixing, loading and spraying of a 5% in-use product dilution (0.85% chlorocresol)

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Mixing, loading and spraying[3], no PPE			
Dermal	4.21	0.3	14.03
Respiratory	0.03	0.3	0.09
Total	4.23	0.3	14.11
Mixing, loading and spraying[3], with PPE[4]			
Dermal	0.26	0.3	0.85
Respiratory	0.03	0.3	0.09
Total	0.28	0.3	0.94

[1] Internal exposure is calculated with: 50% dermal absorption and 100% inhalation absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] Calculations were based on: spraying model 2.
[4] PPE (personal protective equipment): for the dermal exposure, the indicative value of 7.8 mg/min on hands (in gloves) is used from spraying model 2. For dermal body exposure a 90% reduction for the use of protective clothing is taken into account.

Table T.2 Internal professional operator exposure to glycolic acid and risk assessment for the use of Prophyl S during mixing, loading and spraying of a 5% in-use product dilution (0.245% glycolic acid)

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Mixing, loading and spraying[3], no PPE			
Dermal	1.24	0.75	1.65
Respiratory	0.01	0.75	0.01
Total	1.25	0.75	1.66
Mixing, loading and spraying[3], with PPE[4]			
Dermal	0.075	0.75	0.100
Respiratory	0.008	0.75	0.011
Total	0.083	0.75	0.111

[1] Internal exposure is calculated with: 50% dermal absorption and 100% inhalation absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] Calculations were based on: spraying model 2.
[4] PPE (personal protective equipment): for the dermal exposure, the indicative value of 7.8 mg/min on hands (in gloves) is used from spraying model 2. For dermal body exposure a 90% reduction for the use of protective clothing is taken into account.

Based on this risk assessment no systemic effects are expected for the protected (gloves/coverall) professional user, for all dilutions used for spray applications of Prophyl S when exposed to glycolid acid or chlorocresol.

Regarding local effects via inhalation, an $AEC_{inhalation}$ is set for chlorocresol. For glycolic acid no $AEC_{inhalation}$ is available, therefore the external exposure to glycolic acid was not assessed. The indicative inhalation exposure in spraying model 2 is 76 mg biocidal product/m^3. A maximum in-use dilution of 5% is used during spraying, leading to a concentration chlorocresol of 0.85%. This corresponds to a concentration of 0.646 mg/m^3 chlorocresol in air, assuming equal evaporation of all components of the product. The $AEC_{inhalation}$ for long-time exposure of 0.3 mg/m^3 for chlorocresol is exceeded. The use of respiratory protection equipment with a protection factor of 4 (0.646 mg/m3 / 0.3 mg/m3 = 2.15) is therefore required for spraying application with a 5% product dilution. For the other dilutions of the spraying applications this was also calculated and described in the table below. Only if the $AEC_{inhalation}$ is exceeded RPE needs to be calculated.

Table T.3 External professional operator exposure to chlorocresol and local risk assessment for the use of Prophyl S during mixing, loading and spraying of various in use dilutions of Prophyl S.

Prophyl S dilution	Chlorocresol concentration (mg/m3)[1]	$AEC_{inhalation}$ (mg/m3)	RPE factor[2]
5%	**0.646**	0.3	2.15
4%	**0.5168**		1.72
1.5%	0.1938		n.r.
0.6%	0.07752		n.r.

[1]External exposure is calculated based on indicative value of Spraying model 2 (76 mg product/m^3) and percentage chlorocresol in the dilution.
[2] Required protection factor of RPE is calculated by dividing the external exposure by AEC inhalation. "n.r." stands for not required.

Based on the local risk assessment use of respiratory protection equipment is not required for spraying with the dilutions of 1.5% or 0.6%. For the spraying application with 4 or 5% Prophyl S dilution the following sentence is therefore added to the WG/GA: "wear respiratory protection with protection factor 4."

In conclusion, based on this risk assessment, no adverse systemic and local effects after exposure to chlorocresol and glycolic acid are expected for the protected (gloves, protective clothing) professional user when spraying 0.6 or 1.5% Prophyl S in accordance with the WG/GA. For the spraying application with 4 or 5% Prophyl S dilution, no adverse systemic and local effects after exposure to chlorocresol and glycolic acid are expected for the protected (gloves, protective clothing, and suitable respiratory equipment) professional user. In addition, gloves, a coverall and eye/face protection is prescribed during mixing and loading due to the corrosive properties of the undiluted product.

<u>Disinfection of footwear by dipping (foot bath):</u>
Based on the corrosive properties of Prophyl S, gloves, coverall and eye/face protection is prescribed for mixing and loading. The diluted product is not considered to be corrosive. During application direct dermal contact to the diluted product is not to be expected, as it is intended as disinfection of footwear. According to HEAd hoc recommendation 6, for disinfection of footbath for rubber boots only dermal exposure is assessed, with EUROPOEM II database (model the exposure loading /pouring volumes up to 20L). Indicative values include hands: 8 mg/kg active substance and body: 1.95 mg/kg active substance. The foot bath volume from the WG/GA of max 15 L is used, and the calculations of the total dermal exposure is compared with the long-term AEL, as HEAd hoc

recommendation 6 indicates a frequency of 104 times per year. The product dilution for this scenario, as described in the WG/GA is 2%, this corresponds with 0.34% chlorocresol and 0.1% glycolic acid. Lastly, the dermal absorption value of 50% is used for both active substances.

For chlorocresol, the total dermal exposure is 0.004 mg/kg bw/day, compared to the long-term systemic AEL of 0.3 mg/kg bw, this leads to a risk index of 0.01.
For glycolic acid, the total dermal exposure is 0.001 mg/kg bw/day, compared to the long-term systemic AEL of 0.75 mg/kg bw, this leads to a risk index of <0.01.

In conclusion, no adverse systemic and local effects after exposure to chlorocresol and glycolic acid are expected for the protected (gloves, protective clothing, eye/face protection) professional user when mixing and loading Prophyl S for foot baths, in accordance with the WG/GA. Additionally, no adverse systemic effects after exposure to chlorocresol and glycolic acid are expected for the unprotected professional user when disinfecting rubber boots in foot baths containing Prophyl S in accordance with the WG/GA.

6.3.2 Non-professional users, including the general public
Product is used by professionals only.

6.3.3 Indirect exposure as a result of use
Re-entry in the room
According to the CAR (2018) for chlorocresol, one of the elements to be taken into account when authorizing products is: “if an unacceptable risk is identified for professionals following disinfection of animal housings, labels, and where provided, safety data sheets should indicate that there should be no re-entry until treated surfaces are dry”. As an acceptable use for professionals is only obtained by using protection (gloves, coverall and eye/face protection for all in-use dilutions and RPE for the 4% and 5% in-use dilutions), re-entry is not considered acceptable until all surfaces are dry. This sentence will therefore be added to the WG/GA.
For the application of disinfection of foot baths only PPE is prescribed during mixing and loading. In this case no surface is treated or needs to be dry before re-entry.

Dietary exposure
According to the instruction for use, disinfection of animal facilities is performed when no animals are present and it should not be used on surfaces which can be in contact with animal feed. Surfaces are being sprayed at a dosage of 100 ml/m^2 (with concentrations varying per target organism) and a contact time of 2 hours for all target organisms is applied. There is no instruction about rinsing the surfaces after application. Therefore, livestock can be indirectly exposed to the active substances chlorocresol and glycolic acid. Residues may be transferred to food and products from animal origin. As a consequence, a dietary exposure needs to be performed. For glycolic acid no reference values (ADI or ArfD) are available, therefore the dietary exposure assessment is solely based on the chlorocresol residues.

The product is used as disinfectant on non-porous livestock farming buildings surfaces (walls and floors). The exposure to livestock is estimated using the BfR Livestock Exposure Calculator. The assessment includes a screening step as well as a realistic worst-case scenario.
For the screening step, the following scenario of the “BfR Livestock Exposure Calculator” is considered suitable for the intended use: surface treatment of animal housing (floor & wall of stables without partition). This screening step was performed to assess whether the trigger value of 0.004 mg/kg bw/d is exceeded (Tier 1).
For the realistic worst-case scenario (Tier 2), the following settings were selected as relevant:

- oral – animals licking surfaces
- oral – uptake of feed contaminated in trough

- dermal – rubbing against surfaces
- inhalation – Saturated Vapour Concentration Model (SVC)

The default emission factor for the fraction emitted to the treated surface during surface treatment by spraying (0.85) is used to refine oral exposure (licking). For the refinement of dermal exposure the default emission factor for the fraction emitted to the treated surface during surface treatment by spraying (0.85) is corrected with additional refinement of 0.5. As based on HH WGI 2022 discussions, it was agreed that animal systemic availability after dermal exposure is 50%, thus the refinement factor for dermal exposure is 0.425. The default emission factor for the fraction emitted to floor during surface treatment by spraying (1) is used for the oral exposure (contaminated trough). Although the WG/GA indicates Prophyl S should not be used on surfaces that can come in contact with animal feed, the scenario of contaminated trough is added for a worst case assessment, the final conclusion does not change due to the inclusion of this scenario. Based on the relative density of 1.072 kg/L of Prophyl S, the calculated maximum application rate of chlorocresol (with 5% Prophyl S dilution, leading to 0.85% chlorocresol) is 911.2 mg/m2.

T.4 Summary of screening step and realistic worst case report results of livestock exposure to chlorocresol (0.85%)

External dose received by the animal					
Livestock exposure calculator:					
	Animal livestock	Tier 1: Screening step		Tier 2: Realistic worst case	
		Livestock Total exposure (mg/kg bw/d)	Exceedance of threshold value (0.004 mg/kg bw/d)	Livestock Total exposure (mg/kg bw/d)	Exceedance of threshold value (0.004 mg/kg bw/d)
	Beef cattle	14.5792	Y	1.2640	Y
	Dairy cattle	23.4108	Y	1.4559	Y
	Calf	18.7935	Y	2.2552	Y
	Fattening pig	22.0966	Y	2.7747	Y
	Breeding pig	-	-	1.4989	Y
	Breeding pig - individual housing	24.1606	Y	1.9230	Y
	Breeding pig - group housing	30.7981	Y	2.0001	Y
	Sheep	-	-	0.0131	Y
	Lamb	-	-	0.0143	Y
	Slaughter goat	-	-	4.4873	Y
	Lactating goat	-	-	2.5024	Y
	Broilers	-	-	0.0096	Y
	Broiler - free range, litter floor	42.8800	Y	0.0096	Y
	Broilers - parent broilers, free range (grating floor)	45.9429	Y	0.0096	Y
	Broilers - parent broilers in rearing, free range (grating floor)	44.6667	Y	0.0096	Y
	Laying hen	-	-	0.0086	Y
	Laying hen - battery	25.1208	Y	0.5362	Y
	Laying hen - free range (litter floor)	97.3545	Y	0.0086	Y
	Laying hen -free range (grating floor)	43.6896	Y	0.0086	Y
	Turkey	-	-	0.0070	Y
	Horse	-	-	1.5772	Y
	Rabbit	61.2326	Y	0.0295	Y

At Tier 1 – screening step, all estimates are above the trigger value of 0.004 mg/kg bw/day. Further assessment is considered necessary. Refined exposure estimates are performed for all animals.
At Tier 2 – realistic worst case, all estimates are again above the trigger value of 0.004 mg/kg bw/day. Therefore, a worst-case consumer exposure estimate (WCCE) was performed as described in the EMA-CVMP guidance, with the BfR Livestock Exposure Calculator Version 2.0.

T.5 Worst Case Consumer Exposure [mg/kg bw/d] Systemic effects, chronic exposure to chlorocresol

	Tier	ADI/ARfD mg/kg bw/d	$WCCE_{total}$[1] mg/kg bw/d	Estimated uptake/ ADI (%)	Acceptable (yes/no)
EMA Food Basket[2]	1	0.3	0.10	**33.36**	**no**
EFSA PRIMo[3] **- chronic - adult**	1	0.3	0.02	6.85	yes
EFSA PRIMo[3] **- chronic - child**	1	0.3	0.07	21.72	yes

[1] $WCCE_{total} = WCCE_{muscle} + WCCE_{fat} + WCCE_{liver} + WCCE_{kidney} + WCCE_{milk} + WCCE_{eggs}$
WCCE = ((transfer factor (based on $logP_{OW}$) x oral exposure) + (dermal exposure x 50% systemic availability) + inhalative exposure) x food intake ÷ human body weight.
Transfer factors are based on the Octanol-Water Partition Coefficent (logPOW) for the maximum tranfer of an oral dose to livestock edible tissues (Leemans et al. 2007). LogPOW range selected is 2-3, the logPow is derived from the CAR of chlorocresol (2017): 2.73.
Based on HH WGI 2022 discussions, it was agreed that animal systemic availability after dermal exposure is 50%
[2] EMA Food Basket = 300 g muscle, 100 g liver, 50 g fat, 50 g kidney plus 1500 g milk, 100 g eggs and 20 g honey
[3] EFSA PRIMo rev 3.1 (EFSA 2018), also included in BfR calculator, Sheet Defaults 5 Food Cons

T.6 Worst Case Consumer Exposure [mg/kg bw/d] Systemic effects, acute exposure

	Tier	ARfD mg/kg bw/d	WCCE[1] mg/kg bw/d	Estimated uptake/ ARfD (%)	Acceptable (yes/no)
EFSA PRIMo[2] **- acute - adult**	1	0.3	Muscle: 9.72E-03 Fat: 3.60E-03 Liver: 6.87E-03 Kidney: 3.95E-03 Milk: 4.60E-02 Eggs: 3.28E-04	Muscle: 3.24 Fat: 1.20 Liver: 2.29 Kidney: 1.32 Milk: 15.35 Eggs: 0.11	yes
EFSA PRIMo[2] **- acute - child**	1	0.3	Muscle: 2.15E-02 Fat: 3.55E-03 Liver: 1.39E-02 Kidney: 6.47E-03 Milk: 1.26E-01 Eggs: 9.58E-04	Muscle: 7.16 Fat: 1.18 Liver: 4.62 Kidney: 2.16 **Milk: 41.95** Eggs: 0.32	**no**

[1] $WCCE_{total} = WCCE_{muscle} + WCCE_{fat} + WCCE_{liver} + WCCE_{kidney} + WCCE_{milk} + WCCE_{eggs}$

WCCE = ((transfer factor (based on $logP_{OW}$) x oral exposure) + (dermal exposure x 50% systemic availability) + inhalative exposure) x food intake ÷ human body weight.
Transfer factors are based on the Octanol-Water Partition Coefficent (logPOW) for the maximum tranfer of an oral dose to livestock edible tissues (Leeman et al. 2007)
Based on HH WGI 2022 discussions, it was agreed that animal systemic availability after dermal exposure is 50%
[2] EFSA PRIMo rev 3.1 (EFSA 2018), also included in BfR calculator, Sheet Defaults 5 Food Cons

T.7 Animal species with highest exposure (RWCE) taken for worst-case calculations

Animal group	Animal species	Housing type
Bovine	Calf	-
Pig	Fattening pig	-
Sheep	Lamb	-
Goat	Slaughter goat	-
Horse	Horse	-
Milk producing animals	Lactating goat	-
Egg producing animals	Laying hen	battery

Based on the above, the WCCE is slightly > 30% of the ADI and ArfD for two scenarios (33.36% of the ADI based on the EMA food basket and 41.95% of the ArfD for acute exposure of a child to milk). Therefore, a rinsing step after application will be added to the WGGA to minimalize animal exposure. As chlorocresol is readily soluble, it is expected to minimize the exposure to animals and thus dietary consumer exposure.
With regard to MRL, the default MRL of 0.01 mg/kg set in Regulation (EU) No 396/2005 is applicable for chlorocresol. Compliance with these values must thus be demonstrated independent of the estimated consumer risk. MRL compliance can be demonstrated with the experimental study used in the CAR of the chlorocresol (see CAR chlorocresol PT 3, 2.5.1.2.3.3.1. Animal exposure). In these studies, a ready-to-use product containing chlorocresol was used to disinfect animal facilities and after the product had dried animals were allowed in the animal facility and were fed. In all studies in all tissues, all residue levels were below the limit of quantification of 0.01 mg/kg while in the third study this was 0.1 mg/kg for kidney and liver. Considering that the study resulting in residues of 0.1 mg/kg in kidney and liver used an application rate that is 4 times higher than the application rate of Prophyl S, it can be assumed that the MRL will not be not to be exceeded when Prophyl S is used in accordance with the WG/GA.

<u>Animal health exposure</u>
The safety of non-target animals after application of biocidal product has to be addressed as well. For this reason, the safety of chlorocresol and glycolic acid is being assessed. Animals will be exposed after re-entry to the treated animal housing. Exposure scenarios for the animals are considered as chronic scenarios as a worst-case and the NOAEL value for a chronic exposure duration was used to derive a reference value for the animal safety assessment.

Chlorocresol:
The lowest NOAEL is 30 mg/kg bw/day, obtained in the rat developmental toxicity study. The NOAEL from this study has been identified to be the most relevant point of departure for the animal safety assessment. In accordance with the EFSA Guidance on “Risk Assessment for Birds and Mammals” (2009), this NOAEL value is corrected by an inter-species assessment/safety factor of 5 since a margin of safety (MOS) of 5 is considered sufficiently safe for long-term/chronic exposure of animals in this guidance. As result, an orientating reference values of 6 mg/kg bw/day is derived for chlorocresol for the purpose of the animal safety assessment which will be applicable to other animal species.

Glycolic acid:

The lowest NOAEL is 150 mg/kg bw/day, obtained in the 90 day rat developmental toxicity study. Which is corrected for duration for long term calculations by factor 2, therefore being 75 mg/kg bw/ day The NOAEL from this study has been identified to be the most relevant point of departure for the animal safety assessment. In accordance with the EFSA Guidance on “Risk Assessment for Birds and Mammals” (2009), this NOAEL value is corrected by an inter-species assessment/safety factor of 5 since a margin of safety (MOS) of 5 is considered sufficiently safe for long-term/chronic exposure of animals in this guidance. As result, an orientating reference values of 15 mg/kg bw/day is derived for glycolic acid for the purpose of the animal safety assessment which will be applicable to other animal species.

The exposure of animals to the biocidal product as derived in the Tier 2 – realistic worst case assessment using the BfR calculator as described above was be compared to the reference value set for animals as presented below.

Table T.8 Animal exposure assessment of chlorocresol 0.86%

Animal species	Sum of exposure routes (mg AS/kg bw/d)	Exposure/AEL animal*100	Acceptable (Yes/No)
Beef cattle	1.2640	21.07	Yes
Dairy cattle	1.4559	24.27	Yes
Calf	2.2552	37.59	Yes
Fattening pig	2.7747	46.24	Yes
Breeding pig	1.4989	24.98	Yes
Breeding pig - individual housing	1.9230	32.05	Yes
Breeding pig - group housing	2.0001	33.33	Yes
Sheep	0.0131	0.22	Yes
Lamb	0.0143	0.24	Yes
Slaughter goat	4.4873	74.79	Yes
Lactating goat	2.5024	41.71	Yes
Broilers	0.0096	0.16	Yes
Laying hen	0.0086	0.14	Yes

Laying hen - battery	0.5362	8.94	Yes
Turkey	0.0070	0.12	Yes
Horse	1.5772	26.29	Yes
Rabbit	0.0295	0.49	Yes

Table T.9 Animal exposure assessment of glycolic acid 0.245%

Animal species	Sum of exposure routes (mg AS/kg bw/d)	Exposure/AEL animal*100	Acceptable (Yes/No)
Beef cattle	0.5210	3.47	Yes
Dairy cattle	0.5661	3.77	Yes
Calf	0.8420	5.61	Yes
Fattening pig	1.0147	6.76	Yes
Breeding pig	0.6093	4.06	Yes
Breeding pig - individual housing	0.7315	4.88	Yes
Breeding pig - group housing	0.7537	5.02	Yes
Sheep	0.2496	1.66	Yes
Lamb	0.2730	1.82	Yes
Slaughter goat	1.6478	10.99	Yes
Lactating goat	0.9626	6.42	Yes
Broilers	0.1835	1.22	Yes
Laying hen	0.1642	1.09	Yes
Laying hen - battery	0.3162	2.11	Yes

Turkey	0.1337	0.89	Yes
Horse	0.6197	4.13	Yes
Rabbit	0.5616	3.74	Yes

The sum of the exposure routes comes to an acceptable level of risk for animals when Prophyl S is used in accordance with the WG/GA. Moreover, it should be noted that with the addition of a rinsing step after application animal exposure will be further minimized (see Dietary Exposure above).

6.3.4 Combined exposure

The formulation Prophyl S is a mixture of two active substances. The combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity.
Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profiles based on the individual substances. However, both glycolic acid and chlorocresol can cause local effects. Local effects are considered to be additive in nature and are covered in the risk assessment/management by means of assignment of H- and P-statements. As Prophyl S is corrosive, gloves, coverall and eye/face protection is prescribed for mixing and loading.

Based on the Tier 2 calculation of systemic effects the risk index of both active substances added up is 1.051 (with PPE 0.94 for chlorocresol and 0.111 for glycolic acid) for the worst case dilution (5%). However, as the local risk assessment indicates that RPE should be required for spraying application with 5% and 4%, the risk index of the Tier 3 calculation (PPE+RPE) can be used for the combined exposure assessment. The Tier 3 calculations of spraying model 2 are performed with a inhalation penetration of 25%, as RPE with an APF of 4 is prescribed. With the Tier 3 risk index of the total exposure to chlorocresol (0.87) and glycolic acid (0.10) added up, the risk index is 0.97, therefore no adverse systemic effects due to the combined exposure to chlorocresol and glycolic acid, when Prophyl S is used in accordance with the WG/GA.

6.4 Overall conclusions for the aspect human health

Based on this risk assessment, it was concluded that no adverse health effects are expected for the protected (gloves, protective clothing and eye/face protection) professional user after dermal and respiratory exposure to chlorocresol and glycolic acid during mixing and loading of Prophyl S, when used in accordance to the WG/GA. For the application by spraying with a dilution of 1.5% or 0.6% no adverse health effects are expected for the protected (gloves, protective clothing) professional user after dermal and respiratory exposure to chlorocresol and glycolic acid as a result of the use of Prophyl S, when used in accordance to the WG/GA.
For the application by spraying with a dilution of 5% or 4% the use of respiratory equipment with a protection factor 4 is also required for safe use, in addition to the protective measures mentioned for the application of spraying with a 1.5% or 0.6% dilution. The following sentence is therefore added to the WG/GA for these in-use dilutions: “wear respiratory protection with protection factor 4.”
For disinfection of rubber boots in foot baths, no adverse health effects are expected for the unprotected professional user after dermal exposure to chlorocresol and glycolic acid, when Prophyl S is used in accordance with the WG/GA.

As the professional user is required to wear protective clothing, the following sentence will be added to the WG/GA, in accordance with the CAR (2018) of chlorocresol: “no re-entry until surfaces are dry”.

In the absence of dietary reference values for glycolic acid, a dietary risk assessment was only performed for chlorocresol. Based on this dietary risk assessment, the exposure to chlorocresol exceeds 30% of the ADI and ARfD for two scenarios. As chlorocresol is readily soluble, a rinsing step will reduce the exposure to animals and will subsequently also lower the dietary exposure. Therefore, the following sentence will be added to the WG/GA: “rinse treated surfaces that can come in contact with animals with water after application”.

7 Environment

7.1 Introduction

Authorisation is requested for the product Prophyl S containing chlorocresol and glycolic acid as active substances. The biocidal product concerns a veterinary hygiene disinfectant (PT03). The product is for professional use. The intended uses are described in Table E. 1.

Table E. 1 Intended uses, dose, and use concentrations of the active substances.

Area of use envisaged	Concentration active substance in product (g/L)	Concentration active substance in diluted product (g a.s./L)	Spraying rate (mL/m²)	Dose (g a.s./m²)
Disinfection of livestock farming buildings by spraying	Chlorocresol: 170 Glycolic acid: 49	0.6% dilution[a]: Chlorocresol: 1.02 Glycolic acid: 0.294 1.5% dilution[b]: Chlorocresol: 2.55 Glycolic acid: 0.735 4% dilution[c]: Chlorocresol: 6.8 Glycolic acid: 1.96 5% dilution[d]: Chlorocresol: 8.5 Glycolic acid: 2.45	100	0.6% dilution[a]: Chlorocresol: 0.102 Glycolic acid: 0.0294 1.5% dilution[b]: Chlorocresol: 0.255 Glycolic acid: 0.0735 4% dilution[c]: Chlorocresol: 0.68 Glycolic acid: 0.196 5% dilution[d]: Chlorocresol: 0.85 Glycolic acid: 0.245
Disinfection of footwear by dipping*		2% dilution: Chlorocresol: 3.4 Glycolic acid: 0.98	-	-

a: For bactericidal and yeasticidal effect;
b: For mycobactericidal and fungicidal effect;
c: For virucidal effect;
d: For parasitic protozoacidal effect;
* Application rate for disinfection of footwear by dipping is once a week (based on efficacy data – capacity test – 100 boots passages are covered)

7.2 Product related studies

The exposure assessment is based on data for the active substances. There are no fate or ecotoxicity data available for the product.

7.3 List of endpoints

The active substance chlorocresol is approved for the product types [PT] 1, 2, 3, 6, 9 and 13 according to the regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. The environmental risk assessment is based on the list of endpoints as published in the assessment report which is available on ECHA’s website.

The active substance glycolic acid is under review for the product types [PT] 2, 3 and 4 according to the regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal

products. No agreed list of endpoints is therefore available. The risk assessment is based on the information available at the Ctgb.

The data for the active substances applied in the current risk assessment are presented in appendix I and section 7.5.

7.4 Environmental exposure assessment

7.4.1 Environmental fate

In water chlorocresol is hydrolytically stable, but nevertheless considered to be readily biodegradable. A default value for degradation in soil based on the ready biodegradation test is assumed (DT_{50} = 30 days) as no reliable experimental data were available.
The results of a HPLC screening test (K_{oc} = 158.5 L/kg) as well as the K_{oc} values obtained for chlorocresol from a batch equilibrium experiment (195.6 L/kg), reveal chlorocresol to be of moderate mobility in soils. Additionally, chlorocresol was only found in one of 41 soil pore samples in a supportive lysimeter study, indicating that there is no evidence of a relevant leaching potential of the compound. Rapid degradation in air is expected considering the DT_{50} value of 15.0 hours.

Glycolic acid is classified as readily biodegradable. The substance is ubiquitous in the environment, because glycolic acid is a natural component of some foods, and natural sources of glycolic acid form the major source of human and environmental exposure to glycolic acid. Rapid degradation in soil is expected considering the DT_{50} value of 0.161 days at 20°C, corresponding to 0.304 days at 12°C.

No significant metabolites of chlorocresol and glycolic acid, at a level higher than 10% of the active substances, were formed in water/sediment and soil degradation studies.

7.4.2 Distribution in the environment

Various phases in the life cycle of a product may cause emissions and environmental exposure. Significant release to the environment will therefore occur during the application of products holding the biocide. Table E.2 summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different applications. Emissions from active substance production and product formulation are not part of the risk assessment. The routes of entry into the environment are explained in more detail in the next sections.

Table E.2 Foreseeable routes of entry into the environment on the basis of the intended uses.

Main scenario	Environmental compartments exposed				
	STP[1]	Freshwater[2]	Saltwater[2]	Soil[3]	Air
Veterinary hygiene disinfectant (PT03)					
Disinfection of livestock farming buildings by spraying	++	+	+	+	+
Disinfection of footwear by dipping	++	+	+	+	+

++ Compartment directly exposed, + Compartment indirectly exposed, - Compartment not exposed, [1] Sewage Treatment Plant, [2] Including sediment, [3] Including groundwater.

The product needs to be diluted with water and the working solution is used for disinfection of surfaces and footwear. When the product is used for disinfection of surfaces in livestock farming buildings by spraying and footwear by dipping (PT03), rinse water and residues in buckets and dipping baths are usually released to manure which is subsequently applied as a soil fertiliser. Subsequent emission to surface water is possible due to runoff or transport of soil particles from fertilised soils. Alternatively, waste water may be released to the sewer. Nevertheless, most Dutch farms are not connected to the municipal sewer due to the distance to the nearest sewage pipe and regulations concerning animal manure, although a sewer may be present in some stables for poultry emission. Waste water from farms may be purified in an individual wastewater treatment plants (In

Dutch: Individuele Behandeling van Afvalwater (IBA)), but these systems are usually intended to purify domestic waste water. The effluent from IBA is then discharged to the surface water or the infiltrated soils. Although industrial waste water from farms is likely not released to an IBA, residues may enter sinks when surfaces and footwears are cleaned.

Considering that some Dutch STPs discharge to the open sea, the marine environment may be exposed as well. Although soils may be exposed due to the application of sewage sludge as a soil fertiliser, this route is highly unlikely in The Netherlands as its chemical composition does not fulfil the environmental standards regarding organic pollutants and heavy metals. In order to avoid unnecessary contamination of the receiving soils, sewage sludge is treated as hazardous waste instead. Emission to air is likely when the product is applied by spraying. Spray drift may deposit on nearby soils or surface water. Additionally, emission to air and subsequent emission to soils may occur during sewage treatment where sewage sludge is aerated.

7.4.3 Predicted environment concentration calculations

7.4.3.1 General

Predicted Environmental Concentrations (PECs) were calculated according to relevant exposure scenario documents (ESDs, release to the environment), the guidance on biocide legislation, Part B+C, volume IV (distribution in the environment), the Technical Agreement on Biocides (TAB), and the model SimpleTreat (concentrations for micro-organisms in an STP and STP's effluent) by using the default values for parameters, unless otherwise noted. Distribution in the STP has been calculated using SimpleTreat version 4.0 in which the concentration of suspended solids in the effluent has been increased to 30 mg/L in accordance to the TAB. Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substances are added are disposed as solid waste and usually incinerated. Possible pH effects on the environment were not considered, because the STP and receiving compartments are expected to have sufficient buffering. The assessment was made for the highest dose only. The applied methods are explained below. The risk assessment is based on the active substance's physical-chemical properties as listed in appendix I and the concentrations as listed in **Table E. 1**.

Disinfection of surfaces by spraying in livestock farming buildings (PT03)
Predicted Environmental Concentrations (PEC) for indoor applications were calculated in accordance with the scenario from Emissions Scenario Document (ESDs) for PT03 by using the scenario for animal housing disinfection. The fraction of substance disintegrated during or after application (F_{dis}) was set to zero (default) and all of the active substance's mass used for disinfection is expected to be emitted to the sewer or manure.

As the amount of disinfections per year and the surfaces to be disinfected strongly depend on the type of animals housed, emission to the environment due to disinfection of stables vary among the different farm industries. The ESD distinguishes 18 types of farms, which were in this risk assessment grouped in dairy cattle, beef cattle, pig farming, and poultry. Due to the amount of disinfection in duck farming, which is high (13 times a year) compared to other poultry (1-7 times a year), assessments were made for poultry with and without ducks for comparison. Note that battery cages are not allowed in Europe anymore (Regulation No 1999/74/EC) of the European Parliament). This type of farming was therefore excluded from the poultry group.

Degradation of the active substances during storage in the slurry pit is not taken into account, but degradation in soils was considered by using half-lives for chlorocresol and glycolic acid at 12°C (see appendix I). The concentration in soils after 10 years is calculated in accordance to the Addendum on PT18 and the TAB. Considering that slurry is injected into grassland in The Netherlands, the mixing depth was increased from 5 to 10 cm. PECs were only calculated for the nitrogen emission standards.

Disinfection of footwear by dipping (PT03)

Predicted Environmental Concentrations (PEC) for indoor applications were calculated in accordance with the scenario from the Emission Scenario Document (ESDs) for PT03 by using the scenario for disinfection of footwear and by applying a default size of the dipping bath for footwear of 10 L. The interval between two applications is set to 7 days according to information provided by the applicant.

7.5 Environmental effect assessment

Risk assessment is based on Predicted No-Effect Concentrations (PNECs) for the different compartments which are derived from ecotoxicity data and applying assessment factors. The assessment factor depends on the type of test performed (acute or chronic), the toxicological endpoint (effect concentrations (ECs), no-observed effect concentrations (NOECs), etc), and the number of data and is determined according to the guidance on biocide legislation, Part B+C, volume IV. The PNECs based on the ecotoxicological data applied for the current risk assessment are presented in Table E.3.

Table E.3 Predicted no-effect concentrations for chlorocresol and glycolic acid

PNEC	Lowest endpoint	AF	PNEC	Test/species
chlorocresol				
STP	EC_{10}: 5.7 mg/L	10	0.57 mg/L	Activated sludge respiration inhibition test
freshwater	NOEC: 0.15 mg/L	10	1.50E-02 mg/L	*Oncorhynchus mykiss*
Soil	NOEC: 6.8 mg/kg dwt	10	0.6 mg/kg wwt	Reproduction test on earthworm, agreed on WG IV 2019 ENV7-1
Glycolic acid				
STP	NOEC: 100 mg/L	10	10 mg/L	Activated sludge respiration inhibition test
freshwater	NOEC: 89.6 mg/L	50	1.792 mg/L	*Daphnia magna*
Soil	-	-	0.242 mg/kg wwt	Equilibrium partitioning

dwt: dry weight
wwt: wet weight

Note that data on sediment organisms is not available for both chlorocresol and glycolic acid and therefore the PNEC for sediment has to be derived from aquatic data by applying equilibrium partitioning. However, $PEC_{sediment}$ is also derived by using equilibrium partitioning from $PEC_{freshwater}$ and therefore the ratio PEC/PNEC for freshwater covers that of sediment as well.

Because the logarithmic octanol-water partition coefficients (log K_{ow}) of chlorocresol and glycolic acid are below 3 (2.73 and < -1.20 respectively), the active substances have a low potential for bioaccumulation. PNECs for birds and mammals are therefore not presented.

7.6 Risk characterisation for the environment

For each relevant compartment, PECs are divided by PNECs. Risks are considered unacceptable when PEC/PNEC >1.

7.6.1 Aquatic compartment (incl. sediment) and STP

7.6.1.1 Water and sediment organisms and micro-organisms in the STP

The risk characterisation for the aquatic compartment (freshwater and sediment) indirectly exposed via an STP is presented in Table E.4. for disinfection of livestock farming buildings by spraying and for disinfection of footwear by dipping (PT03) below.

Table E.4 PEC and PEC/PNEC ratios for micro-organisms in the STP and freshwater indirectly exposed due to the disinfection of livestock farming buildings by spraying and for disinfection of footwear by dipping (PT03)

	STP		Fresh water	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)[1]	PEC/PNEC
Disinfection of livestock farming buildings by spraying				
Chlorocresol	5.38E-02	0.094	5.38E-03	0.359
Glycolic acid	1.58E-02	0.002	1.58E-03	<0.001
Total	-	0.096	-	0.360
Disinfection of footwear by dipping				
Chlorocresol	1.34E-03	0.002	1.34E-04	0.009
Glycolic acid	3.92E-04	<0.001	3.92E-05	<0.001
Total	-	0.003	-	0.010

[1] removal of the active substance(s) by sorption onto suspended matter is included.

The PEC/PNEC values for the disinfection of livestock farming buildings by spraying and disinfection of footwear by dipping are all below the trigger value of 1. Hence, the risks to STP, freshwater and sediment are acceptable and the standards for the environment are therefore met.

Indirect emission to estuarine and marine water

Considering that some Dutch STPs discharge to the open sea, indirect exposure of the marine environment is likely. In general, the $PNEC_{marine}$ will be 10 times lower than the $PNEC_{freshwater}$ as marine assessment factors are 10 times higher than for fresh water (Guidance on biocide legislation, Part B+C, volume IV). However, the PEC will be 10 times lower than the $PEC_{freshwater}$ as the dilution factor is 100 instead of 10. Risk ratios are thus expected to be similar, and therefore risk assessment for fresh water also covers risks for the marine environment.

7.6.1.2 Aggregated risk assessment

Because the product is multi-purpose, the environment receives the active substances from different applications and therefore a cumulative risk assessment was made. For the cumulative risk assessment the PEC/PNEC ratios were summarised for simultaneous use for the disinfection of livestock farming buildings by spraying and for disinfection of footwear by dipping (PT03). The cumulative risk assessment was only made for the aquatic compartment (freshwater and sediment) as the highest PEC/PNECs were observed for this compartment. The results of the cumulative risk assessment are summarised in Table E.5.

Table E.5 Aggregated risk assessment for direct emission to the STP. Presented values are the PEC/PNEC ratios for the aquatic compartment.

	Risk ratio for the aquatic compartment
Disinfection of livestock farming buildings by spraying	0.360
Disinfection of footwear by dipping	0.010
Total	0.370

Simultaneous exposure from the intended uses of the product results in an acceptable risk for the aquatic compartment as the total PEC/PNEC for direct release to the sewer is <1. Consequently, simultaneous emission from all intended uses shall not results in unacceptable risks for the most vulnerable compartment.

7.6.1.3 Monitoring data (surface water)

Dutch water boards have a well-established programme for monitoring pesticide contamination of surface waters for which the results are publicly available on-line (www.

Bestrijdingsmiddelenatlas.nl). Here, monitoring data are processed in a graphic format aiming to provide an insight into measured pesticide contamination of Dutch surface waters against environmental standards. The Pesticide Atlas was used to evaluate measured concentrations of pesticides in Dutch surface water, but no data are available regarding the presence of chlorocresol and glycolic acid in Dutch surface water.

7.6.1.4 Surface water intended for the abstraction of drinking water

Biocidal products with the active substances chlorocresol and glycolic acid have been on the market for more than three years. The existing active substances are not included in the list of substances of concern due to their presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb (2023). In addition, the active substances are not included in the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010). Considering this the Ctgb concludes that there are in this case insufficient indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. Thus the standards for surface water destined for the production of drinking water are met.

7.6.2 Terrestrial compartment

7.6.2.1 Soil organisms

The risk characterisation for soils resulting from the disinfection of livestock farming buildings by spraying and equipment and footwear by dipping (PT03) is presented in **Fout! Verwijzingsbron niet gevonden.**6.

Table E.6 PEC_{soil} values and PEC/PNEC ratios for soils due to the disinfection of livestock farming buildings by spraying and for disinfection of equipment and footwear by dipping (PT03)

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC/PNEC
Disinfection of livestock farming buildings by spraying				
Chlorocresol				
Dairy cattle	6.61E-03	0.011	9.56E-03	0.016
Beef cattle	9.46E-02	0.158	7.87E-02	0.131
Pig farming	8.13E-02	0.136	6.82E-02	0.114
Poultry, including duck farming	9.39E-02	0.156	1.36E-01	0.226
Poultry, excluding duck farming	5.23E-02	0.087	4.41E-02	0.074
Glycolic acid				
Dairy cattle	1.38E-03	0.006	2.75E-03	0.011
Beef cattle	1.97E-02	0.081	2.27E-02	0.094
Pig farming	1.69E-02	0.07	1.97E-02	0.081
Poultry, including duck farming	1.96E-02	0.081	3.91E-02	0.162
Poultry, excluding duck farming	1.09E-02	0.045	1.27E-02	0.053
Total				
Dairy cattle	-	0.017	-	0.027
Beef cattle	-	0.239	-	0.225
Pig farming	-	0.206	-	0.195
Poultry, including duck farming	-	0.237	-	0.388
Poultry, excluding duck farming	-	0.132	-	0.127

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC/PNEC
Disinfection of footwear by dipping				
Chlorocresol				
Dairy cattle	4.98E-03	0.008	7.17E-03	0.012
Beef cattle	8.85E-02	0.148	1.28E-01	0.213
Pig farming	1.80E-02	0.03	2.59E-02	0.043
Poultry	1.37E-02	0.023	1.97E-02	0.033
Glycolic acid				
Dairy cattle	1.04E-03	0.004	2.07E-03	0.009
Beef cattle	1.84E-02	0.076	3.68E-02	0.152
Pig farming	3.75E-03	0.015	7.47E-03	0.031
Poultry	2.85E-03	0.012	5.68E-03	0.023
Total				
Dairy cattle	-	0.012	-	0.021
Beef cattle	-	0.224	-	0.365
Pig farming	-	0.045	-	0.074
Poultry	-	0.035	-	0.056
Total values for intended uses				
Dairy cattle	-	0.029	-	0.048
Beef cattle	-	0.463	-	0.590
Pig farming	-	0.251	-	0.269
Poultry, including duck farming	-	0.272	-	0.444
Poultry, excluding duck farming	-	0.167	-	0.183

For the intended use of the product for the disinfection of livestock farming buildings by spraying and footwear by dipping the PEC/PNEC values for soil are below the trigger value of 1. Therefore, the standards for the soil compartment are met.

7.6.2.2 Non-target arthropods (including bees)

The risk assessment for non-target arthropods is considered to be similar to the assessment for soil organisms due to their direct contact with soils. Because the active substances are not expected to have a systemic mode of action, farms are not considered foraging areas for bees, manure is injected into soil secondary exposure of bees through pollen is considered negligible. Hence, the risk for non-target arthropods (excluding bees) is considered not acceptable for the active substances for all intended uses.

7.6.2.3 Groundwater

Due to distribution of manure, transportation of the active substances to groundwater is expected.

Table E.7 summarises the concentrations in porewater after application of manure to grassland and arable land. Concentrations are based on the nitrogen emission standards. Degradation of the active substances in soils between two manure events is considered.

Table E.7 PECgw values due to the disinfection of livestock farming buildings by spraying and for disinfection of equipment and footwear by dipping (PT03)

	Concentration in porewater (µg/L)	
	1st Tier	
	Grassland	Arable land
Disinfection of livestock farming buildings by spraying		
Chlorocresol		

	Concentration in porewater (µg/L)	
	1st Tier	
	Grassland	**Arable land**
Dairy cattle	**4.25E-01**	**6.24E-01**
Beef cattle	**6.08E+00**	**5.13E+00**
Pig farming	**5.23E+00**	**4.45E+00**
Poultry, including duck farming	**6.03E+00**	**8.86E+00**
Poultry, excluding duck farming	**3.36E+00**	**2.88E+00**
Glycolic acid		
Dairy cattle	2.46E-02	4.94E-02
Beef cattle	**3.52E-01**	**4.06E-01**
Pig farming	**3.02E-01**	**3.52E-01**
Poultry, including duck farming	**3.49E-01**	**7.01E-01**
Poultry, excluding duck farming	**1.94E-01**	**2.28E-01**
Total		
Dairy cattle	**4.49E-01**	**6.73E-01**
Beef cattle	**6.43E+00**	**5.54E+00**
Pig farming	**5.53E+00**	**4.80E+00**
Poultry, including duck farming	**6.38E+00**	**9.56E+00**
Poultry, excluding duck farming	**3.56E+00**	**3.11E+00**
Disinfection of footwear by dipping		
Chlorocresol		
Dairy cattle	**3.20E-01**	**4.68E-01**
Beef cattle	**5.69E+00**	**8.32E+00**
Pig farming	**1.16E+00**	**1.69E+00**
Poultry, including duck farming	**8.79E-01**	**1.29E+00**
Poultry, excluding duck farming	**8.79E-01**	**1.29E+00**
Glycolic acid		
Dairy cattle	1.85E-02	3.70E-02
Beef cattle	**3.29E-01**	**6.59E-01**
Pig farming	6.68E-02	**1.34E-01**
Poultry, including duck farming	5.08E-02	**1.02E-01**
Poultry, excluding duck farming	5.08E-02	**1.02E-01**
Total		
Dairy cattle	**3.38E-01**	**5.05E-01**
Beef cattle	**6.02E+00**	**8.98E+00**
Pig farming	**1.22E+00**	**1.82E+00**
Poultry, including duck farming	**9.30E-01**	**1.39E+00**
Poultry, excluding duck farming	**9.30E-01**	**1.39E+00**

Most concentrations of the active substances chlorocresol and glycolic acid in pore water are > 0.1 µg/L. A potential risk for groundwater exists and this was assessed using higher tier method, i.e. FOCUS PEARL. In line with the current national assessment of plant protection products, the Kremsmünster scenario was used in FOCUS PEARL (version 4.4.4).

The concentrations in soil were recalculated to kg/ha in order to be entered in PEARL. It was assumed that this concentration is equally distributed over 1 ha, in a soil layer with an incorporation depth of 0.2 m for arable land, an incorporation depth of 0.05 m for grassland and a density of 1700 kg wwt/m³. From these parameters, application rates expressed in kg /ha in manure in arable land or in grassland were calculated and used in PEARL.

The application dates are 1st March, 23rd April, 15th June and 7th August for grassland (crop alfalfa) and 20 days pre-emergence or in two applications on 15th March and 3rd October for arable land (crop maize or winter cereals respectively), conform TAB agreement ENV-165. A simulation period of 20 years was chosen. The Freundlich sorption exponent (1/n) was set at 1 because no information on concentration dependent sorption was available.

Table E.8. PEC_{GW} for chlorocresol and glycolic acid calculated for the highest concentrations calculated at first tier (please refer to Table E.7), using PEARL

	Concentration in porewater (µg/L)[1]	
	Grassland	**Arable land**
Disinfection of livestock farming buildings by spraying		
2nd Tier - chlorocresol		
Dairy cattle	9.86E-05	8.32E-04
Beef cattle	1.41E-03	6.85E-03
Pig farming	1.21E-03	5.94E-03
Poultry, including duck farming	1.40E-03	1.18E-02
Poultry, excluding duck farming	7.80E-04	3.84E-03
2nd Tier – glycolic acid		
Dairy cattle	0.00E+00	0.00E+00
Beef cattle	0.00E+00	0.00E+00
Pig farming	0.00E+00	0.00E+00
Poultry, including duck farming	0.00E+00	0.00E+00
Poultry, excluding duck farming	0.00E+00	0.00E+00
2nd Tier – total		
Dairy cattle	9.86E-05	8.32E-04
Beef cattle	1.41E-03	6.85E-03
Pig farming	1.21E-03	5.94E-03
Poultry, including duck farming	1.40E-03	1.18E-02
Poultry, excluding duck farming	7.80E-04	3.84E-03
Disinfection of footwear by dipping		
2nd Tier - chlorocresol		
Dairy cattle	7.42E-05	6.25E-04
Beef cattle	1.32E-03	1.11E-02
Pig farming	2.68E-04	2.26E-03
Poultry, including duck farming	2.04E-04	1.72E-03
Poultry, excluding duck farming	2.04E-04	1.72E-03
2nd Tier – glycolic acid		
Dairy cattle	0.00E+00	0.00E+00
Beef cattle	0.00E+00	0.00E+00
Pig farming	0.00E+00	0.00E+00
Poultry, including duck farming	0.00E+00	0.00E+00
Poultry, excluding duck farming	0.00E+00	0.00E+00
2nd Tier – total		
Dairy cattle	7.42E-05	6.25E-04
Beef cattle	1.32E-03	1.11E-02
Pig farming	2.68E-04	2.26E-03
Poultry, including duck farming	2.04E-04	1.72E-03
Poultry, excluding duck farming	2.04E-04	1.72E-03

[1] average concentrations closest to the 80th percentile

The concentrations of both active substances in groundwater are below the 0.1 µg/L criterion for disinfection of livestock farming buildings by spraying and disinfection of footwear by dipping. Conclusively, emission to groundwater is not of concern regarding the active substances.

Therefore, application of the product according to the instructions of use will not result in unacceptable risks for the groundwater compartment.

7.6.2.4 Persistence in soil

The actives substances' half lives in soils (see appendix I) do not exceed the criteria for persistence in soils (180 days). The standard for persistence in soils is therefore met.

7.6.3 Non compartment specific effects relevant to the food chain

7.6.3.1 Bioconcentration

As the log K_{ow} of all active substances is <3 (see appendix I) and the active substances are not highly adsorptive (K_{oc} <20000 L/kg in sediment and/or 50000 L/kg in soils), bioconcentration is not expected according to the trigger values presented in the Guidance on biocide legislation, Part B+C, volume IV. The potential for bioconcentration is considered to be low and no further assessment of secondary poisoning is deemed necessary.

7.6.3.2 Primary and secondary poisoning of birds and mammals

The low BCF (see above) indicates that the risk for birds and mammals is low regarding secondary poisoning. Hence the product meets the standards for the risk to birds and mammals. Primary poisoning is not expected for the intended uses.

7.6.4 Atmosphere

Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimize the risk for stratospheric ozone depletion. There are no indications that chlorocresol contributes to depletion of the ozone layer as the compound is not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Moreover, AOPwin calculates for the active substance a half-life of 15.0 hours in air (OH timeframe 24 hrs/day, 0.5×10^6 OH radicals/cm^3). The calculated half-life is below the trigger of 2 days, which is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. The environmental risk to air is therefore considered acceptable.

A half-life of 123.742 hours in air (based on a 24 hour day OH concentration of 0.5E+6 OH radicals/cm^3) was estimated for glycolic acid via the AOPWIN (v1.90) QSAR model. It exceeds the cut-off value of 2 days, which indicates that the active substance could be of potential concern for long range transport through the atmosphere. However, it is very unlikely that the active substance evaporate to the air due to its low vapour pressure and Henry's Law constant (see appendix I). Additionally, glycolic acid is known to be rapidly biodegraded once deposited and unacceptable risks to terrestrial and aquatic environments are therefore not expected. Consequently, the environmental risk resulting from emission to air is considered acceptable.

7.7 Measures to protect the environment (risk mitigation measures)

The applicant did not include any risk mitigation measures for the environment in the draft WG/GA and PGB-PUB. Additional risk mitigation measures are not required, considering that risks to the environment are acceptable for the intended uses.

7.8 Overall conclusion for the aspect Environment

An authorisation of a biocide in The Netherlands is only possible when the risks related to the product application are acceptable. When used in accordance with the legal Instructions for Use (WG/GA), Prophyl S complies with the environmental standards and is not expected to cause unacceptable risks to the environment. No risk mitigation measures are necessary.

7.9 Data requirements

There are no additional data required.

8 Conclusion

The applicant has proven that Prophyl S under the proposed Legal Conditions for Use and the Directions for Use (WG/GA), is sufficiently effective and that no unacceptable risk is expected to human health, the person who uses the product and the environment.

9 Classification and labelling

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
chlorocresol			
Pictogram:	GHS05 GHS07	Signal word:	Danger
H-statements:	H314	Causes severe skin burns and eye damage.	
	H317	May cause an allergic skin reaction.	
	H412	Harmful to aquatic life with long lasting effects.	
P-statements:	P260	Do not breathe dust/fume/gas/mist/vapours/spray.	
	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].	
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
	P310	Immediately call a POISON CENTER/doctor/…	
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.	
	P501	Dispose of contents/container to	
Supplemental Hazard information:	-		
Child-resistant fastening obligatory?			**Not applicable**
Tactile warning of danger obligatory?			**Not applicable**

10 References

Guidance
Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017.
Technical Agreements for Biocides Environment (ENV). October 2022. European Chemicals Agency, Helsinki, Finland.
SimpleTreat
Struijs J. SimpleTreat 3.0: A model to predict the distribution and elimination of chemicals by sewage treatment plants. National Institute for Human Health and the Environment. RIVM report 719101025, Bilthoven, The Netherlands, 1996.
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Emission scenario documents
Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, JRC Scientific and Technical Reports, Report nr. EUR 25116 EN, Publications Office of the European Union, Luxembourg, 2011
List of Endpoints
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products: Evaluation of active substances. Assessment Report for chlorocresol (CMK). Product-type 3. November 2017, European Chemical Agency, Helsinki, Finland
Surface water
Bakker, J. Biociden in oppervlaktewater voor drinkwaterproductie, National Institute of Public Health and the Environment, RIVM report 601712007, 2010, Bilthoven, The Netherlands.
Database with monitoring data from pesticides in surface water obtained from regional water boards. http://www.bestrijdingsmiddelenatlas.nl
Lijst met probleemstoffen voor de bereiding van drinkwater uit oppervlaktewater, VEWIN, 2023 (http://www.vewin.nl/probleemstoffen)
Other
Regulation (EC) No 1005/2009 of the European Parliament and the Council of 16 September 2009 on substances that deplete the ozone layer.

Appendix I. Input environmental parameters for modelling

	Value	Remarks
parameter	**Chlorocresol**	
molecular weight (g/mol)	142.6	
Melting point (°C)	64.2	
vapour pressure at test temperature (Pa)	1.4E-3	
test temperature vapour pressure (°C)	20	
solubility at test temperature (mg/L)	3400	pH 7
test temperature solubility (°C)	20	
Henry constant (Pa m^3/ mol)	5.87E-05	pH 7, Calculated
test temperature Henry constant (°C)	20	
octanol-water partition coefficient (L/kg)	537	
organic carbon-water partition coefficient (L/kg)	195.6	Experimental value
organic matter-water partition coefficient (L/kg)	113.5	=Koc/1.724
characterisation of biodegradability	Readily biodegradable	
Freundlich exponent	1	not determined experimentally
half-life for biodegradation in fresh water at 12°C (days)	-	
half-life for biodegradation in sediment at 12°C (days)	-	
half-life for biodegradation in soil at 12°C (days)	30	Default value for readily degradable substances
rate constant for biodegradation in STP (/d)	24	
half-life in air (hrs)	15.0	AOPWIN calculation, considering an OH-radicals concentration of 0.5E+6 molec.cm^{-3} and 24 hours

parameter	**Value**	**remarks**
	Glycolic acid	
molecular weight (g/mole)	76.05	
Melting point (°C)	79.5-81	
vapour pressure at test temperature (Pa)	0.05	
test temperature vapour pressure (°C)	20	
solubility at test temperature (mg/L)	>852000	pH 7
test temperature solubility (°C)	20	
octanol-water partition coefficient (L/kg)	< 0.06	pH 7
organic carbon-water partition coefficient (L/kg)	1	Worst-case value for risk assessment purposes based on KOCWIN (v2.01) estimate
Organic matter-water partition coefficient (L/kg)	0.58	=Koc/1.724
characterisation of biodegradability	Readily biodegradable	
Freundlich exponent	1	not determined experimentally
Henry constant (Pa × m^3 × mol^{-1})	4.46E-06	Calculated based on the vapour pressure of 0.05 Pa (at 20°C) and water solubility of 8.52E+5 mg/L (at 20°C)
half-life for biodegradation in fresh water at 12°C (days)	-	
half-life for biodegradation in sediment at 12°C(days)	-	

parameter	Value	remarks
	Glycolic acid	
half-life for biodegradation in soil at 12°C (days)	0.304	Obtained from OECD 307 study, 0.161 (at 20°C)
rate constant for biodegradation in STP (/d)	24	
half-life in air (hrs)	123.742	The UV/Vis absorption spectra of glycolic acid demonstrates no absorption in the visible region (i.e. wavelengths ≥290 nm). A half-life of 123.742 hours in air (based on a 24 hour day OH concentration of 0.5E+6 OH radicals/cm^3) was estimated for glycolic acid via the AOPWIN (v1.90) QSAR model