14672 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 30 april 2014 is van

Schulke & Mayr Benelux B.V.
Oudeweg 8 d
2031 CC HAARLEM

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

desderman pure gel

op basis van de werkzame stof(fen) 2-fenylfenol, ethanol.

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.

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.

- 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.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder “toelatingsinformatie” in bijlage I.

2 WETTELIJKE GRONDSLAG

Besluit	artikel 121, eerste lid, de juncto artikel 44, eerste lid Wet gewasbeschermingsmiddelen en biociden
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 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 5 december 2014

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

14672 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20145256 TB
Type aanvraag:	aanvraag tot toelating van de biocide op basis van niet geplaatste stof(fen) (overgangsrecht)
Middelnaam:	desderman pure gel
Verzenddatum aanvraag:	28 april 2014
Formele registratiedatum: *	14 mei 2014
Datum in behandeling name:	

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

2 Stofinformatie

Werkzame stof	Gehalte
2-fenylfenol	0,1%
ethanol	78,2%

De werkzame stoffen 2-fenylfenol en ethanol zijn opgenomen in het reviewprogramma maar nog niet geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

3 Toelatingsinformatie

Toelatingsnummer:	14672 N
Expiratiedatum:	1 december 2024
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Zowel niet-professioneel als professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Andere vloeistoffen voor directe toepassing

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BIJLAGE II Etikettering van het middel desderman pure gel

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:

Pictogram	GHS02 GHS07
Signaalwoord	GEVAAR
Gevarenaanduidingen	H225 Licht ontvlambare vloeistof en damp. H319 Veroorzaakt ernstige oogirritatie.
Voorzorgsmaatregelen	P210 Verwijderd houden van warmte, hete oppervlakken, vonken, open vuur en andere ontstekingsbronnen. Niet roken. P233 In goed gesloten verpakking bewaren. P305 + P351 + P338 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. P403 + P235 Op een goed geventileerde plaats bewaren. Koel bewaren.
Aanvullende etiketelementen	
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

Niet-professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:

Pictogram	GHS02 GHS07
Signaalwoord	GEVAAR
Gevarenaanduidingen	H225 Licht ontvlambare vloeistof en damp. H319 Veroorzaakt ernstige oogirritatie.
Voorzorgsmaatregelen	P210 Verwijderd houden van warmte, hete oppervlakken, vonken, open vuur en andere ontstekingsbronnen. Niet roken. P233 In goed gesloten verpakking bewaren. P305 + P351 + P338 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. P403 + P235 Op een goed geventileerde plaats bewaren. Koel bewaren.
Aanvullende etiketelementen	
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Ja

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BIJLAGE III WG/GA van het middel desderman pure gel

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel voor
- hygiënische handdesinfectie ter bestrijding van bacteriën (exclusief bacteriesporen), mycobacteriën, gisten en schimmels.
- chirurgische handdesinfectie ter bestrijding van bacteriën (exclusief bacteriesporen), mycobacteriën, gisten, schimmels en virussen.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is bestemd voor professioneel en niet-professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Het middel alleen gebruiken wanneer handdesinfectie noodzakelijk is, niet voor handreiniging.

Algemeen: Zichtbaar verontreinigde handen schoonmaken voorafgaand aan de behandeling. Desderman pure gel onverdund op schone en droge handen opbrengen door middel van handpompje of dispenser.

Hygiënische handdesinfectie: Breng minimaal 3 ml aan op de schone en droge handen. Vervolgens intensief uitwrijven over beide handen waarbij ook de vingertoppen, duimen, nagels en plooien tussen de vingers goed bevochtigd dienen te worden. Zorg dat de handen gedurende de gehele inwerktijd van 30 seconden vochtig blijven. Daarna handen goed laten drogen, niet afspoelen.

Minimale inwerktijd: 30 seconden.

Dosering: minimaal 3 ml middel voor beide handen samen. Bij gebruik dispensers: instellen op 3 ml per slag, 1 slag voor 3 ml.

Chirurgische handdesinfectie: Breng voldoende product (3 x 3 ml) aan op de schone en droge handen en onderarmen. Vervolgens intensief uitwrijven over beide handen en onderarmen en daarbij alle huidplooien goed raken. Zorg dat de handen gedurende de gehele inwerktijd van 90 seconden vochtig blijven. Daarna handen goed laten drogen, niet afspoelen.

Minimale inwerktijd: 90 seconden.

Dosering: 3 x 3 ml middel voor beide handen samen. Bij gebruik dispensers: instellen op 3 ml per slag, 3 slagen voor 9 ml.

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BIJLAGE IV

RISKMANAGEMENT

Contents

1 Introduction

1.1 Applicant

Schulke & Mayr Benelux B.V.
Oudeweg 8 d
2031 CC HAARLEM

1.2 Active substance

Ethanol and 2-phenylphenol

1.3 Product

Desderman pure gel

1.4 Function

This concerns a biocidal product for human hygiene purposes (PT01).

1.5 Background to the application

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

1.6 Intended uses

The proposed field of use of desderman pure gel is the control of
- bacteria (excluding bacterial spores), mycobacteria, yeasts and fungi for hygienic hand disinfection
- bacteria (excluding bacterial spores), mycobacteria, yeasts, fungi and viruses for surgical hand disinfection.

1.7 Packaging details

100ml, 500ml, 1L and 5L in HDPE

2 Identity

H.2.1 Identity of the active substance

Common name	2-phenylphenol
Name in Dutch	*2-fenylfenol*
Chemical name	2-phenylphenol
CAS no	90-43-7
EC no	201-993-5 (EINECS)

The active substance is not yet included in the Union List of Actice Substances according to EU 52/2012. A CAR of the active substance is available (April 2014, eCA Spain).

For data on the identity of 2-phenylphenol is referred to the assessment of Desderman Pure (14463N)

H.2.1 Identity of the active substance

Common name	Ethanol
Name in Dutch	*Ethanol*
Chemical name	Ethanol
CAS no	64-17-5
EC no	200-578-6 (EINECS)

The active substance is not yet included in the Union list of approved substances of EU Regulation 528/2012. A CAR of the active substance is available for PT1, PT2 and PT4.

For data on the identity of ethanol is referred to the assessment of Desderman Pure (14463N)

H.2.2 Identity of the biocidal product

Name	Desderman Pure Gel
Formulation type	AL
Content active substance	Ethanol: 78.2 % w/w 2-Phenylphenol: 0.1 % w/w

Packaging information:

	Material	Size / content	Other information
Professional use	HDPE	100ml, 500ml, 1L and 5L	-
Non-professional use	HDPE	100ml, 500ml, 1L	-

H.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

H.3.1 Physical and chemical properties of the active substance

For data on the physical and chemical properties of 2-phenylphenol and ethanol is referred to the assessment of Desderman Pure (14463N)

H.3.2 Physical and chemical properties of the biocidal product

For data on the physical and chemical properties of Desderman Pure Gel is referred to the assessment of Desderman Pure (14463N)

4 Analytical methods for the technical active substance

For data on the analytical methods is referred to the assessment of Desderman Pure (14463N)

5 Efficacy

5.1 Function

Desderman pure gel is a disinfectant based on 2-phenylphenol (0.1% w/w) and ethanol (78.2% w/w).

5.2 Field of use envisaged

The proposed field of use of desderman pure gel is the control of
- bacteria (excluding bacterial spores), mycobacteria, yeasts and fungi for hygienic hand disinfection
- bacteria (excluding bacterial spores), mycobacteria, yeasts, fungi and viruses for surgical hand disinfection.

These uses are included in PT01.

The product is intended for professional and non-professional use.

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

No new data was submitted. The evaluation of the efficacy of the product desderman pure gel was based on a comparison with data provided for the almost identical product desderman pure that was authorised in the Netherlands under registration number 14436 N. The differences in formulation between desderman pure gel and desderman pure is a minor difference in the non-active part of the formulation. It is not expected that this minor difference will affect the efficacy of the product. Since both products have an identical claim, it can be concluded that desderman pure gel when used in accordance with the proposed label (WG/GA) is effective in controlling bacteria (excluding bacterial spores), mycobacteria, yeasts and fungi for hygienic hand disinfection (30 seconds, 3 ml, clean conditions) and in controlling bacteria (excluding bacterial spores), mycobacteria, yeasts, fungi and viruses for surgical hand disinfection (90 seconds, 3 ml, clean conditions).

5.3.2 Evaluation of the label (WG/GA)

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

5.4 Mode of action

This product contains 2-phenylphenol and ethanol as active substances, which are membrane-active compounds. 2-Phenylphenol (as a phenol) poisons the protoplasm and also damages the cellular membrane of the target organisms. Ethanol (as an alcohol) denatures proteins and solubilizes lipids in the cell membrane of the mentioned target organisms.

5.5 Limitations on efficacy including resistance

5.5.1 Resistance and resistance management strategies

The following information on the possible occurrence of resistance of target organisms to desderman pure gel has been submitted: Regarding desderman pure gel no restrictions related to preventing the development of resistance are known at present.
Considering that the authorisation is done under article 121 of the WGB this is acceptable.

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 desderman pure gel, when used in accordance with the proposed label (WG/GA), is effective in controlling

- bacteria (excluding bacterial spores), mycobacteria, yeasts and fungi for hygienic hand disinfection
- bacteria (excluding bacterial spores), mycobacteria, yeasts, fungi and viruses for surgical hand disinfection.

6 Human toxicology

6.1 Product application

An application has been submitted for the authorisation of the biocidal product desderman pure gel. Desderman pure gel is a ready to use gel containing 78.2% ethanol and 0.1% 2-phenylphenol and intended for hygienic and surgical hand disinfection (PT1) for professional and non-professional use.

6.2 Toxicity of the formulated product

No studies with desderman pure gel 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

Desderman pure gel is a ready to use for hygienic or surgical hand disinfection for professional and non-professional use. In this risk assessment desderman pure gel is compared to the reference product desderman pure (14436 N). The presence of two co-formulants which makes desderman pure gel a gel is the only difference between desderman pure gel and desderman pure. The concentration active substances and intended uses are identical. The two co-formulants do not contribute to the human toxicological classification of desderman pure gel.

Based on the risk assessment for desderman pure, no adverse health effects are expected for the unprotected professional and non-professional users after dermal and respiratory exposure to ethanol and 2-phenylphenol as a result of the application of desderman pure. Considering that the concentration active substances and intended uses are identical, exposure to ethanol and 2-phenylphenol will be the same for both professional and non-professional users and therefore this conclusion can also be applied to the risk assessment for both professional and non-professional users of desderman pure gel.

Based on the risk assessment for desderman pure, no adverse health effects are expected for the general public by indirect exposure to ethanol and 2-phenylphenol by the use of desderman pure. Considering that the concentration active substances and intended uses are identical for desderman pure and desderman pure gel, this conclusion can also be applied to the risk assessment for desderman pure gel.

Based on the risk assessment for desderman pure, a substance of concern (SoC Human Toxicology 1) was identified. However, it was concluded that no adverse health effects are expected for the unprotected (non-)professional user, including the general public, after exposure to SoC Human Toxicology 1 by the use of desderman pure. Desderman pure gel contains the same substance in the same concentration as present in desderman pure and the intended uses are identical, therefore this conclusion can also be applied to the risk assessment for the (non-)professional user of desderman pure gel.

6.4 Overall conclusions for the aspect human health

Based on the comparable risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional and non-professional user after dermal and respiratory exposure to ethanol and 2-phenylphenol as a result of the application of desderman pure gel, when used in accordance to the WG/GA.

Furthermore, when used according to the WG/GA, no adverse health effects are expected for the general public by indirect exposure to ethanol and 2-phenylphenol as a result of the application of desderman pure gel.

7 Environment

7.1 Introduction

Authorisation is requested for the product desderman pure gel containing the active substances ethanol (CAS 64-17-5) and 2-phenylphenol 0.10 %(CAS 90-43-7). The biocidal product concerns a ready-to-use disinfectant of the hands (PT01), intended for use in the public health area. The product is for professional and non-professional use. The intended uses, dosage and concentration of the active substance per treatment are described in table E.1.

Table E.1 Intended use of desderman pure gel, dosage and concentration of the active substance per treatment.

Product		Conc a.s in product (% w/w)		Dosage product	Use concentration active substance (g per treatment)	
		Ethanol	2-phenyl phenol		Ethanol	2-phenyl phenol
desderman pure gel	Hygienic hand disinfection (prof and non-prof)	78.20	0.1	3ml	2.35	0.003
	Surgical hand disinfection	78.20	0.1	3 ml×3 repetitions=9 ml	7.04	0.009

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. The data for the active substance 2-phenylphenol applied in the current risk assessment is presented in appendix I.

7.3 Environmental exposure assessment

7.3.1 Chemistry and/or metabolism

The risk assessment is carried out for the active substances only, considering that the tests available do not indicate formation of metabolites at a level higher than 10% of the active substances.
The active substance ethanol is resistant to hydrolysis, but is readily biodegradable. The breakdown products of ethanol are water and carbon dioxide. These are not considered relevant for the environmental risk assessment as these are natural occurring compounds. Ethanol has a high vapour pressure and therefore is readily released to air. Degradation in air is fast, when considering a DT50 of 24 hours.
2-Phenylphenol is readily biodegradable and no relevant metabolites have been identified. No information on biodegradation in water and sediment is available. 2-Phenylphenol degrades quickly in soils (DT_{50} is 0.21 days at 12℃).

7.3.2 Distribution in the environment

Various phases in the life cycle of a product may cause emissions and environmental exposure. In the risk assessment, emissions from the application phase, service life and waste phase of the product are considered. Emissions from active substance production and product formulation are not part of the risk assessment. Table E.3 summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different applications.

Table E.3. Foreseeable routes of entry into the environment on the basis of the intended use.

Main scenario	Environmental compartments and groups of organisms exposed					
	STP	Freshwater[1]	Saltwater[1]	Soil[2, 3]	Air	Birds and mammals
Hand and skin disinfectant (PT1)	++	+	-	-	++ (Q)	-

++ Compartment directly exposed, + Compartment indirectly exposed, (+) Compartment potentially exposed (but unlikely significant concern due to a.s. hazard data and scale of exposure), - Compartment not exposed, (Q) Qualitative assessment for ethanol, [1] Including sediment, [2] Including groundwater, and soil invertebrates and arthropods, [3] In the Netherlands, surplus sludge of public STPs is not applied for fertilization and soil improvement of agricultural soil. Therefore, exposure of soil and groundwater via STP surplus sludge application is not part of the risk assessment.

According to the instructions of use, the product is left to dry. Because ethanol is volatile, this active substance is emitted to the air. However, residues of 2-phenylphenol will be released to the sewer when hands and skin surfaces are washed. Therefore, the main and major emission route for the proposed uses of the product is release to the sewer and via the STP

to surface water. Since indoor application prevents direct emissions to soil and surface water, direct exposure via these emission routes is not assessed. As STP surplus sludge is not applied as a soil fertiliser, the soil compartment is not exposed. The risks for the soil compartment via STP surplus sludge are therefore not assessed.

7.3.3 Predicted environment concentration calculations

General
For 2-phenylphenol, predicted environmental concentrations (PEC) were calculated using the following Emission Scenario Documents for emission scenarios:
- For professional use: Disinfection of hand and skins: Supplement to the methodology for risk evaluation of biocides, Environmental Emission Scenarios for biocides used as human hygiene biocidal products (product type 1)
- For surgical use: Development of an emission scenario for Product type 01 – hand disinfection, RIVM VSP Advisory report 13969a01.

The available scenario for hand disinfection for professionals assumes that hospital personnel disinfects their hands between each contact with patients and that the active substance is discharged to the sewer when hands are washed. The amount of 2-phenylphenol emitted to the environment after each disinfection depends on the dosage and the concentration of the active substances in the product (see table E.1). Subsequent emission to the environment was based on the default parameters for this specific scenario. The available scenario for hand disinfection by surgeons uses the default settings of 47 operations per hospital per day and 4 persons performing hand disinfection per operation. In addition, it is assumed that the fraction of product released to wastewater is 1. Considering the use concentration of the active substance per treatment (see Table E.1), the emission rate can be calculated by multiplying these values.

For the assessment of hand disinfection by non-professionals currently no distinctive scenario is available. The risk for non-professional use is covered by the risk assessment for hand disinfection by professionals.

The calculated emission rates of the active substances were used to determine concentrations of the active substances in the STP, water, and sediment compartments. These concentrations were calculated with respectively Simple Treat model and the Technical Guidance Document (TGD) by using the default parameters and the active substance’s physical-chemical parameters as listed in Appendix I.

Ethanol is expected to mostly evaporate and emission to the sewer is expected to be negligible. Furthermore, if ethanol reaches the sewer, it will be rapidly degraded. Considering this, PECs for this active substance were not calculated and the risk assessment for ethanol was qualitatively.

7.4 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 Technical Guidance document (version 2003 chapter 3). The PNECs based on the ecotoxicological data applied for the current risk assessment are presented in table E.2.
It is to be expected that most of the ethanol will evaporate and the main emission into the environment will be to air. The risk to air is assessed in a qualitative manner for these active substances and therefore no predicted no effect levels (PNECs) are presented for ethanol. Primary poisoning due to direct exposure to these products is not expected, therefore the risk to birds and mammals is relatively low and these PNECs are not presented.

Table E.2. PNECs for 2-phenylphenol

Compartment	Lowest endpoint	AF	PNEC	Test/species
Aquatic	NOEC: 0.009 mg/L	10	0.9 µg/L	*Daphnia magna*
Sediment	NOEC: 1.85 mg/kg wwt	100	0.0185 mg/kg wwt	*Chironomus riparius*
STP	EC_{50}: 62.2 mg/L	100	0.622 mg/L	Activated sludge

7.5 Risk characterisation for the environment

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

7.5.1 Aquatic compartment (incl. sediment) and STP

Water and sediment organisms and micro-organisms in the STP
Table E.4 shows the PEC/PNEC ratio for the different compartment for all intended uses. Individual PECs are not presented, but can be derived from the PEC/PNEC ratio.

Table E.4. PEC/PNEC ratios

Product	STP		freshwater		sediment	
desderman pure gel	PEC (myg/L)	PEC/PNEC	PEC (mg/L)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Hygienic hand disinfection	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Surgical hand disinfection	<0.001	<0.001	<0.001	0.008	0.001	0.068

No risks have been identified for 2-phenylphenol to micro-organisms in the STP and freshwater and sediment organisms when used in compliance with the directions for use (WG/GA) as the PECs are below the PNEC. The standards for micro-organisms in the STP and freshwater and sediment organisms are met for the professional (also covering the non-professional use) and the surgical use of desderman pure gel.

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 ethanol and 2-phenylphenol in Dutch surface water.

Surface water intended for the abstraction of drinking water
Biocidal products with the active substances ethanol and 2-phenylphenol 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 its presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb. In addition, the active substances are not included on 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 for all products.

7.5.2 Terrestrial compartment

Soil organisms and non-target arthropods (including bees)
For the intended uses of the product, emission of the active substances to soil is not expected. In addition, direct exposure is negligible for bees as the product is used indoors. The exposure of soil organisms and non-target arthropods (including bees) to the active substances is therefore deemed negligible. Hence, the risk for soil organisms and non- target arthropods (including bees) is considered acceptable for the intended uses.

Groundwater
Direct exposure to groundwater is not expected for the intended uses. Therefore the risk for groundwater is considered acceptable for the intended uses

Persistence in soil
The half-lives of the active substances 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.

7.5.3 Non compartment specific effects relevant to the food chain

Bioconcentration
As the log K_{ow} of ethanol is < 3 (-0.31) and therefore the risk for bioconcentration in the proposed uses is considered not relevant. For 2-phenylphenol the log K_{ow} is >3 (3.18). However, the experimental BCF of 21.7 L/kg indicates that the potential for bioconcentration is low. The standards for bioconcentration are met and no further assessment of secondary poisoning is deemed necessary.

Primary and secondary poisoning of birds and mammals

As direct exposure of birds and mammals to the product is not expected, primary poisoning of birds and mammals is not considered relevant. Additionally, as the potential for bioconcentration is low for both active substances, the risk for birds and mammals is low regarding secondary poisoning. Hence, the product meets the standards for the risk to birds and mammals.

7.5.4 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 ethanol and 2-phenylphenol contribute to depletion of the ozone layer as the compounds are not listed as ‘controlled substance’ listed in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Moreover, the calculated half-lives are 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.

7.6 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.

7.7 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), desderman pure gel complies with the environmental standards and will not cause unacceptable effects to the environment. No risk mitigations measures are necessary.

7.8 Data requirements

There are no additional data required.

8 Conclusion

The applicant has proven that desderman pure gel 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 (Art. 121 jo art. 49 first paragraph Dutch 2007 Plant Protection Products and Biocides Act).

9 Classification and labelling

Professional use

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	GHS02	Signal word:	Danger
	GHS07		
H-statements:	H225	Highly flammable liquid and vapour.	
	H319	Causes serious eye irritation.	
P-statements:	P210	Keep away from heat. - No smoking.	
	P233	Keep container tightly closed.	
	P305+P351 +P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
	P403+P235	Store in a well-ventilated place. Keep cool.	
Supplemental Hazard information:	-	-	
Child-resistant fastening obligatory?		**Not applicable**	
Tactile warning of danger obligatory?		**Not applicable**	

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

Remarks:
• P-statements as proposed by the applicant.

Non professional use

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	GHS02	Signal word:	Danger
	GHS07		
H-statements:	H225	Highly flammable liquid and vapour.	
	H319	Causes serious eye irritation.	

P-statements:	P210	Keep away from heat. - No smoking.
	P233	Keep container tightly closed.
	P305+P351 +P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P403+P235	Store in a well-ventilated place. Keep cool.
Supplemental Hazard information:	-	-
Child-resistant fastening obligatory?		**no**
Tactile warning of danger obligatory?		**yes**

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

Remarks:

- For non professional use a tactile warning is required for a category 2 flammable liquid..
- P-statements as proposed by the applicant.

10 References

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 waterboards. http://www.bestrijdingsmiddelenatlas.nl
Lijst met probleemstoffen voor de bereiding van drinkwater uit oppervlaktewater, VEWIN, 2013, http://www.vewin.nl/probleemstoffen
Regulation (EC) No 1005/2009 of the European Parliament and the Council of 16 September 2009 on substances that deplete the ozone layer.
Technical guidance document on risk assessment. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, 2003, Ispra, Italy.

Appendix I. Input parameters for modelling
Identity and physico-chemical properties relevant for environmental assessment

2-phenylphenol	Value	Remarks
molecular weight (g/mole)	170.2	
vapour pressure (Pa)	0.474	
test temperature vapour pressure (℃)	20℃	
solubility at test temperature (mg/L)	560	At pH 7
test temperature solubility (℃)	20℃	
Henry constant (Pa m³/ mol)	0.14E-03	At pH 7
test temperature Henry constant (℃)	20°	
octanol-water partition coefficient (L/kg)	1514	Tested at 22.5℃
organic carbon-water partition coefficient (L/kg)	347 L/kg	(HPLC-studies), 252-392 L/kg (adsorption/desoprtion studies)
half-life for biodegradation in fresh water at 12℃ (days)	stable to hydrolysis, rapid	
half-life for biodegradation in sediment at 12℃ (days)	DT50 1-7 d in water and 2-14 days in sediment	
half-life for biodegradation in soil at 12℃ (days)	DT50 = 30 days	TGD default (worst case) and 1 day (refinement)