HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 TOELATING

Gelet op de aanvraag d.d. 10 mei 2013 (20130820 TBG) van

Schülke & Mayr Benelux B.V.
Prins Bernhardlaan 2 C
2032 HA HAARLEM

tot verkrijging van een toelating als bedoeld in artikel 49, eerste lid, Wet gewasbeschermingsmiddelen en biociden voor de biocide, op basis van de werkzame stof(fen) ethanol en 2-fenylfenol,

desderman pure

gelet op artikel 121, eerste lid, jo. artikel 44, eerste lid, Wet gewasbeschermingsmiddelen en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Toelating

1. Het middel desderman pure is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 14436 N met ingang van datum dezes. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.

2. De toelating geldt tot 1 mei 2024.

1.2 Samenstelling, vorm en verpakking

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

1.3 Gebruik

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

1.4 Classificatie en etikettering

Gelet op artikel 50 Wet gewasbeschermingsmiddelen en biociden worden voorschriften gegeven.

Dit leidt tot de volgende voorschriften:

De aanduidingen, welke moeten worden vermeld, worden hierbij vastgesteld als volgt:

aard van het preparaat: Andere vloeistoffen voor directe toepassing

werkzame stof:	*gehalte:*
ethanol	782 g/kg
2-fenylfenol	1 g/kg

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

PICTOGRAM(MEN)

pictogram:
GHS02-ontvlambaar
GHS07-schadelijk

SIGNAALWOORD

Gevaar

Gevarenaanduidingen

H225	Licht ontvlambare vloeistof en damp.
H319	Veroorzaakt ernstige oogirritatie.

Voorzorgsmaatregelen

P210	Verwijderd houden van warmte/vonken/open vuur/hete oppervlakken. — 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.

Overeenkomstig de Warenwet en artikel 1, 3 en 4 van het Warenwetbesluit veilige verpakking huishoudchemicaliën dienen uitsluitend die verpakkingen van bestrijdingsmiddelen die (mede) voor niet-professioneel gebruik zijn bestemd te worden voorzien van:

- tastbare gevaarsaanduiding.

Behalve de voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:

a. letterlijk en zonder enige aanvulling:
het wettelijk gebruiksvoorschrift
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.

b. hetzij letterlijk, hetzij naar zakelijke inhoud:
de gebruiksaanwijzing
De tekst van de gebruiksaanwijzing is opgenomen in Bijlage I, onder B.
De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.

De vervaldatum (36 maanden na de productiedatum desderman pure) dient op het etiket te worden vermeld.

2 DETAILS VAN DE AANVRAAG

Het betreft een aanvraag tot verkrijging van een toelating van het middel desderman pure (14436 N), een middel op basis van de werkzame stof(fen) ethanol en 2-fenylfenol.

De aanvrager heeft een adequaat aanvraagdossier ingediend. Het Ctgb is in de beoordeling uitgegaan van de wetenschappelijk gezien beste eindpunten.

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel desderman pure op basis van de werkzame stof(fen) ethanol en 2-fenylfenol voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu (artikel 49, Wet gewasbeschermingsmiddelen en biociden).

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, 11 april 2014

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

ir. J.F. de Leeuw
voorzitter

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 11 april 2014 tot toelating van het middel desderman pure, toelatingnummer 14436 N

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 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 hand desinfectie:
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

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 11 april 2014 tot toelating van het middel desderman pure, toelatingnummer 14436 N

RISKMANAGEMENT

Contents **Page**

1. Introduction....2
2. Identity....2
3. Physical and chemical properties....4
4. Efficacy....6
5. Human toxicology....8
6. Environment....13
7. Conclusion....17
8. Classification and labelling....18
9. References....19

1. Introduction

This assessment concerns the biocidal product desderman pure based on the active substances ethanol and 2-phenylphenol. This application has been submitted under the differentiated enforcement policy of biocides.

The assessment includes the following product:

Product	Applicant	PT	Application number
desderman pure	Schülke & Mayr Benelux B.V.	PT 1	20130820 TBG

The active substance ethanol has been notified for product types 1, 2 and 4. The active substance 2-phenylphenol has been notified for product types 1, 2, 3, 4, 6, 7, 9, 10, 13. Ethanol and 2-phenylphenol have not been placed on the Union list of approved substances of EU Regulation 528/2012

2. Identity

a. Identity of the active substance Ethanol

General

Active substance (ISO Common Name)	Ethanol (non-ISO)
Name in Dutch	Ethanol

Identity

Chemical name (IUPAC)	Ethanol
Chemical name (CA)	Ethanol
CAS No	64-17-5
EC No	200-578-6 (EINECS)
Other substance No.	-
Molecular formula	C_2H_6O
Molecular mass	46.07
Structural formula	CH_3-CH_2-OH

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.

Physical and chemical properties of the active substance

Appearance	Colourless clear liquid
Surface tension	21.82 - 21.97 mN/m
Vapour pressure (Pa)	5726 Pa at 19.6 °C 5903 Pa at 25 °C
Henry's law constant (Pa m^3 mol^{-1})	0.53 Pa m^3/mol at 25°C (calculated)
Solubility in water (g/L or mg/L)	1000 g/L at 25 °C (ethanol is indefinitely miscible with water The effect of pH is not required. The pKa is 15.9. Therefore, dissociation is not expected within an environmentally relevant pH range.

Partition coefficient (log P_{OW})	0.31 The effect of pH is not required. The pKa is 15.9. Therefore, dissociation is not expected within an environmentally relevant pH range.
Dissociation constant	No dissociation within an environmentally relevant pH range (pKa 15.9 at 25°C).
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No UV maximum >290 nm

Hazard identification for classification and labelling

Flammability	Flashpoint: Highly flammable Flammability: Not applicable Auto-flammability: 363°C
Oxidising properties	Not oxidising
Explosive properties	Not explosive

Analytical methods for the technical active substance

Adequate analytical methodology is available to determine the content of active substance and significant and/or relevant impurities in the technical active substance.

Overall conclusions active substance

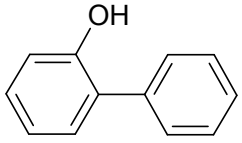
The identity, physical and chemical properties and analytical methods of the active substance are sufficiently described.

b. Identity of the active substance 2-phenylphenol

General

Active substance (ISO Common Name)	2-phenylphenol or *ortho*-phenylphenol (non-ISO)
Name in Dutch	2-fenylfenol or *ortho*-fenylfenol

Identity

Chemical name (IUPAC)	2-phenylphenol [IUPAC]
Chemical name (CA)	No data
CAS No	90-43-7
EC No	EINECS: 201-993-5
Other substance No.	CIPAC: 246
Molecular formula	$C_{12}H_{10}O$
Structural formula	
Molecular mass	170.2 g/mol

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 not available.

Physical and chemical properties relevant to the risk assessment

Appearance	Colourless solid flakes with slight phenolic odour (purity: 99.9%)
Surface tension	58.72 mN/m at 20.1 °C (90% saturated solution).
Vapour pressure (Pa)	0.475 Pa at 20 °C 0.906 Pa at 25 °C
Henry's law constant (Pa m^3 mol^{-1})	0.15 Pa×m^3×mol^{-1} at 20 °C and pH 5 0.14 Pa×m^3×mol^{-1} at 20 °C and pH 7

	0.13 Pa×m^3×mol^{-1} at 20 °C and pH 9
Solubility in water (g/L or mg/L)	pH 5 430 mg/L at 10°C 530 mg/L at 20°C 700 mg/L at 30°C pH 7 450 mg/L at 10°C 560 mg/L at 20°C 730 mg/L at 30°C pH 9 520 mg/L at 10°C 640 mg/L at 20°C 840 mg/L at 30°C
Partition coefficient (log P_{OW})	pH 6.3: 3.18 at 22.5 °C pH 5: 2.4 at 25 °C pH 7: 2.5 at 25 °C pH 9: 2.3 at 25 °C No pH dependence within an environmentally relevant pH range.
Dissociation constant	pK = 9.5 at 20 °C
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Molar absorption (acetonitrile solution): 12800 $L.mol^{-1}.cm^{-1}$ at 245 nm 8200 $L.mol^{-1}.cm^{-1}$ at 267 nm >290nm: no data

Hazard identification for classification and labelling

Flammability	Flashpoint: N/A Flammability: Not highly flammable Auto-flammability: Not self-igniting
Oxidising properties	Not oxidising
Explosive properties	Not explosive

Analytical methods for the technical active substance

Adequate analytical methodology is available to determine the content of active substance and significant and/or relevant impurities in the technical active substance.

Overall conclusions active substance

The identity, physical and chemical properties and analytical methods of the active substance are sufficiently described.

3. Physical and chemical properties

3.1 Identity of the biocidal product

Name	desderman pure
Content active substance	Ethanol: 782 g/kg 2-Phenylphenol: 1 g/kg
Formulation type	AL
Packaging	100ml, 500ml, 1L and 5L HDPE bottle with HPDE (1L, 5L) and PP (100ml, 500ml, 1L) closure

3.2 Physical and chemical properties of the biocidal product

Appearance	Clear colourless solution with alcoholic odour
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not auto flammable
Flashpoint	16°C
pH 1% solution	Expected 5-9
Relative density	0.8304
Storage stability/ Shelf life	36 months in HDPE
Physical and chemical compatibility	Not applicable
Viscosity	Not applicable
Surface tension	Not applicable

3.3 Analytical methods for detection and identification

3.3.1 Analytical methods for analysis of the biocidal product

Preparation (principle of method)	2-Phenylphenol: HPLC-UV (287nm) Ethanol: GC-FID

3.3.2 Residue analytical methods

Adequate residue analytical methodology is available to monitor residues of the biocide taking into account all possible exposure scenarios and the toxicity of the active substance(s).

3.4 Overall conclusions biocidal product

The identity, the physical and chemical properties and the analytical methods of the biocidal product are sufficiently described.

4. Efficacy

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

Field of use envisaged
The proposed field of use of desderman pure is the control of bacteria, yeasts, fungi and viruses for hygienic and surgical hand disinfection.

These uses are included in PT01.

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

Effects on target organisms and efficacy
The available information was sufficient to evaluate the efficacy of desderman pure considering that the authorisation is done under article 121 of the WGB. Several studies testing efficacy were provided for desderman pure, some were considered to be suitable and acceptable.
Bacteria and yeasts
For the intended use of hygienic hand disinfection several tests on bactericidal and yeasticidal efficacy have been provided according to acknowledged standards. Efficacy was demonstrated in quantitative suspension tests (phase 2, step1) with the required standard organisms for bacteria and yeasts at low level soiling conditions of 0.3 g/L bovine albumin (BSA) and a contact time of 30 seconds.
In addition, a handrub test (phase 2, step 2) according to EN1500 - mandatory for PT01 hygienic hand disinfection - was provided, carried out with 15 test persons and a contact time of 30 seconds.The mean log reduction for the product is 4.17 and for the reference product 4.18. Statistical testing at p=0.1 demonstrated that the product is not significantly less effective than the reference product.
To substantiate the claim for surgical hand disinfection, efficacy against natural bacterial flora on hands was demonstrated in a simulated use test (phase 2, step 2) according to EN 12791, carried out with a contact time of 90 seconds.
Mycobacteria
A quantitative suspension test according to EN 14348 was provided that demonstrates efficacy against the mycobacteria *Mycobacterium terrae* and *Mycobacterium avium* at a contact time of 30 seconds with low level soiling conditions of 0.3 g/L BSA and high level soiling conditions for the medical area of 3 g/L BSA + 3 ml/L sheep erythrocytes..
Fungi
A quantitative suspension test according to EN 13624 was provided that demonstrates efficacy against *Aspergillus brasiliensis* at low level soiling conditions of 0.3 g/L bovine albumin and a contact time of 30 seconds..
Viruses
Several tests on virucidal efficacy have been provided according to acknowledged standards. Efficacy was demonstrated in quantitative suspension tests (phase 2, step 1) at low level soiling conditions of 0.3 g/L bovine albumin and a contact time of 15 seconds against Adenovirus type 5 and murine norovirus and 60 seconds for Poliovirus type 1. This is in accordance with the intended use of surgical hand disinfection but not with the intended use of hygienic hand disinfection since the effective contact time against Poliovirus type 1 is 60 seconds in the submitted test while 30 seconds is required.

4.3.1 Evaluation of the label (WG/GA)

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

The intended use against viruses has been removed from the WG/GA for hygienic hand disinfection as no efficacy has been demonstrated for this intended use at the required contact time of 30 seconds.

4.3.4. Mode of action

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

Resistance and resistance management strategies

The following information on the possible occurrence of resistance of target organisms to desderman pure has been submitted:
Regarding desderman pure 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.

Conclusions

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

- in controlling bacteria, yeasts, fungi and viruses for surgical hand disinfection and
- in controlling bacteria, yeasts and fungi for hygienic hand disinfection.

The following use of desderman pure has been removed from the WG/GA:

- Hygienic hand disinfection against viruses.

5. Human toxicology

5.1 Human health effects assessment active substance

Ethanol
Ethanol is an existing active substance, not included in Annex I of Directive 98/8/EG. This assessment is based on the LoEP submitted by the applicants, but also on public data from previous evaluations made at Ctgb for ethanol. A draft CA-report is not yet available.
For ethanol a EPA RED (1995) and a DECOS evaluation (2006) are available.

List of Endpoints
In previous evaluations no threshold values are set to be used for the risk assessment. Threshold values were not required based on the representative use.

At the request of the Minister of Social Affairs and Employment, the Health Council of the Netherlands sets health-based recommended occupational exposure limits for chemicals in air at the workplace in 2006. These recommendations are made by the Council's Dutch Expert Committee on Occupational Standards (DECOS).
Epidemiological studies suggest that consumption levels below 10-12 grams of ethanol per day will probably not cause liver cirrhosis. However, the Committee on Alcohol consumption and reproduction concluded that at these consumption levels effects on fertility and development have been reported. Even long term oral exposure to levels of 1-12 gram ethanol per day might result in effects on the development (like increased incidence of spontaneous abortion, foetal death, pre-term delivery and decreased length of gestation) and fertility, according to the Committee on Alcohol consumption and reproduction. Considering the fact that the maximal alcohol concentration in blood after one (oral) drink is approximately 10-100 times higher than the ethanol concentration in blood after inhalatory exposure to1300 mg/m^3, the committee was of the opinion that a HBC-OCRV (Health based calculated occupational cancer risk value) of 1300 mg/m^3 is low enough to protect against these effects. Other toxic effect manifest themselves after exposure to higher exposure levels. DECOS calculates an HBC-OCRV of 1300 mg/m^3, resulting in a breast cancer risk of 4 additional death cases per 1000 ($4*10^{-3}$) deaths for 40 years.
In addition, DECOS recommends a short term exposure limit (STEL) of 1900 mg/m^3 TWA 15 minutes and a skin notation, as dermal exposure can substantially contribute to the body burden of ethanol.
In the report of DECOS it is stated that, as a worst case estimate, a penetration rate of 0.7 mg/cm^2/h can be used to calculate the internal dose after dermal exposure. From the available meta-analysis and pooled studies, the committee concluded that drinking of one glass of alcoholic beverage per day the internal intake will be 10 gram ethanol.

2-phenylphenol (Biphenyl-2-ol / Ortho-phenylphenol (OPP))
2-Phenylphenol is an existing active substance, not included in Annex I of Directive 98/8/EC. For the active substance an application for inclusion is submitted, for which Spain is the Reporting Member State (RMS). At present a CAR for 2-phenylphenol is not available. However, 2-phenylphenol is included in Annex I of Directive 91/414/EEC (RMS Spain). This assessment is based on the final list of endpoints taken from the EFSA Scientific Report on 2-phenylphenol (2008, 215;1-67, d.d. 19 December 2008).

2-Phenylphenol is not acute toxic by the oral, dermal and inhalation route. 2-Phenylphenol is irritating to skin and eyes and to the respiratory system. 2-Phenylphenol is not a skin sensitizer. 2-Phenylphenol has no genotoxic potential but induced papillomas and transitional cell

carcinomas in urinary bladder of males rats and hepatic tumours in male mice. The NOAEL in a 13-weeks study in the rat was 391 mg/kg bw/day based on abnormal growth in the in the bladder urothelium and kidney damage in males.

For 2-phenylphenol an AEL of 0.4 mg/kg bw/day was derived, based on a NOAEL of 39 mg/kg bw/day for a 2-year oral toxicity study in rats and application of a safety factor 100. Based on a body weight of 60 kg, an AEL of 24 mg/day is calculated.

Both oral and dermal absorption were set at 100%.

Local effects
2-Phenylphenol induces local effects after single exposure (skin, eye and respiratory tract). Moreover, the repeated dose dermal studies showed several signs of dermal irritation (erythema and scaling in one study, in the other one ulcerative lesions were observed), without systemic effects. The dermal NOAEL for local effects was 100 mg/kg bw/day, from a 21-day dermal study in rats. Assuming an body surface area of 400 cm^2, an exposed body surface area of 10% and a 200 gram rat (100 x 0.2 / 40), this results in an area dose of 0.5 mg/cm^2.

Data requirements active substance
No additional data requirements are identified.

5.2 Human exposure assessment active substance

5.2.1 General aspects

desderman pure is a ready to use liquid containing 0.1% biphenyl-2-ol and 78% ethanol.
Intended uses of desderman pure are:
PT1: hygienic and surgical hand disinfection by professionals and non-professionals.

The surgical disinfection is related to applications in the health care sector in which surgical disinfection is required. Hygienic disinfection can be applied in all situations necessary, e.g. hospitals, dental practices, pharmaceutical industries, laboratories and production sites.

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

An assessment of uses and exposure scenarios was made for the products. A summary of uses is given in Table T.1 below.

Table T.1 Summary of uses

	Concentration a.s. in product	Use concentration	PT	Application method	Frequency	Potential secondary exposure
desderman pure	Ethanol: 78.2% 2-Phenylphenol: 0.1%	Hygienic: 1 x 3 ml Surgical: 3 x 3 ml	1[1,2]	Ready to use; hand disinfection	Multiple times daily	Considered negligible

[1] Professional use
[2] Non-professional use

Professional and non-professional users will be exposed to the biocidal product during application.

The vapour pressure of ethanol (5903 Pa at 25°C) is high, therefore inhalation exposure to the active substances is possible. In addition dermal exposure can occur.
The vapour pressure of 2-phenylphenol (about 0.474 Pa at 20°C) indicates that the substance is slightly volatile and that volatilisation can not be ruled out. Therefore, an estimation of respiratory exposure is made. In addition, dermal exposure can occur.

Considering the nature of the use of the products, in hygienic supervised setting, oral exposure of children through hand-mouth contact is not likely to occur and is therefore not further considered.

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

The exposure of non-professional users of desderman pure (see Table 1, paragraph 5.2.2) is identical to the exposure of professional users. However, the non-professional user is exposed less frequent compared to the professional user of desderman pure.

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

As ethanol evaporates quickly, indirect exposure by touching of treated hands or via inhalation is considered negligible. Evaporation of 2-phenylphenol is not to be expected, considering the concentration of 2-phenylphenol in the formulation, secondary exposure by touching of treated hands or via inhalation is considered negligible.

5.3 Human health effects assessment product

5.3.1 Toxicity of the formulated product
No studies with desderman pure 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.

5.3.2 Data requirements formulated product
No additional data requirements are identified.

5.4 Risk characterisation for human health

5.4.1 General aspects
No models for estimation of hand disinfection products are available.

As a reasonable worst-case scenario for professional exposure during hygienic hand disinfection it is assumed that a hospital nurse visits 3 patients per hour. Disinfection is prescribed before and after visiting the patient, so the total number of applications will be about 36 times per day (3/h x 2 times x 6 h = 36). According to the WG/GA a contact time of 30 seconds is considered for hygienic hand disinfection. Thus the total application duration will be 18 minutes per working day. As a reasonable worst case 3 ml per application is used, resulting in 36 x 3 = 108 ml per day.
As a reasonable worst-case scenario for professional exposure during surgical hand disinfection it is assumed that a surgeon disinfects his/her hands and forearms 5 times a day. For surgical hand disinfection each time at least 9 ml is rubbed onto dry hands and forearms for 2 minutes, resulting in 5 x 9 = 45 ml per day for 10 minutes.
Therefore, as the overall worst-case scenario, hygienic hand disinfection will be estimated.

5.4.2 Professional users

Ethanol
For a product based on 95% ethanol (20110771), meant for hygienic hand disinfection, a safe use was calculated (for dermal and respiratory exposure of professionals in hospitals). It was assumed that 108 ml of this product was rubbed into the dry hands as a worst-case scenario. It was concluded that there was no additional risk for human health when compared to the intake by drinking one alcoholic consumption and/or the use of cosmetics as lotions and perfume. Considering the concentration of ethanol in desderman pure (78.2%, as described in Table T.1), and based on the anticipated exposure during hand disinfection, compared to already authorized products based on ethanol, unacceptable health effects for the professional user through use of the desderman pure are not to be expected.

2-phenylphenol
Since 2-phenylphenol is slightly volatile, exposure by inhalation cannot be excluded. In addition dermal exposure will occur. The exposure depends on the number of applications and the room volume together with the duration of staying in the room.
The exposure via inhalation was estimated with the exposure to vapour model in Consexpo v4.1, as a worst-case, using a maximum concentration of 0.1% 2-phenylphenol. Assuming a room volume of 100 m^3 (40 m^2 x 2.5 m) with a ventilation rate of 1.5 per hour, the total amount of 2-phenylphenol, the total application time of 18 minutes and the vapour pressure of the substance, the mean event concentration was estimated to be 0.00087 mg/m^3 for 2-phenylphenol. Considering a inhalation rate of 10 m^3/day, this results in an exposure of 0.87 mg/day. This well below the AEL of 24 mg/day.

Dermal exposure to 2-phenylphenol can occur. Considering the worst-case use of 108 ml per day, spread over 2 hands of in total 820 cm^2 (HEEG 2013, endorsed TMII 2013), a potential dermal exposure of 108 ml/820 cm^2 is considered. Based on 0.1% 2-phenylphenol, and a dermal worst-case absorption of 75% (default) with Consexpo (instant application) an external exposure of 0.000132 mg/cm^2 and an internal exposure of 0.00135 mg/kg bw/day is calculated. This is well below the AEL of 0.4 mg/kg bw/day, and the dermal local AEC of 0.05 mg/cm^2 (assuming a safety factor 10 for intraspecies differences).

5.4.3 Non-professional users, including the general public

The exposure of non-professional users (see Table 1, paragraph 5.2.2) is identical to the exposure of professional users. However, the non-professional user is exposed less frequent compared to the professional user.

5.4.4 Indirect exposure as a result of use

As ethanol evaporates quickly, indirect exposure by touching of treated hands or via inhalation to ethanol is considered negligible. As primary exposure to 2-phenylphenol is very low, indirect exposure to 2-phenylphenol is considered negligible.

5.4.5 Combined exposure
The formulation desderman pure 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. In a worst-case approach the risk indices calculated for both active substances are added. As calculated under

paragraph 5.4.2, no adverse health effects are expected after exposure to a product containing ethanol and 2-phenylphenol.

5.4.6 Substance of Concern

The formulation desderman pure contains 10% of a co-formulant which could be indicated as a substance of concern. For this co-formulant, referred to as SoC Human Toxicology 1, a risk assessment is performed. Based on a comparable risk assessment with a product containing 70% SoC Human Toxicology 1, no adverse health effects are expected for the unprotected professional user, including the general public, after exposure to SoC Human Toxicology 1 by the use of desderman pure.

5.5 Overall conclusions for the aspect human health

Based on this 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, 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.

6. Environment

6.1. Introduction

Authorisation is requested for the product desderman pure containing as active substances ethanol 78.2 % (CAS 64-17-5) and 2-phenylphenol 0.10 % (CAS 90-43-7).
The biocidal product concerns a disinfectant for application in product type PT1 (human hygiene). The product is for professional and non-professional use.

The intended uses are described in table E.1.

Table E.1. Intended uses

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	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

6.2 Environmental profile of active substance

The predicted no effect levels (PNECs) based on the ecotoxicological data 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 (see section 6.3.2), 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/L	100	0.0185 mg/L	*Chironomus riparius*
STP	EC_{50}: 62.2 mg/L	100	0.622 mg/L	Activated sludge

6.3 Environmental exposure assessment

6.3.1 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 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.

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°C).

6.3.2 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 use 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.

6.3.3. Predicted environment concentration calculations

Predicted environmental concentrations (PEC) were calculated using the following Emission Scenario Documents for emission scenarios:

- 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)

The available scenario for hand disinfection assumes that hospital personnel disinfects their hands between each contact with patients and that the active substances are 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. For the assessment of hand disinfection by non-professionals and for surgical hand disinfection, currently no distinctive scenario is available. The risk for non-professional use is covered by the risk assessment for hand disinfection by professionals. The risk for surgical hand disinfection will be assessed using the hygienic hand disinfection scenario.

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.

6.4 Risk characterisation for the environment

6.4.1. Aquatic compartment (incl. sediment) and STP

6.4.1.1. 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	**PEC (myg/L)**	**PEC/PNEC**	**PEC (mg/L)**	**PEC/PNEC**	**PEC (mg/kg wwt)**	**PEC/PNEC**
Hygienic hand disinfection	1.0E-3	<0.001	4.5E-6	0.005	3.7E-5	0.002
Surgical hand disinfection	1.7.E-3	0.003	1.4E-5	0.015	1.1E-4	0.006

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 non professional and professional use (both hygienic and surgical hand disinfection) of desderman pure. No risk mitigation are required.

6.4.1.2. Surface water intended for the abstraction of drinking water

The active substances ethanol and 2-phenylphenol are 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. None of the active substances are included on the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010). From 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 this product.

6.4.2. 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, yet, is aimed to minimize the risk for stratospheric ozone depletion. There are no indications that 2-phenylphenol contributes to depletion of the ozone layer as the calculated half life are for both below the trigger of < 2 days. Furthermore, 2-phenylphenol is not listed as 'controlled substance' listed in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. The risk to air is therefore considered acceptable.

6.4.3. Terrestrial compartment

6.4.3.1. Soil organisms and non target arthropods (including bees)

For the intended use of the product, emission of the active substance to soil is not expected. Direct exposure is negligible for bees as the products are used indoors. The exposure of non target arthropods and soil organisms (including bees) to 2-phenylphenol is therefore deemed negligible. Hence, the risk for soil organisms and non target arthropods (including bees) is considered acceptable for the intended use.

6.4.3.2. Groundwater

Assessment of the drinking water criterion defines that the concentration of the active substance and the relevant metabolites in groundwater for the preparation of drinking water needs to be < 0.1 µg/L. No risk is expected for 2-phenylphenol as the active substances are not directly or indirectly released to soils. Hence, the risk for groundwater is considered acceptable.

6.4.3.3. Persistence in soil

2-Phenylphenol is considered readily biodegradable. Half live in soil for 2-phenylphenol is 0.21 at 12°C, and therefore the product meets the persistence criteria (<180 days). Note that emission to soils is not expected as the active substances are not released to soils

6.4.3. Non compartment specific effects relevant to the food chain

6.4.4.1. Bioconcentration

The experimental BCF of 2-phenylphenol (whole fish) is 21.7 L/kg, indicating that 2-phenylphenol has a low potential for bioconcentration. Hence desderman pure meets the standard for bioaccumulation.

6.4.4.2. 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.

6.5 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.

6.6 Overall conclusion for the aspect Environment

When used in accordance with the legal Instructions for Use (WG/GA) desderman pure complies with the environmental standards and will not cause unacceptable effects to the environment. No risk mitigations are required.

7. Conclusion

The proposed field of use of desderman pure is the control of bacteria, yeasts, fungi and viruses for hygienic and surgical hand disinfection.
These uses are included in PT01. The product is intended for professional and non-professional use.

The intended use against viruses has been removed from the WG/GA for hygienic hand disinfection as no efficacy has been demonstrated for this intended use at the required contact time of 30 seconds.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants:

- in controlling bacteria, yeasts, fungi and viruses for surgical hand disinfection and
- in controlling bacteria, yeasts and fungi for hygienic hand disinfection.

when used as described on the Legal Conditions for Use and the Directions for Use (WG/GA).
The authorised uses as mentioned on the WGGA fall within product type 1.

8. Classification and labelling

Proposed for classification and labelling for the formulation
Based on Reg. (EC) 1272/2008:

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.

9. References

ESD	Supplement to the methodology for risk evaluation of biocides Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1), European Commission DG ENV / RIVM, January 2004
Regulation (EC) no 1005/2009	Regulation (EC) No 1005/2009 of the European Parliament and the Council of 16 September 2009 on substances that deplete the ozone layer.
TGD	Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances; Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, Ispra, Italy, 2003.
Pesticide Atlas	www.pesticidesatlas.nl
VEWIN	http://www.vewin.nl/Probleemstoffen/Pages/default.aspx
RIVM	Biociden in oppervlaktewater voor drinkwaterproductie., National institute for public health and the environment, RIVM-report 601712007/2010, Bilthoven, The Netherlands.
Monitoring	Körner, W., Bolz, U., Sußmuth, W., Hiller, G., Schuller, W., Hanf,V., and Hagenmaier, H. 2000. Input/output balance of estogenic active compounds in a major municipal sewage plant in Germany. Chemospere 40, 1131-1142.
Ctgb	Information about the active substance from the Ctgb database