HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 28 februari 2017 is van

Deb-STOKO Europe GmbH
Bäkerpfad 25
D-47805 KREFELD
Germany

een uitbreiding toelating biocide ontvangen voor het middel

Deb InstantFOAM Complete

op basis van de werkzame stof ethanol.

HET COLLEGE BESLUIT tot uitbreiding 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.
- 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	art 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

Beoordeeld is de uitbreiding van het toegelaten gebruik in de hygiënische handdesinfectie met een beperkte virusclaim bij een contacttijd van 30 seconden (professioneel gebruik) en een volledige virusclaim met een contacttijd van 40 seconden (professioneel en niet-professioneel gebruik).

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. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Ede, 5 oktober 2018

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

Ir. J.F. de Leeuw

14946 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20170331 UB
Type aanvraag:	uitbreiding toelating biocide
Middelnaam:	Deb InstantFOAM Complete
Verzenddatum aanvraag:	20 februari 2017
Formele registratiedatum: *	30 maart 2017
Datum in behandeling name:	2 augustus 2018

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

2 Stofinformatie

Werkzame stof	Gehalte
ethanol	80 %

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

3 Toelatingsinformatie

Toelatingsnummer:	14946 N
Expiratiedatum:	1 november 2025
Afgeleide of parallel:	Uitbreiding middel
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel en niet-professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Andere vloeistoffen voor directe toepassing

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BIJLAGE II Etikettering van het middel Deb InstantFOAM Complete

Professioneel gebruik		
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.
	P337 + P313	Bij aanhoudende oogirritatie: een arts raadplegen.
	P404	In gesloten verpakking bewaren.
	P501	Inhoud/verpakking afvoeren naar ....
Aanvullende etiketelementen		
Kinderveilige sluiting verplicht		Nee
Voelbare gevaarsaanduiding verplicht		Nee

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BIJLAGE III WG/GA van het middel Deb InstantFOAM Complete – professional use

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van

- bacteriën (exclusief bacteriesporen), mycobacteriën, gisten en omkapselde en een beperkt aantal niet-omkapselde virussen* bij een inwerktijd van 30 seconden voor hygiënische handdesinfectie;

- bacteriën (exclusief bacterie sporen), mycobacteriën, gisten en virussen (omkapselde en niet-omkapselde virussen)* bij een inwerktijd van 40 seconden voor hygiënische handdesinfectie;

- bacteriën (exclusief bacteriesporen), mycobacteriën, gisten, schimmels en virussen (omkapselde en niet-omkapselde virussen)* voor chirurgische handdesinfectie.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

*Een beperkte en volledige virusclaim is gedefinieerd in EN14885 (2016). Tegen welke virussen dit middel werkzaam is, is te vinden op www.ctgb.nl onder ‘uitleg virusclaim’.

B.
GEBRUIKSAANWIJZING

Deb InstantFOAM Complete is een handdesinfectiemiddel op alcoholbasis voor desinfectie van de handen zonder water.

Aanbrengen op schone en droge handen. Indien nodig, meerdere keren per dag aanbrengen.

***Voor hygiënische handdesinfectie*:**
3 tot 3,5 ml aanbrengen en goed inwrijven in alle delen van de handen. Zorg ervoor dat het schuim continu in contact is met de huid gedurende de minimale inwerktijd.

Minimale inwerktijd:
Voor bestrijding van
- bacteriën, mycobacteriën en gisten: 30 seconden
- omkapselde virussen en een beperkt aantal niet-omkapselde virussen: 30 seconden
- virussen (omkapselde en niet-omkapselde virussen): 40 seconden

Dosering: 3 tot 3,5 ml voor beide handen samen. Zie etiket voor doseringsvolume van de pomp.

***Voor chirurgische handdesinfectie*:**
3 tot 3,5 ml aanbrengen en telkens opnieuw aanbrengen zolang als nodig is om de handen gedurende de inwerktijd vochtig te houden.

Minimale inwerktijd: 3 minuten.

Dosering: 3 tot 3,5 ml voor beide handen samen, zo nodig herhalen. Zie etiket voor doseringsvolume van de pomp.

BIJLAGE III WG/GA van het middel Deb InstantFOAM Complete – non-professional use

A.

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van bacteriën (exclusief bacterie sporen), mycobacteriën, gisten en virussen (omkapselde en niet-omkapselde virussen)* voor hygiënische handdesinfectie.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor niet-professioneel gebruik.

*Een volledige virusclaim is gedefinieerd in EN14885 (2016). Tegen welke virussen dit middel werkzaam is, is te vinden op www.ctgb.nl onder ‘uitleg virusclaim’.

B.

GEBRUIKSAANWIJZING

Deb InstantFOAM Complete is een handdesinfectiemiddel op alcoholbasis voor desinfectie van de handen zonder water.

Het middel alleen gebruiken wanneer handdesinfectie noodzakelijk is, niet voor handreiniging. Aanbrengen op schone en droge handen. Indien nodig, meerdere keren per dag aanbrengen.

***Voor hygiënische handdesinfectie*:**
3 tot 3,5 ml aanbrengen en goed inwrijven in alle delen van de handen. Zorg ervoor dat het schuim continu in contact is met de huid gedurende de minimale inwerktijd.

Minimale inwerktijd:
Voor bestrijding van:

- bacteriën, mycobacteriën en gisten: 30 seconden.
- virussen: 40 seconden.

Dosering: 3 tot 3,5 ml voor beide handen samen. Zie etiket voor doseringsvolume van de pomp.

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BIJLAGE IV

RISKMANAGEMENT

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1 Introduction

1.1 Applicant

Deb-STOKO Europe GmbH
Bäkerpfad 25
D-47805 KREFELD
Germany

1.2 Active substance

ethanol

1.3 Product

Deb InstantFOAM Complete

1.4 Function

Disinfectant (PT01)

1.5 Background to the application

This concerns an extension of an existing authorisation.

1.6 Intended uses

Deb InstantFOAM Complete is currently authorised (14946 N) as a ready to use product for the control of:

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

The current application concerns an extension of the claim with a limited virus claim at a contact time of 30 seconds (professional use) and a full virus claim at a contact time of 40 seconds (professional and non-professional use) for hygienic hand disinfection. In addition, the applicant requests to remove the authorised use against fungi for surgical hand disinfection.

1.7 Packaging details

HDPE (1L and 400mL) en PET (47mL and 250 mL)

2 Identity

The identity of Deb InstantFOAM Complete has not been changed, and therefore this assessment was not performed.

3 Physical and chemical properties

The physical and chemical properties of Deb InstantFOAM Complete have not been changed, and therefore this assessment was not performed.

4 Analytical methods for detection and identification

The analytical methods for detection and identification of Deb InstantFOAM Complete have not been changed, and therefore this assessment was not performed.

5 Efficacy

5.1 Function

Deb InstantFOAM Complete is a skin disinfectant based on ethanol (80%).

5.2 Field of use envisaged

Deb InstantFOAM Complete is currently authorised (14946 N) as a ready to use product for the control of:

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

The current application concerns an extension of the claim with a limited virus claim at a contact time of 30 seconds (professional use) and a full virus claim at a contact time of 40 seconds (professional and non-professional use) for hygienic hand disinfection. In addition, the applicant requests to remove the authorised use against fungi for surgical hand disinfection.

These uses are included in PT01

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

To substantiate the proposed extension of use with limited and full virucidal efficacy for hygienic hand disinfection at different contact times, one study was provided and evaluated.
The study is summarised in Table 1.

Table 1. Summary of studies assessed

Test (version) Phase, step	**Test organism**	**Test parameters**	**Results***
Mycobacteria			
EN 14348 (2005) 2,1	*Mycobacterium terrae* *Mycobacterium avium*	**Concentration (%):** 10%, 50%, and 80% **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 seconds **Test temperature:** 20°C	**log R>4.25:** 80 % Clean 30 s 20°C
Viruses / Bacteriophages			
EN 14476 (2013+A1 :2015) 2,1	*Poliovirus*	**Concentration (%):** 10%, 80%, and undiluted (97%) **Interfering substances:** 0.3 g/L BSA **Contact time:** 30, 40, and 50 seconds 30 minutes **Test temperature:** 20°C	**log R>4.25:** 97 % Clean 40 s 20°C

* For phase 2, step 1 studies the most challenging test conditions resulting in the required lg reduction are given

The available information was sufficient to evaluate the efficacy of the proposed extension of Deb InstantFOAM Complete with a claim for limited virucidal efficacy at a contact time of 30 seconds, and full virucidal efficacy at a contact time of 40 seconds for hygienic hand disinfection, considering evaluation is done under article 121 of the WGB.
For the current authorisation two efficacy studies with resp. Adenovirus Type 5 and murine norovirus were evaluated that demonstrated sufficient efficacy at clean conditions and a contact time of 30 seconds. This is sufficient to demonstrate limited spectrum virucidal activity. In addition, the new provided test with Poliovirus is sufficient to substantiate the claim for full virucidal efficacy at a contact time of 40 seconds.

In addition to the study with poliovirus, one study with *Mycobacteria terrae* and *M. avium* was provided. Although mycobacteria were already authorised organisms, it appears that the tests previously submitted were only sufficient for a tuberculocidal claim. In response, the applicant provided a test with both *M. avium* and *M. terrae* to justify the mycobactericidal claim. This test is also summarised in table 1 above. Sufficient mycobactericidal efficacy was demonstrated at a contact time of 30 seconds.

Overall it can be concluded that the provided studies show that Deb InstantFOAM Complete complies with the criteria for log reduction for viruses and mycobacteria when used in accordance with the instructions described on the WG/GA.

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.
Separate WG/GA's are available for professional and non-professional use.
The use against fungi (optional organism) will be removed from the WGGA on request of the applicant.

5.4 Mode of action
Ethanol exhibits an unspecific mechanism of effect. It affects the outer cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular activity resulting in the cell's death.

5.5 Limitations on efficacy including resistance

5.5.1 General limitations
No limitations are mentioned.

5.5.2 Resistance
Due to the non-specific nature of the mode of action it is unlikely that target organisms will be able to develop resistance to ethanol.

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 Deb InstantFOAM Complete, when used in accordance with the proposed label (WG/GA), is effective - both for professional and non-professional use - for control of:

- viruses (enveloped and non-enveloped) at a contact time of 40 seconds for hygienic handrub;

- enveloped and a limited number of non-enveloped viruses at a contact time of 30 seconds for hygienic handrub;
- mycobacteria for hygienic and surgical hand disinfection at a contact time of 30 seconds.

6 Human toxicology

Human health effects assessment active substance
The active substance ethanol is considered a bulk chemical. Therefore, limited data is required because the properties of ethanol are well documented. The applicants are allowed to use the IUCLID database of this active substance.

For ethanol also a first draft CAR is available for PT 1, 2 and 4. This assessment is based on the List of Endpoints (LoEP) from the first draft CA-report (July 2013) for which Greece is the Reporting Member State. Since the active substance is still in the process of evaluation/discussion, the toxicological profile below should be regarded as provisional. 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:	>90 %
Rate and extent of dermal absorption:	0.4 – 2 % from biocidal solutions with 55-95 % ethanol during an exposure typical for disinfectant application
Distribution:	Ethanol is rapidly transported throughout the body. The volume of distribution is equivalent to the total body water. Equilibrium is reached 1-1.5 hours after ethanol consumption.
Potential for accumulation:	No
Rate and extent of excretion:	90-98 % by oxidation to CO2 and H2O 1-5 % exhaled as ethanol via the lungs 0.5-2 % via urine up to 0.5 % via sweat
Toxicologically significant metabolite(s)	Acetaldehyde

Acute toxicity

Rat LD50 oral	> 6000 mg/kg b.w.	
Rat LD50 dermal	> 20000 mg/kg b.w. (rabbit)	
Mouse LC50 inhalation	39 mg/L	
Skin irritation	Non irritant	
Eye irritation	Irritant	**Eye Irritation Cat.2; H319**
Skin sensitization (test method used and result) * M&K test	Not a skin sensitiser*	

Repeated dose toxicity[1]

Species/ target / critical effect	Rat / multiple tissues (liver, nerve) / tissue damage
Lowest relevant oral NOAEL / LOAEL	Subchronic: NOAEL = 3100 mg/kg b.w./day (rat) Chronic: LOAEL= 1000 mg/kg b.w./day (rat)

[1] The available data are not relevant for the hazard identification and the setting of reference values for the risk assessment of ethanol for the intended use as a biocide.

Lowest relevant dermal NOAEL / LOAEL	No data. Not required.
Lowest relevant inhalation NOAEL / LOAEL	Not adequate data.

Genotoxicity[2]	Genotoxic both *in vitro* and *in vivo* (positive in dominant lethal assays, induction of aneuploidy in germinal cells) following exposure to very high, markedly toxic doses

Carcinogenicity[2]

Species/type of tumour	<u>Oral exposure</u> Rat: endocrine (pituitary) tumours Mouse: hepatocellular adenomas & adenomas/ carcinomas combined
lowest dose with tumours	<u>Oral exposure</u> Rat: 1000 mg/kg b.w./day Mouse: 7300 mg/kg b.w./day

Reproductive toxicity[2]

Species/ Reproduction target / critical effect	<u>Oral exposure</u> Mouse: male reproductive system: decreased sperm motility & decreased reproductive organ weight / offspring toxicity: reduced live litter size & compromised growth during lactation
Lowest relevant reproductive NOAEL / LOAEL	LOAEL = 20700 mg/kg b.w./day (reproductive and offspring, mouse)

Developmental toxicity

Species/Developmental target / critical effect	<u>Oral exposure</u> Mouse & rat: fetotoxicity (increased resorptions incidence) and teratogenicity (limb, eye, brain, heart and urogenital malformations) Rabbit / no developmental effect
Lowest relevant developmental NOAEL / LOAEL	LOAEL = 15000 mg/kg b.w./day (mouse, oral) LOAEL = 7900 mg/kg b.w./day (rat, oral)

Neurotoxicity / Delayed neurotoxicity[2]

Species/ target/critical effect	<u>Oral exposure</u> Rat: peripheral nervous system / demyelination
Lowest relevant NOAEL / LOAEL.	LOAEL = 1000 mg/kg bw/d (chronic, oral, rat)

Other toxicological studies	-
Medical data[2]	• Acute oral exposure to ethanol (BAC = 200-300 mg/L) can impair the central nervous system. • Short-term inhalatory exposure to ethanol for one hour will not cause irritation or other effects at concentrations below

[2] The available data are not relevant for the hazard identification and the setting of reference values for the risk assessment of ethanol for the intended use as a biocide.

	1900 mg/m3. Concentrations higher than 3000 mg/m3 might result in transient cough, dry throat and tickling of the nose. Levels over 40000 mg/m3 (21000 ppm) are suffocating. • Based on available human experience from the widespread use of ethanol in cosmetics and in skin antiseptic formulations, ethanol is not considered a skin or respiratory allergen and there is no concern for skin irritancy • Concentrated ethanol solution is very irritating to the eyes. • Long-term consumption of large doses of alcohol causes toxic effects in almost all organ systems. The most prominent non-carcinogenic critical effect in humans appears to be liver cirrhosis as the irreversible and very serious (usually fatal) end stage of a liver disease process. Consumption of up to 10-12 g ethanol/day both for men and women is regarded as relatively safe. • Consumption of alcoholic drinks has been shown to increase the incidence of tumours in the oral cavity, pharynx, larynx, oesophagus, liver and breast cancer. • High consumption of ethanol-containing beverages during pregnancy, is associated with developmental toxicity. • Intake of less than 10 g ethanol per day has an adverse effect on reproduction characterised by decreased male and female fertility, increased incidence of spontaneous abortion, foetal death, preterm delivery, decreased length of gestation. • The central nervous system is a major target of ethanol toxicity and degeneration.

Summary	Value	Study	Safety factor
Non-professional user			
ADI (acceptable daily intake, external long-term dose - if residues in food or feed)	Not relevant		
AEL (acceptable exposure level resembling the AOEL)*	960 mg/m3	comparison of occupational exposure with the background exposure to ethanol (DECOS, 2006; OECD, 2004)	
ARfD (acute reference dose)	Not relevant		
Professional user			
Reference value for inhalation (proposed OEL)	960 mg/m3	comparison of occupational exposure with the background	

	exposure to ethanol (DECOS, 2006; OECD, 2004)
Reference value for dermal absorption	Not applicable. Limited exposure by the dermal route due to the phys/chem. properties of ethanol.
	Not applicable. Limited exposure by the dermal route due to the phys/chem. properties of ethanol.

** DECOS: Most human data on the effects of long term exposure to ethanol concern the consumption of alcoholic beverages. Several epidemiological studies reported that the dose-effect curve for ethanol and overall mortality appears to be U- or J-shaped; beneficial effects due to the consumption of low levels of ethanol are observed, like a reduced risk of coronary heart disease. The most critical non-carcinogenic effects in humans appear to be liver cirrhosis and effects on the development of offspring and fertility. 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. With respect to carcinogenicity the most relevant types of cancers appear to be breast and colorectal cancer. All the available data concern the association of the consumption of alcoholic beverages and these cancer types. Pooled studies or meta-analyses can be used to estimate the cancer risk in a quantitative way. Adequate studies are only available for breast cancer, resulting in a risk ratio of 1.1 per each 10 grams of ethanol per day consumed. Such studies are not (yet) available for colorectal cancer.*
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. 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 to 1300 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 The Netherlands the following legal exposure limit values have been set for ethanol: 8-h TWA of 260 mg/m^3 and 15-min STEL of 1900 mg/m^3. These values will be used in the risk assessment for long-term and acute exposure, respectively
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.

Local effects
Ethanol produces local effects after a single exposure (eye irritation), but these local effects are covered in the risk assessment/management by means of assignment of H- and P-phrases. Ethanol does not produce local effects after repeated exposure.

Data requirements active substance
No additional data requirements are identified.

6.1 Human exposure assessment active substance

6.1.1 General aspects

An extension of the application has been submitted for the biocidal product Deb InstantFOAM Complete ready-to-use liquid containing 80% w/w ethanol. The product has been already authorised (14946 N) for the control of bacteria, tuberculosis bacteria and viruses of hands (PT01) for both hygienic and surgical disinfection by professional and non-professional users. The application for extension concerns the addition of claim against mycobacteria, yeast and virus (disinfection duration 40 seconds) to the current claim (disinfection duration 30 sec).

The formulation Deb InstantFOAM Complete is for both professional and non-professional use.

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

Professional users are dermally exposed to ethanol by the use of Deb InstantFOAM Complete. The vapour pressure and Henry's Law Constant of ethanol are considered high (5903 Pa at 25 °C and 0.53 Pa m^3 mol^{-1}, respectively), therefore inhalation exposure to ethanol is highly likely.
As the product is an hand disinfectant and for professional use, oral exposure is considered negligible.

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

The exposure of non-professional users is identical to the exposure of professional users. However, the non-professional user is exposed less frequent compared to the professional user. Therefore the risk assessment for the professional can be considered as worst case.

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

As ethanol evaporates quickly, indirect dermal exposure by touching of treated hands and skin or via inhalation is considered negligible.

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

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

No new toxicological studies with Deb InstantFOAM Complete have been submitted. As there is no alteration in the composition, the classification and labelling of the authorised formulation, which has been prepared based on the calculation method described in Annex I of Regulation 1272/2008/EC remain unchanged.

6.2.2 Data requirements formulated product

No additional data requirements are identified.

6.3 Risk characterisation for human health

6.3.1 General aspects

Deb InstantFOAM Complete is intended to be used for disinfection of hands for both hygienic and surgical disinfection by professionals and for hand disinfection by non-professional users. Deb InstantFOAM Complete is an already authorized product (14946 N) and the exposure duration is the only difference between the new extension of application (40 sec vs. 30 sec, respectively) that has an influence on the risk assessment for human health, as the intended uses and compositions are identical.

6.3.2 Professional users

Based on Recommendation no. 1 of the BPC Ad hoc Working Group on Human Exposure (March 2014) a harmonized frequency in use of hand disinfection of 25 applications per day can be taken as a realistic default value for professional exposure during hygienic hand disinfection. A surgical hand disinfection may include both hands and forearms and is applied for longer duration, but due to the specific situation it is carried out less frequently than a hygienic hand disinfection e.g. four times per working day if it is assumed that a medical professional carries out four surgeries. So the exposure scenario for hygienic hand disinfection also reflects the situation for surgical hand disinfection.

In the risk assessment for Deb InstantFOAM Complete (14946 N) original application, no adverse health effects were expected for the unprotected professional user after dermal and respiratory exposure to ethanol as a result of the application of Deb InstantFOAM Complete during 30 seconds contact time x 25 applications per day.

Exposure via inhalation was estimated with the exposure to vapour model in Consexpo v4.1 (constant rate), assuming a room volume of 100 m^3 with a ventilation rate of 1.5 per hour, an amount of 3.5 ml Deb InstantFOAM Complete per application (87.5 ml = 73.9 g using a density of 0.844 g/ml), an exposure duration of 12.5 minutes (= contact duration of 30 seconds x 25 applications per day), an emission duration of 6 hours, and the vapour pressure of the active substance of 5903 Pa. The estimated ethanol concentration 9 mg/m^3 was well below OEL of 960 mg/m^3 (resulting risk index 9/960 < 0.01) for ethanol.

Considering the very low risk index of <0.01 in the original authorisation, the new application with a prolonged contact time of 40 second will not result in the exceedance of ethanol air concentration above the OEL of 960 mg/m^3. No adverse health effects are expected from inhalation exposure for the unprotected users after using Deb InstantFOAM Complete for hand disinfection with contact time of 40 seconds.

Regarding dermal exposure, in the original authorisation the resulting total exposure was calculated to be 25 x 3.5 ml = 87.5 ml per day. Taking the relative density of 0.844 g/ml and a penetration of 0.4-2% into account, an internal dose after dermal exposure of 0.2-1.2 g was calculated. As this internal dermal exposure is 2-12% of the ethanol intake by drinking one glass of alcohol (10 gram ethanol), and it was concluded that no adverse effects are expected via dermal exposure to ethanol contained in Deb InstantFOAM Complete. As the application rate and use remains the same, no adverse health effects are expected from idermal exposure for the unprotected users after using Deb InstantFOAM Complete for hand disinfection with contact time of 40 seconds.

6.3.3 Non-professional users, including the general public

It is expected that the non-professional user will apply less frequently the hand disinfectant compared to the professional user. Therefore, the risk assessment for the professional user covers also the non-professional use. Based on that risk assessment, no adverse health effects are expected for the non-professional user from exposure to ethanol by using Deb InstantFOAM Complete for hand disinfection with contact time of 40 seconds.

6.3.4 Indirect exposure as a result of use

As safe use was concluded for the unprotected professional user after dermal exposure to ethanol by using Deb InstantFOAM Complete no adverse health effects are expected for the general public.

6.3.5 Combined exposure

Deb InstantFOAM Complete contains only one active substance and it is not described that it should be used in combination with other formulations.

6.3.6 Substances of concern

The formulation Deb InstantFOAM Complete does not contain potential substances of concern.

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 unprotected professional user and non-professional users, after dermal and respiratory exposure to ethanol as a result of the application of Deb InstantFOAM Complete for hand disinfection with contact time of 40 seconds, when used in accordance to the WG/GA.

When used in accordance to the WG/GA, no adverse health effects are expected for the general public by indirect exposure to ethanol as a result of the application of Deb InstantFOAM Complete.

7 Environment

7.1 Introduction

Deb InstantFOAM Complete containing Ethanol (CAS: 64-17-5) as the active substance is currently authorised (14946 N) as a hygienic and chirurgical hand disinfectant (PT01).
The product is for professional and non-professional use. The authorized uses are described in Table E.1.

Table E.1. Intended uses, dosage, and use concentrations of the active substance.

Area of use envisaged	Concentration active substance in product (g/L)	Dosage product per treatment (mL)	Use concentration active sub-stance per treatment (g)
Professional use			
Hygienic and chirurgical hand disinfection (PT01)	800	3-3.5	2.4-2.8
Non-professional use			
Hygienic hand disinfection (PT01)	800	3-3.5	2.4-2.8

The current request for authorisation concerns an amendment of the current authorisation (14946 N) to include limited virucidal claims at 30 seconds and full virucidal claims at 40 seconds. This amendment has no influence on the environmental exposure assessment done for the current authorisation.

7.2 Product related studies

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

7.3 Environmental exposure assessment

7.3.1 Chemistry and/or metabolism

The active substance ethanol is resistant to hydrolysis, but readily biodegradable. The degradation products of this substance are water and carbon dioxide. These are not considered relevant for the environmental risk assessment as these are natural occurring compounds. The active substance has a high vapour pressure and therefore easily evaporates to air.

7.3.2 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. Compartments indicated with a 'Q' will be qualitatively assessed only. 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 use.

Main scenario	**Environmental compartments exposed**				
	STP	**Freshwater[1]**	**Saltwater[1]**	**Soil[2,3]**	**Air**
Hygienic and chirurgical hand disinfection (PT01)	- (Q)	+ (Q)	-	+ (Q)	++ (Q)

++ Compartment directly exposed, + Compartment indirectly exposed, (Q) Qualitative assessment, depending on application, [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.

Once the hands are disinfected the product is left to dry and the active substance evaporates to the air. Therefore, emission to the sewage treatment plant (STP) and subsequently to surface water and sediment is regarded as negligible for the active substance. However, the active substance may enter the aquatic and terrestrial environment due to deposition of airborne product.

7.3.3 Predicted environment and effect calculations

Generally, risk assessment is based generally based on comparing Predicted Environmental Concentrations (PECs) with Predicted No-Effect Concentrations (PNECs) for the relevant environmental compartments. However, for the active substance ethanol it is to be expected that it will mostly evaporate and the main emission into the environment will be to air. Therefore, the risk to the environment is assessed in a qualitative manner for the active substance, and therefore no PECs were calculated and no PNECs are presented.

7.4 Risk characterisation for the environment

7.4.1 Aquatic compartment (incl. sediment) and STP

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

As disinfected hands are not rinsed (directly) after use of the product and the active substance completely evaporates to the air, no emission to the sewer is expected. In addition, subsequent emissions to the STP and the aquatic compartment are also not expected. Therefore, the risks for micro-organisms in the STP and aquatic and sediment-dwelling organisms are considered acceptable. However, the active substance may enter the aquatic environment due to deposition of airborne product. Considering that the active substance is diluted in the air and moreover degraded quickly once deposited, concentrations above environmental risks limits are not expected and the accompanied risk are considered acceptable. The standards for the aquatic environment are therefore met.

7.4.1.2 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 in Dutch surface water.

7.4.1.3 Surface water intended for the abstraction of drinking water

Biocidal products with the active substance ethanol have been on the market for more than three years. The existing active substance ethanol is 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

(2015). In addition, the active substance is 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.

7.4.2 Terrestrial compartment

7.4.2.1 Soil organisms and non-target arthropods (including bees)

Deposition of airborne active substance on soils may occur. However, possible risks for terrestrial organisms are expected to be low as the active substance is highly diluted in air, and quickly degraded once entering the soil compartment. In addition, direct exposure is negligible for bees considering the intended use of the product indoors. Hence, the risks for soil organisms and non-target arthropods (including bees) are considered acceptable for the intended uses.

7.4.2.2 Groundwater

Assessment of the drinking water criterion defines that the concentration of the active substances and the relevant metabolites in groundwater for the preparation of drinking water needs to be < 0.1 µg/L. Deposition of airborne ethanol on soils may occur. However, considering that significant contamination of the soil compartment is not expected and ethanol is quickly degraded, transport to groundwater is expected to be negligible. Hence, the risk for groundwater is considered acceptable for the intended uses.

7.4.2.3 Persistence in soil

Ethanol is considered readily biodegradable and not expected to persist in soil. Hence, the criteria for the persistence in soils are met.

7.4.3 Non compartment specific effects relevant to the food chain

7.4.3.1 Bioconcentration

As the logarithmic octanol-water partitioning coefficients (log Kow) of ethanol is < 3 (-0.31) bioconcentration is not expected according to the trigger values presented in the Guidance on biocide legislation, Part B+C, volume IV. Therefore, the potential for bioaccumulation is considered low and no further assessment of secondary poisoning is deemed necessary.

7.4.3.2 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. In addition, the low log Kow value for ethanol (as discussed in 7.4.3.1) indicates that indirect exposure of birds and mammals through consumption of aquatic or soil organisms is considered low. Hence, the product meets the standards for the risk to birds and mammals.

7.4.4 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 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.

AOPwin calculates a half-life in air for ethanol of 4.3 days (OH timeframe 24 hrs/day, 0.5×10^6 OH radicals/cm^3) which is above 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. Because the expected atmospheric half-life of the active substance in air exceeds the trigger value, long distance transport and contamination of surface water and deposition in distant areas may occur. However,

because no risks were identified for the latter, deposition from air will not result in unacceptable risks. Therefore, the environmental risk resulting from emission to air is considered acceptable.

7.5 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.

7.6 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), Deb InstantFOAM Complete complies with the environmental standards and will not cause unacceptable effects to the environment. No risk mitigation measures are necessary.

7.7 Data requirements

There are no additional data required.

8 Conclusion

The applicant has proven that the extension of Deb InstantFOAM Complete 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

This concerns an extension of an existing authorisation. Classification and labelling have not been changed.

10 References

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