



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 TOELATING

Gelet op de aanvraag d.d. 15 juni 2012 (20120736 TBO) van

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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,

Alcohol podior 70%

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 Alcohol podior 70% is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 14061 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 2023.

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 onder A bij dit besluit is voorgeschreven.

1.4 Classificatie en etikettering

Gelet op artikel 50, eerste lid, sub d, Wet gewasbeschermingsmiddelen en biociden,

1. De aanduidingen, welke ingevolge artikelen 9.2.3.1 en 9.2.3.2 van de Wet milieubeheer en artikelen 14, 15a, 15b, 15c en 15d van de Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten op de verpakking moeten worden vermeld, worden hierbij vastgesteld als volgt:

aard van het preparaat: Andere vloeistoffen voor directe toepassing

werkzame stof:
ethanol

gehalte:
62,4 % m/m

letterlijk en zonder enige aanvulling:

andere zeer giftige, giftige, bijtende of schadelijke stof(fen):

-

gevaarsymbool:
F

aanduiding:
Licht ontvlambaar

Waarschuwingszinnen:

R11 Licht ontvlambaar.

Veiligheidsaanbevelingen:

S16 Verwijderd houden van ontstekingsbronnen - Niet roken.

S35 Deze stof en de verpakking op veilige wijze afvoeren.

Specifieke vermeldingen:

-

2. Behalve de onder 1. bedoelde en de overige bij de Wet Milieugevaarlijke Stoffen en Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten 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.

- c. De vervaldatum (2 jaar na de productiedatum) dient op het etiket te worden vermeld.

2 DETAILS VAN DE AANVRAAG

Het betreft een aanvraag tot verkrijging van een toelating van het middel Alcohol podior 70% (14061 N), een middel op basis van de werkzame stof ethanol.

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 Alcohol podior 70% op basis van de werkzame stof(fen) ethanol 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 119, eerste lid, Wet gewasbeschermingsmiddelen en biociden 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, 12 april 2013

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. 12 april 2013 tot toelating van het middel Alcohol podior 70%, toelatingnummer 14061 N

A. WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van bacteriën (exclusief mycobacteriën en bacteriesporen), gisten en schimmels:

- op harde oppervlakken in de gezondheidszorg, in pedicurepraktijken, in tattoo-praktijken, in schoonheidssalons en in nagelstudio's, met uitzondering van oppervlakken die in contact kunnen komen met eet- en drinkwaren en grondstoffen hiervoor.

De dosering en inwerktijd zoals aangegeven in de gebruiksaanwijzing moeten worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B. GEBRUIKSAANWIJZING

Het middel is een gebruiksklare vloeistof die onverdund gebruikt moet worden.

Desinfectie van harde oppervlakken

Het middel alleen toepassen op kleine oppervlakken (maximaal 0,5 m²).

Te behandelen oppervlakken eerst reinigen. Een daarbij gebruikt reinigingsmiddel afspoelen met schoon water. Overtollig water verwijderen. Breng het middel met een doekje of prop watten aan op het te behandelen oppervlak (verbruik 20-50 ml per 0,5 m²) en laat minimaal 5 minuten inwerken. Bij het desinfecteren zo veel vloeistof gebruiken dat de oppervlakken gedurende de gehele inwerktijd nat blijven. Hierna met behulp van een celstof doekje het oppervlak droogwrijven.

Minimale inwerktijd: 5 minuten

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 12 april 2013 tot toelating van het middel Alcohol podior 70%, toelatingnummer 14061 N

RISKMANAGEMENT

Contents	Page
1. Introduction	2
2. Identity of the active substance ethanol	3
3. Physical and chemical properties biocidal products	4
4. Efficacy	10
5. Human toxicology	19
6. Environment	28
7. Conclusions	33
8. Classification and labelling	37
9. References	43

1. Introduction

This assessment concerns the biocidal products based on the active substance ethanol. These applications have been submitted under the differentiated enforcement policy of biocides.

The assessment includes the following products:

Product	Applicant	PT	Application number
Bleko Ethylalcohol 80%	Bleko Chemie B.V.	PT01, PT02, PT04	20120665 TBO
DES-O	Cargill BV	PT01, PT02, PT04	20120816 TBO
Direct disinfect spray	Herome Cosmetics B.V.	PT01, PT02	20120818 TBO
S-Clean 80	Qlean-tec B.V.	PT01, PT02, PT04	20120821 TBO
Alcohol podior 70%	REYMERINK B.V.	PT01, PT02	20120736 TBO
Alcohol 70% met 10% IPA Denteck BV	Denteck B.V.	PT01, PT02, PT04	20120731 TBO
Alcohol dilutus	Cargill BV	PT01, PT02, PT04	20120896 TBO
Alcohol fortior	Cargill BV	PT01, PT02, PT04	20120898 TBO
Alcohol Ketonatus 70% Denteck BV	Denteck B.V.	PT01, PT02, PT04	20120901 TBO
Ethades	Spectro B.V.	PT01, PT02, PT04	20120905 TBO

The active substance ethanol has been notified for product type 1, 2 and 4. Ethanol has not been placed on annex 1 of Directive 98/8/EC yet. Some of the products listed above contain 2- propanol. The Ctgb doesn't see 2- propanol as active substance in these products, because of the low concentrations of 2- propanol present.

2. 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
Other substance No.	-
Molecular formula	C ₂ H ₆ O
Molecular mass	46.07
Structural formula	CH ₃ -CH ₂ -OH

The active substance is not yet included in annex I of Directive 98/8/EC.
A CAR of the active substance is not yet available.

Physical and chemical properties of the active substance relevant to the risk assessment

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)	0.57 Pa x m ³ /mol
Solubility in water (g/L or mg/L)	1000 g/L at 25 °C (ethanol is indefinitely miscible with water)
Partition coefficient (log P _{ow})	0.31
Dissociation constant	No dissociation within an environmentally relevant pH range.
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: N/A 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.

Conclusions active substance ethanol

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

3. Physical and chemical properties biocidal products

3.1 Bleko Ethylalcohol 80%

Identity of the biocidal product Bleko Ethylalcohol 80%

Name	Bleko Ethylalcohol 80%
Content active substance	Ethanol: 76% w/w (600g/L)
Formulation type	AL
Packaging	0.25-25L HDPE

Physical and chemical properties of the biocidal product Bleko Ethylalcohol 80%

Appearance	Clear colourless liquid with an alcohol-like odour
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not self-igniting, 363 °C
Flashpoint	23 °C
pH 1% solution	No data. Expected to remain within the range 4 – 10.
Relative density	0.831 g/cm ³
Storage stability/ Shelf life	2 years in HDPE
Physical and chemical compatibility	Not applicable
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification

Analytical methods for analysis of the biocidal product Bleko Ethylalcohol 80%

Preparation (principle of method)	ASTM E-1100-92 (GC method for analysis of denatured ethanol)
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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).

Conclusions biocidal product Bleko Ethylalcohol 80%

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

3.2 DES-O

Identity of the biocidal product DES-O

Name	DES-O
Content active substance	Ethanol: 75.6% w/w
Formulation type	AL
Packaging	100 mL PET bottle with atomiser 500mL, 5000mL PET bottles

Physical and chemical properties of the biocidal product DES-O

Appearance	Colourless transparent liquid
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not self-igniting
Flashpoint	18 °C
pH 1% solution	100 g/L: 5.3
Relative density	0.84 kg/L
Storage stability/ Shelf life	2 years in PET
Physical and chemical compatibility	Not applicable
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification

Analytical methods for analysis of the biocidal product DES-O

Preparation (principle of method)

GC, densitometry

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).

Conclusions biocidal product DES-O

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

3.3 Direct desinfect spray

Identity of the biocidal product Direct desinfect spray

Name	Direct desinfect spray
Content active substance	Ethanol: 68%w/w
Formulation type	AL
Packaging	75mL PET with atomiser

Physical and chemical properties of the biocidal product Direct desinfect spray

Appearance	Clear liquid
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not self-igniting
Flashpoint	21 °C
pH 1% solution	Expected to be within the range of 4 – 10.
Relative density	0.87 at 20 °C
Storage stability/ Shelf life	2 years
Physical and chemical compatibility	Not applicable
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification

Analytical methods for analysis of the biocidal product Direct desinfect spray

Preparation (principle of method)

HPLC-UV

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).

Conclusions biocidal product Direct desinfect spray

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

3.4 S-Clean 80

Identity of the biocidal product S-Clean 80

Name	S-Clean 80
Content active substance	76%w/w (ca. 81%v/v)
Formulation type	AL
Packaging	5L or 20L HDPE

Physical and chemical properties of the biocidal product S-Clean 80

Appearance	Clear liquid with characteristic alcohol-like odour
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not self-igniting
Flashpoint	17 °C
pH 1% solution	7
Relative density	Density: 0.84 g/mL
Storage stability/ Shelf life	2 years.

Physical and chemical compatibility	Not applicable
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification

Analytical methods for analysis of the biocidal product S-Clean 80

Preparation (principle of method)	Densitometry (Anton Paar)
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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).

Conclusions biocidal product S-Clean 80

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

3.5 Identity of the biocidal product alcohol podior 70%

Name	Alcohol podior 70%
Content active substance	62,4% w/w pure ethanol (70% v/v; 552 g/L)
Formulation type	AL
Packaging	100 mL glass bottle, 1 and 5L HDPE bottle

Physical and chemical properties of the biocidal product alcohol podior 70%

Appearance	Colourless, transparent liquid
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not self-igniting
Flashpoint	21 °C
pH 1% solution	7<pH<7.5
Relative density	0.886
Storage stability/ Shelf life	2 years in glass and HDPE
Physical and chemical compatibility	No mixing intended
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification for analysis of the biocidal product alcohol podior 70%

Preparation (principle of method)	Density measurement, GC-FID
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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).

Conclusions biocidal product alcohol podior 70%

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

3.6 Identity of the biocidal product alcohol 70% met 10% IPA Denteck BV

Name	Alcohol 70% met 10% IPA Denteck BV
Content active substance	64% w/w pure ethanol (559 g/L; 71% v/v)
Formulation type	AL
Packaging	100, 250, 500 and 1000 mL HDPE bottle 5 and 10 L HDPE can

Physical and chemical properties of the biocidal product alcohol 70% met 10% IPA Denteck BV

Appearance	Clear liquid with characteristic alcoholic odour.
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not self-igniting

Flashpoint	FP < 21 °C
pH 1% solution	6-9
Relative density	0.873
Storage stability/ Shelf life	2 years in HDPE
Physical and chemical compatibility	No mixing intended
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification for analysis of the biocidal product alcohol 70% met 10% IPA Denteck BV

Preparation (principle of method)	Density measurement
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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).

Conclusions biocidal product alcohol 70% met 10% IPA Denteck BV

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

3.7 Identity of the biocidal product alcohol dilutus

Name	Alcohol dilutus
Content active substance	62% w/w (550 g/L; 70% v/v) pure ethanol
Formulation type	AL
Packaging	5L HDPE can

Physical and chemical properties of the biocidal product alcohol dilutus

Appearance	Colourless, transparent liquid
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	363 °C
Flashpoint	FP 21 °C
pH 1% solution	5.3 (20 °C)
Relative density	0.886
Storage stability/ Shelf life	3 years in HDPE
Physical and chemical compatibility	No mixing intended
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification for analysis of the biocidal product alcohol dilutus

Preparation (principle of method)	Densitometry, gas chromatography
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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).

Conclusions biocidal product alcohol dilutus

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

3.8 Identity of the biocidal product alcohol fortior

Name	Alcohol fortior
Content active substance	94.1% w/w pure ethanol (96% v/v; 759 g/L)
Formulation type	AL
Packaging	1L HDPE bottle with PP screw cap 5L HDPE can with HDPE cap and PE ring

Physical and chemical properties of the biocidal product alcohol fortior

Appearance	Colourless, transparent liquid
Explosive properties	Not explosive
Oxidising properties	Not oxidising

Auto-flammability	363 °C
Flashpoint	15 °C
pH 1% solution	5.3 (12% v/v, 20 °C)
Relative density	0.806
Storage stability/ Shelf life	3 years
Physical and chemical compatibility	No mixing intended
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification for analysis of the biocidal product alcohol fortior

Preparation (principle of method)	Densitometry, gas chromatography
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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).

Conclusions biocidal product alcohol fortior

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

3.9 Identity of the biocidal product alcohol Ketonatus 70% Denteck BV

Name	Alcohol Ketonatus 70% Denteck BV
Content active substance	65% w/w pure ethanol (72% v/v; 570 g/L)
Formulation type	AL
Packaging	100, 20, 500, 1000 mL HDPE bottle 5 and 10L HDPE -can

Physical and chemical properties of the biocidal product alcohol Ketonatus 70% Denteck BV

Appearance	Clear liquid with characteristic alcoholic odour
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	310 °C
Flashpoint	18 °C
pH 1% solution	6-9
Relative density	0.881-0.886
Storage stability/ Shelf life	2 years in HDPE
Physical and chemical compatibility	No mixing intended
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification

Analytical methods for analysis of the biocidal product alcohol Ketonatus 70% Denteck BV

Preparation (principle of method)	Density measurement
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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).

Conclusions biocidal product alcohol Ketonatus 70% Denteck BV

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

3.10 Identity of the biocidal product ethades

Name	Ethades
Content active substance	67% w/w pure ethanol (580 g/L)
Formulation type	AL
Packaging	50 mL – 25 L HDPE and PET bottles

Physical and chemical properties of the biocidal product ethades

Appearance	Clear, colourless liquid with alcoholic odour
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not self-igniting
Flashpoint	21 °C
pH 1% solution	8.5 (neat formulation)
Relative density	0.87
Storage stability/ Shelf life	12 months
Physical and chemical compatibility	No mixing intended
Viscosity	Not applicable
Surface tension	Not applicable

Analytical methods for detection and identification for analysis of the biocidal product ethades

Preparation (principle of method)	GC-FID
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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).

Conclusions biocidal product ethades

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

4. Efficacy

4.1 Products based on 70-75%v/v ethanol

Function

The products Alcohol 70% met 10% IPA Denteck BV, Alcohol dilutus, Alcohol Ketonatus 70% Denteck BV, Alcohol podior 70%, Direct Desinfect Spray and Ethades are disinfectants (PT01, PT02 and/or PT04) based on ethanol 70 - 75% v/v.

Field of use envisaged

The proposed field of use: see table 1.

All uses are included in PT01, PT02 and/or PT04.

The products are intended for professional use and/or non-professional use.

Table 1: Field of use envisaged.

Product name:	% ethanol (v/v)	Field of use envisaged:
Alcohol 70% met 10% IPA Denteck BV	71	The control of bacteria, yeasts, fungi and viruses on: <ul style="list-style-type: none">• human skin;• surfaces;• instruments. These uses are included in PT01, PT02 and PT04. The product is intended for professional use.
Alcohol dilutus	70	The control of bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on: <ul style="list-style-type: none">• human skin;• surfaces in hospitals and dental, medical and veterinary practices;• surfaces that come into contact with food and animal feed;• instruments used in dental, medical and veterinary practices. These uses are included in PT01, PT02 and PT04. The product is intended for professional use only.
Alcohol Ketonatus 70% Denteck BV	72	The control of bacteria, yeasts, fungi and viruses on: <ul style="list-style-type: none">• human skin;• surfaces. These uses are included in PT01, PT02 and PT04. The product is intended for professional and non-professional use.
Alcohol podior 70%	70	The control of bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on: <ul style="list-style-type: none">• human skin;• surfaces;• instruments; in health care, pedicure practices, tattoo-shops, beauty saloons and nailstudios. These uses are included in PT01 and PT02. The product is intended for professional use only.

Direct Desinfect Spray	75	<p>The control of bacteria, yeasts and viruses on</p> <ul style="list-style-type: none"> • hands; • surfaces. <p>These uses are included in PT01 and PT02.</p> <p>The product is intended for non-professional use only.</p>
Ethades	73.4	<p>The control of bacteria (excluding bacterial spores) for:</p> <ul style="list-style-type: none"> • human hygiene; • for private use and for the public health area; • for use in the area food and animal feed; <p>These uses are included in PT01, PT02 and PT04.</p> <p>The product is intended for professional and non-professional use.</p>

Effects on target organisms and efficacy

The available information was sufficient to evaluate the efficacy, considering that the authorisation is done under article 121 of the WGB.

Several references / studies testing efficacy were provided, some were considered to be suitable and acceptable.

PT01

For the intended use of hand disinfection several references/tests have been provided according to acknowledged standards. Sufficient 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 and a contact time of 30 seconds. In addition several handrub tests (phase 2, step 2) according to EN 1500 are provided with the required standard bacteria organism *Escherichia coli*. Some of the tests were carried out with a contact time that exceeded 30 seconds. This is not acceptable as the maximum acceptable contact time for hand disinfection is 30 seconds. Other tests were not acceptable either because the test validation criteria and/or the pass criteria at the required significance level (p) of 0.1 were not met. Therefore, not sufficient bactericidal efficacy in handrub tests has been demonstrated. As this is a mandatory requirement, PT01 handdisinfection will be removed from the claim.

PT02 and PT04

Bacteria and yeasts

References are provided and tests following EN standards have been done with the required standard organisms for the intended use and the required test temperature. The tests demonstrated efficacy against bacteria and yeasts at the use concentration (100%, undiluted), a range of contact times of 30 seconds to 5 minutes, and low level soiling conditions of 0.3 g/L bovine albumin. For Alcohol dilutus tests are performed that demonstrate bactericidal and yeasticidal efficacy with the use concentration (100%, undiluted), a contact time of 30 seconds and high level soiling conditions of 3 g/L bovine albumin + 3 ml/L sheep erythrocytes.

Fungi

For Alcohol podior 70% and Alcohol dilutus fungicidal efficacy was demonstrated in quantitative suspension tests according to EN 13624 with the required standard organism at a concentration of 100% (i.e. use concentration), low level soiling conditions of 0.3 g/L bovine albumin and a contact time of resp. 30 seconds (Alcohol podior 70%) and 5 minutes (Alcohol dilutus).

Viruses

No acceptable studies/references were provided with (one of) the required standard organisms.

Non-professional use

For non-professional use there is an additional requirement to demonstrate efficacy in phase 2, step 2 tests for bacteria and yeasts (basic requirement) and other claimed organisms (optional). For Alcohol Ketonatus 70% Denteck BV only data on bactericidal

control with one bacteria species were provided and no data on yeasts. For Direct Desinfect Spray and Ethades sufficient bactericidal and yeasticidal efficacy has been demonstrated in quantitative surface tests according to EN 13697 and EN 13624 with the use concentration (100%, undiluted), clean conditions of 0.3 g/L bovine albumin and a contact time of 30 seconds. This is in accordance with the intended use.

Evaluation of the WG/GA

The applicants have provided Dutch WG/GA's. These have been adapted to our standards.

On the WG/GA's of all products:

- Mycobacteria and bacterial spores will be excluded from the bacterial claim, because these are not claimed organisms and no data on mycobactericidal or sporicidal efficacy have been provided.

On the WGGA's of Alcohol podior 70% and Direct Desinfect Spray:

- the use on surfaces that come into contact with food and drink or raw materials thereof will be excluded, as these products are claimed for PT02 only.

Specific modifications for each product are summarised in the second column of Table 2 (see 4.5 Conclusions).

Mode of action

The following information is provided:

Ethanol exhibits an unspecific mechanism of effect. It affects the outer cell membrane causing alteration of the 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. Ethanol rapidly inactivates the target microorganisms without time delay due to the unspecific mode of action (topical disinfectant).

Resistance

The following information is provided:

Resistances for ethanol are not reported. As ethanol is not specific for just one cellular target but interferes with membrane integrity and denatures proteins, the development of true resistances is not to be expected.

Considering that the authorisation is done under article 121 of the WGB this information 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 the products, when used in accordance with the proposed label (WG/GA), are effective in (see Table 2, 2nd column):

Table 2: Conclusions.

Product name:	The product, when used in accordance with the proposed label (WG/GA), is effective in:
Alcohol 70% met 10% IPA Denteck BV	Controlling bacteria (excluding mycobacteria and bacterial spores) and yeasts on: <ul style="list-style-type: none"> • hard surfaces in public health areas, including areas that come into contact with food and drink and the raw materials thereof. <p>WGGA</p> <ul style="list-style-type: none"> - The use against fungi has been removed on request of the applicant; - The use against viruses has been removed from the claim as not sufficient data are provided with the required (non-enveloped) virus standard organisms; - The use on human skin (i.e. hand disinfection) has been removed from the claim as not sufficient data are provided to substantiate the claim. The provided handrubtest is not acceptable as (a.o.) the test validation criteria were not met and thus the test should have been repeated;

	<p>- The use for instrument disinfection has been removed from the claim as virucidal efficacy is mandatory for this use and not sufficient data are provided with the required (non-enveloped) virus standard organisms.</p>
Alcohol dilutus	<p>Controlling bacteria (excluding mycobacteria and bacterial spores) yeasts and fungi on:</p> <ul style="list-style-type: none"> • hard surfaces in hospitals and dental, medical and veterinary practices; • hard surfaces in research laboratories; • hard surfaces that come into contact with food and animal feed, excluding milking machines; • pipelines that come into contact with food and animal feed (CIP), excluding milking machines. <p>WGGA</p> <p>- The use on human skin (i.e. hand disinfection) has been removed from the claim as not sufficient data on bactericidal efficacy are provided with the required contact time of maximum 30 seconds;</p> <p>- The use for instrument disinfection has been removed from the claim as virucidal efficacy is mandatory for this use and no data are provided to substantiate virucidal efficacy.</p>
Alcohol Ketonatus 70% Denteck BV	<p>Controlling bacteria (excluding mycobacteria and bacterial spores) and yeasts on:</p> <ul style="list-style-type: none"> • hard surfaces in public health areas, including areas that come into contact with food and drink and the raw materials thereof <p>WGGA</p> <p>- The use against fungi has been removed on request of the applicant;</p> <p>- The use against viruses has been removed from the claim as not sufficient data are provided with the required (non-enveloped) virus standard organisms;</p> <p>- The use on human skin (i.e. hand disinfection) has been removed from the claim as not sufficient data are provided to substantiate the claim. The provided handrubtest is not acceptable as the test validation criteria were not met and thus the test should have been repeated;</p> <p>- The non-professional use (PT02 and PT04) has been removed from the claim as no acceptable simulated use test (phase 2, step 2) with the required standard organisms for bacteria and yeasts and a contact time of 30 seconds (i.e. according to the intended use) was provided, which is a mandatory requirement for non-professional use.</p>
Alcohol podior 70%	<p>Controlling bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on:</p> <ul style="list-style-type: none"> • hard surfaces in the health care, pedicure practices, tattoo-shops, beauty saloons and nailstudios, <p>excluding surfaces that come into contact with food and drink and the raw materials thereof</p> <p>WGGA</p> <p>- The use on human skin (i.e. hand disinfection) has been removed from the claim as not sufficient data on bactericidal efficacy are provided with the required contact time of maximum 30 seconds;</p> <p>- The use for instrument disinfection has been removed from the claim as virucidal efficacy is mandatory for this use and not sufficient data are provided to substantiate virucidal efficacy.</p>
Direct Desinfect Spray	<p>Controlling bacteria (excluding mycobacteria and bacterial spores) and yeasts on</p> <ul style="list-style-type: none"> • hard surfaces in rooms where people reside, excluding surfaces that come into contact with food and drink and raw materials thereof . <p>WGGA</p>

	<ul style="list-style-type: none"> - The use for disinfection of hands (PT01) has been removed from the claim on request of the applicant - The use against viruses has been removed on request of the applicant
Ethades	<p>Controlling bacteria (excluding mycobacteria and bacterial spores) and yeasts on:</p> <ul style="list-style-type: none"> • hard surfaces in the public health area; • hard surfaces in the food and animal feed area, excluding milking machines. <p>WGGA</p> <ul style="list-style-type: none"> - The non-professional use has been removed on request of the applicant - The use for disinfection of hands (PT01) has been removed from the claim as not sufficient bactericidal efficacy has been demonstrated in a handrub test (EN 1500) at the required significance level of p=0.1 - A contacttime of minimal 30 seconds has been added to the GA as efficacy against bacteria and yeasts has been demonstrated with this contact time.

4.2 Products based on 80-81%v/v ethanol

Function

Bleko Ethylalcohol 80%, DES-O and S-Clean 80 are disinfectants (PT01, PT02 and/or PT04) based on ethanol 80 – 81v/v.

Field of use envisaged

The proposed field of use: see table 1.

All uses are included in PT01, PT02 and/or PT04

The products are intended for professional use. In addition, Bleko Ethylalcohol 80% is intended for non-professional use.

Table 1: Field of use envisaged.

Product name:	% ethanol (v/v)	Field of use envisaged:
Bleko Ethylalcohol 80%	80	<p>The control of bacteria on</p> <ul style="list-style-type: none"> • skin and hands <p>The control of bacteria, yeasts, fungi and viruses on</p> <ul style="list-style-type: none"> • small surfaces in households, food production sector, health care, animal housing and industry. <p>These uses are included in PT1, PT2, and PT4.</p>
DES-O	80	<p>The control of bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses (including norovirus) on</p> <ul style="list-style-type: none"> • human skin • hard surfaces and instruments in the public health area and the food and animal feed industry. <p>These uses are included in PT01, PT02 and PT04.</p>
S-Clean 80	81	<p>The control of bacteria and fungi</p> <ul style="list-style-type: none"> • on surfaces that come into contact with food or drink • during hand disinfection. <p>These uses are included in PT1, PT2 and PT4.</p>

Effects on target organisms and efficacy

The available information was sufficient to evaluate the efficacy, considering that the authorisation is done under article 121 of the WGB.

Several references / studies testing efficacy were provided, some were considered to be suitable and acceptable.

PT01

For the intended use of hand disinfection several references/tests 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 and a contact time of 30 seconds. In addition several handrub tests (phase 2, step 2) according to EN 1500 - mandatory for PT01 handdisinfection - are provided with the required standard bacteria organism *Escherichia coli*.

For DES-O and S-Clean 80 the provided handrubtests were not acceptable because the pass criteria of the test were not met and/or the test conditions and validation criteria were not met. For Bleko ethylalcohol 80% no handrub test had been provided.

PT02 and PT04

Bacteria and yeasts

References/tests following EN standards have been provided with the required standard organisms for the intended use and the required test temperature. The tests demonstrated efficacy against bacteria and yeasts at a concentration of 62.5 – 100%, a range of contact times of 30 seconds to 5 minutes, and low level soiling conditions of 0.3 g/L bovine albumin. This is in accordance with the intended use.

In addition, for DES-O tests are performed with the use concentration (100%, undiluted), a contact time of 30 seconds and high level soiling conditions of 3 g/L bovine albumin and 3 ml sheep erythrocytes. These soiling conditions are dirty conditions for PT02, medical area.

Fungi

For Bleko Ethylalcohol 80% and DES-O fungicidal efficacy was demonstrated in tests following EN standards with the required standard organism. The tests demonstrated efficacy against fungi at the use concentration (100%, undiluted), low level soiling conditions of 0.3 g/L bovine albumin and a contact time of resp. 30 seconds (Bleko Ethylalcohol 80%) and 5 minutes (DES-O).

Viruses

For most products no acceptable studies/references were provided with (one of) the required standard organisms.

For DES-O virucidal efficacy was demonstrated in quantitative suspension tests following EN standards with the required standard organisms. The tests demonstrated efficacy against viruses at the use concentration (100%, undiluted), low level soiling conditions of 0.3 g/L bovine albumin and a contact time of 5 minutes.

Non-professional use

For non-professional use there is an additional requirement to demonstrate efficacy in phase 2, step 2 tests for bacteria and yeasts (basic requirement) and other claimed organisms (optional).

For Bleko Ethylalcohol 80% bactericidal, yeastocidal and fungicidal efficacy has been demonstrated in a quantitative surface test according to EN 13697 on non-porous surface with the use concentration (100%, undiluted), clean conditions of 0.3 g/L bovine albumin and a contact time of 5 minutes. This is in accordance with the intended use.

Evaluation of the WG/GA

The applicants have provided Dutch WG/GA's. These have been adapted to our standards.

On the WG/GA's of all products:

- Mycobacteria and bacterial spores will be excluded from the bacterial claim, because these are not claimed organisms and/or no data on mycobactericidal or sporicidal efficacy have been provided.

Specific modifications for each product are summarised in the second column of Table 2 (see 4.5 Conclusions).

Mode of action

The following information is provided:

Ethanol exhibits an unspecific mechanism of effect. It affects the outer cell membrane causing alteration of the 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. Ethanol rapidly inactivates the target microorganisms without time delay due to the unspecific mode of action (topical disinfectant).

Resistance

The following information is provided:

Resistances for ethanol are not reported. As ethanol is not specific for just one cellular target but interferes with membrane integrity and denatures proteins, the development of true resistances is not to be expected.

Considering that the authorisation is done under article 121 of the WGB this information 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 the products, when used in accordance with the proposed label (WG/GA), are effective in (see Table 2, 2nd column):

Table 2: Conclusions.

Product name:	The product, when used in accordance with the proposed label (WG/GA), is effective in:
Bleko Ethylalcohol 80%	Controlling bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi <ul style="list-style-type: none">on hard surfaces in households, food production sector and health care. WGGA <ul style="list-style-type: none">The use on skin and hands (i.e. hand disinfection) has been removed from the claim as no data are provided on bactericidal efficacy in a handrub test, a mandatory requirement for this intended use;The use against viruses has been removed from the claim as no data are provided with the required (non-enveloped) virus standard organisms;The use in animal housing is removed as this is PT03;There are 2 separate WG/GA's, one for professional use and one for non-professional use.
DES-O	Controlling bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses <ul style="list-style-type: none">on hard surfaces and instruments in the public health area;on hard surfaces in the food and animal feed industry. WGGA <ul style="list-style-type: none">The use on human skin (i.e. hand disinfection) has been removed as not sufficient bactericidal efficacy has been demonstrated in a handrubtest.
S-Clean 80	Controlling bacteria (excluding mycobacteria and bacterial spores) and yeasts <ul style="list-style-type: none">on hard surfaces in institutional kitchens of catering facilities, that come into contact with food and drink and the raw materials thereof;on hard surfaces in the public health area. WGGA <ul style="list-style-type: none">The use on hands (PT01) has been removed from the claim as no acceptable handrub test is provided on bactericidal efficacy;The use against fungi has been removed on request of the applicant.

4.3 Products based on 96%v/v ethanol

Function

Alcohol fortior is a disinfectant (PT01, PT02 and PT04) based on ethanol (96% v/v).

Field of use envisaged

The proposed field of use of Alcohol fortior is the control of bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi:

- for disinfection of human skin
- on surfaces in hospitals and dental, medical and veterinary practices
- on surfaces that come into contact with food and animal feed
- on instruments used in dental, medical and veterinary practices
- on piping that comes into contact with food and animal feed

These uses are included in PT01, PT02 and PT04.

The product is intended for professional use only.

Effects on target organisms and efficacy

The available information was sufficient to evaluate the efficacy, considering that the authorisation is done under article 121 of the WGB.

Several studies testing efficacy were provided, some were considered to be suitable and acceptable.

PT01

Quantitative suspension tests following EN standards have been done with the required standard organisms for the intended use and the required test temperature. The tests demonstrated efficacy against bacteria and yeasts at a concentration of 85% v/v ethanol (i.e. use concentration), high level soiling conditions for the medical area and a contact time of 30 seconds. Not sufficient efficacy has been demonstrated against fungi at a concentration of 85% v/v ethanol (i.e. use concentration), high level soiling conditions for the medical area and a contact time of 30 seconds.

In addition a handrub test according to EN 1500 has been done with the required standard organism for bacteria, a concentration of 85% v/v ethanol (i.e. use concentration), a dose of 3 ml, and a contact time of 30 seconds. Alcohol fortior did not demonstrate sufficient bactericidal efficacy compared to the reference product.

PT02 and PT04

Quantitative suspension tests following EN standards have been done with the required standard organisms for the intended use and the required test temperature. The tests demonstrated efficacy against bacteria, yeasts and fungi at the use concentration, low level soiling conditions of 0.3 g/L bovine albumin and a contact time of 5 minutes. This complies with the intended use as specified on the WG/GA.

No studies with viruses are provided. As virucidal efficacy is mandatory for the use of disinfection of instruments, this use has to be removed from the WG/GA.

Evaluation of the WG/GA

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

- The use for disinfection of human skin (i.e. hand disinfection, PT01) has been removed from the claim as not sufficient bactericidal efficacy has been demonstrated in the handrub test;
- The use for instrument disinfection has been removed from the claim as virucidal efficacy is mandatory for this use and no data on virucidal efficacy have been provided.

Mode of action

The following information is provided: denature proteins and disrupt cytoplasmatic membrane by dissolving lipid.

Resistance

The applicant provided the following information: Resistances are not reported. As ethanol is not specific for just one cellular target but interferes with membrane integrity and denatures proteins, the development of true resistances is not to be expected. 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 the product Alcohol fortior, when used in accordance with the proposed label (WG/GA), is effective in controlling bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on

- hard surfaces in hospitals and dental, medical and veterinary practices;
- hard surfaces in research laboratories;
- hard surfaces that come into contact with food and animal feed, excluding milking equipment;
- piping that comes into contact with food and animal feed through Cleaning-In-Place, excluding milking equipment..

Disinfection of hands was excluded from the claim since not sufficient bactericidal efficacy was demonstrated in a handrubtest. Disinfection of instruments was excluded from the claim since virucidal efficacy is mandatory for this claim and viruses were not included in efficacy testing.

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 to 1300 mg/m³, the committee was of the opinion that a HBC-OCR_V (Health based calculated occupational cancer risk value) of 1300 mg/m³ is low enough to protect against these effects. Other toxic effect manifest themselves after exposure to higher exposure levels. DECOS calculates an HBC-OCR_V of 1300 mg/m³, 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/m³ 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/cm²/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.

Data requirements active substance

No additional data requirements are identified.

5.2 Human exposure assessment active substance

5.2.1 General aspects

Bleko Ethylalcohol 80% is a ready to use liquid and contains ethanol (76% w/w; 600 g/L). The proposed field of use is PT1, PT2 and PT4.

DES-O is a ready to use liquid and contains ethanol (75.6% w/w; 636 g/L). The proposed field of use is PT1, PT2 and PT4.

Direct Desinfect Spray is a ready to use liquid and contains ethanol (68% w/w). The proposed field of use is PT1 and PT2.

S-Clean 80 is a ready to use liquid and contains ethanol (76% w/w). The proposed field of use is PT1, PT2 and PT4.

Alcohol podior 70% is a ready to use liquid and contains ethanol (62.4% w/w; 70% v/v; 552 g/L). The proposed field of use is PT1 and PT2.

Alcohol 70% met 10% IPA Denteck BV is a ready to use liquid and contains ethanol (63.7% w/w; 559 g/L). The proposed field of use is PT1, PT2 and PT4.

Alcohol dilutus is a ready to use liquid and contains ethanol (62% w/w; 550 g/L). The proposed field of use is PT1, PT2 and PT4.

Alcohol fortior is a ready to use liquid and contains ethanol (94% w/w; 759 g/L). The proposed field of use is PT1, PT2 and PT4.

Alcohol Ketonatus 70% Denteck BV is a ready to use liquid and contains ethanol (65% w/w; 570 g/L). The proposed field of use is PT1, PT2 and PT4.

Ethades is a ready to use liquid and contains ethanol (67% w/w; 580 g/L). The proposed field of use is PT1, PT2 and PT4.

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
Bleko Ethylalcohol 80%	76% w/w (600 g/L)	6.3-9.5g a.s./m ²	1 ^{1,2}	Ready to use liquid, skin disinfection	Not specified	Dermal/respiratory exposure of (co-)workers, persons who get their skin disinfected.
		25.2-31.6 g a.s./m ²	2 ^{1,2}	Ready to use liquid, surface disinfection	Not specified	Dermal/respiratory exposure of (co-)workers and/or general public
		25.2-31.6 g a.s./m ²	4 ^{1,2}	Ready to use liquid, surface disinfection	Not specified	Dermal/respiratory exposure of (co-)workers and/or general public
DES-O	75.6% w/w (636 g/L)	65g a.s./m ²	1 ¹	Ready to use liquid,	Not specified	Dermal/respiratory

	Concentration a.s. in product	Use concentration	PT	Application method	Frequency	Potential secondary exposure
				skin disinfection		exposure of (co-)workers, persons who get their skin disinfected.
		Disinfection of surfaces 65 g a.s./m ² Disinfection of equipment bij immersie: 636 g/L	2,4 ¹	Ready to use liquid, surface and equipment disinfection	Not specified	Dermal/respiratory exposure of (co-)workers and/or general public
Direct Desinfect Spray	68% w/w	3 ml of ready to use product	1 ²	Ready to use: liquid, skin disinfection	Not specified	Dermal/respiratory exposure of persons who get their skin disinfected.
		70.5% w/w	2 ²	Ready to use: liquid for surface disinfection	Not specified	Dermal/respiratory exposure of general public
S-Clean 80	76% w/w	2 ml of ready to use product	1 ¹	Ready to use liquid, skin disinfection	Not specified	Dermal/respiratory exposure of persons who get their skin disinfected.
		16 g a.s./m ²	2 ¹	Ready to use liquid, surface disinfection	Not specified	Dermal/respiratory exposure of general public
		16 g a.s./m ²	4 ¹	Ready to use liquid, surface disinfection	Not specified	Dermal/respiratory exposure of general public
Alcohol podior 70%	62.4% w/w (70% v/v; 552 g/L)	22.1- g 55.3 g a.s./m ²	1 ¹	Ready to use: liquid, skin disinfection	Not specified	Dermal/respiratory exposure of (co-)workers, persons who get their skin disinfected.
		For	2 ¹	Ready to	Not	Dermal/res

	Concentration a.s. in product	Use concentration	PT	Application method	Frequency	Potential secondary exposure
		surfaces:22.1- g 55.3 g a.s./m2 For immersion: see concentration a.s. in product (approximately 1 L product/day)		use: liquid for surface disinfection And immersing for disinfection of equipment	specified	piratory exposure of (co-)workers.
Alcohol 70% met 10% IPA Denteck BV	64% w/w (559 g/L)	5.6 g a.s./m2	1 ¹	Ready to use liquid, skin disinfection	Not specified	Dermal/respiratory exposure of (co-)workers , persons who get their skin disinfected.
		11.2 g a.s./m2	2 ¹	Ready to use liquid, surface disinfection	Not specified	Dermal/respiratory exposure of (co-)workers
		11.2 g a.s./m2	4 ¹	Ready to use liquid, surface and equipment disinfection	Not specified	Dermal/respiratory exposure of co-workers, general public
		For surfaces:24.8- g 61.9 g a.s./m2 For immersion: see concentration a.s. in product (approximately 1 L product/day)	2 ¹	Ready to use: liquid for surface disinfection And immersing for disinfection of equipment	Not specified	Dermal/respiratory exposure of (co-)workers.
Alcohol dilutus	62% w/w (550 g/L)	55 g a.s./m2	1 ¹	Ready to use liquid, skin disinfection	Not specified	Dermal/respiratory exposure of (co-)workers , persons who get

	Concentration a.s. in product	Use concentration	PT	Application method	Frequency	Potential secondary exposure
						their skin disinfected.
		55 g a.s./m ² , For piping systems: see concentration a.s. in product	2 ¹	Ready to use liquid, surface disinfection and piping disinfection	Not specified	Dermal/respiratory exposure of (co-)workers
		55 g a.s./m ² For piping systems and equipment disinfection (by immersion): see concentration a.s. in product	4 ¹	Ready to use liquid, surface disinfection, piping disinfection, equipment disinfection	Not specified	Dermal/respiratory exposure of co-workers, general public
Alcohol fortior	94% w/w (759 g/L)	85% (900 ml product + 100 ml water)	1 ¹	Ready to use liquid, skin disinfection	Not specified	Dermal/respiratory exposure of (co-)workers, persons who get their skin disinfected.
		76 g a.s./m ² , For piping systems: see concentration a.s. in product	2 ¹	Ready to use liquid, surface disinfection and piping disinfection	Not specified	Dermal/respiratory exposure of (co-)workers
		76 g a.s./m ² For piping systems and equipment disinfection (by immersion): see concentration a.s. in product	4 ¹	Ready to use liquid, surface disinfection, piping disinfection, equipment disinfection	Not specified	Dermal/respiratory exposure of co-workers, general public

	Concentration a.s. in product	Use concentration	PT	Application method	Frequency	Potential secondary exposure
Alcohol Ketonatus 70% Denteck BV	65% w/w (570 g/L)	5.7 g a.s./m ²	1 ^{1,2}	Ready to use liquid, skin disinfection	Not specified	Dermal/respiratory exposure of (co-)workers, persons who get their skin disinfected.
		11.4 g a.s./m ²	2 ^{1,2}	Ready to use liquid, surface disinfection	Not specified	Dermal/respiratory exposure of co-workers, and/or general public
		11.4 g a.s./m ²	4 ^{1,2}	Ready to use liquid, surface disinfection	Not specified	Dermal/respiratory exposure of co-workers, and/or general public
Ethades	67% w/w (580 g/L)	2,5 – 5 mL voor beide handen samen.	1 ¹	Ready to use liquid, skin disinfection	Not specified	Dermal/respiratory exposure of (co-)workers, persons who get their skin disinfected.
		22.4-28 g a.s./m ²	2 ¹	Ready to use liquid, surface disinfection	Not specified	Dermal/respiratory exposure of (co-)workers and/or general public
		22.4-28 g a.s./m ²	4 ¹	Ready to use liquid, surface and equipment disinfection	Not specified	Dermal/respiratory exposure of co-workers, and/or general public

¹ Professional use

² Non-professional use

Dermal and respiratory exposure of (non-)professional users to ethanol during spray and swapping, surface disinfection, and/or equipment/piping immersion, cannot be excluded.

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

Some of the products are for both non-professional as trained professional use. See identification of the main paths of exposure in Table T.1.

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

Co-worker or general public dermal contact with treated surfaces (max 94% ethanol) could occur. Secondary inhalation exposure to ethanol are also considered, due to the vapour pressure of ethanol.

5.3 Human health effects assessment product

5.3.1 Toxicity of the formulated product

No studies with Bleko Ethylalcohol 80% 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.

No studies with DES-O have been submitted and the classification and labelling of the formulation has been prepared based on the calculation method described in Annex II of Directive 1999/45/EC.

No studies with Direct Desinfect Spray 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.

No studies with S-Clean 80 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.

No studies with Alcohol podior 70% have been submitted and the classification and labelling of the formulation has been prepared based on the calculation method described in Annex II of Directive 1999/45/EC.

No studies with Alcohol 70% met 10% IPA Denteck BV 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.

No studies with Alcohol dilutus have been submitted and the classification and labelling of the formulation has been prepared based on the calculation method described in Annex II of Directive 1999/45/EC.

No studies with Alcohol fortior 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.

No studies with Alcohol Ketonatus 70% Denteck BV 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.

No studies with Ethades 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 Professional users

For a product based on 95% ethanol (20110771), to be used as hygienic hand disinfection by professionals in hospitals, a safe use resulting from the dermal and respiratory exposure was calculated. 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 compared to the intake by drinking one alcoholic consumption and/or the use of cosmetics as lotions and perfume.

Considering the concentration of ethanol (described in Table.1), one product is almost comparable in ethanol concentration (94%) and the other products contain less ethanol (below 76%). It is anticipated that the exposure through swapping, wiping, spraying or immersing equipment will be comparable to the exposure assessed for the already authorized product based on ethanol. Therefore, it can be concluded that unacceptable health effects for the professional user through use of the products described in Table.1 are not to be expected.

For DES-O, Alcohol podior 70%, Alcohol dilutus, and Alcohol fortior it is stated in the WG/GA that gloves should be used, when removing equipment from the disinfection bath in order to keep it clean.

5.4.2 Non-professional users, including the general public

As the exposure for professionals are considered worst-case compared to non-professional exposure, and as a safe use was concluded for the professional user (see paragraph 5.4.2) no adverse health effects are expected this conclusion also applies for the non-professional user.

5.4.3 Indirect exposure as a result of use

Co-worker or general public (when used for example in nail studio's) dermal contact with treated surfaces (max 94% ethanol) could occur. It can be assumed that dermal contact longer than a few seconds with the recently cleaned and wet surfaces by co-workers/general public is not to be expected.

Secondary inhalation exposure to ethanol are also considered, due to the vapour pressure of ethanol.

Bleko Ethylalcohol 80% , DES-O, Alcohol dilutus, and Alcohol fortior are used for the disinfection of surfaces in health care areas.

Indirect or secondary exposure might occur through dermal contact of treated surfaces or by inhalation by colleagues, patients or visitors after entrance of rooms with treated surfaces.

Overall it is concluded that considering the limited dermal contact time for visitors, patients or colleagues to recently treated surfaces, no health effects are to be expected for unprotected persons after indirect exposure.

For indirect respiratory exposure, although the respiratory exposure duration of the patient, visitor or colleagues might be longer than for the professional user, since due to normal ventilation of the rooms, exposure will be equal or lower than the exposure of the professional user. As no risks were anticipated for the professional user, no risk is anticipated for indirect respiratory exposure after use of Bleko Ethylalcohol 80% , DES-O, Alcohol dilutus, and Alcohol fortior.

5.4.4 Combined exposure

All products contain only one active substance and it is not described that it should be used in combination with other formulations.

5.5 Overall conclusions for the aspect human health

Bleko Ethylalcohol 80%

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of Bleko Ethylalcohol 80%, when used in accordance to the WG/GA.

When used according 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 Bleko Ethylalcohol 80%.

DES-O

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of DES-O, when used in accordance to the WG/GA.

When used according 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 DES-O.

Direct Desinfect Spray

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of Direct Desinfect Spray, when used in accordance to the WG/GA.

When used according 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 Direct Desinfect Spray.

S-Clean 80

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of S-Clean 80, when used in accordance to the WG/GA.

When used according 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 S-Clean 80.

Alcohol podior 70%

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of Alcohol podior 70% , when used in accordance to the WG/GA.

When used according 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 Alcohol podior 70% .

Alcohol 70% met 10% IPA Denteck BV

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of Alcohol 70% met 10% IPA Denteck BV, when used in accordance to the WG/GA.

When used according 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 Alcohol 70% met 10% IPA Denteck BV.

Alcohol dilutus

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of Alcohol dilutus, when used in accordance to the WG/GA.

When used according 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 Alcohol dilutus.

Alcohol fortior

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of Alcohol fortior, when used in accordance to the WG/GA.

When used according 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 Alcohol fortior.

Alcohol Ketonatus 70% Denteck BV

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of Alcohol Ketonatus 70% Denteck BV, when used in accordance to the WG/GA.

When used according 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 Alcohol Ketonatus 70% Denteck BV.

Ethades

Based on the risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after exposure to ethanol as a result of the application of Ethades, when used in accordance to the WG/GA.

When used according 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 Ethades.

6. Environment

6.1 Introduction

Authorisation is requested for the following products: Alcohol podior 70% ; Alcohol 70% met 10% IPA Denteck BV; Alcohol dilutus ; Alcohol fortior; Alcohol Ketonatus 70% Denteck BV; Ethades;; Bleko Ethylalcohol 80 %; DES-O; Direct Desinfect Spray; S-Clean 80 containing ethanol as active substance. .

The products are disinfectants (PT1: human hygiene biocidal products, PT2: private area and public health disinfectants and other biocidal products and PT4: food and feed area disinfectants) for professional and/or non-professional use based on the active substance ethanol. The intended uses are described in table E.1.

Table E.1 Intended uses

PT	Area of use envisaged	Application product	Use concentration a.s.
1	Disinfection of hands and other skin surfaces	3 ml hands, up to 100 ml/m ² (un)diluted product on other skin surfaces	62-94.1%w/w
2	Disinfection of surfaces, materials, equipment and furniture	up to 100 ml/m ² (un)diluted product on surfaces, 1L (un)diluted product for flushing of pipelines and dipping of materials and equipment	62-94.1% w/w
4	Food and feed area disinfectants	Up to 100ml/m ² (un)diluted product on surfaces, 1L (un)diluted product for flushing of pipelines and dipping of materials and equipment	62-94.1% w/w

These products are mainly used for disinfection of unbroken skin and surfaces. Alcohol fortior, however, is also used for the cleaning and disinfection of pipelines, a process called cleaning in place (CIP). Undiluted product is pumped through the pipelines. After 5 minutes contact time the pipelines are emptied and rinsed with clean water. The concentrated waste material has to be collected for further treatment (recycling or incineration) and diluted waste will be discharged to the STP.

Alcohol Podior 70 % and 80 %, Alcohol dilutus, Alcohol fortior and DES-O are also used for dipping of instruments. The instruments have to be cleaned first. Then they should be immersed entirely in undiluted product. After 5 minutes contact time the instruments will be removed and left to dry. The used product needs to be removed as chemical waste or collected for further treatment (recycling or incineration).

6.2 Environmental profile of active substance

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 for the active substance are presented in Table E.2.

Ethanol has a low potential for bioaccumulation due to low log Kow. 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 ethanol

Compartment	Lowest endpoint	AF	PNEC	Test/species
Aquatic	NOEC: 79 mg/L	10	7.9 mg/L	<i>Oryzias latipes</i>
Sediment	-	-	6.4 mg/kg wwt	Equilibrium partitioning
STP	NOEC: ≥ 1000 mg/L	10	≥ 100 mg/L	Respiration test
Soil	-	-	1.2 mg/kg wwt	Equilibrium partitioning
Birds	-	-	-	-
Mammals	-	-	-	-

6.3 Environmental exposure assessment

6.3.1 Chemistry and/or metabolism

The environmental risk has been assessed solely for the active substance as the available tests do not indicate formation of metabolites at a level higher than 10% of the active substance. It is thereby assumed that the risk assessment for the active substance also covers risks for the metabolites forming < 10%.

There are no fate nor ecotoxicity data available for the products. It is considered acceptable that the exposure assessment is based on data for the active substance.

6.3.2 Distribution in the environment

Emission routes

Various phases in the life cycle of a product may cause emissions and environmental exposure. Emissions from active substance production and product formulation are considered less relevant compared to emissions from the application phase, in service and waste phase of the product.

Application phase and in-service phase

The application phase consists of adding the product to hands, (skin) surfaces, materials, equipment and furniture. The in-service phase is the period that the products express their disinfection properties. The waste phase is the phase when the products are removed.

The latter two phases are considered relevant for the environmental risk assessment.

Waste phase

According to the legal instructions for use (WGGA) the products applied indoors and/or outdoors on exterior surfaces need to be left to dry after application. Thus the disinfectants are released to the air due to evaporation. Emission to the STP and secondary compartments surface water/sediment via STP effluent is therefore considered negligible for ethanol applied on exterior surfaces. However, significant release to the STP and subsequently to surface water and sediment when applied to disinfect piping systems by cleaning in place (CIP) and other equipment in the food industry (PT4) can take place. The content of the tub with undiluted product in which materials or equipment are dipped for cleaning needs to be removed as chemical waste. Emission to soil is considered negligible.

Table E.2. Foreseeable routes of entry into the environment on the basis of the use envisaged

No	Use scenario	Environmental compartments and groups of organisms exposed					
		STP	Freshwater ¹	Saltwater*	Soil ^{2,3}	Air	Birds and mammals
1	Disinfection of hands and other skin surfaces (PT1)	-	-	-	-	+(Q)	-
2	Disinfection of surfaces, materials, equipment and furniture (PT2)	-/++	-/+	-	-	+(Q)	-
3	Food and feed area disinfectants (PT4)	-/++	-/+	-	-	+(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, 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.

6.3.3 Predicted environment concentration calculations

Predicted Environmental Concentrations (PEC) for applications on exterior surfaces were not calculated considering that emission of these volatile products to STP, surface water and soil and exposure of biota can be considered negligible. PECs were calculated for those applications in which the products will be discharged to the STP in diluted form (from cleaning of pipelines in the food industry by flushing)). PECs were calculated according to the exposure scenario document (ESD, release to the environment) for product type 4: Disinfectants used in food and feed areas, the Technical Guidance Document (distribution in the environment), and the model SimpleTreat (concentrations for micro-organisms in a STP and the STPs' effluent) by using the default values for parameters, unless otherwise noted.

Emission to air will be evaluated in a more qualitative approach (see below).

6.4 Risk characterisation for the environment

6.4.1 Aquatic compartment (incl. sediment) and STP

When disinfectants are applied in order to clean pipelines in the food industry by flushing, emission of the active substance to waste water and STP is possible. The application of disinfectants containing ethanol for cleaning of pipelines in the food industry (CIP) is therefore considered worst-case for the risk assessment for the aquatic compartment (incl. sediment) and STP. The applicants of the ethanol disinfectants destined for the cleaning of materials or equipment estimated that 1 L undiluted product will be used daily which roughly coincides with the average annual consumption per plant from table 6 of the ESD for PT4 for propan-1-ol/propan-2-ol of 143 kg.

As the product Alcohol Fortior (20120898 TBO) has the highest use concentration a.s. (684g/L) of the products used for cleaning of pipelines in the food industry, this use concentration is used for emission calculations.

The distribution and degree of removal of ethanol in the STP is determined by the processes of biodegradation, adsorption onto sludge, removal due to sludge removal and volatilisation, and was estimated using the following physical/chemical parameters

- Molecular weight (46.07 g/mol)
- Solubility (1000 g/L at 25°C)
- Vapour pressure (5726 Pa at 19.6°C)
- Organic carbon-water partition coefficient (calculated Koc = 1 L/kg)
- Octanol – water partition coefficient (Kow = 0.49 L/kg)
- Henry coefficient (0.57 Pa * m³/mol at 25°C)
- biodegradability (readily biodegradable)
- Emission rate chemical (0.2 kg a.s./d, which is calculated from information for propan-1-ol/propan-2-ol from table 6 of the ESD for PT4)

The corresponding PEC/PNECs in surface water, sediment and STP are presented in table E.3.

Table E.3 PEC/PNECs of ethanol for surface water, sediment and STP

	STP		fresh water		sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)	PEC/PNEC	PEC (mg/L)	PEC/PNEC
Disinfection of food vessels, machinery, and bottles which may come into contact with food and beverages (PT04)						
without on-site pre-treatment	0.017	0.0002	0.0017	0.0002	0.0011	0.0002

It can be concluded from table E.3 that a low risk for aquatic and sediment organisms and micro-organisms in the STP is expected even without on-site pre-treatment of waste water. The proposed applications, when used in compliance with the directions for use (WG/GA), therefore meet the standards for aquatic and sediment organisms and for micro-organisms in the STP.

When cleaning materials or equipment by dipping in a tub filled with undiluted product, the waste has to be disposed of as chemical waste in accordance with the Dutch Environmental Management Act.

As the proposed applications of the products on exterior surfaces will not result in emission to the sewer and exposure of the aquatic compartment, the risk for micro-organisms in the STP and aquatic and sediment dwelling organisms is considered acceptable.

6.4.1.1 Surface water intended for the abstraction of drinking water

There are no data available in the Pesticide Atlas regarding the presence of ethanol in surface water. From the general scientific knowledge collected by the Ctgb about the products used for cleaning of piping lines in the food industry by flushing and of materials and equipment by dipping and the active substance, the Ctgb concludes that there are in

this case no concrete 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. The standards for surface water destined for the production of drinking water are met. Ethanol is not on the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010).

As the proposed use of the products on exterior surfaces will not result in exposure of the aquatic compartment, risk for surface water used for the production of drinking water is considered acceptable.

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. As there are no indications that ethanol contributes to depletion of the ozone layer (calculated half life is below the trigger of < 2 days). Ethanol is not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament and thus the environmental risk to air is considered acceptable.

6.4.3 Terrestrial compartment

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

For the proposed use there is no exposure of soil. The standards for soil organisms, non target arthropods including bees are met.

6.4.3.2. Groundwater

As the proposed use will not result in exposure of the groundwater compartment, risk for the groundwater is considered acceptable.

6.4.3.3. Persistence in soil

Ethanol is readily biodegradable. The proposed use will not result in exposure of soil. Therefore standards for persistence in soil are met.

6.4.4. Non compartment specific effects relevant to the food chain

Ethanol has a log K_{ow} of < 3 and has no bioaccumulative properties. Thus the standard for bioconcentration is met. The proposed use will not result in exposure of the birds and mammals, and thus the risk for the primary and secondary poisoning is considered acceptable.

6.5 Measures to protect the environment (risk mitigation measures)

The applicants 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 for the proposed use as disinfectant for hands and other skin surfaces and for flushing of pipelines considering that risks to the environment are acceptable for these intended uses.

The proposed use of some products in cluster 24 as disinfectant for materials or equipment by dipping is acceptable for the environment but only in case a restriction is included in the WG/GA stating that left over product needs to be removed as chemical waste: *[resten die het middel bevatten, zoals niet (her) te gebruiken oplosmiddel, moeten worden verwijderd als chemisch afval]*. This is the case for the products Alcohol podior 70% and 80 %, , Alcohol dilutus, Alcohol fortior and Des-O. This is based on the Dutch Environmental Management Act (Wet Milieubeheer).

6.6 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. An overview of the risks for products for which authorisation is requested is given in Table E.4.

Table E.4 Overall conclusions

Product	Product type (PT)	Aquatic organisms	Sediment organisms	Micro-organisms in STP	Air	Drinking water from surface water	Soil organisms	Non target arthropods	Bees	Groundwater	Persistence in soil	BCF	Birds and mammals	Overall
Alcohol podior 70%	1,2	√	√	√	√	√	√	√	√	√	√	√	√	√
Alcohol 70% met 10% IPA Denteck BV	1,2	√	√	√	√	√	√	√	√	√	√	√	√	√
Alcohol dilutus	1,2,4	√	√	√	√	√	√	√	√	√	√	√	√	√
Alcohol fortior	1,2,4	√	√	√	√	√	√	√	√	√	√	√	√	√
Alcohol Ketonatus 70% Denteck BV	1,2, 4	√	√	√	√	√	√	√	√	√	√	√	√	√
Ethades	1,2,4	√	√	√	√	√	√	√	√	√	√	√	√	√
Bleko Ethylalcohol 80%	1,2,4	√	√	√	√	√	√	√	√	√	√	√	√	√
DES-O	1,2,4	√	√	√	√	√	√	√	√	√	√	√	√	√
Direct Desinfect Spray	1,2,	√	√	√	√	√	√	√	√	√	√	√	√	√
S-Clean 80	1,2,4	√	√	√	√	√	√	√	√	√	√	√	√	√

Based on the available data, it can be concluded that the products listed above, when used in accordance with the proposed label (WG/GA) do comply with the environmental standards.

7. Conclusions

7.1 Bleko Ethylalcohol 80%

The use on skin and hands (i.e. hand disinfection) has been removed from the claim as no data are provided on bactericidal efficacy in a handrub test, a mandatory requirement for this intended use. The use against viruses has been removed from the claim as no data are provided with the required (non-enveloped) virus standard organisms. The use in animal housing is removed as this is PT03. There are 2 separate WG/GA's, one for professional use and one for non-professional use.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on hard surfaces in households, food production sector and health care when used as described on the Legal Conditions for Use and the Directions for Use (WG/GA's).

The authorised uses as mentioned on the WGGA 's fall within product types 02 and 04.

7.2 DES-O

The use on human skin (i.e. hand disinfection) has been removed as no sufficient bactericidal efficacy has been demonstrated in a handrub test.

As a result of the assessment safe use and efficacy are demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses

- on hard surfaces and instruments in the public health area;
- on hard surfaces in the food and animal feed industry,

when used as described on the Legal Conditions for Use and the Directions for Use (WG/GA's)

The authorised uses as mentioned on the WGGA fall within product types 02 and 04.

7.3 Direct desinfect spray

The use for disinfection of hands (PT01) and the use against viruses has been removed on request of the applicant

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores) and yeasts on hard surfaces in rooms where people reside, excluding surfaces that come into contact with food and drink and raw materials thereof, 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 02.

7.4 S-Clean 80

The use on hands (PT01) has been removed from the claim as no acceptable handrub test is provided on bactericidal efficacy. The use against fungi has been removed on request of the applicant.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores) and yeasts

- on hard surfaces in institutional kitchens of catering facilities, that come into contact with food and drink and the raw materials thereof;
- on hard surfaces in the public health area,

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 types 02 and 04.

7.5 Alcohol podior 70%

The use on human skin (i.e. hand disinfection) has been removed from the claim as not sufficient data on bactericidal efficacy are provided with the required contact time of maximum 30 seconds;

The use for instrument disinfection has been removed from the claim as virucidal efficacy is mandatory for this use and not sufficient data are provided to substantiate virucidal efficacy.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on hard surfaces in the health care, pedicure practices, tattoo-shops, beauty saloons and nail studios, excluding surfaces that come into contact with food and drink and the raw materials thereof, when used as described on the Legal Conditions for Use and the Directions for Use (WG/GA).

The authorised uses as mentioned on the WGGGA fall within product type 02.

7.6 Alcohol 70% met 10% IPA Denteck BV

The use against fungi has been removed on request of the applicant. The use against viruses has been removed from the claim as not sufficient data are provided with the required (non-enveloped) virus standard organisms. The use on human skin (i.e. hand disinfection) has been removed from the claim as not sufficient data are provided to substantiate the claim. The provided handrubtest is not acceptable as (a.o.) the test validation criteria were not met and thus the test should have been repeated. The use for instrument disinfection has been removed from the claim as virucidal efficacy is mandatory for this use and not sufficient data are provided with the required (non-enveloped) virus standard organisms.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores) and yeasts on hard surfaces in public health areas, including areas that come into contact with food and drink and the raw materials thereof, when used as described on the Legal Conditions for Use and the Directions for Use (WG/GA).

The authorised uses as mentioned on the WGGGA fall within product types 02 and 04.

7.7 Alcohol dilutus

The use on human skin (i.e. hand disinfection) has been removed from the claim as not sufficient data on bactericidal efficacy are provided with the required contact time of maximum 30 seconds.

The use for instrument disinfection has been removed from the claim as virucidal efficacy is mandatory for this use and no data are provided to substantiate virucidal efficacy.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores) yeasts and fungi on:

- hard surfaces in hospitals and dental, medical and veterinary practices;
- hard surfaces in research laboratories;
- hard surfaces that come into contact with food and animal feed, excluding milking machines;
- pipelines that come into contact with food and animal feed (CIP), excluding milking machines,

when used as described on the Legal Conditions for Use and the Directions for Use (WG/GA).

The authorised uses as mentioned on the WGGGA fall within product types 02 and 04

7.8 Alcohol fortior

The use for disinfection of human skin (i.e. hand disinfection, PT01) has been removed from the claim as not sufficient bactericidal efficacy has been demonstrated in the handrub test. The use for instrument disinfection has been removed from the claim as virucidal efficacy is mandatory for this use and no data on virucidal efficacy have been provided.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on

- hard surfaces in hospitals and dental, medical and veterinary practices;
- hard surfaces in research laboratories;

- hard surfaces that come into contact with food and animal feed, excluding milking equipment;
 - piping that comes into contact with food and animal feed through Cleaning-In-Place, excluding milking equipment,
- 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 types 02 and 04

7.9 Alcohol Ketonatus 70% Denteck BV

The use against fungi has been removed on request of the applicant. The use against viruses has been removed from the claim as not sufficient data are provided with the required (non-enveloped) virus standard organisms. The use on human skin (i.e. hand disinfection) has been removed from the claim as not sufficient data are provided to substantiate the claim. The provided handrubtest is not acceptable as the test validation criteria were not met and thus the test should have been repeated. The non-professional use (PT02 and PT04) has been removed from the claim as no acceptable simulated use test (phase 2, step 2) with the required standard organisms for bacteria and yeasts and a contact time of 30 seconds (i.e. according to the intended use) was provided, which is a mandatory requirement for non-professional use.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores) and yeasts on hard surfaces in public health areas, including areas that come into contact with food and drink and the raw materials thereof, 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 types 02 and 04

7.10 Ethades

The non-professional use has been removed on request of the applicant. The use for disinfection of hands (PT01) has been removed from the claim as not sufficient bactericidal efficacy has been demonstrated in a handrub test (EN 1500) at the required significance level of $p=0.1$. A contact time of minimal 30 seconds has been added to the GA as efficacy against bacteria and yeasts has been demonstrated with this contact time.

As a result of the assessment safe use and efficacy is demonstrated for the use as disinfectants to control bacteria (excluding mycobacteria and bacterial spores) and yeasts on:

hard surfaces in the public health area;

hard surfaces in the food and animal feed area, excluding milking machines,

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 types 02 and 04

8. Classification and labelling

8.1 Bleko Ethylalcohol 80%

Labelling proposal for non-professional use

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

The identity of all substances in the mixture that contribute to the classification of the mixture *:

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Pictogram:	GHS02	Signal word: Danger
H-statements:	H225	Highly flammable liquid and vapour
P-statements:	P 101	If medical advice is needed, have product container or label at hand
	P 102	Keep out of reach of children
	P 103	Read label before use
	P 210	Keep away from heat/sparks/open flames/hot surfaces. No smoking
	P 233	Keep container tightly closed
	P 261	Avoid breathing dust/fume/gas/mist/vapours/spray
Supplemental Hazard information:	-	-
Child-resistant fastening obligatory?		Yes
Tactile warning of danger obligatory?		Yes

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

Remarks:

- H336 is not assigned based on the concentration of the co-formulant being below the generic classification limit for H336.
- The flashpoint of Bleko Ethylalcohol 80% is assumed to be <23°C. Therefore, Bleko Ethylalcohol 80% is classified as a cat. 2 flammable liquid and H225 is assigned.
- A cat. 2 flammable liquid requires a tactile warning and a child-resistant fastening for non-professional use

Labelling proposal for professional use

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

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-

Pictogram:	GHS02	Signal word: Danger
H-statements:	H225	Highly flammable liquid and vapour
P-statements:	P 210	Keep away from heat/sparks/open flames/hot surfaces. No smoking
	P 233	Keep container tightly closed
	P 261	Avoid breathing dust/fume/gas/mist/vapours/spray

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:

- H336 is not assigned based on the concentration of the co-formulant being below the generic classification limit for H336.
- The flashpoint of Bleko Ethylalcohol 80% is assumed to be <23°C. Therefore, Bleko Ethylalcohol 80% is classified as a cat. 2 flammable liquid and H225 is assigned.

8.2 DES-O

**Proposed for classification and labelling for the formulation
Based on 1999/45/EC:**

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances) *:

-

Symbol:	F	Indication of danger: Highly flammable
R phrases	R11	Highly flammable
S phrases	S16	Keep away from sources of ignition - No smoking.
	S35	This material and its container must be disposed of in a safe way.
Special provisions: DPD-phrases	-	-
Child-resistant fastening obligatory?		Not applicable
Tactile warning of danger obligatory?		Not applicable

* according to 1999/45/EC, article 10, point 2.3

Remarks:

- In combination with R11, for professional use S35 is assigned.
- S7 is not considered required for liquids classified as highly flammable.
- S2 and S46 are not obligatory with the assigned R-phrase(s).

8.3 Direct desinfect spray

Proposed for classification and labelling for the formulation

Based on Reg. (EC) 1272/2008 (non-professional use):

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-		
Pictogram:	GHS02	Signal word: Danger
H-statements:	H225	Highly flammable liquid and vapour.
P-statements:	P102	Keep out of reach of children
	P210	Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
	P305+P351	IF IN EYES: Rinse cautiously with water for several minutes.
Supplemental Hazard information:	-	-
Child-resistant fastening obligatory?		Yes
Tactile warning of danger obligatory?		Yes

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

Remarks:

- P261 is proposed by the applicant.
- P305 is proposed by the applicant. This is combined with P351.

8.4 S-Clean 80

Proposed for classification and labelling for the formulation

Based on Reg. (EC) 1272/2008:

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-		
Pictogram:	GHS02	Signal word: Danger
H-statements:	H225	Highly flammable liquid and vapour.
P-statements:	P210	Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
	P233	Keep container tightly closed.
	P240	Ground/bond container and receiving equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P370+P378	In case of fire: Use ... for extinction.
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)

8.5 Alcohol podior 70%

Proposed for classification and labelling for the formulation

Based on 1999/45/EC:

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances) *:

-			
Symbol:	F	Indication of danger:	Highly flammable
R phrases	R11	Highly flammable	
S phrases	S16	Keep away from sources of ignition – No smoking	
	S35	This material and its container must be disposed of in a safe way	
Special provisions: DPD-phrases	-	-	
Child-resistant fastening obligatory?		Not applicable	
Tactile warning of danger obligatory?		Not applicable	

* according to 1999/45/EC, article 10, point 2.3

Remarks:

- S35 is required since the formulation is to be used professionally. S2 is only needed for non-professional use.
- S7 is only required for solid materials or products, and is therefore not included in the Ctgb proposal
- The active substance does not need to be included in this table, as it is mandatory to show the identity of every active substance and its concentration on the label (according to BPD 98/8/EC, art 20, 3a)

8.6 Alcohol 70% met 10% IPA Denteck BV

Proposed for classification and labelling for the formulation

Based on Reg. (EC) 1272/2008:

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-			
Pictogram:	GHS02	Signal word: Danger	
H-statements:	H225	Highly flammable liquid and vapour.	
P-statements:	P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking.	
	P233	Keep container tightly closed.	
	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:

- Classification as a category 2 flammable liquid is required based on the flash-point and initial boiling point of the product (FP 16 °C, BP> 35 °C).
- P210 and P403+P235 are highly recommended, and will therefore be included in the Ctgb classification proposal. P233 is recommended for cat 2 flammable liquids.

8.7 Alcohol dilutus

Proposed for classification and labelling for the formulation

Based on 1999/45/EC:

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances) *:

-

Symbol:	F	Indication of danger:	Highly flammable
R phrases	R11	Highly flammable	
S phrases	S16	Keep away from sources of ignition – No smoking	
	S35	This material and its container must be disposed of in a safe way.	
Special provisions: DPD-phrases	-	-	
Child-resistant fastening obligatory?		Not applicable	
Tactile warning of danger obligatory?		Not applicable	

* according to 1999/45/EC, article 10, point 2.3

Remarks:

- An R11 classification is proposed instead of R10, since the flashpoint of the formulation is < 22 °C.
- S7 is recommended for highly flammable solid materials, and is therefore not required for this formulation.
- S2 is not assigned, since the formulation is only intended for professional use. S35 is assigned on the same grounds.

8.8 Alcohol fortior

Proposed for classification and labelling for the formulation

Based on Reg. (EC) 1272/2008:

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-

Pictogram:	GHS02	Signal word: Danger
H-statements:	H225	Highly flammable liquid and vapour.
P-statements:	P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking.
	P233	Keep container tightly closed.
	PP303+P361+P353	BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen.
	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:

- H319 is not assigned as none of the (co-)formulants are classified with eye irritation.
- P303+P361+P353 is proposed by the applicant.

8.9 Alcohol Ketonatus 70% Denteck BV

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
H-statements:	H225	Highly flammable liquid and vapour
P-statements:	P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking
	P233	Keep container tightly closed.
	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)

Non-professional use

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-

Pictogram:	GHS02	Signal word: Danger
H-statements:	H225	Highly flammable liquid and vapour.

P-statements:	P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking
	P233	Keep container tightly closed.
	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)

8.10 Ethades

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
H-statements:	H225	Highly flammable liquid and vapour.
P-statements:	P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking.
	P233	Keep container tightly closed.
	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)

9. References

ESD	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, JRC Scientific and Technical Reports, Report nr. EUR 25117 EN, Publications Office of the European Union, Luxembourg, 2011
EU	EU summary dossier of ethanol (RMS DE)
IUCLID	IUCLID data sheet of ethanol
USEPA	USEPA RED document on aliphatic alcohols (1995) EPA 738-R-95-013
Wet Milieubeheer	Landelijke Afval beheersplan 2
RIVM 2010	RIVM, 2010: Biociden in oppervlaktewater voor drinkwaterproductie, National institute for public health and the environment, RIVM-report 601712007/2010, Bilthoven, The Netherlands