Toelatingsnummer 14331 N

Alcohol Podior 80% 14331 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 TOELATING

Gelet op de aanvraag d.d. 15 juni 2012 (20120750 TBO) van

REYMERINK B.V.
Stichtse Kade 47 A
1244 HW ANKEVEEN

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 80%

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 80% is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 14331 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 januari 2024.

1.2 Samenstelling, vorm en verpakking

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

1.3 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage I 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:	*gehalte:*
ethanol	80 %v/v

letterlijk en zonder enige aanvulling:

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

gevaarsymbool:	*aanduiding:*
F	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 van Alcohol podior) 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 80% (14331 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 80% 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 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 13 december 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. 13 december 2013 tot toelating van het middel Alcohol Podior 80%, toelatingnummer 14331 N

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van

- bacteriën (exclusief mycobacteriën en bacteriesporen), gisten en schimmels op blijvend intacte huidoppervlakken in de humane gezondheidszorg, in pedicurepraktijken, in schoonheidssalons en in nagelstudio's;
- bacteriën (exclusief mycobacteriën en bacteriesporen), gisten, schimmels en virussen op harde oppervlakken en instrumenten in de humane en veterinaire gezondheidszorg, in pedicurepraktijken, in schoonheidssalons, in nagelstudio's en in laboratoria, 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.

Gebruikte dompelvloeistof moet worden verwijderd als chemisch afval.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

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

Desinfectie van de huid
Het middel is alleen bestemd voor desinfectie van de blijvend intacte huid, d.w.z. huid die na desinfectie niet geopend of doorboord zal worden.
De te desinfecteren huid eerst reinigen en goed afdrogen. Het middel op de te behandelen huid aanbrengen met bijvoorbeeld een celstofdepper. Zoveel van het

middel aanbrengen, dat de behandelde huid gedurende de gehele inwerktijd (minimaal 30 seconden) vochtig blijft. Vervolgens de huid laten drogen.

Minimale inwerktijd: 30 seconden.

Desinfectie van harde oppervlakken
Het middel alleen toepassen op kleine oppervlakken (maximaal 0,5 m^2).
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 en laat minimaal 5 minuten inwerken. Bij het desinfecteren zoveel vloeistof gebruiken dat het oppervlak gedurende de gehele inwerktijd tijd nat blijft. Hierna met bijvoorbeeld een celstofdoek het oppervlak droogwrijven.

Minimale inwerktijd: 5 minuten

Desinfectie van instrumenten door middel van dompelen
De materialen eerst reinigen. Een daarbij gebruikt reinigingsmiddel afspoelen met schoon water. Overtollig water verwijderen. Dompel de materialen vervolgens gedurende minimaal 5 minuten in z'n geheel in Alcohol podior 80%. Neem hierna met schone handschoenen de materialen uit het desinfectiemiddel en laat ze op een schone plaats drogen.

Minimale inwerktijd: 5 minuten

Voorkom teruglopen van de werkzaamheid van de dompelvloeistof door verdamping of vervuiling. De dompelvloeistof daarom afdekken en dagelijks verversen.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 13 december 2013 tot toelating van het middel Alcohol Podior 80%, toelatingnummer 14331 N

RISKMANAGEMENT

Contents **Page**

1. Introduction

This assessment concerns the biocidal product Alcohol podior 80% based on the active substance ethanol. This application has been submitted under the differentiated enforcement policy of biocides.

The assessment includes the following product:

Product	Applicant	PT	Application number
Alcohol podior 80%	REYMERINK B.V.	PT 1, PT 2	20120750 TBO

The active substance ethanol has been notified for product types 1, 2, 4. Ethanol has not yet been included in the Union list of approved substances of EU Regulation 528/2012.

2. Identity

2.1 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_2H_6O
Molecular mass	46.07
Structural formula	CH_3-CH_2-OH

The active substance has not yet been included in the Union list of approved substances of EU Regulation 528/2012.
A CAR of the active substance is not yet available.

2.2 Physical and chemical properties of the active substance

2.2.1 Ethanol

Physical and chemical properties 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 e 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

2.3 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.

2.4 Overall conclusions active substance

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

3. Physical and chemical properties

3.1 Identity of the biocidal product

Name	Alcohol podior 80%
Content active substance	73.5% w/w pure ethanol (80% v/v; 634 g/L)
Formulation type	AL
Packaging	100 mL glass bottle; 1 and 5L HDPE bottle

3.2 Physical and chemical properties of the biocidal product

Appearance	Colourless, transparent liquid
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-flammability	Not self-igniting
Flashpoint	20 °C
pH 1% solution	~7
Relative density	0.859
Storage stability/ Shelf life	2 years in glass and HDPE
Physical and chemical compatibility	No mixing intended
Viscosity	Not applicable
Surface tension	Not applicable

3.3 Analytical methods for detection and identification

3.3.1 Analytical methods for analysis of the biocidal product

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

3.3.2 Residue analytical methods

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

3.4 Overall conclusions biocidal product

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

4. Efficacy

Function

Alcohol podior 80% is a disinfectant (PT01 and PT02) based on ethanol 80% v/v.

Field of use envisaged

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

- intact skin
- hard surfaces
- instruments

in the human and veterinary health care, pedicure practices, beauty saloons, nailstudios and laboratoria.
These uses are included in PT01 and PT02.

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 references / studies testing efficacy were provided, some were considered to be suitable and acceptable.
PT01
For the intended use of skin 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, yeasts and fungi at low level soiling conditions of 0.3 g/L bovine albumin and a contact time of 30 seconds. In addition, bactericidal efficacy has been demonstrated in a handrub test (phase 2, step 2) according to EN 1500 - mandatory for PT01 skin disinfection - at the required contact time of 30 seconds.
PT02
Bacteria and yeasts
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 the use concentration (100%, undiluted), a contact time of 30 seconds and low level soiling conditions of 0.3 g/L bovine albumin. This is in accordance with the intended use.
Fungi
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 5 minutes.
Viruses
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 of 100% (undiluted), low level soiling conditions of 0.3 g/L bovine albumin and a contact time of 5 minutes. This is in accordance with the intended use.

4.3.1 Evaluation of the label (WG/GA)
The applicant have provided a Dutch WG/GA. This has been adapted to our standards.
- Surfaces that come into contact with food and drink and the raw materials thereof will be excluded as only PT02 has been claimed.

4.3.2 Mode of action
The following information is provided:
Denaturation of proteins and disruption of cytoplasmic membrane by dissolving lipid.

Resistance and resistance management strategies
The following information is provided:
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 Alcohol podior 80%, when used in accordance with the proposed label (WG/GA), is effective in controlling:
- bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on intact skin in human, health care, pedicure practices, beauty saloons and nailstudios;
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses on hard surfaces and instruments in human and veterinary health care, pedicure practices, beauty saloons, nailstudios and laboratories, excluding surfaces that come into contact with food and drink and the raw materials thereof.

5. Human toxicology

5.1 Human health effects assessment active substance

Ethanol
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 first draft CA-report from RMS Greece is available (July 2013).
For ethanol a EPA RED (1995) and a DECOS evaluation (2006) are available.

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

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

Data requirements active substance
No additional data requirements are identified.

5.2 Human exposure assessment active substance

5.2.1 General aspects
Alcohol podior 80% is a ready to use liquid and contains ethanol (73.5% w/w; 634 g/L). The proposed field of use is PT1 and PT2.

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 product. 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
Alcohol Podior 80%	73.5% w/w (634 g/L)	24.8- g 61.9 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.
		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 - immersing for disinfection of equipment	Not specified	Dermal/respiratory exposure of (co-)workers.

[1] Professional use

Dermal and respiratory exposure of professional users to ethanol during swapping/surface disinfection, and/or equipment immersion, cannot be excluded.

5.2.3 Identification of main paths of non-professional exposure towards active substance from its use in biocidal product
The product is intended for professional use only.

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 73.5% w/w 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 Alcohol podior 80% 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.

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.

Alcohol podior 80% contains 73.5% ethanol which is lower than the authorized product. It is anticipated that the exposure through swapping, wiping, 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 Alcohol podior 80% are not to be expected.
For Alcohol podior 80% 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
The product is intended for professional use only.

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 73.5% 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.

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

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 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 Alcohol podior 80% .

6. Environment

6.1 Introduction

Authorisation is requested for Alcohol podior 80% containing ethanol as active substance. The product is a disinfectant (PT1: human hygiene biocidal products and PT2: private area and public health 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

No	Area of use envisaged	Application product	Use concentration a.s.
1	Disinfection of hands and other skin surfaces	40-100 ml/m^2 product on skin surfaces	24.8- 61.9 g a.s./m^2
2	Disinfection of surfaces	40-100 ml/m^2 undiluted product on hard small (≤0.5m^2) surfaces	24.8- 61.9 g a.s./m^2
3	Disinfection of equipment	1L undiluted product, dipping of materials and equipment	1 L undiluted product, □0.62kg a.s./day

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 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	*Oryzias latipes*
Sediment	-	-	6.4 mg/kg wwt	Equilibrium partitioning
STP	NOEC: [3] 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 product. 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 product expresses its disinfection properties. The waste phase is the phase when the product is removed.
The latter two phases are considered relevant for the environmental risk assessment.

Waste phase

According to the legal instructions for use (WGGA) the product applied indoors on exterior surfaces need to be left to dry after application. Thus the disinfectant is 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. 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		Environmental compartments and groups of organisms exposed					
	Use scenario	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)	-

++ 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 skin and exterior surfaces were not calculated considering that emission of this volatile product to STP, surface water and soil and exposure of biota can be considered negligible.
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 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 product on skin surface or 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 product used for dipping of materials and equipment 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 product on skin surfaces and 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 uses 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 uses 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 exterior surfaces considering that risks to the environment are acceptable for these intended uses.

The proposed use of Alcohol podior 80% 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: [Gebruikte dompelvloeistof moet worden verwijderd als chemisch afval]. 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 the product for which authorisation is requested is given in Table E.3.

Table E.3 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	P
Alcohol podior 80%	1,2	√	√	√	√	√	√	√	√	√	

Based on the available data, it can be concluded that Alcohol podior 80% when used in accordance with the proposed label (WG/GA) complies with the environmental standards.

7. Conclusion

The applicant has proven that Alcohol podior 80%, under the proposed Legal Conditions for Use and the Directions for Use (WG/GA), is sufficiently effective and that no unacceptable risk is expected to human health, the person who uses the product and the environment (Art. 121 jo art. 49 first paragraph Dutch 2007 Plant Protection Products and Biocides Act).

As a result Alcohol podior 80% can be authorized for the use of controlling:
- bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on intact skin in human health care, pedicure practices, beauty saloons and nail studios;
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses on hard surfaces and instruments in human and veterinary health care, pedicure practices, beauty saloons, nailstudios and laboratories, excluding surfaces that come into contact with food and drink and the raw materials thereof.

The authorised uses as mentioned on the WGGA fall within product types PT 1 and PT 2.

8. Classification and labelling

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)

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