HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 1 november 2021 is van

Hypred S.A.
Blvd Jules Verger 55
B.P. 10180, F-35803 DINARD CEDEX
Frankrijk

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

FORCE 7

op basis van de werkzame stoffen alkyl (C12-16) dimethylbenzylammoniumchloride, didecyldimethylammoniumchloride en glutaaraldehyde.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:
- Bijlage I voor details van de aanvraag en toelating;
- Bijlage II voor de etikettering;
- Bijlage III voor wettelijk gebruik;
- Bijlage IV voor de onderbouwing.

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen op de verpakking te worden vermeld:

1. De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
2. Het toelatingsnummer.
3. De etikettering zoals opgenomen in bijlage II bij dit besluit, deze moet volgens de voorschriften op de verpakking worden vermeld.
4. Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III, onder A.
5. De gebruiksaanwijzing, hetzij letterlijk, hetzij naar zakelijke inhoud, zoals opgenomen in bijlage III, onder B. De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.
6. Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 89, tweede lid van EU 528/2012 jo art 130a, vierde lid Wet gewasbeschermingsmiddelen en biociden (Wgb) jo art 4, tweede lid Wgb (oud) jo art 121 Wgb (oud) jo art 44 Wgb (oud).
Classificatie en etikettering	artikel 89, tweede lid, Verordening 528/2012, jo. artikel 130a, vierde lid, WBB, jo. artikel 50 WGB oud
Gebruikt toetsingskader	RGB (Hoofdstuk 10)

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden.

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

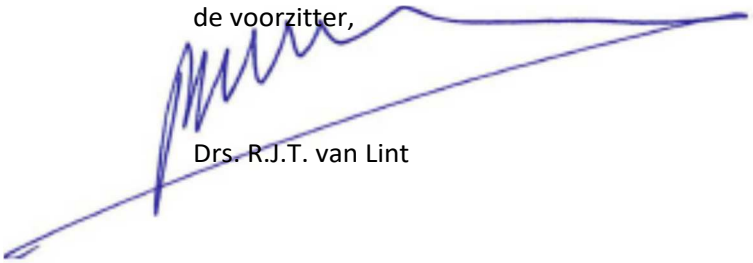
Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Bezwaarmogelijkheid

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het college voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Ede, 7 oktober 2022

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



Drs. R.J.T. van Lint

16441 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20211639 TB
Type aanvraag:	toelating van de biocide op basis van niet geplaatste stoffen (overgangsrecht)
Middelnaam:	FORCE 7
Formele registratiedatum: *	1 december 2021

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

2 Stofinformatie

Werkzame stof	Gehalte
Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))	8 %
Didecyldimethylammoniumchloride (DDAC)	1,5 %
Glutaaraldehyde	13 %

De werkzame stoffen alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16)) en didecyldimethylammoniumchloride (DDAC) zijn opgenomen in het reviewprogramma en zullen per 1 november 2022 worden geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012 voor het aangevraagde PT03 en PT04.

De werkzame stof glutaaraldehyde is per 1 oktober 2016 geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012 voor het aangevraagde PT03 en PT04.

3 Toelatingsinformatie

Toelatingsnummer:	16441 N
Expiratiedatum:	1 oktober 2032
Afgeleide of parallel:	n.v.t. (nieuw middel)
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Met water mengbaar concentraat

Uiterste gebruiksdatum:
6 maanden na productiedatum

16441 N

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BIJLAGE II Etikettering van het middel FORCE 7

Professioneel

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: Alkyl(C12-C14)dimethylbenzylammoniumchloride (ADBAC (C12-C14)), didecyldimethylammonium chloride (DDAC (C8-10)), glutaaraldehyde en trimethyldecanolethoxylaat

Pictogram	GHS05 GHS07 GHS08 GHS09
Signaalwoord	Gevaar
Gevarenaanduidingen	H302 Schadelijk bij inslikken. H314 Veroorzaakt ernstige brandwonden en oogletsel. H317 Kan een allergische huidreactie veroorzaken. H332 Schadelijk bij inademing. H334 Kan bij inademing allergie- of astmasymptomen of ademhalingsmoeilijkheden veroorzaken. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P260 Stof/rook/gas/nevel/damp/spuitnevel niet inademen. P273 Voorkom lozing in het milieu. P280 Draag beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming/gehoorbescherming/... P284 Adembescherming dragen. P303 + P361 + P353 BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken. Huid met water afspoelen/afdouchen. P304 + P340 NA INADEMING: de persoon in de frisse lucht brengen en ervoor zorgen dat deze gemakkelijk kan ademen. P305 + P351 + P338 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. P310 Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P342 + P311 Bij ademhalingssymptomen: een ANTIGIFCENTRUM of een arts raadplegen. P501 Inhoud/verpakking afvoeren naar ....
Aanvullende etiketelementen	EUH071 Bijtend voor de luchtwegen.

16441 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE III WG/GA van het middel FORCE 7

A.

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van:

1. bacteriën (excl. bacteriesporen en mycobacteriën) en gisten in de voedingsindustrie op plaatsen waar eet- en drinkwaren worden bereid, behandeld of bewaard, met uitzondering van melkwinningsapparatuur op de boerderij;
2. bacteriën (excl. bacteriesporen en mycobacteriën), gisten en virussen (omkapselde en niet omkapselde virussen)* op oppervlakken, materialen en gereedschappen in dierverblijfplaatsen en bijbehorende ruimten, met uitzondering van de buitenkant van transportvoertuigen voor dieren.

Om verminderd functioneren van een Individuele Behandeling Afvalwater (IBA) bij toepassing van dit middel op de boerderij te voorkomen, dienen afvalresten die het middel bevatten geloosd te worden op de mestopslag of op de gemeentelijke riolering.

Bij gebruik van dit middel in de voedselindustrie en bij desinfectie van transportmiddelen voor dieren is een additionele vetafscheider en slibvangput conform NEN-EN 1825-1 en 1825-2 en/of een biologische of chemische voorzuivering verplicht met afvoer op de gemeentelijke riolering.

Maak in het geval van desinfectie van materialen en gereedschappen in dierverblijfplaatsen middels dippen niet meer dan 10 L desinfectievloeistof per dag aan.

Tijdens mengen en laden:
Gebruik handschoenen, overall en adembescherming.

Tijdens spuiten of schuimen:
Gebruik handschoenen, overall en adembescherming.
Onbeschermde mensen en dieren mogen niet in de ruimte aanwezig zijn tijdens desinfectie via spuiten of schuimen.

Tijdens dompelen:
Gebruik handschoenen en overall.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

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

B.

GEBRUIKSAANWIJZING

Het middel kan worden toegepast door middel van schuimvormende apparatuur (bijv. schuimpistool of schuim satelliet), besproeiing, of door de te behandelen materialen in een dompelbad te plaatsen.

16441 N

De te desinfecteren materialen en oppervlakken eerst grondig reinigen met schoon water. Het daarbij gebruikte reinigingsmiddel goed afspoelen met schoon water. Overtollig water verwijderen.

1. Desinfectie van oppervlakken en materialen in de voedingsindustrie, met uitzondering van melkwinningsapparatuur op de boerderij:

Behandeling met schuimvormende apparatuur of door middel van besproeiing:
Bij het desinfecteren zo veel vloeistof gebruiken dat de oppervlakken gedurende de inwerktijd nat blijven. Toepassen bij 10 °C.
Dosering: bacteriën en gisten: 0,5 % v/v (50 ml middel met water aanvullen tot 10 liter);
Minimale inwerktijd: 30 minuten
Naspoelen met schoon water.

Dompelbad:
Toepassen bij 10°C.
Dosering: bacteriën en gisten 0,5 % v/v (50 ml middel met water aanvullen tot 10 liter)
Minimale inwerktijd: 30 minuten
Naspoelen met schoon water. De oplossing vervangen wanneer deze zichtbaar vuil is.

2. Desinfectie van oppervlakken, materialen en gereedschappen in dierverblijfplaatsen en bijbehorende ruimten, met uitzondering van de buitenkant van transportvoertuigen voor dieren:

Behandeling met schuimvormende apparatuur of door middel van besproeiing :
Bij het desinfecteren zo veel vloeistof gebruiken dat de oppervlakken gedurende de inwerktijd nat blijven.
Dosering: bacteriën en gisten: 0,75% v/v (75 ml middel met water aanvullen tot 10 liter);
Virussen 1,5% v/v (150 ml middel met water aanvullen tot 10 liter
Minimale inwerktijd: 30 minuten
Materialen en gereedschappen in contact met diervoeding naspoelen met schoon water.

Dompelbad :
Dosering: bacteriën en gisten: 0,75% v/v (75 ml middel met water aanvullen tot 10 liter);
virussen 1,5% v/v (150 ml middel met water aanvullen tot 10 liter)
Minimale inwerktijd: 30 minuten
Materialen en gereedschappen in contact met diervoeding naspoelen met schoon water. De oplossing vervangen wanneer deze zichtbaar vuil is.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV RISKMANAGEMENT

Contents

1 Introduction

1.1 Applicant

Hypred S.A.
Blvd Jules Verger 55
B.P. 10180, F-35803 DINARD CEDEX
France

1.2 Active substance

- Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))
- Didecyldimethylammoniumchloride (DDAC)
- Glutaraldehyde

1.3 Product

FORCE 7

1.4 Function

FORCE 7 is a disinfectant (PT03 and PT04).

1.5 Background to the application

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

1.6 Intended uses

The proposed field of use of FORCE 7 is the control of bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses) on:

- hard surfaces that come into contact with food, feed or the raw materials thereof, with the exception of milking equipment on farms;
- hard surfaces, materials and tools in the veterinary sector, with the exception of the outside of animal transport vehicles.

The product is intended for professional use.

1.7 Packaging details

	Material	Size / content	Other information
Professional use	HDPE	5kg	Canister
	HDPE	10kg	Canister
	HDPE	22kg	Canister
	HDPE	220kg	Drum
	HDPE	1000kg	IBC

2 Identity

2.1 Identity of the active substance

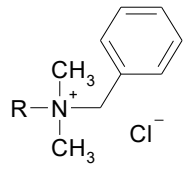
2.1.1 Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC)

Common name	Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12-16}))
Name in Dutch	Alkyl(C_{12-16}) dimethylbenzylammoniumchloride (ADBAC/BKC (C_{12-16}))
Chemical name (CA)	Quaternary ammonium compounds, benzyl-(C12-16)-alkyldimethyl, chlorides
CAS no	68424-85-1

EC no 270-325-2

The active substance Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16)) is included in the Union list of approved substances of EU Regulation 528/2012 for PT3, 4 and 8. The substance is under review for PT 1, 2, 10, 11, 12 and 22. A first draft CAR is available for PT 1 and PT 2 (eCA Italy, March 2021).

The list of endpoints presented below is taken from the AR (PT8, June 2015, eCA Italy)

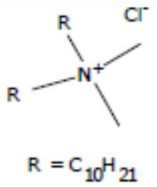
Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Quaternary ammonium compounds, benzyl-(C12-16)-alkyldimethyl, chlorides
CAS No	68424-85-1
EC No	270-325-2
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	**US ISC** 940 g/kg (dry weight) **EQC** 981 g/kg (dry weight)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{n+9}H_{2n+14}N.Cl$ (n = 12, 14, 16) Alkyl chain lengths distribution: *Chain Length* / *Range* *C12* / *39 - 76%* *C14* / *20 - 52%* *C16* / *<12%*
Molecular mass	340.0 – 396.1 g/mol
Structural formula	 R = $C_{12}H_{25}$, $C_{14}H_{29}$ or $C_{16}H_{33}$

2.1.2 Didecyldimethylammonium chloride (DDAC)

Common name	DDAC
Name in Dutch	Didecyldimethylammonium chloride
Chemical name	Didecyldimethylammonium chloride
CAS no	7173-51-5
EC no	230-525-2

The active substance Didecyldimethylammonium chloride (DDAC) is included in the Union list of approved substances of EU Regulation 528/2012 for PT 3, 4 and 8. A first draft CAR is available for PT 1 and 2 (January 2012 RMS IT). No CAR is available yet for PT 6, 10, 11 and 12.

The list of endpoints presented below is taken from the AR (PT8, June 2015, eCA Italy).

Chemical name (IUPAC)	N,N-Didecyl-N,N-dimethylammonium Chloride
Chemical name (CA)	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride
CAS No	7173-51-5
EC No	230-525-2
Other substance No.	612-131-00-6 (Annex I Index number)
Minimum purity of the active substance as manufactured (g/kg or g/l)	**US ISC** 870 g/kg (dry weight) **EQC** 979 g/kg (dry weight)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	C22H48N.Cl
Molecular mass	362.1 g/mol
Structural formula	

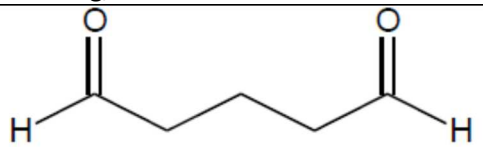
2.1.3 Glutaraldehyde

Common name	Glutaraldehyde (non-ISO)
Name in Dutch	Glutaaraldehyde
Chemical name	1,5-pentanedial (IUPAC)
CAS no	111-30-8
EC no	203-856-5 (EINECS)

The active substance Glutaraldehyde is included in the Union list of approved substances of EU Regulation 528/2012 for PT2, 3, 4, 6, 11, 12. A CAR is available for PT3 (eCA Finland, September 2014).

The List of End Points below is taken from the AR (PT2, 3, 4, 6, 11, 12, September 2014, eCA Finland).

Chemical name (IUPAC)	1,5-pentanedial
Chemical name (CA)	Glutaraldehyde
CAS No	111-30-8
EC No	203-856-5
Other substance No.	-
Minimum purity of the active substance as manufactured (g/kg or g/l)	Glutaraldehyde content in the aqueous solution is in a range of 48.5-52.5 % (wt), 485-525 g/kg. The theoretical dry weight specification: minimum purity is 95.0 % (wt), 950 g/kg. The applicant specific information and specifications are in the confidential documents [Doc III A4.1/02 confidential (Dow) and Doc V Confidential (BASF) in detail].

Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	The specifications are in the confidential documents [Doc III A4.1/02 confidential (Dow) and Doc V Confidential (BASF)].
Molecular formula	$C_5H_8O_2$
Molecular mass	100.11 g/mol
Structural formula	

2.2 Identity of the biocidal product

Name	FORCE 7
Formulation type	SL
Content active substance	ADBAC: 8.0 % w/w DDAC: 1.5 % w/w Glutaraldehyde: 13.0 % w/w

Packaging information:

	Material	Size / content	Other information
Professional use	HDPE	5kg	Canister
	HDPE	10kg	Canister
	HDPE	22kg	Canister
	HDPE	220kg	Drum
	HDPE	1000kg	IBC

2.3 Overall conclusions identity

The identity of the active substances and the biocidal product is sufficiently described.

Data requirements

None.

3 Physical and chemical properties

3.1 Physical and chemical properties of the biocidal product

Appearance	Colourless clear liquid
Explosive properties	No data provided. Based on the composition the product is not expected to be explosive.
Oxidative properties	Not oxidising. Based on the absence of chemical groups associated with oxidizing properties the product is not expected to be oxidising.
Autoflammability	No data provided. This is considered acceptable as this data is not required for classification and labelling purposes for this product.
Flashpoint	> 110 °C
pH 1% solution	neat pH (20°C) = 3.8 acidity = 0.14 % w/w expressed as H_2SO_4

	Based on the pH value between 2 and 4 and the absence of H290 classified components the product is not considered to be corrosive to metals.
Particle size distribution	Not applicable
Surface tension	Not applicable
Viscosity	Not applicable
Relative density	1.027+/-0.01
Storage stability/Shelf life/Packaging	Claim 12 months Interim data at time point 6 months were provided of a 24-month shelf life study in HDPE at 20°C. The following parameters were determined before and after the storage: **ADBAC concentration:** t0 = 8.12% w/w t6 month = 8.15% w/w **DDAC concentration:** t0 = 1.46% w/w t6 month = 1.52% w/w **Glutaraldehyde concentration:** t0 = 12.96% w/w t6 month = 12.66% w/w **Appearance of the packaging:** t0 and t6 month = white package with no apparent defect, white stopper with no apparent defect. **Appearance of the biocidal product:** t0 and t6 month = colorless clear liquid **Odor:** t0 and t6 month = aldehyde **neat pH:** t0 and t6 month at 20°C = 3.8 **Acidity:** t0 = 0.14 % w/w expressed as H2SO4 t6 month = 0.17 % w/w expressed as H2SO4 **Combined weight of the packaging with the tested product:** t0 = 5360.6 g t6 month = 5359.7 g

	Based on the available data a shelf life of 6 months in HDPE is supported.
Technical properties	Dilution stability (CIPAC MT 41) at 3% V/V = colourless clear liquid Persistent foaming data are not required as the product is intended to foam during application.
Physical and chemical compatibility	Not applicable. The biocidal product is not intended to be used in combination with other products.

3.2 Overall conclusions physical and chemical properties

The physical and chemical properties of the active substances and the biocidal product are sufficiently described by the available information.

Supported shelf life of the formulation is 6 months in HDPE. When the shelf-life study is finished the applicant can apply for a longer shelf life via minor change procedure.

Data requirements

None

4 Analytical methods for detection and identification

4.1 Analytical methods for analysis of the biocidal product

Preparation (principle of method)	HPLC-UV (ADBAC) Titration with sodium laurylsulfate (DDAC) HPLC-UV (Glutaraldehyde)

4.2 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements

None.

5 Efficacy

5.1 Function

FORCE 7 is a disinfectant based on Alkyldimethylammonium chloride (8.0% w/w), Didecyldimethylammonium chloride (1.5% w/w) and Glutaraldehyde (13% w/w).

5.2 Field of use envisaged

The proposed field of use of FORCE 7 is the control of bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses on:

- hard surfaces that come into contact with food, feed or the raw materials thereof, with the exception of milking equipment on farms;
- hard surfaces, materials and tools in the veterinary sector, with the exception of the outside of animal transport vehicles.

These uses are included in PT03 and PT04.

The product is intended for professional use.

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

Thirteen studies were provided all of which were used in this assessment. These are summarised in Table 1.

Table 1. Summary of studies assessed

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Bacteria (excluding mycobacteria and bacterial spores)			
EN 1656 (2019) 2, 1	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Proteus hauseri*	**Concentration (%):** 0.1, 0.5, 0.75, 1.0 and 1.5 % **Interfering substances:** 3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>5.46:** 0.1 % Clean 30 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 1276 (2019) 2, 1	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Escherichia coli*	**Concentration (%):** 0.1, 0.5, 0.75, 1.0 and 1.5 % **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>5.11:** 0.5 % Clean 30 min 10°C
EN 1276 (2019) 2, 1	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Escherichia coli*	**Concentration (%):** 1.0, 3.0 and 5.0 % **Interfering substances:** 0.3 g/L BSA **Contact time:** 4 hours **Test temperature:** 20°C	**log R=0.11:** 5 % Clean 4 hours 20°C
EN 14349 (2012) 2, 2	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Proteus vulgaris*	**Concentration (%):** 0.1, 0.5, 0.75, 1.0 and 1.5 % **Interfering substances:** 3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>4.80:** 0.75 % Clean 30 min 10°C
EN 13697 (2019) 2, 2	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Escherichia coli*	**Concentration (%):** 0.1, 0.5, 0.75, 1.0 and 1.5 % **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>6.17:** 0.5 % Clean 30 min 10°C
Yeasts			
EN 1657 (2016) 2, 1	*Candida albicans*	**Concentration (%):** 0.1, 0.5, 0.75, 1.0 and 1.5% **Interfering substances:** 3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>4.52:** 0.5 % Clean 30 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 1650 (2019) 2, 1	*Candida albicans*	**Concentration (%):** 0.1, 0.5, 0.75, 1.0 and 1.5% **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>4.46:** 0.5 % Clean 30 min 10°C
EN 16438 (2014) 2, 2	*Candida albicans*	**Concentration (%):** 0.1, 0.5, 0.75, 1.0 and 1.5% **Interfering substances:** 3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R=3.70:** 0.5 % Clean 30 min 10°C
EN 13697 (2019) 2, 2	*Candida albicans*	**Concentration (%):** 0.1, 0.5, 0.75, 1.0 and 1.5% **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R>3.94:** 0.5 % Clean 30 min 10°C
Viruses / Bacteriophages			
EN 14675 (2015) 2, 1	*Bovine enterovirus*	**Concentration (%):** 0.75, 1.0, 1.5, 2.0, 2.5 and 3.0 % **Interfering substances:** 3 g/L BSA **Contact time:** 5 and 30 minutes **Test temperature:** 10°C	**log R=4.48:** 1.5 % Clean 30 min 10°C
EN 14476 (2019) 2, 1	*Adenovirus*	**Concentration (%):** 0.01, 0.1, 1.0 and 1.5 % **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**Not valid** The control of efficiency of suppression of product's activity is not valid.

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 14476 (2019) 2, 1	*Murine norovirus*	**Concentration (%):** 0.01, 0.1 and 1.0 % **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R≥4.63:** 1.0 % Clean 30 min 10°C
EN 16777 (2018) 2, 2	*Murine norovirus*	**Concentration (%):** 0.01, 1.5 and 2.0 % **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 minutes **Test temperature:** 10°C	**log R=4.47:** 1.5 % Clean 30 min 10°C

* The most challenging test conditions resulting in the required lg reduction should be given.

The available information was sufficient to evaluate the efficacy of FORCE 7 for control of bacteria (excluding bacterial spores and mycobacteria), yeasts for PT3 and PT4 and viruses for PT3, considering evaluation is done under article 121 of the WGB. The studies show that FORCE 7 complies with the criteria for log reduction for disinfectants for the key species of the target organisms, when used in accordance with the instructions described on the WG/GA.

Efficacy against viruses for PT4 was not demonstrated as the suppression control validity criterium was not passed for the EN14476 test with Adenovirus.

The applicant provided evidence in the form of an efficacy study confirming that acetic acid in the product does not contribute to efficacy of the biocidal product.

5.3.2 Evaluation of the label (WG/GA)

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

5.4 Mode of action

Glutaraldehyde
The mechanisms of action of glutaral involve a strong association with the outer layers of bacterial cells, specifically with unprotonated amines on the cell surface.
Such an effect could explain its inhibitory action on transport and on enzyme system, where access of substrate to enzyme is prohibited.

Quaternary ammonium compounds (ADBAC + DDAC)
Its mode of action is to destroy the cell walls by sticking on the exterior structures and by entering and disintegrating the inner phospholipid-bilayer-based membrane structures. Due to its interaction with phospholipid- bilayer-based structures, it severely alters the cell wall permeability, disturbs membrane- bound ion-translocation mechanisms and may facilitate the uptake of other biocides. Furthermore, a precipitation or coagulation of proteins and nucleic acid can be observed.

5.5 Limitations on efficacy including resistance

5.5.1 General limitations
No limitations are mentioned.

5.5.2 Resistance
Glutaraldehyde
No cases of resistance against the claimed target organisms have been reported.

Quaternary ammonium compounds (ADBAC + DDAC)
For the group of quaternary ammonium compounds, resistances at sublethal and subbiocidal levels due to active transport by efflux pumps have been reported. The corresponding strains did not show resistance against biocidal concentrations of the substance, however, they did at minimal inhibitory concentration (MIC) and showed cross-resistance against antibiotics at use concentrations. Therefore, it is recommended for products that only contain quaternary ammonium compounds as active substance that resistance management should be applied when using this product.

5.5.3 Resistance management strategies
As the product contains active substances with two different modes of action, no resistance management strategy is necessary.

5.6 Overall conclusions of efficacy
Based on the data submitted and considering that the evaluation is done under article 121 of the WGB, it can be concluded that FORCE 7, when used in accordance with the proposed label (WG/GA), is effective in controlling:

bacteria (excluding mycobacteria and bacterial spores) and yeasts on hard surfaces that come into contact with food, feed or the raw materials thereof, with the exception of milking equipment on farms;

bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses on hard surfaces, materials and tools in the veterinary sector, with the exception of the outside of animal transport vehicles.

Based on the data submitted and considering that the evaluation is done under article 121 of the WGB, it **cannot** be concluded that FORCE 7, when used in accordance with the proposed label (WG/GA), is effective in controlling:

- viruses on hard surfaces that come into contact with food, feed or the raw materials thereof, with the exception of milking equipment on farms.

6 Human toxicology

Human health effects assessment active substance
Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC):
ADBAC-BKC is an existing active substance, not yet included in Union list of approved active substances for PT02. A final CAR exists for PT08 (RMS IT) and a concept Assessment Report (AR) is available for PT03-04 (BPC-28 Dec 2018). Therefore, this assessment is based on the toxicological data presented in the List of Endpoints (LoEP) taken from these ARs, in which a combined LoEP, integrating the LoEP for PT08, was presented.

List of endpoints

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	**US ISC** Based on data on urine excretion (5-8%) and tissue residues (<1%), and on the highly ionic nature of the a.s., it is expected that the oral absorption is around 10% at non-corrosive concentrations. **EQC** Due to its ionic nature, C12-16-BKC is expected not to easily pass biological membranes. Indeed, the fraction of the oral dose absorbed was about 10%, based on the urinary mean value 3-4% (with a single peak value = 8.3%) and biliary excretion values (3.7-4.6%), as well as on the absence of residues in the carcass. The oral absorption value of 10 % at non-corrosive concentrations. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION**: The oral absorption value of 10 % at non-corrosive concentrations.
Rate and extent of dermal absorption*:	**US ISC** Based on data from an in vitro study on human skin, the % absorbable was almost identical for 2 different dilutions (0.03% and 0.3%). Summing up the radioactivity present in the receptor fluid, in the skin at the application site (after stratum corneum removal) and in the tape strips 6-20 the value for dermal absorption of the a.s. is 8.3% at non-corrosive concentrations. **EQC** Based on the level of radioactivity at the skin application site after removal of the stratum corneum layers (6.5-8.7% of the dose), and considering the ionic nature of C12-16-BKC, it can be expected that the dermal absorption is not different from the oral one (10%). **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION**:

	The dermal absorption value has to be considered of 10% at non-corrosive concentrations
Distribution:	**US ISC** Most radioactivity was confined to the intestines. Levels in central organs (liver and kidney) were low and decreased rapidly over time **EQC** The plasma, blood and organ radioactivity levels were essentially non-quantifiable. At the high oral dose-level only, quantifiable levels of radioactivity were found in some central organs (highest levels in the liver and kidney) at 8 hours post-dosing; otherwise, most radioactivity was confined to the intestines. Levels decreased rapidly over time **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION**: Most radioactivity was confined to the intestines. Levels in central organs (liver and kidney) were low and decreased rapidly over time **(US ISC; EQC)**
Potential for accumulation:	**US ISC** None noted **EQC** None. No residues were measured in the carcass after 168h. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION**: None relevant **(US ISC; EQC)**
Rate and extent of excretion:	**US ISC** Following oral administration in rats: 87 –99% excreted in faeces as unabsorbed material, 5 – 8% excreted in urine **EQC** Following oral administration in rats: 87 –99% excreted in faeces as unabsorbed material, 5 – 8% excreted in urine

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: Excretion was rapid (within a 48 to 72-hour period). The vast majority of the oral dose was excreted in the faeces (80-90%) as unabsorbed material; 5 – 8% excreted in urine. About 4% of the oral dose was eliminated in the bile in a 24-hour period **(US ISC; EQC)**
Toxicologically significant metabolite	**US ISC** None. Four major metabolites of C_{12-16}-ADBAC were identified, as the product of alkyl chain hydroxylation. It can be hypothesized that C_{12-16}-ADBAC metabolism is carried out by gut microflora. **EQC** None. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION**: None **(US ISC; EQC)**

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	**US ISC** 344 mg/kg bw **EQC** 358 mg (obtained with C_{8-18}-BKC/kg bw) Although the test item is different, this result can be considered valid for C_{12-16}-BKC, based on the similar mechanism for oral toxicity shown by QUATS with this alkyl chain length. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION**: 350 mg/kg bw **(US ISC; EQC)**

Rabbit LD_{50} dermal	**US ISC** 2848 mg/kg bw **EQC** Testing not allowed, active substance is corrosive to skin Literature LD_{50} values = 800-1400 mg/kg **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 2848 mg/kg bw **(US ISC)**
Rat LC_{50} inhalation	**US ISC** Study not conducted **EQC** Study not conducted - not relevant C_{12-16}-BKC is not volatile (calculated vp < $1x10^{-2}$ Pa at 20°C) and is corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted - not relevant The a.s. is not volatile and is corrosive **(US ISC; EQC)**
Skin corrosion/irritation	**US ISC** Corrosive NOAEC = 0.3% in water at 2.0 mL/kg body weight per day (2 week-treatment) **EQC** Corrosive The maximum concentration reported in the literature that does not produce irritating effect on intact skin is established at 0.1% a.s. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive NOAEC = 0.3% in water at 2.0 mL/kg body weight per day (2 week-treatment/rat) The maximum concentration reported in the literature that does not produce irritating effect on intact skin is established at 0.1% a.s. **(US ISC; EQC)**
Eye irritation	**US ISC** Corrosive **EQC**

	Testing not allowed, active substance is corrosive to skin The maximum concentration reported in the literature without irritating effect in the eyes = 0.02% a.s **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive. The maximum concentration reported in the literature without irritating effect in the eyes = 0.02% a.s **(US ISC; EQC)**
Respiratory tract irritation	**US ISC** No study available, but expected to be corrosive **EQC** No study available, but expected to be corrosive **Literature data**: Irritant for the airways mucosa. LOAEC= 19 mg/m^3 **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** $LOAEC_{inhalation}$= 19 mg/m^3 (**literature data**)
Skin sensitisation (test method used and result)	**US ISC** None (Buehler Test on guinea pig) **EQC** None (modified Draize test, guinea pig) Result confirmed by a published study with GPMT test **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None **(US ISC; EQC)**
Respiratory sensitisation (test method used and result)	**US ISC** No study available, but expected to be not a sensitiser **EQC** No study available, but expected to be not a sensitiser

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: No study available, but expected to be not a sensitiser

Repeated dose toxicity

Short term

Species/ target / critical effect	**US ISC** No short-term study available **EQC** Rat/dog, no specific toxic effects/ critical effects: body weight and body weight gain reduction associated to lower food intake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Dog: no specific toxic effects/ critical effects: body weight and body weight gain reduction associated to lower food intake **(EQC)**
Lowest relevant oral NOAEL	**US ISC** No short-term study available **EQC** LOAEL: 43-53 mg/kg/day (28-day dog- Supporting study) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** LOAEL: 43-53 mg/kg/day (28-day dog- Supporting study) **(EQC)**
Lowest relevant dermal NOAEL	**US ISC** No short-term study available **EQC** Study not conducted – not relevant Effects are characterised by local corrosive effects related to concentration rather than systemic toxicity due to dermal uptake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted – not relevant Effects are characterised by local corrosive effects related to concentration rather than systemic toxicity due to dermal uptake

	(US ISC; EQC)
Lowest relevant inhalation NOAEL	**US ISC** No study available. Expected to be irritant/corrosive. **EQC** No study available. Expected to be irritant/corrosive. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Expected to be irritant/corrosive**(US ISC; EQC)**

Subchronic

Species/ target / critical effect	**US ISC** Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **EQC** Rat/dog, no specific toxic effects/ critical effects: body weight and body weight gain reduction associated to lower food intake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat/dog: Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **(US ISC; EQC)**
Lowest relevant oral NOAEL	**US ISC** 13.1 mg/kg/day (1 year, Dog) **EQC** 1250 ppm = 45 mg a.s./kg bw/day (90-day, Dog) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 13.1 mg/kg/day (1 year, Dog) **(US ISC)**
Lowest relevant dermal NOAEL	**US ISC** 20 mg/kg bw/day (highest dose tested) **EQC**

	Study not conducted – not relevant Effects are characterised by local corrosive effects related to concentration rather than systemic toxicity due to dermal uptake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 20 mg/kg bw/day (highest dose tested) **(US ISC)**
Lowest relevant inhalation NOAEL	**US ISC** No study available. Expected to be irritant/corrosive. **EQC** No study available. Expected to be irritant/corrosive. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Expected to be irritant/corrosive. **(US ISC; EQC)**

Long term

Species/ target / critical effect	**US ISC** Rat/mouse: Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **EQC** Rat/mouse: Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat/mouse: Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **(US ISC; EQC)**
Lowest relevant oral NOAEL	**US ISC** 44 mg/kg/day (2-years rats) **EQC** 47 mg/kg/day (2-years rats)

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: 44-47 mg/kg/day (2-years rats) **(US ISC; EQC)**
Lowest relevant dermal NOAEL	**US ISC** Study not conducted **EQC** Study not conducted – not relevant Effects are characterised by local corrosive effects related to concentration rather than systemic toxicity due to dermal uptake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted – not relevant **(US ISC; EQC)**
Lowest relevant inhalation NOAEL	**US ISC** Study not conducted **EQC** Study not conducted – not relevant Active substance is not volatile and corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted – not relevant **(US ISC; EQC)**

Genotoxicity

In-vitro: In-vivo:	**US ISC** **In vitro:** Ames test – negative (with and without metabolic activity) Chromosomal aberration test – negative (with and without metabolic activity) Mammalian cell gene mutation assay – negative (with and without metabolic activity) **In vivo:** Micronucleus assay - negative **EQC** **In vitro:**

	Not genotoxic in vitro gene mutation study in bacteria and in vitro cytogeneticity and gene mutation assays in mammalian cells **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** The substance can be considered not genotoxic based on: in vitro (Ames test, Chromosomal aberration test, Mammalian cell gene mutation assay) and in vivo test (Chromosomal aberration test in rat bone marrow) **(US ISC)**

Carcinogenicity

Species/type of tumour	**US ISC** Rat/none, Mouse/none **EQC** C_{12-16}-ADBAC is not carcinogenic **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No neoplastic lesions were found that were considered treatment related. Rat study **(US ISC; EQC)** Mouse study **(US ISC)**
Relevant NOAEL/LOAEL	**US ISC** The NOELs related to non neoplastic effects in chronic oral toxicity studies were 44 mg/kg/day for rats and 73 mg/kg/day for mice. **EQC** In rats the NOAEL for non neoplastic effects was 47 mg a.s./kg/day. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No carcinogenic effects were observed. **(US ISC; EQC)**

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	**US ISC** Rabbit/maternal toxicity **EQC**

	Rat /maternal toxicity Rabbit / maternal toxicity **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for developmental toxicity **(US ISC; EQC)**
Relevant maternal NOAEL	**US ISC** Rabbit: 4 mg/kg bw **EQC** Rat: 10 mg/kg bw/day Rabbit: 3 mg/kg bw/day **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific concern for developmental toxicity. Maternal NOAELs consistently lower than developmental NOAELs. Maternal effects mostly due to gastrointestinal distress, not relevant to systemic toxicity **(US ISC; EQC)** **Lowest NOAEL for maternal toxicity:** Rabbit: 3 mg/kg bw/day (**EQC**)
Relevant developmental NOAEL	**US ISC** Rabbit: 12 mg/kg bw **EQC** Rat: ≥ 100 mg/kg bw/day Rabbit: ≥ 9 mg/kg bw/day **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for developmental toxicity **(US ISC; EQC)**

Fertility

Species/ critical effect	**US ISC** Rat/ cortical adrenal hypertrophy in F0 females, lower weight gain and higher spleen weights in F1 **EQC** Rat/reduced weight gain and food consumption in parental and F1 animals **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:**

	No specific concern for reproductive toxicity **(US ISC; EQC)**
Relevant parental NOAEL	**US ISC** 608 mg/kg food (≥ 30 mg/kg bw/day) **EQC** 1000 mg/kg food (≥ 50 mg/kg bw/day) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific concern for reproductive toxicity. Parental NOAELs related to general toxicity **(US ISC; EQC)**
Relevant offspring NOAEL	**US ISC** 608 mg/kg food (≥ 30 mg/kg bw/day) **EQC** 1000 mg/kg food (> 50 mg/kg bw/day) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific concern for reproductive toxicity. NOAELs in F1 related to general toxicity and equal to the parental ones **(US ISC; EQC)**
Relevant fertility NOAEL	**US ISC** 1620 mg/kg food (≥ 52 mg/kg bw/day) **EQC** > 2000 mg/kg food (> 100 mg/kg bw/day) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for reproductive toxicity **(US ISC; EQC)**

Neurotoxicity

Species/ target/critical effect	**US ISC** Study not conducted/ not relevant **EQC** Study not conducted – not relevant **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific concern for neurotoxicity **(US ISC; EQC)**

Developmental Neurotoxicity

Species/ target/critical effect	**US ISC** No indication from available studies **EQC** No indication from available studies **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for developmental neurotoxicity **(US ISC; EQC)**

Immunotoxicity

Species/ target/critical effect	**US ISC** Study not conducted. No indication of such an effect in the available toxicity studies **EQC** Study not conducted. No indication of such an effect in the available toxicity studies. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific concern for immunotoxicity. **(US ISC; EQC)**

Developmental immunotoxicity

Species/ target/critical effect	**US ISC** No indication from available studies **EQC** No indication from available studies **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for developmental immunotoxicity **(US ISC; EQC)**

Other toxicological studies

US ISC No further study conducted/ not relevant **EQC** No further study conducted/ not relevant **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No further study conducted/ not relevant

(US ISC; EQC)

Medical data

US ISC

No substance-specific effects have been noted. No specific observations or sensitivity/allergenicity have been reported.

EQC

Skin reactions observed after dermal exposure to C_{12-16}-BKC can be regarded as an irritant reaction rather than a true sensitisation reaction. This is supported by the results from animal tests, which do not indicate a sensitising potential

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION

Skin reactions observed after dermal exposure to C_{12-16}-BKC can be regarded as an irritant reaction rather than a true sensitisation reaction. This is supported by the results from animal tests, which do not indicate a sensitising potential **(EQC)**

Summary for Local effects

	Value	**Study**
Dermal NOAEC	**0.6%**	2-week skin irritation study with rats on DDAC **(US ISC)**
Oral NOAEC	**0.03%**	52-week oral gavage study in dogs on DDAC **(US ISC)**

Summary for systemic effects

	Value	**Study**	**Safety factor**
$AEL_{long\text{-}term}$	Not relevant		
$AEL_{medium\text{-}term}$	Not relevant		
$AEL_{short\text{-}term}$	Not relevant		
ADI*	0.12	maternal toxicity in developmental tox rabbit **(EQC)**	25
ARfD*	0.12	maternal toxicity in developmental tox rabbit **(EQC)**	25
$NOAEC_{dermal}$	**0.6%**	2-week skin irritation study with rats on DDAC **(US ISC)**	

AEC $_{inhalation}$	0.25 mg/m^3	Larsen et al., 2012 (LOAEC=19 mg/m^3)	75

* If residues in food or feed.

MRLs

Relevant commodities	Not applicable

Reference value for groundwater

According to BPR Annex VI, point 68	**US ISC** 0.1 µg/L **EQC** 0.1 µg/L

Dermal absorption

Study (*in vitro/vivo*), species tested	**US ISC** In vitro study (human skin samples) **EQC** 2 in vivo study available on rats, none of them allowing a quantitative determination (oral exposure not prevented; radioactivity in the stratum corneum included)
Formulation (formulation type and including concentration(s) tested, vehicle)	**US ISC** C_{12-16}-ADBAC aqueous solution (0.03% and 0.3% w/w) **EQC** 1: 1.5 and 15 mg a.s. /kg bw, as 6-hour exposure over 10% of the body surface 2: 0.4 mL of a 0.77% w/w aqueous solution of C_{8-18}-BKC
Dermal absorption values used in risk assessment	**US ISC** The sum of the absorbed dose, the exposed skin (2.18%-2.13) and the % of radioactivity present in tape strips 6-20 gave rise to a value of 8.3%. **EQC** Estimated similar to the oral absorption (10%). **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Dermal absorption is considered as not relevant because C_{12-16}-ADBAC/BKC toxicity is based on local

	effects only (with systemic effects secondary to local effects at high doses) In the absence of clear systemic effects, the dermal absorption value is not deemed relevant (although available for the active substance at non-irritant conc. =8.3%)

Local effects

Due to its corrosive properties, ADBAC primary produces local effects after single exposure (skin and eye corrosion) and repeated exposure (GI-tract irritation). As indicated in the CAR, systemic effects only occur as a result of these local effects. Therefore, the current risk assessment will be based on local effects only.

The local dermal NOAEC is set at 0.6 % based on a 2-week skin irritation study with rats with DDAC. The $AEC_{inhalation}$ is based on a LOAEC for respiratory irritation of 19 mg/m^3. By applying an AF of 75 (to the 25 used above an additional factor of 3 was considered to account for the use of a LOAEC instead of a NOAEC) an inhalation AEC= 0.25 mg/m^3 is obtained.

For the calculation of the $AEC_{local\ inhalation}$ of 0.25 mg/m^3 the following was considered: for this type of local inhalation effect the ordinary safety factor of 10 x 10 for intra- and interspecies variation needs to be modified. The factor of 10 for intraspecies variation is still relevant while the factor 10 for inter species variation (that is 4 for toxicokinetics x 2.5 for toxicodynamics) has to be modified. The 4 for interspecies variation in toxicokinetics should be excluded since the active substance is not expected to be metabolised before reaching the target organ. Only the factor for interspecies variation in toxicodynamics (2.5) is therefore relevant, resulting in a total safety factor of 10 x 2.5 = 25.

DDAC

DDAC (didecyldimethylammonium chloride) is an existing active substance, not yet included in Union list of approved active substances for PT1, and PT2. A final CAR exists for PT4 (1-11-2021). Therefore this assessment is based on the toxicological data presented in the List of Endpoints (LoEP) taken from this AR.

List of Endpoints

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	**US ISC** Based on data on urine excretion (≈3%) and tissue residues (<1%), and on the 90% recovery of radioactivity in faeces as unabsorbed material DDAC oral absorption is limited to 10% at non-corrosive concentrations. **EQC** Based on the urinary excretion (3-4%), biliary excretion values (2.6%), the absence of residues in the carcass, and 85-90% recovery of radioactivity in faeces as unabsorbed material the actual absorbed fraction is approximately10% of the orally

	administered dose, at non-corrosive concentrations.
Rate and extent of dermal absorption*:	**US ISC** About 0.1% of a DDAC dose delivered as aqueous solution fully penetrated human skin in vitro in 24 h; including the radioactivity present in the dermis and epidermis at the dose site mean total absorbable DDAC was 9.41% (rounded to 10%) at non-corrosive concentrations. **EQC** No possible to quantify DDAC in the available study; indication of similarity between oral and the dermal bioavailability. It is estimated as a worst case that DDAC dermal absorption is limited to ≈10% at non-corrosive concentrations.
Distribution:	**US ISC** Mainly in the g.i. tract, tissue residues (<1%). **EQC** Radioactivity mainly detected in the g.i. tract, and at a much lower level in the liver and in the kidney. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Mainly detected in the g.i. tract, and at a much lower level in the liver and in the kidney. No detectable residues at 168 h **(US ISC; EQC)**
Potential for accumulation:	**US ISC** None. Tissue residues (<1%) **EQC** None. No residues in the carcass **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None **(US ISC; EQC)**
Rate and extent of excretion:	**US ISC** The majority (>90%) of orally administered DDAC is excreted, very likely unabsorbed, via the faeces. Urine excretion ≈3% in 24-48 hours **EQC** The vast majority (86-96%) of the oral dose was excreted in the faeces as unabsorbed material. Urinary excretion was 3-4% and biliary excretion 2.6%, in a 24-hour period. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Around 90% of the oral dose was excreted in the faeces as unabsorbed material. Urinary excretion was 3-4% and biliary excretion 2.6% within 24 hours **(US ISC; EQC)**

Toxicologically significant metabolite	**US ISC** None. The majority of DDAC metabolism is expected to be carried out by intestinal flora giving rise to hydroxylation products in the alkyl chain, none of them exceeding 10% **EQC** None. Conjugated metabolites were detected in the urine **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None. The majority of DDAC metabolism is expected to be carried out by intestinal flora forming hydroxylation products in the alkyl chain, none of them exceeding 10%. In addition conjugated metabolites were excreted in urines **(US ISC; EQC)**

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	**US ISC** 238 mg/kg **EQC** 264 mg/kg bw **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** The lowest value is 238 mg/kg **(US ISC)**
Rabbit LD_{50} dermal	**US ISC** 3342 mg/kg **EQC** No test available. Literature data : >2000 mg/kg **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 3342 mg/kg **(US ISC)**
Rat LC_{50} inhalation	**US ISC** No test available. Not allowed since DDAC is corrosive **EQC** No test available. Not necessary since the active substance is not volatile, (vapour pressure < 1×10^{-2} Pa at 20°C) and only spraying with big, not inhaled, droplets with MMAD > 40 µm is recommended. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Test unnecessary: DDAC is not volatile, (vapour pressure < 1×10^{-2} Pa at 20°C); only spraying with

	big, not inhaled, droplets with MMAD > 40 µm is recommended; testing is not allowed with corrosive chemicals **(US ISC; EQC)**
Skin corrosion/irritation	**US ISC** Corrosive **EQC** Corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive **(US ISC; EQC)**
Eye irritation	**US ISC** Corrosive **EQC** Corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive **(US ISC; EQC)**
Respiratory tract irritation	**US ISC** No data available. Expected to be irritant/corrosive **EQC** No data available. Expected to be irritant/corrosive **Literature data**: Irritant for the airways mucosa. LOAEC= 19 mg/m^3 **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Irritant/corrosive $LOAEC_{inhalation}$= 19 mg/m^3 (**literature data**)
Skin sensitisation (test method used and result)	**US ISC** Not a skin sensitiser (Magnusson and Kligman procedure - OECD Guideline 406) **EQC** Not a skin sensitiser (Magnusson and Kligman procedure - OECD Guideline 406) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Not a skin sensitiser (Magnusson and Kligman procedure - OECD Guideline 406) **(US ISC; EQC)**
Respiratory sensitisation (test method used and result)	**US ISC** No data available. Expected to be not a respiratory sensitizer. **EQC** No data available. Expected to be not a respiratory sensitizer.

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: No data available. Expected to be not a respiratory sensitizer

Repeated dose toxicity

Short term

Species/ target / critical effect	**US ISC** No study available **EQC** Rat/gi tract/ irritation corrosivity leading to body weight reduction. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat/gi tract/ irritation corrosivity leading to body weight reduction. **(EQC)**
Relevant oral NOAEL / LOAEL	**US ISC** None **EQC** None. The only availbale study is by gavage in rat /28-day/ NOAEL = 2.5 mg/kg/day: not relevant **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Data available only via gavage, which is not an appropriate route of exposure for NOAEL derivation.
Relevant dermal NOAEL / LOAEL	**US ISC** Local effects NOAEC=0.6% DDAC in water at 2 mL/kg bw per day (5 day application) Local effects NOAEC =0.3% DDAC in water at 2 mL/kg bw per day (2-week application). **EQC** No study available. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Local effects NOAEC =0.6% DDAC in water at 2 mL/kg bw per day (5 day application) **(US ISC)** Local effects NOAEC =0.3% DDAC in water at 2 mL/kg bw per day (2-week application). **(US ISC)**
Relevant inhalation NOAEL / LOAEL	**US ISC** No study available. Not necessary. **EQC** No study available. Not necessary.

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: No study available. Not necessary.

Subchronic

Species/ target / critical effect	**US ISC** Rat and dog/gi tract/ irritation corrosivity leading to body weight reduction. **EQC** Rat and dog/gi tract/ irritation corrosivity leading to body weight reduction. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat and dog/gi tract/ irritation corrosivity leading to body weight reduction **(US ISC; EQC)**
Relevant oral NOAEL / LOAEL	**US ISC** 1 year dog: NOAEL for local effects: 3 mg/kg/d NOAEL for systemic effects: 10 mg/kg/d **EQC** 90 days dog: NOAEL for systemic effects: 15 mg/kg/d **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** NOAEL for local effects: 3 mg/kg/d **(US ISC)** NOAEL for systemic effects: 10 mg/kg/d **(US ISC)**
Relevant dermal NOAEL / LOAEL	**US ISC** 90-day rat Systemic NOAEL = 12 mg/kg /d (highest dose tested) Local effects NOAEL = 2 mg/kg/d. **EQC** None **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Systemic NOAEL = 12 mg/kg /d (highest dose tested) **(US ISC)** Local effects NOAEL = 2 mg/kg/d. **(US ISC)**
Relevant inhalation NOAEL / LOAEL	**US ISC** No study available. Expected to be irritant/corrosive. **EQC** No study available. Expected to be irritant/corrosive.

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: No study available. Expected to be irritant/corrosive.

Long term

Species/ target / critical effect	**US ISC** Rat/mice /gi tract/ irritation corrosivity leading to body weight reduction. **EQC** Rat/mice /gi tract/ irritation corrosivity leading to body weight reduction. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat and mice/gi tract/ irritation corrosivity leading to body weight reduction **(US ISC; EQC)**
Relevant oral NOAEL / LOAEL	**US ISC** 2 year Rat: Non neoplastic effects lowest NOAEL: 32 mg/kg/day **EQC** 2 year Rat: Non neoplastic effects lowest NOAEL: 27 mg/kg/day **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Non neoplastic effects NOAEL: 27 mg/kg/day **(EQC)**
Relevant dermal NOAEL / LOAEL	**US ISC** No study available. Not necessary. **EQC** No study available. Not necessary. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Not necessary.
Relevant inhalation NOAEL / LOAEL	**US ISC** No study available. Expected to be irritant/corrosive. **EQC** No study available. Expected to be irritant/corrosive. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Expected to be irritant/corrosive.

Genotoxicity

In-vitro: In-vivo:	**<u>US ISC</u>** **<u>In vitro:</u>** Ames test – negative (with and without metabolic activation) Chromosomal aberration test – negative (with and without metabolic activation) Mammalian cell gene mutation assay – negative (with and without metabolic activation). **<u>In vivo:</u>** Chromosomal aberration test in rat bone marrow – negative. **<u>EQC</u>** Not genotoxic in vitro gene mutation study in bacteria and in vitro cytogeneticity and gene mutation assays in mammalian cells. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** DDAC can be considered not genotoxic based on: In vitro Ames test with and without metabolic activation **(US ISC)** In vitro chromosomal aberration test with and without metabolic activation with OECD 473 **(EQC)** In vitro mammalian cell gene mutation assay with and without metabolic activation with OECD 476 **(EQC)** In vivo chromosomal aberration test in rat bone marrow **(US ISC)**

Carcinogenicity

Species/type of tumour	**<u>US ISC</u>** Rat/none Mouse/none **<u>EQC</u>** Rat/none **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** DDAC was not found to be carcinogenic **(US ISC; EQC)**
Relevant NOAEL/LOAEL	**<u>US ISC</u>** None **<u>EQC</u>** None **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:**

	Rat study **(US ISC; EQC)** Mouse study **(US ISC)**

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	**US ISC** 1) Rat / NOAEL / maternal toxicity 2) Rabbit / NOAEL /maternal toxicity **EQC** Rabbit/ maternal toxicity (cases of discoloured urine, splayed legs) / severe toxicity with abortion at top dose level (32 mg/kg) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for developmental toxicity; prenatal effects only seen as unspecific consequence of maternal distress **(US ISC or EQC)**
Relevant maternal NOAEL	**US ISC** 1) 0.8 mg/kg bw/day 2) 1.0 mg/kg bw/day **EQC** 4 mg/kg bw
Relevant developmental NOAEL	**US ISC** 1)≥ 16.2 mg/kg bw/day 2) ≥ 3 mg/kg bw/day **EQC** 12 mg/kg bw **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Prenatal toxicity only seen in rabbits, clearly secondary to maternal effects: NOAEL 12 mg/kg bw **(EQC)**

Fertility

Species/ critical effect	**US ISC** Rat /NOEL/reduced body weight and food consumption in parental and F1-F2 animals **EQC** Rat/ two-generation/ systemic toxicity Cortical adrenal hypertrophy in F0 females; lower weight gain and increased spleen weight in F1 **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:**

	Available studies do not indicate any specific potential for reproductive toxicity. Observed effects concern solely general toxicity **(US ISC; EQC)**
Relevant parental NOAEL	**US ISC** 750 mg/kg food (≥ 31 mg/kg bw/day) **EQC** 608 mg/kg food, corresponding to ≥ 30 mg/kg bw
Relevant offspring NOAEL	**US ISC** 750 mg/kg food (≥ 31 mg/kg bw/day) **EQC** 608 mg/kg food, corresponding to ≥ 30 mg/kg bw
Relevant fertility NOAEL	**US ISC** ≥ 750 mg/kg food (≥ 31 mg/kg bw/day) **EQC** > 608 mg/kg food, corresponding to ≥ 30 mg/kg bw **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific potential for reproductive toxicity, overall NOAEL (parental effects) at least 31 mg/kgbw/d (608mg/kg feed) **(EQC)**

Neurotoxicity

Species/ target/critical effect	**US ISC** No study available. Not necessary. **EQC** No study available. Not necessary. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Not necessary. (No structural similarity to known neurotoxin; no alert for neurotoxic effects; no sign of neurotoxicity found in sub-chronic/chronic study)

Developmental Neurotoxicity

Species/ target/critical effect	**US ISC** n.a. **EQC** n.a.

Immunotoxicity

Species/ target/critical effect	**US ISC** No study available. Not necessary. **EQC** No study available. Not necessary. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Not necessary.

Developmental immunotoxicity

Species/ target/critical effect	**US ISC** n.a. **EQC** n.a.

Other toxicological studies

US ISC

No other study available.

EQC

No other study available.

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

No study available. Not necessary.

Medical data

US ISC

No medical reports on the manufacturing personnel have been submitted.

EQC

No study available. Statements from medical doctors from different production locations indicate that during production no problems are found which can be related to exposure to DDAC.

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

No specific observations or sensitivity/allergenicity or any medical information have been reported **(US ISC; EQC)**

Summary for Local effects

	Value	Study
Dermal NOAEC	**0.6%**	2-week skin irritation study with rats **(US ISC)**
Oral NOAEC	**0.03%**	52-week oral gavage study in dogs **(US ISC)**

Summary

	Value	Study	Safety factor
$AEL_{long\text{-}term}$	Not relevant		

$AEL_{medium\text{-}term}$	Not relevant		
$AEL_{short\text{-}term}$	Not relevant		
ADI[5]	0.12	1-year oral gavage study in dogs **(US ISC)**	**25**
ARfD**Fout! Bladwijzer niet gedefinieerd.**	0.12	1-year oral gavage study in dogs **(US ISC)**	**25**
$NOAEC_{dermal}$	0.6%	2-week skin irritation study with rats **(US ISC)**	
$AEC_{inhalation}$	0.25 mg/m^3	Larsen *et al.*, 2012 (LOAEC=19 mg/m^3)	**75**

[5] If residues in food or feed.

MRLs

All commodities (Temporary MRL to be reviewed in conjunction with EFSA-https://eurlex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32014 R1119&from=EN)	0.1 mg/kg

Reference value for groundwater

According to BPR Annex VI, point 68	**US ISC** 0.1 µg/L **EQC** 0.1 µg/L

Dermal absorption

Study (*in vitro/vivo*), species tested	**US ISC** In vitro study on Human dermatomed skin membranes **EQC** In vivo study on rats (some cross-contamination due to grooming and possible concomitant oral exposure-quantification not possible)
Formulation (formulation type and including concentration(s) tested, vehicle)	**US ISC** 1. 1.85% (w/v) DDAC in water 2. NP-1 formulation 1.85% (w/v) DDAC plus components other than water (not specified) **EQC** 1.5 and 15 mg/kg (40% DDAC in water)
Dermal absorption values used in risk assessment	**US ISC** 7. 10% (for water dilutions only) 8. 17.8% (for non-water dilutions formulations) **EQC** 10% (as for the oral route) is taken as worst case approach.

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: 10% for simple aqueous formulations **(US ISC)** To be checked at MS levels at the moment of authorization of single product with other co-formulants.

Local effects
Due to its corrosive properties, DDAC primary produces local effects after single exposure (skin and eye corrosion) and repeated exposure (GI-tract irritation). As indicated in the CAR, systemic effects only occur as a result of these local effects. Therefore, the current risk assessment will be based on local effects only.

The local dermal NOAEC is set at 0.6 % based on a 2-week skin irritation study with rats. The $AEC_{inhalation}$ for DDAC is based on a LOAEC for respiratory irritation of 19 mg/m^3. By applying an AF of 75 (to the 25 used above an additional factor of 3 was considered to account for the use of a LOAEC instead of a NOAEC) an inhalation AEC= 0.25 mg/m^3 is obtained.

Glutaraldehyde:

For the active substance glutaraldehyde a draft final CAR is available for PT2, 3, 4, 6, 11 and 12 (June 2014). The List of Endpoints below is taken from this draft final CAR.

List of Endpoints

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	Approx. 37 to 51% for both sexes depending on dose level and method of calculation (measured as radioactivity of ^{14}C labeled GA). Oral absorption of 40% is proposed for estimating the systemic dose.
Rate and extent of dermal absorption:	10% is proposed based on the weight of evidence.
Distribution:	All organs and tissues (radioactive label).
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Rapid and almost complete, independent of sex
Toxicologically significant metabolite	Metabolites are poorly known, but non expected to be toxicologically significant.

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	77 mg/kg bw for pure substance; H301
Rabbit LD_{50} dermal	> 1000 mg/kg bw for pure substance; highly dependent on concentration

Rat LC_{50} inhalation	0.28 mg/L in male rats and 0.35 mg/L in female rats; H330
Skin irritation	Corrosive; Skin Corr. 1B, H314
Eye irritation	Corrosive; H314
Skin sensitisation (test method used and result)	Sensitizing; guinea pig maximization test; H317

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect	Rat/kidney/increased kidney weight coupled with a slight increase in urea nitrogen in females Mouse/kidney/increased kidney weight Dog/GI tract/increased incidence of vomiting
Lowest relevant oral NOAEL	NOAEL 2.9 mg/kg bw/day (2.9 and 3.6 mg/kg bw/day for males and females, respectively), rat
Lowest relevant dermal NOAEL	NOAEL/LOAEL not established; skin irritation, but no systemic effects
Lowest relevant inhalation NOAEL	LOAEC 0.26 µg/L, mice (local irritant effects; no indications of systemic toxicity other than secondary to irritation)

Genotoxicity (Annex IIA, point 6.6)

In-vitro:	Positive results in Ames test; sister chromatid exchange assay; chromosomal aberration assay; forward mutation assay
In-vivo:	Slightly positive in an intraperitoneal micronucleus test and equivocal in all oral studies presumed due to test substance not reaching the target organ

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	Large Granular Lymphocytic Leukaemia in female rats Testis Leydig cell adenomas in male rats
lowest dose with tumours	LGLL: 5.5 mg/kg wbd/ay (2-year oral study, not treatment related) Leydig cells: 3.5 mg/kg bw/day (2 year oral study)

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	1. Increased resorption rate, increased post-implantation losses, reduction in mean placental weights (teratogenicity study in rabbits) 2. Testes Leydig cell hyperplasia, cystic degeneration (2-year oral study in Wistar rats) 3. Testes consistency changes (2-year oral study in Fischer 344 rats) 4. Diffuse degeneration of the testes (1-year oral study in Wistar rats)
Lowest relevant reproductive NOAEL / LOAEL	4. NOAEL 15 mg/kg bw/day 5. LOAEL 3.5 mg/kg bw/day 6. NOAEL 3.6 mg/kg bw/day 7. NOAEL 3.2 mg/kg bw/day
Species/Developmental target / critical effect	None in rabbits or rats
Lowest relevant developmental NOAEL / LOAEL	Not relevant

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect	None
Lowest relevant developmental NOAEL / LOAEL	Not relevant

Other toxicological studies (Annex IIIA, VI/XI)

Respiratory irritation	Moderately potent peripheral sensory irritant; peripheral sensory irritation test in mice
Respiratory sensitization	Potential respiratory sensitizer; mouse IgE test

Medical data (Annex IIA, point 6.9)

	Cohort studies and case studies have identified respiratory and skin sensitization as the main effects on human health. Glutaraldehyde is among the most common causes of occupational asthma among health care workers. Other health risks are due to the corrosive properties of glutaraldehyde.

Summary

	Value	Study	Safety factor
Non-Professional users			
ADI (if residues in food or feed)	Not relevant		
$AEL_{medium\text{-}term}$	0.014 mg.kg bw/day*	Rat 90-day oral study	100
$AEL_{long\text{-}term}$	0.014 mg/kg bw/day*	Rat 90-day oral study	100
$AEC_{inhalation}$	10.6 µg/m^3 (2.6 ppb)	2-year inhalation study, mouse	24
$AEC_{acute\ inhalation}$	0.5 mg/m^3 (122 ppb)	Human study on odour detection and chemesthetic detection	3.2
AEC_{dermal}	Not established**		
Reference value for dermal absorption	10% estimated value		
Drinking water limit	0.1 µg/L	As set by EU Drinking Water Directive (98/83/EC)	
ARfD (acute reference dose)	0.60 mg/kg bw/day	Rabbit teratogenicity study	25

** $AEL_{medium\text{-}term/\ long\text{-}term}$ is based on the NOAEL of 3.5 mg/kg bw/day of a rat carcinogenicity study (instead of the stated 90-day oral study in rats) and corrected for 40% oral absorption.*

*** From the human volunteer- and occupational studies an NOEL of 0.2% glutaraldehyde was derived. For the risk assessment an NOEClocal dermal of 0.2% (without additional assessment factors) will be used.*

Local effects
Glutaraldehyde is a skin and respiratory sensitiser and corrosive to both skin and eyes.

6.1 Human exposure assessment active substance

6.1.1 General aspects

FORCE 7 is a liquid concentrate and contains 8% ADBAC, 1.5% DDAC and 13% glutaraldehyde as active substances. The proposed field of use of FORCE 7 is as disinfectants for veterinary hygiene (PT3) and in places where food or drink is prepared, treated or stored (PT4).

The dosage is 100 ml (for PT3 use) or 50 ml (for PT4 use) FORCE 7 in 10 liters of water, resulting in the following concentrations: 0.08% ADBAC, 0.015% DDAC, 0.13% glutaraldehyde for the 1% FORCE 7 solution and 0.04% ADBAC, 0.0075% DDAC and 0.065% glutaraldehyde for the 0.5% FORCE 7 solution.

The formulation FORCE 7 is for professional use.

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

The professional user can be dermally and respiratory exposed to ADBAC, DDAC and glutaraldehyde during mixing and loading and application via dipping, foaming and course spraying using FORCE 7.

The vapour pressure of ADBAC and DDAC is very low (6.03 x 10-4 Pa at 20 ºC for ADBAC, 5.9x10-6 Pa at 20oC voor DDAC), its Henry's law constant is very low (5.03 x 10-7 Pa x m3/mol at 20 ºC for ADBAC, 4.27E-09 Pa m3/mol at 20 ºC for DDAC), indicating poor partitioning from aqueous solution. Therefore, respiratory exposure to ADBAC and DDAC is considered to be negligible and only dermal exposure is possible. This is also shown by the following calculation:

The inhalation exposure to ADBAC and DDAC during the application by foaming was estimated using the Spraying Model 1 . The indicative value for inhalation exposure is 104 mg/m3. Considering the total concentration of ADBAC and DDAC in the in-use dilution of FORCE 7 of maximal 0.095%.
For glutaraldehyde inhalation exposure is possible due to the higher vapour pressure (44 Pa at 20 °C) and higher Henry's law constant (0.0086 Pa m3/mol at 20 ºC). During application by spraying, inhalation exposure to ADBAC and DDAC in aerosol may still occur.

As FORCE 7 is used by professionals, oral exposure to ADBAC, DDAC and glutaraldehyde is considered negligible.

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

The formulation FORCE 7 is to be used by professionals only.

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

During application of FORCE 7 by spraying or foaming, secondary respiratory bystander exposure to ADBAC, DDAC and glutaraldehyde may occur.

Indirect exposure may occur when professionals or general public touch treated surfaces before dry, as the surfaces need to be wet for at least 30 minutes.
Dietary exposure to ADBAC, DDAC or glutaraldehyde by consuming food handled on treated surface is considered negligible, because the disinfected surfaces or objects that can come into contact with food or feed are rinsed off using clean water, in accordance with the WG/GA.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

No studies with FORCE 7 have been submitted and the classification and labelling of the formulation has been prepared based on the calculation method described in Annex I of Regulation 1272/2008/EC.

6.2.2 Data requirements formulated product

No additional data requirements are identified.

6.3 Risk characterisation for human health

6.3.1 Professional users

Exposure by mixing/loading and application by foaming

To estimate systemic dermal and respiratory, and local respiratory exposure to glutaraldehyde during the application of the in-use dilution of FORCE 7 by foaming, Spraying Model 1 is considered to be applicable.

To estimate potential respiratory exposure to glutaraldehyde during spraying and foaming Spraying model 1 (1-3 bar) or Spraying model 2 (4-7 bar) can be used, depending on the operation pressure. In the WGGA, however, the operation pressure is not specified. From the two Spraying models, Spray model 1 is used as it provides the higher indicative value for the product concentration in air, thus represents the worst case between the two models for inhalation exposure. This model also includes mixing and loading step; therefore no separate assessment of mixing and loading is performed, as it is considered to be covered by Spraying Model 1.

The concentration glutaraldehyde in the in-use solution is 0.13%. The indicative exposure values are 273 mg/min for hand exposure without protective gloves, 7.8 mg/min for hand exposure inside protective gloves, 222 mg/min for body exposure and 76 mg/m3 for respiratory exposure. The exposure duration for professional users is considered to be 2 hours/day. The results of exposure estimates are presented in table below.

Table T.1a Internal professional operator exposure to glutaraldehyde and risk assessment for the use of FORCE 7 during mixing, loading and spraying of a 0.13% in-use dilution (1.0% dilution of the product).

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Mixing, loading and spraying[3], no PPE			
Dermal	0.07	0.014	5.1
Respiratory	<0.01	0.014	0.4
Total	0.08	0.014	5.5
Mixing, loading and spraying[3], with PPE[4]			
Dermal	0.005	0.014	0.37
Respiratory	<0.01	0.014	0.4
Total	0.011	0.014	0.77

[1] Internal exposure is calculated with: 10% dermal absorption and 100% inhalation absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] Calculations were based on: Spraying Model 1.
[4] PPE (personal protective equipment): for the dermal exposure, the indicative value of 10.7 mg/min on hands (in gloves) is used from Spraying model 1. For body exposure a 90% reduction for the use of protective clothing is taken into account.

Table T.1b Internal professional operator exposure to glutaraldehyde and risk assessment for the use of FORCE 7 during mixing, loading and spraying of a 0.065% in-use dilution (0.5% dilution of the product).

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Mixing, loading and spraying[3], no PPE			
Dermal	0.04	0.014	2.5
Respiratory	<0.01	0.014	0.2
Total	0.04	0.014	2.7
Mixing, loading and spraying[3], with PPE[4]			
Dermal	0.0003	0.014	0.18
Respiratory	<0.01	0.014	0.2
Total	0.0005	0.014	0.38

[1] Internal exposure is calculated with: 10% dermal absorption and 100% inhalation absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] Calculations were based on: Spraying Model 1.
[4] PPE (personal protective equipment): for the dermal exposure, the indicative value of 10.7 mg/min on hands (in gloves) is used from Spraying model 1. For body exposure a 90% reduction for the use of protective clothing is taken into account.

Local dermal exposure to ADBAC, DDAC and glutaraldehyde can occur during mixing and loading of FORCE 7 and during application by foaming.

During mixing and loading, the professional user is dermally exposed to the concentrate (containing 8% w/w ADBAC, 1.5% w/w DDAC and 13% w/w glutaraldehyde), and during the application the professional user is dermally exposed to the in-use dilution of FORCE 7.
For glutaraldehyde, the $NOAEC_{local\ dermal}$ of 0.2% will be considered. As the $NOAEC_{local\ dermal}$ for ADBAC and DDAC is derived from the same study, the combined concentration of ADBAC and DDAC is compared to the $NOAEC_{local\ dermal}$ dermal of 0.6%.

For the exposure to the concentrated product, the $NOAEC_{local\ dermal}$ for all actives is exceeded. The concentration of glutaraldehyde in the in-use dilution (0.13%) does not exceed the $NOAEC_{local\ dermal}$ of 0.2% for glutaraldehyde and the combined concentration of ADBAC and DDAC (0.095%) is lower than to the $NOAEC_{local\ dermal}$ of 0.6%. In conclusion, gloves and coverall are prescribed for the professional user during mixing and loading.

For local effects via inhalation an $AEC_{inhalation}$ is set. The indicative inhalation exposure in Spraying model 1 is 104 mg biocidal product/m^3. Considering the concentration of ADBAC and DDAC in the in-use dilution of respectively 0.08% and 0.015%, the concentration in air of 0.08 mg/m^3 is calculated for ADBAC and 0.02 mg/m^3 for DDAC. The concentrations are below the $AEC_{local\ inhalation}$ of 0.25 mg/m^3 for ADBAC and DDAC. Considering the concentration of glutaraldehyde of 0.13%, this corresponds to a concentration of glutaraldehyde of 0.14 mg/m3 in air assuming equal evaporation of all components of the product. This is above $AEC_{inhalation}$ for long-time exposure of 10.6 µg/m^3 for glutaraldehyde. The use of adequate/suitable respiratory protection equipment is required based on the risk assessment of local respiratory effects of 0.13% glutaraldehyde in the in-use dilution. Since RPE is needed for safe use, the sentence "Use respiratory protective equipment during application via spraying/foaming" is to be added in the WG/GA.

Based on the risk assessment, adverse systemic and local respiratory effects after exposure to glutaraldehyde are not expected for the protected (gloves, protective clothing, respiratory protective equipment) professional user.

Exposure by mixing and loading and dipping of small items
To estimate systemic dermal and respiratory, and local respiratory exposure to glutaraldehyde during mixing/loading and application of the in-use dilution of FORCE 7 by dipping, "Mixing and loading Model 7: manual pouring and pumping liquids" and "Dipping Model 1" is considered to be applicable. This approach is in accordance to HEAd hoc recommendation 6.

The concentration glutaraldehyde in the in-use solution is 0.13%. For exposure during mixing and loading, the indicative exposure values are 101 mg/min for hand exposure without protective gloves, 1.01 mg/min for hand exposure inside protective gloves, and 0.94 mg/m3 for respiratory exposure. The exposure duration for professional users is considered to be 10 minutes/day. For exposure during dipping, the indicative exposure values are 25.7 mg/min for hand exposure inside protective gloves, 178 mg/min for body exposure and <1 mg/m3 for respiratory exposure. The exposure duration for professional users is considered to be 30 minutes/day.

Table T.2 Internal professional operator exposure to glutaraldehyde and risk assessment for the use of FORCE 7 during mixing and loading.

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Mixing, loading and spraying[3], no PPE			
Dermal	0.22	0.014	15.6
Respiratory	<0.01	0.014	0.03
Total	0.22	0.014	15.7
Mixing, loading and spraying[3], with PPE[4]			

Dermal	0.002	0.014	0.16
Respiratory	<0.01	0.014	0.03
Total	0.003	0.014	0.19

[1] Internal exposure is calculated with: 10% dermal absorption and 100% inhalation absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL.
[3] Calculations were based on: M&L model 7
[4] PPE (personal protective equipment): for the dermal exposure, the indicative value of 1.01 mg/min on hands (in gloves) is used from M&L model 7. For body exposure a 90% reduction for the use of protective clothing is taken into account.

Table T.3a Internal professional operator exposure by immersion to glutaraldehyde and risk assessment for the use of FORCE 7 (0.13% glutaraldehyde, 1.0% dilution)

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Dipping – Tier 1[3], no PPE			
Dermal	0.179	0.014	12.8
Respiratory	<0.001	0.014	0.001
Total	0.179	0.014	12.8
Dipping – Tier 2[3], with PPE[4]			
Dermal	0.003	0.014	0.20
Respiratory	<0.001	0.014	0.001
Total	0.003	0.014	0.20

[1] Internal exposure is calculated with: 10% dermal absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL 0.014 mg/kg bw per day.
[3] Calculations were based on: Dipping model 1.
[4] PPE: for gloves actual measurements inside gloves are used from Dipping Model 1, the use of coverall is considered to result in a 90% reduction of the dermal exposure.

Table T.3b Internal professional operator exposure by immersion to glutaraldehyde and risk assessment for the use of FORCE 7 (0.065% glutaraldehyde, 0.5% dilution)

Route	Internal exposure (mg/kg bw/day) [1]	Systemic AEL (mg/kg bw/day)	Risk-index[2]
Dipping – Tier 1[3], no PPE			
Dermal	0.09	0.014	6.4
Respiratory	<0.001	0.014	0.0
Total	0.09	0.014	6.4
Dipping – Tier 2[3], with PPE[4]			
Dermal	0.001	0.014	0.10
Respiratory	<0.001	0.014	0.0
Total	0.001	0.014	0.10

[1] Internal exposure is calculated with: 10% dermal absorption.
[2] Risk index is derived by dividing the internal exposure by systemic AEL 0.014 mg/kg bw per day.
[3] Calculations were based on: Dipping model 1.
[4] PPE: for gloves actual measurements inside gloves are used from Dipping Model 1, the use of coverall is considered to result in a 90% reduction of the dermal exposure.

Adverse systemic health effects after exposure to glutaraldehyde are not expected for protected (gloves, protective clothing) professional user during dipping of small items.

Local dermal exposure to ADBAC, DDAC and glutaraldehyde can occur during mixing and loading of FORCE 7 and during application by dipping.
During mixing and loading, the professional user is dermally exposed to the concentrate (containing 8% w/w ADBAC, 1.5% w/w DDAC and 13% w/w glutaraldehyde), and during the application the professional user is dermally exposed to the in-use dilution of FORCE 7.
For glutaraldehyde, the $NOAEC_{local\ dermal}$ of 0.2% will be considered. As the $NOAEC_{local\ dermal}$ for ADBAC and DDAC is derived from the same study, the combined concentration of ADBAC and DDAC is compared to the $NOAEC_{local\ dermal}$ of 0.6%.

For the exposure to the concentrated product, the $NOAEC_{local\ dermal}$ for all actives is exceeded. The concentration of glutaraldehyde in the in-use dilution (maximal 0.13%) is below the $NOAEC_{local\ dermal}$ of 0.2% for glutaraldehyde and the combined maximal concentration of ADBAC and DDAC (0.095%) is lower compared to the $NOAEC_{local\ dermal}$ of 0.6%. In conclusion, gloves and coverall are prescribed for the professional user during mixing and loading.

Local inhalation exposure can occur during mixing and loading of FORCE 7 during mixing and loading. According to HEAd hoc recommendation no. 6 inhalation exposure does not need to be taken into account when the vapour pressure is < 0.01 Pa. Therefore, inhalation exposure is not assessed for ADBAC and DDAC (see section 6.1.2.) For local effects via inhalation an $AEC_{inhalation}$ is set. The indicative inhalation exposure in Mixing and loading model 7 is 0.94 mg biocidal product/m^3. Considering the concentration of glutaraldehyde of 13%, this corresponds to a concentration of glutaraldehyde of 12.2 mg/m3 in air assuming equal evaporation of all components of the product. This is above $AEC_{inhalation}$ for short-time exposure of 0.5 mg/m^3 for glutaraldehyde. The use of adequate/suitable respiratory protection equipment is required based on the risk assessment of local respiratory effects of 0.13% glutaraldehyde in the in-use dilution. Since RPE is needed for safe use, the sentence “Use respiratory protective equipment during mixing and loading” is to be added in the WG/GA.

In conclusion, adverse systemic and local respiratory effects after exposure to glutaraldehyde using FORCE 7 are not expected for protected (gloves, protective clothing, respiratory protective equipment) professional user.
With the 1% and 0.5% dilution, no adverse health effects are expected for the protected (gloves, coverall and respiratory equipment) professional user after dermal and respiratory exposure to ADBAC, DDAC, and glutaraldehyde by the use of FORCE 7 during spraying and foaming and for the protected (gloves, coverall) professional user during dipping of small items.

6.3.2 Non-professional users, including the general public

The formulation FORCE 7 is to be used by professionals only.

6.3.3 Indirect exposure as a result of use
For PT4 applications, in the WG/GA is included that the treated surfaces need to be washed thoroughly after the treatment. Based on this, secondary dermal exposure for the general public including children via touching treated surfaces is not envisaged for PT4 uses.

However, for PT3 uses, according to the proposed WG/GA, the disinfected surfaces can be left to dry, meaning that residue of the active substances may be found on the treated surfaces. Animals transported may be dermally and orally exposed to ADBAC, DDAC and glutaraldehyde by touching or licking the surfaces disinfected with FORCE 7.

For local effects the sum of the concentrations of ADBAC (0.08%) and DDAC (0.015%) in the in-use solution of FORCE 7 is lower than the $NOAEC_{local\ dermal}$ (0.6%). In addition, the concentration of glutaraldehyde (0.13%) is lower than its $NOAEC_{local\ dermal}$ 0.2%. Therefore no local adverse effects are

expected due to the exposure due to dermal exposure to ADBAC, DDAC and glutaraldehyde by touching disinfected surface.

For glutaraldehyde, systemic effects need to be taken into account for the risk assessment. To consider the worst case 100% of glutaraldehyde is assumed to remains on disinfected surface if the surface is left to dry. According to the applicant the application rate is 200 mL/m^2, glutaraldehyde residue is calculated to be 267 mg per m^2 (200 mL/m^2 x 1.027 g/mL x 0.13% x 100%).

The AEL values of 0.014 mg/kg bw for glutaraldehyde is the limit value derived for human exposure. For animal health assessment, the assessment factor of 5 instead of 100 can be applied based on the EFSA guidance on birds and mammals (2009). Considering the NOAEL of 3.5 mg/kg bw/day, correction for 40% oral absorption (CAR), and using an assessment factor of 5, an animal$AEL_{medium\text{-}term}$ of 0.28 mg/kg bw/day can be derived. Assuming 100% transfer from the disinfected surface to mouth as the worst case, the area to be licked to reach the systemic AEL for a lamb of 40 kg is calculated as following:

(0.28 mg/kg bw/day x 40 kg bw) ÷ 40% ÷ 127 mg glutaraldehyde/m^2 = 0.1049 m^2 =1049 cm^2

It is unlikely that a lamb licks a disinfected surface of 1049 cm^2 (e.g. a square with ca. 33 cm side). Therefore, the risk for the animals due to the secondary exposure to glutaraldehyde contained in FORCE 7 is considered acceptable.

Furthermore, as the treated surfaces, that can come into contact with food or feed, need to be rinsed off thoroughly with drinking water after the treatment, no residues are envisaged via consumption of food or via livestock.

For secondary respiratory exposure of bystanders, a concern has been identified for the unprotected professional users applying the formulation by spraying or foaming. Therefore adverse effects after respiratory exposure of bystanders can also not be excluded. In order to avoid possible respiratory exposure during the treatment, the following sentence will be added to WG/GA: “No people may be present in the facilities during the treatment”.

For secondary respiratory exposure of animals, a concern has been identified for the unprotected professional users applying the formulation by spraying or foaming. Therefore adverse effects after respiratory exposure of animals, for the animal itself or for humans by indirect exposure via potential residues in food, can also not be excluded. In order to avoid possible respiratory exposure during the treatment, leading to potential residues in food, the following sentence will be added to WG/GA: “No animals may be present in the facilities during the treatment”.

6.3.4 Combined exposure

The formulation FORCE 7 is a mixture of three active substances. The combined toxicological effect of these three active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profiles based on the individual substances. Only for glutaraldehyde systemic effects were evaluated, therefore no addition on systemic effects are expected. As this risk assessment is based on local effects, the principle of addition has been applied.

For dermal exposure during application by coarse spraying, the total concentration of irritating substances in solution is 0.225%. Comparing this value with the lowest $NOAEC_{local}$ dermal of 0.2% (for glutaraldehyde) the professional user needs to use PPE (gloves and coverall). When PPE are worn no concern for combined dermal exposure to three substances exists.

Regarding inhalation exposure, combined exposure to the three active substances is possible. However, it is not yet established how the combined effects should be evaluated for local inhalation effects. Furthermore, respiratory protection has been prescribed during mixing and

loading and application by spraying or foaming(see above 6.3.1). The local effects due to inhalation exposure to the three active substances is therefore not evaluated.

6.4 Overall conclusions for the aspect human health

Based on this risk assessment, it was concluded that no adverse health effects are expected for the protected (gloves, suitable protective clothing respiratory equipment) professional user after dermal and respiratory exposure to ADBAC, DDAC and glutaraldehyde as a result of the application of FORCE 7, when used in accordance to the WG/GA.

In order to avoid possible bystander exposure during the treatment, the following sentence will be added to WG/GA: “No people may be present in the facilities during the treatment”.

In order to avoid possible animal exposure during the treatment, leading to potential residues in food, the following sentence will be added to WG/GA: “No animals may be present in the facilities during the treatment”.

Furthermore, when used according to the WG/GA, no adverse health effects are expected for the general public or animals by indirect exposure to ADBAC, DDAC and glutaraldehyde as a result of the application of FORCE 7.

7 Environment

7.1 Introduction

Authorisation is requested for the product containing alkyl (C12-16) dimethylbenzyl ammonium chloride, hereafter referred to as ADBAC, didecyldimethylammoniumchloride, hereafter referred to as DDAC, and glutaraldehyde as active substances. The product also contains two substances of concern, which will be referred to as SE1 and SE2, respectively, throughout this document.
The biocidal product concerns a veterinary hygiene disinfectant (PT03) and a disinfectant for food and feed areas (PT04). The product is for professional use. The intended uses are described in Table E. 1.

Table E. 1 Intended uses, dose, and use concentrations of the active substances.

Area of use envisaged	Concentration active substance in product (g/L)	Dose (mL product/L)	Use concentration active substances (g/L)
Disinfection of surfaces, materials and equipment by spraying, foaming or dipping in accommodations and annexes for animals, including vehicles used for animal transport (PT03)	ADBAC: 80 DDAC: 15 Glutaraldehyde: 130	Foaming, spraying and dipping: 5	ADBAC: 0.4 DDAC: 0.075 Glutaraldehyde: 0.65
Disinfection of surfaces by spraying, foaming or dipping in places where food or drinks are prepared, treated or stored (PT04)		Foaming, spraying and dipping: 10	ADBAC: 0.8 DDAC: 0.150 Glutaraldehyde: 1.30

7.2 Product related studies

The exposure assessment is based on data for the active substances, SE1 and SE2. There are no fate or ecotoxicity data available for the product.

7.3 List of endpoints

ADBAC is a mixture for which the composition may vary amongst the different manufacturers.
- Alkyl (C12-C14) dimethylbenzylammonium chloride (ADBAC (C12-C14)): CAS 85409-22-9
- Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16)): CAS 68424-85-1
- Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18)): CAS 68391-01-5

Alkyl (C12-16) dimethylbenzyl ammonium chloride is (or will be) included in the Union list of approved substances for PT3 and 4 (Regulation (EU) 2021/1063) and 8 (Directive 2013/7/EU) with approval dates 01/11/2022 (PT3 and 4) and 01/02/2015 (PT8). Approval of ADBAC for PT1 and 2 is awaiting for the final commission decision. Final draft CARs for the active substance are available for the aforementioned PTs. The dossiers have been commented on by NL. The risk assessment was based on the List of Endpoints (LoEP) from the available Assessment Report. Note that the three mixtures were considered technically equivalent regarding the environment. Therefore, only one endpoint per environmental parameter is available and the general abbreviation ADBAC will therefore be applied throughout the risk assessment report. Evaluation for PT10, 11, 12, and 22 is in progress, but not yet been commented by the member states.

DDAC is notified for inclusion for the product types PT1, 2, 3, 4, 6, 10, 11, 12 (RMS is IT).
DDAC is (or will be) included in the Union list of approved substances for PT3 and 4 (Regulation (EU) 2021/1045) and 8 (Directive 2013/4/EU) with approval dates 01/11/2022 (PT3 and 4) and 01/02/2015 (PT8). The dossiers for PT1 and 2 are awaiting the Commission decision on approval for inclusion in the Union list.

Glutaraldehyde is approved for the product types 3 and 4 (Directive 2015/1759 with approval date 01/10/2016) according to the regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. The environmental risk assessment is based on the list of endpoints as published in the assessment reports which are available on ECHA's website.

The data for the active substances applied in the current risk assessment are presented in appendix I and section 7.5. SE1 and SE2 will be addressed qualitatively due to their chemical properties and therefore no input parameters are presented, and no PECs and PEC/PNECs are calculated.

7.4 Environmental exposure assessment

7.4.1. Environmental fate

ADBAC is a cationic surfactant which is characterized by near irreversible binding or interaction with organic matter. The active substance is classified as readily biodegradable. Metabolites are not formed >10% in all environmental compartments. An OECD 303 STP simulation study demonstrated that ADBAC is effectively removed from waste water (99.8% removal).

DDAC is a cationic surfactant which is characterized by near irreversible binding or interaction with organic matter, corresponding to a very high K_{oc}. 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. DDAC is readily biodegradable. The substance is effectively removed from waste water during sewage treatment (99.8%) as demonstrated in an OECD 303A study. DDAC is not persistent in soils as it degrades rapidly (DT_{50} is 20.9 days at 12°C).

Glutaraldehyde is highly hydrophilic, non-ionisable and fully soluble in water. Although glutaraldehyde is volatile, it does not easily evaporate from water due to its high water solubility and corresponding low Henry constant. The active substance is hydrolytically and photolytically stable under environmental relevant conditions. Glutaraldehyde is subject to rapid photochemical degradation in air with a half-life of 8.2 h, and classified as readily biodegradable. The degradation rate constant in activated sludge is 2.9/h. Glutaraldehyde is considered to be moderately mobile in

soil and sediment based on the average organic carbon-water partitioning coefficient (K_{oc}) of 326 L/kg. However, as a result of chemisorption, glutaraldehyde is likely covalently bound to organic and proteinaceous material and loses its identity as glutaraldehyde once released to manure and soils.

The active substance's physical-chemical properties applied for the exposure assessment are summarised in appendix I.

7.4.2. Distribution in the environment

Various phases in the life cycle of a product may cause emissions and environmental exposure. Significant release to the environment will therefore occur during the application of products holding the biocide. Table E.2 summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different applications. Emissions from active substance production and product formulation are not part of the risk assessment. The routes of entry into the environment are explained in more detail in the next sections.

Table E.2 Foreseeable routes of entry into the environment on the basis of the intended uses.

Main scenario	Environmental compartments exposed				
	STP[1]	Freshwater[2]	Saltwater[2]	Soil[3]	Air[4]
Disinfection of surfaces, materials and equipment by spraying, foaming or dipping in accommodations and annexes for animals, including vehicles used for animal transport (PT03)	++	+	+	+	++
Disinfection of surfaces, materials and equipment by spraying, foaming or dipping in places where food or drinks are prepared, treated or stored (PT04)	++	+	+	-	++

++ Compartment directly exposed, + Compartment indirectly exposed, - Compartment not exposed, [1] Sewage Treatment Plant, [2] Including sediment, [3] Including groundwater.

The product needs to be diluted with water and the working solution is used for disinfection of surfaces, materials and equipment. Release to the sewer is the main emission pathway for disinfection of surfaces, materials and equipment in places where food or drinks are prepared, treated or stored (PT04). Residues left on the surfaces are rinsed with clean water afterwards or prior to the next disinfection event when wet cleaning prior disinfection is prescribed. Additionally, left-overs of diluted product in buckets and dipping baths are also released to the sewer. Consequently, the active substances end up in the aquatic environment after waste water treatment in the sewage treatment plant (STP). Considering that some Dutch STPs discharge to the open sea, the marine environment may be exposed as well. Although soils may be exposed due to the application of sewage sludge as a soil fertiliser, this route is highly unlikely in The Netherlands as its chemical composition does not fulfil the environmental standards regarding organic pollutants and heavy metals. In order to avoid unnecessary contamination of the receiving soils, sewage sludge is treated as hazardous waste instead.

When the product is used for disinfection of surfaces, materials and equipment by spraying, foaming or dipping in accommodations and annexes for animals (PT03), rinse water and residues in buckets and dipping baths are released via manure or waste water may occur which is subsequently applied as a fertiliser for agricultural soils. Subsequent emission to surface water is possible due to runoff or transport of soil particles from fertilised soils. In The Netherlands most farms are not connected to the municipal sewer due to the distance to the nearest sewage pipe. However, in the case of some housing types for poultry emission to waste water, with subsequent release via the STP into the aquatic environment, can take place.

When the product is used for disinfection of vehicles for animal transport (PT03), direct exposure of soils and surface water is not expected. These vehicles have to be disinfected above liquid-tight floors in line with regulation for professional use of biocides for the disinfection of veterinary transport vehicles. Most transport vehicles are disinfected on the premises of slaughterhouses after the animals have been unloaded. Here, waste water is discharged to an on-site waste water treatment plant and subsequently to the municipal sewer. Pre-treatment of waste water is mandatory for slaughterhouses in order to fulfil the standards set by local water authorities regarding e.g. suspended solids, lipids contents, and biological oxygen demands. Hence, the main emission pathway for this use is emission to the waste water, with subsequent release via the STP into the aquatic environment. Emission to air may also take place.
Disinfection of vehicles used for animal transport at farms might also occur; although this is not common practice and generally only includes disinfection of parts of transport vehicles (wheels etc). Then emission to the manure is expected, with subsequent emission to soils when manure is applied as a fertilizer. Emission to the (individual) sewage treatment plants may also occur, when present.

Farms may be connected to individual wastewater treatment plants (In Dutch: Individuele Behandeling van Afvalwater (IBA)) which purify domestic waste water. The effluent from IBA is then discharged to the surface water or the infiltrated soils. IBA's are however intended to purify small volumes of domestic waste water. Although industrial waste water from farms is likely not released to an IBA, residues may enter sinks when materials and equipment is cleaned.

Emission to air is likely when the product is applied by spraying. Spray drift may deposit on nearby soils or surface water.

7.4.3. Predicted environment concentration calculations

7.4.3.1. General

Predicted Environmental Concentrations (PECs) were calculated according to relevant exposure scenario documents (ESDs, release to the environment), the guidance on biocide legislation, Part B+C, volume IV (distribution in the environment), the Technical Agreement on Biocides (TAB) and the model SimpleTreat (concentrations for micro-organisms in an STP and the STP's effluent) by using the default values for parameters, unless otherwise noted. Distribution in the STP has been calculated using SimpleTreat version 4.0 in which the concentration of suspended solids in the effluent has been increased to 30 mg/L in accordance to the TAB (agreement ENV-9).
Studies demonstrated that STPs effectively remove ADBAC and DDAC. ADBAC and DDAC concentrations in the STP's effluent were therefore based on an OECD 303A study demonstrating 0.2% emission to effluent.
For glutaraldehyde, the tier 1 refinement as discussed in the Assessment Report (2014) was used to establish STP distribution, using Simple Treat 4.0. The emission to effluent was calculated to be 2.18% based on a degradation rate constant of 2.9/h.

Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substances are added are disposed as solid waste and usually incinerated. Possible pH effects on the environment were not considered, because the STP and receiving compartments are expected to have sufficient buffering. The applied methods are explained below. The risk assessment is based on the active substance's physical-chemical properties as listed in appendix I and the concentrations as listed in Table E. 1.

Disinfection of surfaces, materials and equipment in accommodations and annexes for animals (PT03)
Predicted Environmental Concentrations (PEC) for indoor applications were calculated in accordance with the scenario from Emissions Scenario Document (ESDs) for PT03 by using the scenario for animal housing disinfection. The scenario requires an amount of product applied per m^2, which was

set to the default value of 0.1 L product per m^2. The fraction of substance disintegrated during or after application (F_{dis}) was set to zero (default) and all of the active substance's mass used for disinfection is expected to be emitted to the sewer or manure.

As the amount of disinfections per year and the surfaces to be disinfected strongly depend on the type of animals housed, emission to the environment due to disinfection of stables vary among the different farm industries. The ESD distinguishes 18 types of farms, which were in this risk assessment grouped in dairy cattle, beef cattle, pig farming, and poultry. Due to the amount of disinfection in duck farming, which is high (13 times a year) compared to other poultry (1-7 times a year), assessments were made for poultry with and without ducks for comparison. Note that battery cages are not allowed in Europe anymore (Regulation No 1999/74/EC) of the European Parliament). This type of farming was therefore excluded from the poultry group.

Degradation of the active substances during storage in the slurry pit is not taken into account, but degradation in soils was taken into account by using half-lives for ADBAC, DDAC and glutaraldehyde at 12°C (see appendix I). The concentration in soils after 10 years is calculated in accordance to the Addendum on PT18 and the TAB. However, the formulas as applied in these documents assume that each manure application on grassland is contaminated with biocides while some stables are disinfected less than four times annually. To avoid overestimation of the PEC, only the fourth manure application on grassland is contaminated with biocides for stables that are disinfected once annually, the third and fourth in case of two annual disinfections, and the last three when stables are disinfected three times annually. The concentration after ten years is subsequently calculated in accordance to the addendum and TAB.
Considering that slurry is injected into grassland in The Netherlands, the mixing depth was increased from 5 to 10 cm. PECs were only calculated for the nitrogen emission standards.

Disinfection of animal transport vehicles (PT03)
Predicted Environmental Concentrations (PEC) for indoor applications were calculated in accordance with the scenario from Emissions Scenario Document (ESDs) for PT03 by using the scenario for animal transport vehicles disinfection. The scenario requires an amount of product applied per m^2, which was set to the default value of 0.1 L product per m^2.
Emission to the STP resulting from the disinfection of veterinary transport vehicles was calculated for mammals and poultry separately, as slaughterhouses are considered to be specialised in animal groups. Considering that large scale disinfection of veterinary transport vehicles is done on the premises of slaughterhouses where waste water is pre-treated by grease and sediment separation tanks, removal of ADBAC during pre-treatment was in accordance to TAB agreement ENV-196 set to 70% for ADBAC and DDAC being hydrophobic compounds and 90% for glutaraldehyde that disappears rapidly by abiotic degradation.

Indirect release to soils via manure may occur when vehicles are disinfected on farms. It is assumed that the frequency of disinfection is similar to that of stables, because stables are only disinfected when animals are transported to or from the farm. Considering that the surface of transport vehicles is negligible compared to that of stables, the risk is covered by the stable scenario.

Disinfection of surfaces, materials and equipment in places where food or drinks are prepared, treated or stored (PT04)
For the PT04 applications, Predicted environmental concentrations (PECs) were calculated according to the exposure scenarios described in the ESD for PT04 (final draft, January 2011) by applying the scenario for large scale catering kitchens and canteens. In The Netherlands, it is mandatory for large canteens and kitchens to have a grease and sediment separation tank before waste water is emitted to the sewer (Wet milieubeheer) to fulfil the requirements for e.g. lipid contents and biological oxygen demands in waste water. However, not all food processing facilities requires a grease and sediment separation tank due to their waste water's properties. Therefore, the risks have been calculated with and without a sediment and grease separation tank. The removal efficiency of a

grease and sediment sedimentation tank was set to 70% for ADBAC and DDAC being hydrophobic compounds and 90% for glutaraldehyde that disappears rapidly by abiotic degradation in accordance to TAB agreement ENV-195.

The diluted product is applied on the surfaces, materials and equipment to be disinfected. Typical application rates are 0.02-0.1 L sanitising solution/m² in case the product is applied by spraying or foaming. The scenario requires an amount of product applied per m^2, which was set to the maximum value of 0.1 L product per m^2.

The environmental risk assessment for the intended use for dipping of materials and equipment for both the PT3 and PT4 applications is performed according TAB agreements ENV 55 and ENV 217. The applicant proposed to reduce the default size of the dipping bath for PT3 applications of 100 L (see ENV 55 of the TAB) to 10 L and to include a risk mitigation measure in the draft label (WG/GA) in order to reduce the risk for the soil compartment to an acceptable level. This risk mitigation measure states that a maximum of 10 L of dipping solution needs to prepared on a daily basis for the disinfection of materials and equipment (PT3).

7.5 Environmental effect assessment

Risk assessment is based on Predicted No-Effect Concentrations (PNECs) for the different compartments which are derived from ecotoxicity data and applying assessment factors. The assessment factor depends on the type of test performed (acute or chronic), the toxicological endpoint (effect concentrations (ECs), no-observed effect concentrations (NOECs), etc), and the number of data and is determined according to the guidance on biocide legislation, Part B+C, volume IV. The PNECs based on the ecotoxicological data applied for the current risk assessment are presented in Table E.3.

Table E.3 Predicted no-effect concentrations for ADBAC, DDAC and glutaraldehyde

PNEC	Lowest endpoint	AF	PNEC	Test/species
ADBAC				
STP	EC_{50}: 7.75 mg/L	100	0.0775 mg/L	NOEC and EC_{50} available (respiration studies)
freshwater	NOEC: 4.15 µg/L	10	0.415 µg/L	NOECs are available for three species belonging to three trophic levels (fish, Daphnia and algae). Daphnids are most sensitive
sediment	NOEC: 520 mg/kg dwt	100	1.13 mg/kg wwt	*Chironomus tentans* study
soil	EC_{10}: 70 mg/kg wwt (83 mg/kg dwt)	100	0.70 mg/kg wwt	Chronic endpoint only available for soil microorganisms (nitrogen transformation test) – acute data available for earthworms, terrestrial plants and microorganisms (endpoint as agreed at BPC-36)
DDAC				
STP	3h EC_{50}: 17.9 mg/L	100	0.14 mg/L	2 EC_{50}s for STP micro-organisms (respiration inhibition studies)
freshwater	NOEC 0.011 mg/L	10	1.1 µg/L	Acute and chronic data available. Algae are the most sensitive
sediment	NOEC 530 mg/kg dwt	100	1.15 mg/kg wwt	Based on a chronic study with midge larvae (*Chironomus*)

soil	EC_{10}: 70 mg/kg wwt (79.1 mg/kg dwt)	50	1.4 mg/kg wwt	DDAC was tested on soil dwelling invertebrates, micro-organisms and plants. Soil micro-organisms are most sensitive
Glutaraldehyde				
STP	EC_{50} = 51.0 mg/L	100	0.51 mg/L	Respiration inhibition test
freshwater	0.025 mg/L	10	0.0025 mg/L	Data available for three trophic levels. Lowest NOEC for algae
soil	EC_{10}: 9.2 mg/kg wwt	50	0.184 mg/kg wwt	Chronic endpoint available for soil microorganisms (carbon transformation test) and plant study also considered chronic – acute data available for earthworms, terrestrial plants and microorganisms

dwt dry weight
wwt wet weight

Note that data on sediment organisms is not available for glutaraldehyde. As discussed previously, an assessment for sediment is not performed, in line with the Assessment Report for glutaraldehyde (2014).

7.6 Risk characterisation for the environment

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

7.6.1. Aquatic compartment (incl. sediment) and STP

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

The risk characterisation for the aquatic compartment (freshwater and sediment) indirectly exposed via an STP is presented in Table E.4 for disinfection of surfaces, materials and equipment in accommodations and annexes for animals, including vehicles used for animal transport (PT03) and in Table E.5 for disinfection of surfaces, materials and equipment in places where food or drinks are prepared, treated or stored (PT04) below.

Table E.4 PEC and PEC/PNEC ratios for micro-organisms in the STP and freshwater indirectly exposed due to the disinfection of surfaces, materials and equipment in accommodations and annexes for animals including vehicles used for animal transport (PT03)

	STP		Fresh water		Sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)[1]	PEC/PNEC	PEC (mg/kg ww)	PEC/PNEC
Disinfection of surfaces by spraying or foaming in accommodations and annexes for animals (PT03)[2]						
Disinfection of surfaces						
ADBAC	6.43E-05	<0.001	1.86E-06	0.004	6.63E-02	0.059
DDAC	1.21E-05	<0.001	6.54E-07	<0.001	8.00E-03	0.007
Glutaraldehyde	1.14E-03	0.002	1.14E-04	0.046	-	-[3]
Total	-	0.004	-	0.051	-	0.066
Disinfection of animal transport vehicles (PT03)						
Mammal transport						
ADBAC	3.68E-04	0.005	1.06E-05	0.026	3.79E-01	0.336
DDAC	6.90E-05	<0.001	3.75E-06	0.003	4.58E-02	0.04
Glutaraldehyde	2.90E-04	<0.001	2.90E-05	0.012	-	-[3]
Total	-	0.007	-	0.041	-	0.376

	STP		Fresh water		Sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)[1]	PEC/PNEC	PEC (mg/kg ww)	PEC/PNEC
Poultry transport						
ADBAC	3.62E-04	0.005	1.05E-05	0.025	3.74E-01	0.331
DDAC	6.80E-05	<0.001	3.69E-06	0.003	4.51E-02	0.039
Glutaraldehyde	2.85E-04	<0.001	2.85E-05	0.011	-	-[3]
Total	-	0.007	-	0.039	-	0.370

[1] removal of the active substance(s) by sorption onto suspended matter is included.

[2] In line with EU agreement, emission to the STP is only considered after disinfection of housing for poultry. For disinfection of materials and equipment in accommodations and annexes for animals (PT03) no emission to the STP is assumed.

[3] The risk to sediment is not required, in line with the Assessment report for glutaraldehyde (2014).

Table E.5 PEC and PEC/PNEC ratios for micro-organisms in the STP and freshwater indirectly exposed due to the disinfection of surfaces, materials and equipment in places where food or drinks are prepared, treated or stored (PT04)

	STP		Fresh water		Sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)[1]	PEC/PNEC	PEC (mg/kg ww)	PEC/PNEC
Disinfection of materials and equipment by dipping in accommodations and annexes for animals (PT03)						
ADBAC	4.00E-06	<0.001	1.16E-07	<0.001	4.12E-03	0.004
DDAC	7.50E-07	<0.001	4.07E-08	<0.001	4.97E-04	<0.001
Glutaraldehyde	7.09E-05	<0.001	7.08E-06	0.003	-	-[2]
Total	-	0.003	-	0.005	-	0.005
Disinfection of surfaces, materials and equipment by spraying, foaming or dipping in places where food or drinks are prepared, treated or stored (PT04)						
Disinfection of surfaces – without on-site treatment						
ADBAC						
large scale canteens	1.60E-04	0.002	4.62E-06	0.011	1.65E-01	0.146
slaughterhouses	8.00E-04	0.01	2.31E-05	0.056	8.24E-01	0.730
combined	9.60E-04	0.012	2.77E-05	0.067	9.89E-01	0.875
DDAC						
large scale canteens	3.00E-05	<0.001	1.63E-06	0.001	1.99E-02	0.017
slaughterhouses	1.50E-04	0.001	8.14E-06	0.007	9.95E-02	0.086
combined	1.80E-04	0.001	9.76E-06	0.009	1.19E-01	0.104
Glutaraldehyde						
large scale canteens	2.83E-03	0.006	2.83E-04	0.113	-	-[2]
slaughterhouses	1.42E-02	0.028	1.42E-03	0.567	-	-[2]
combined	1.70E-02	0.033	1.70E-03	0.68	-	-[2]
Total						
large scale canteens	-	0.009	-	0.125	-	0.163

	STP		Fresh water		Sediment	
	PEC (mg/L)	**PEC/PNEC**	**PEC (mg/L)[1]**	**PEC/PNEC**	**PEC (mg/kg ww)**	**PEC/PNEC**
slaughterhouses	-	0.039	-	0.630	-	0.816
combined	-	0.046	-	0.756	-	**1.0**
Disinfection of surfaces – with on-site treatment						
ADBAC						
large scale canteens	1.60E-05	<0.001	4.62E-07	0.001	1.65E-02	0.015
slaughterhouses	8.00E-05	0.001	2.31E-06	0.006	8.24E-02	0.073
combined	9.60E-05	0.001	2.77E-06	0.007	9.89E-02	0.088
DDAC						
large scale canteens	3.00E-06	<0.001	1.63E-07	<0.001	1.99E-03	0.002
slaughterhouses	1.50E-05	<0.001	8.14E-07	<0.001	9.95E-03	0.009
combined	1.80E-05	<0.001	9.76E-07	<0.001	1.19E-02	0.01
Glutaraldehyde						
large scale canteens	2.83E-04	<0.001	2.83E-05	0.011	-	-[2]
slaughterhouses	1.42E-03	0.003	1.42E-04	0.057	-	-[2]
combined	1.70E-03	0.003	1.70E-04	0.068	-	-[2]
Total						
large scale canteens	-	0.003	-	0.013	-	0.017
slaughterhouses	-	0.005	-	0.064	-	0.1082
combined	-	0.005	-	0.076	-	0.098
Disinfection of materials and equipment by dipping - without on-site treatment						
ADBAC	4.00E-04	0.005	1.16E-05	0.028	4.12E-01	0.365
DDAC	7.50E-05	<0.001	4.07E-06	0.004	4.97E-02	0.043
Glutaraldehyde	7.09E-03	0.014	7.08E-04	0.283	-	-[2]
Total	-	0.02	-	0.315	-	0.408
Disinfection of materials and equipment by dipping - with on-site treatment						
ADBAC	4.00E-05	<0.001	1.16E-06	0.003	4.12E-02	0.04
DDAC	7.50E-06	<0.001	4.07E-07	<0.001	4.97E-03	0.004
Glutaraldehyde	7.09E-04	0.001	7.08E-05	0.028	-	-[2]
Total	-	0.002	-	0.032	-	0.041

[1] removal of the active substance(s) by sorption onto suspended matter is included.

[2] The risk to sediment is not required, in line with the Assessment report for glutaraldehyde (2014).

The PEC/PNEC values for the disinfection of surfaces, materials and equipment in accommodations and annexes for animals, including vehicles used for animal transport (PT03) are all below the trigger value of 1. Note that emission from transport vehicles was based on additional waste water treatment as waste water is led through a lipid separation tank that removes 70% of ADBAC and

DDAC, and 90% of glutaraldehyde. As the PEC:PNEC ratios will slightly exceed one when waste water is not purified on-site, a lipid separation tank is required to reduce emission to acceptable concentrations. Consequently, a risk mitigation measure is added to the WG/GA. Hence, the risks to STP, freshwater and sediment are acceptable and the standards for the environment are therefore met.

However, discharge to an IBA may result in malfunctioning of the waste water treatment system as high loads of the active substances may kill the microbial population as the system's volume is limited (3-6 m^3) and additional degradation in the sewer is not expected as these are short and not fully loaded with organic material. Conclusively, the proposed application when used in compliance with the legal directions for use (WG/GA) meets the standards for aquatic organisms, sediment organisms and micro-organisms in the STP. A precautionary measure to avoid discharge to an IBA was added to the WG/GA by the applicant.

For the disinfection of surfaces in places where food or drinks are prepared, treated or stored (PT04) the PEC:PNEC values for sediment are above the trigger value of 1 when waste water is directly emitted to the sewer, which indicate unacceptable risks.

For large-scale kitchens and canteens and for slaughterhouses (PT04) on-site pre-treatment of waste water using a grease and sediment separation tank is a possible risk mitigation measure. When on-site pre-treatment of waste water is included in the scenario, PEC:PNEC ratios are below 1 and the risks are considered acceptable. Consequently, the following risk mitigation measure should therefore be included in the draft label (WG/GA):

NL: *Bij gebruik van dit middel in de voedselindustrie is een additionele vetafscheider en slibvangput conform NEN-EN 1825-1 en 1825-2 en/of een biologische of chemische voorzuivering verplicht met afvoer op de gemeentelijke riolering.*

EN: *Application of this product in the food, feed, and beverage industry requires an additional sediment grease separation tank according to NEN-EN 1825-1 and 1825-2 and/or a biological or chemical pre-treatment connected to the municipal sewer.*

For SE1 and SE2 concentrations above environmental risks limits are not expected and the accompanied risks are considered acceptable.

Indirect emission to estuarine and marine water
Considering that some Dutch STPs discharge to the open sea, indirect exposure of the marine environment is likely. In general, the $PNEC_{marine}$ will be 10 times lower than the $PNEC_{freshwater}$ as marine assessment factors are 10 times higher than for fresh water (Guidance on biocide legislation, Part B+C, volume IV). However, the PEC will be 10 times lower than the $PEC_{freshwater}$ as the dilution factor is 100 instead of 10. Risk ratios are thus expected to be similar, and therefore risk assessment for fresh water also covers risks for the marine environment.

7.6.1.2 Aggregated risk assessment

Because the product is multi-purpose, the environment receives the active substances and SoCs from different applications and therefore a cumulative risk assessment was made. For the cumulative risk assessment the PEC:PNEC ratios were summarised for simultaneous use as disinfectant in accommodations and annexes for animals, including vehicles used for animal transport (PT03) and in places where food or drinks are prepared, treated or stored (PT04) and discharge to a municipal STP. The cumulative risk assessment was only made for sediment as the highest PEC:PNEC were observed for this compartment. The results of the cumulative risk assessment are summarised in Table E.6.

Table E.6 Aggregated risk assessment for direct emission to the STP. Presented values are the PEC:PNEC ratios for sediment.

	risk ratio for the sediment compartment	
	Without on-site treatment (PT04)	**With on-site treatment (PT04)**
Disinfection of surfaces by spraying or foaming in accommodations and annexes for animals (PT03)	0.066	0.066
Disinfection of materials and equipment by dipping in accommodations and annexes for animals (PT03)	0.005	0.005
Disinfection of animal transport vehicles (PT03) – mammal transport	0.376	0.376
Disinfection of animal transport vehicles (PT03) – poultry transport	0.370	0.370
Disinfection of surfaces by spraying or foaming in places where food or drinks are prepared, treated or stored (PT04)	**1.0**	0.098
Disinfection of materials and equipment by dipping in places where food or drinks are prepared, treated or stored (PT04)	0.408	0.041
Total	**2.2**	0.96

Simultaneous exposure from the intended uses as disinfectant in accommodations and annexes for animals, including vehicles used for animal transport (PT03) and in places where food or drinks are prepared, treated, or stored (PT04) results in an unacceptable risk for the sediment compartment as the total PEC:PNEC for direct release to the sewer is >1 without on-site pre-treatment of waste water. With on-site pre-treatment of waste water the total PEC:PNEC for sediment is < 1 and thus acceptable.
The proposed risk mitigation measure for on-site pre-treatment of waste water by a grease and sediment separation tank should be included in the draft label (WG/GA) to avoid unacceptable risks for surface disinfection and for disinfection of materials and equipment by dipping (PT04).

7.6.1.3 Monitoring data (surface water)

Dutch water boards have a well-established programme for monitoring pesticide contamination of surface waters for which the results are publicly available on-line (www. bestrijdingsmiddelenatlas.nl). Here, monitoring data are processed in a graphic format aiming to provide an insight into measured pesticide contamination of Dutch surface waters against environmental standards. The Pesticide Atlas was used to evaluate measured concentrations of pesticides in Dutch surface water, but no data are available regarding the presence of ADBAC, DDAC and glutaraldehyde and SE1 and SE2 in Dutch surface water.

7.6.1.4 Surface water intended for the abstraction of drinking water

Biocidal products with the active substance DDAC have been on the market for more than three years. The existing active substances ADBAC, DDAC and glutaraldehyde and SE1 and SE2 are not included in the list of substances of concern due to their presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb (2022). In addition, the active substance glutaraldehyde is not included in the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010). RIVM did include quaternary ammonium compounds in general on the monitoring list. The report states that these substances are expected to be removed in the STP, but that monitoring is recommended due to potential large scale use. From the general scientific knowledge collected by the Ctgb about the product and its active substances and SoCs the Ctgb concludes that there are in this case insufficient indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in

compliance with the directions for use. Thus the standards for surface water destined for the production of drinking water are met.

7.6.2 Terrestrial compartment

7.6.2.1 Soil organisms

The risk characterisation for soils resulting from disinfection of surfaces, materials and equipment by spraying, foaming or dipping in accommodations and annexes for animals (PT03) is presented in **Fout! Verwijzingsbron niet gevonden.**7.

As discussed previously, indirect release to soils (via manure) may occur when vehicles are disinfected on farms. However, it is assumed that the frequency of disinfection is similar to that of stables, because stables are only disinfected when animals are transported to or from the farm. Considering that the surface of transport vehicles is negligible compared to that of stables, the risk is covered by the stable scenario.

Table E.7 PEC_{soil} values and PEC/PNEC ratios for soils due to the disinfection of surfaces, materials and equipment in accommodations and annexes for animals by spraying, foaming or dipping (PT03)

	Grassland		Arable land	
	PEC (mg/kg wwt)	**PEC:PNEC**	**PEC (mg/kg wwt)**	**PEC/PNEC**
Disinfection of surfaces				
ADBAC				
Dairy cattle	2.54E-04	<0.001	4.50E-04	<0.001
Beef cattle	3.64E-03	0.005	3.70E-03	0.005
Pig farming	3.13E-03	0.004	3.21E-03	0.005
Poultry, including duck farming	3.61E-03	0.005	6.38E-03	0.009
Poultry, excluding duck farming	2.01E-03	0.003	2.08E-03	0.003
DDAC				
Dairy cattle	5.09E-05	<0.001	8.43E-05	<0.001
Beef cattle	7.28E-04	<0.001	6.94E-04	<0.001
Pig farming	6.26E-04	<0.001	6.02E-04	<0.001
Poultry, including duck farming	7.23E-04	<0.001	1.20E-03	<0.001
Poultry, excluding duck farming	4.03E-04	<0.001	3.89E-04	<0.001
Glutaraldehyde				
Dairy cattle	5.07E-04	0.003	7.31E-04	0.004
Beef cattle	7.25E-03	0.039	6.01E-03	0.033
Pig farming	6.23E-03	0.034	5.21E-03	0.028
Poultry, including duck farming	7.20E-03	0.039	1.04E-02	0.056
Poultry, excluding duck farming	4.01E-03	0.022	3.37E-03	0.018
Total				
Dairy cattle	-	0.005	-	0.006
Beef cattle	-	0.045	-	0.039
Pig farming	-	0.039	-	0.034
Poultry, including duck farming	-	0.045	-	0.066
Poultry, excluding duck farming	-	0.026	-	0.022

	Grassland		Arable land	
	PEC (mg/kg wwt)	**PEC:PNEC**	**PEC (mg/kg wwt)**	**PEC/PNEC**
Disinfection of materials and equipment by dipping				
ADBAC				
Dairy cattle	3.34E-03	0.005	5.90E-03	0.008
Beef cattle	5.94E-02	0.085	1.05E-01	0.15
Pig farming	1.21E-02	0.017	2.13E-02	0.03
Poultry, including duck farming	9.18E-03	0.013	1.62E-02	0.023
Poultry, excluding duck farming	9.18E-03	0.013	1.62E-02	0.023
DDAC				
Dairy cattle	6.68E-04	<0.001	1.11E-03	<0.001
Beef cattle	1.19E-02	0.008	1.97E-02	0.014
Pig farming	2.41E-03	0.002	4.00E-03	0.003
Poultry, including duck farming	1.84E-03	0.001	3.04E-03	0.002
Poultry, excluding duck farming	1.84E-03	0.001	3.04E-03	0.002
Glutaraldehyde				
Dairy cattle	6.68E-03	0.036	9.59E-03	0.052
Beef cattle	1.19E-01	0.645	1.71E-01	0.927
Pig farming	2.41E-02	0.131	3.47E-02	0.188
Poultry, including duck farming	1.83E-02	0.1	2.64E-02	0.143
Poultry, excluding duck farming	1.83E-02	0.1	2.64E-02	0.143
Total				
Dairy cattle	-	0.042	-	0.061
Beef cattle	-	0.738	-	**1.1**
Pig farming	-	0.150	-	0.221
Poultry, including duck farming	-	0.114	-	0.168
Poultry, excluding duck farming	-	0.114	-	0.168

The intended use as disinfectant of surfaces by spraying or foaming in accommodations and annexes for animals, including vehicles used for animal transport (PT03) results in an acceptable risk for the soil compartment.

For the intended use as disinfectant of materials and equipment by dipping in accommodations and annexes for animals (PT03) the PEC:PNEC values for soil are above the trigger value of 1 which indicates unacceptable risks for the soil compartment. This exceedance is considered to be acceptable as it may be expected that the concentration of glutaraldehyde significantly reduces during manure storage due to degradation. Moreover, glutaraldehyde binds strongly onto organic matter (crosslinking) and therefore incorporates in the soil's organic matrix. Therefore, the standards for the terrestrial environment are met provided that a maximum bath volume of 10 L per day is used. For SE1 and SE2 concentrations above environmental risks limits are not expected and the accompanied risks are considered acceptable.

To avoid unacceptable emission from dipping baths, the following risk mitigation measure should be included in the draft label (WG/GA):

NL*: Maak in het geval van desinfectie van materialen en gereedschappen in dierverblijfplaatsen middels dippen niet meer dan 10 L desinfectievloeistof per dag aan.*

EN: *Do not prepare more than 10 L disinfection solution on a daily basis for the disinfection of materials and equipment in accommodations and annexes for animals by dipping.*

7.6.2.2 Non-target arthropods (including bees)

The risk assessment for non-target arthropods is considered to be similar to the assessment for soil organisms due to their direct contact with soils. Because the active substances and SoCs are not expected to have a systemic mode of action, farms are not considered foraging areas for bees, manure is injected into soil secondary exposure of bees through pollen is considered negligible. Hence, the risk for non-target arthropods (including bees) is considered acceptable for the active substances and SoCs for all intended uses.

7.6.2.3 Groundwater

Due to distribution of manure, transportation of the active substances and SE1 and SE2 to groundwater is expected.

Table E.8 summarises the concentrations in porewater after application of manure to grassland and arable land. Concentrations are based on the nitrogen emission standards. Degradation of the active substances in soils between two manure events is considered.

Table E.8 PECgw values and PEC/PNEC ratios due to the disinfection of surfaces, materials and equipment in accommodations and annexes for animals (PT03)

	Concentration in porewater (µg/L)	
	1st Tier	
	Grassland	**Arable land**
Disinfection of surfaces		
ADBAC		
Dairy cattle	8.79E-06	1.55E-05
Beef cattle	1.26E-04	1.28E-04
Pig farming	1.08E-04	1.11E-04
Poultry, including duck farming	1.25E-04	2.21E-04
Poultry, excluding duck farming	6.96E-05	7.17E-05
DDAC		
Dairy cattle	5.13E-06	8.49E-06
Beef cattle	7.34E-05	6.99E-05
Pig farming	6.31E-05	6.06E-05
Poultry, including duck farming	7.28E-05	1.21E-04
Poultry, excluding duck farming	4.06E-05	3.92E-05
Glutaraldehyde		
Dairy cattle	8.63E-02	**1.24E-01**
Beef cattle	**1.24**	**1.02**
Pig farming	**1.06**	**8.88E-01**
Poultry, including duck farming	**1.23**	**1.77**
Poultry, excluding duck farming	**6.83E-01**	**5.75E-01**
Total		
Dairy cattle	8.63E-02	**1.24E-01**
Beef cattle	**1.24**	**1.02**
Pig farming	**1.06**	**8.88E-01**
Poultry, including duck farming	**1.23**	**1.77**
Poultry, excluding duck farming	**6.83E-01**	**5.75E-01**
Disinfection of materials and equipment by dipping		
ADBAC		
Dairy cattle	1.15E-04	2.04E-04
Beef cattle	2.05E-03	3.63E-03
Pig farming	4.17E-04	7.37E-04

	Concentration in porewater (µg/L)	
	1st Tier	
	Grassland	Arable land
Poultry, including duck farming	3.17E-04	5.60E-04
Poultry, excluding duck farming	3.17E-04	5.60E-04
DDAC		
Dairy cattle	6.73E-05	1.12E-04
Beef cattle	1.20E-03	1.98E-03
Pig farming	2.43E-04	4.03E-04
Poultry, including duck farming	1.85E-04	3.06E-04
Poultry, excluding duck farming	1.85E-04	3.06E-04
Glutaraldehyde		
Dairy cattle	**1.14**	**1.63**
Beef cattle	**2.02E+01**	**2.91E+01**
Pig farming	**4.11**	**5.90**
Poultry, including duck farming	**3.13**	**4.49**
Poultry, excluding duck farming	**3.13**	**4.49**
Total		
Dairy cattle	1.14	1.63
Beef cattle	2.02E+01	2.91E+01
Pig farming	4.11	5.90
Poultry, including duck farming	3.13	4.49
Poultry, excluding duck farming	3.13	4.49

The concentrations of the active substance ADBAC and DDAC in pore water are all <0.1 µg/L. For glutaraldehyde most concentrations exceed the trigger value for grassland and arable land. Since the exceedance of limit also for the total was due to glutaraldehyde, it was concluded that a potential risk for groundwater exists for glutaraldehyde and this was assessed using higher tier method, i.e. FOCUS PEARL. In line with the current national assessment of plant protection products, the Kremsmünster scenario was used in FOCUS PEARL (version 4.4.4).

The concentrations in soil were recalculated to kg/ha in order to be entered in PEARL. It was assumed that this concentration is equally distributed over 1 ha, in a soil layer with an incorporation depth of 0.2 m for arable land, an injection depth of 0.05 m for grassland and a density of 1700 kg wwt/m³. From these parameters, application rates expressed in kg /ha in manure in arable land or in grassland were calculated and used in PEARL.

The application dates are 1st March, 23rd April, 15th June and 7th August for grassland (crop alfalfa) and 20 days pre-emergence or in two applications on 15th March and 3rd October for arable land (crop maize or winter cereals respectively), conform the EU agreed data (WG II 2014).
PEARL does include degradation in soil. The plant uptake factor was set at 0. A simulation period of 20 years was chosen. The Freundlich sorption exponent (1/n) was set at 1 because no information on concentration dependent sorption was available.

Table E.9. PEC_{GW} for glutaraldehyde calculated for the highest concentrations calculated at first tier (please refer to Table E.8), using PEARL

	Concentration in porewater (µg/L)[1]	
	Grassland	Arable land
2nd Tier - glutaraldehyde		
Dairy cattle	< 0.001	< 0.001
Beef cattle	< 0.001	< 0.001
Pig farming	< 0.001	< 0.001

Poultry, including duck farming	< 0.001	< 0.001
Poultry, excluding duck farming	< 0.001	< 0.001

[1] average concentrations closest to the 80th percentile

PEARL calculations demonstrate that the worst-case concentrations of glutaraldehyde are below the groundwater criterion (0.1 µg/L). Thus for all scenarios the groundwater concentrations are expected to be below 0.1 µg/L. Hence, the risk to groundwater is considered to be acceptable for the intended uses.

For SE1 and SE2 concentrations above environmental risks limits are not expected and the accompanied risks are considered acceptable. No risk mitigation measures are deemed necessary.

7.6.2.4 Persistence in soil

The half-lives in soils of ADBAC, DDAC and glutaraldehyde do not exceed the criteria for persistence in soils (180 days). SE1 and SE2 are considered readily biodegradable and not expected to persist in soil.

7.6.3 Non compartment specific effects relevant to the food chain

7.6.3.1 Bioconcentration

For ADBAC the octanol-water partition coefficient is not available (is deemed inaccurate). When taking into account the available mammalian data on metabolism and distribution and also the low BCF for fish (79 L/kg), ADBAC is also considered to have a low potential for bioaccumulation.
DDAC is a surfactant and therefore a normal K_{ow} could not be established. The experimental BCF (whole fish) is 81 L/kg, indicating that DDAC has a low potential for bioconcentration.
The logarithmic octanol-water partition coefficient (log K_{ow}) is below 3 (0.4677) for glutaraldehyde and therefore the potential for bioaccumulation is considered to be low.

7.6.3.2 Primary and secondary poisoning of birds and mammals

As direct exposure of birds and mammals to the product is not expected, primary poisoning of birds and mammals is not considered relevant. In addition, the low log K_{ow} or BCF values for ADBAC, DDAC, glutaraldehyde and SE1 and SE2 (as discussed in 7.6.3.1) indicate that indirect exposure of birds and mammals to ADBAC, DDAC, glutaraldehyde and SE1 and SE2 through consumption of aquatic or soil organisms is considered to be low. Hence the product meets the standards for the risk to birds and mammals.

7.6.4 Atmosphere

Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimize the risk for stratospheric ozone depletion. There are no indications that ADBAC, DDAC, glutaraldehyde and SE1 and SE2 contribute to depletion of the ozone layer as the compounds are not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Moreover, AOPwin calculates for the active substance a half-life of a half-life of 8.8, 8.3 and 8.2 hours in air (OH timeframe 24 hrs/day, 0.5×10^6 OH radicals/cm^3), respectively. The calculated half-lives of ADBAC, DDAC and glutaraldehyde are below the trigger of two days, which is used as cut-off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. The environmental risk to air is therefore considered acceptable.
The expected atmospheric half-lives of SE1 and SE2 in air exceed the trigger of 2 days, which is used as cut-off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. However, SE1 and SE2 are known to disappear rapidly from the environment by biodegradation once deposited. Unacceptable risks to terrestrial and aquatic

environments are therefore not expected. Consequently, the environmental risks related to emission to air are considered acceptable.

7.7 Measures to protect the environment (risk mitigation measures)

The applicant included a precautionary measure for the environment in the draft WG/GA: "*Resten die het middel bevatten dienen uitsluitend te worden afgevoerd naar het riool met aansluiting op de RWZI of de mestkelder. In geen geval mag dit middel worden geloosd op een Individuele Behandeling Afvalwater (IBA)*.''

This measure is adjusted to the standard precautionary measure used by CTGB:

NL: *Om verminderd functioneren van een Individuele Behandeling Afvalwater (IBA) bij toepassing van dit middel op de boerderij te voorkomen, dienen afvalresten die het middel bevatten geloosd te worden op de mestopslag of op de gemeentelijke riolering.*

EN: *To prevent the inhibition in functioning of an on-site wastewater treatment system (IBA), possible residues containing the product must be discharged to the slurry pit or to a municipal STP.*

Furthermore, for the intended use as disinfectant of materials and equipment by dipping in accommodations and annexes for animals (PT03) the applicant proposed to include the following risk mitigation measure in the draft label (WG/GA):

NL*: Maak in het geval van desinfectie van materialen en gereedschappen in dierverblijfplaatsen middels dippen niet meer dan 10 L desinfectievloeistof per dag aan.*

EN: *Do not prepare more than 10 L disinfection solution on a daily basis for the disinfection of materials and equipment in accommodations and annexes for animals by dipping.*

Because the intended use as disinfectant of surfaces, materials and equipment by spraying, foaming or dipping in places where food or drinks are prepared, treated or stored (PT04) may result in unacceptable risks for the aquatic environment, risk mitigation measures are required. These are discussed in the next section.

7.8 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.50.

Table E.50 Overall conclusions for the aspect Environment

product and intended use	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
FORCE 7														
Disinfection of surfaces by spraying or foaming in accommodations and annexes for animals (PT03)	3	√	√	√	√	√	√	√	√	√	√	√	√	√
Disinfection of animal transport vehicles (PT03)	3	√	**R**	√	√	√	√	√	√	√	√	√	√	**R**
Disinfection of materials and equipment by dipping in accommodations and annexes for animals (PT03)	3	√	√	√	√	√	**R**	**R**	**R**	√	√	√	√	**R**
Disinfection of surfaces by spraying or foaming in places where food or drinks are prepared, treated or stored (PT04)	4	√	**R**	√	√	√	-	-	-	-	√	√	√	**R**
Disinfection of materials and equipment by dipping in places where food or drinks are prepared, treated or stored (PT04)	4	√	**R**	√	√	√	-	-	-	-	√	√	√	**R**

X risk unacceptable, √ risk acceptable, **R** risk acceptable with proposed restriction mitigation measure

When used in accordance with the proposed label (WG/GA) the application of FORCE 7 as a disinfectant for

- surfaces by spraying or foaming in accommodations and annexes for animals, excluding vehicles used for animal transport (PT03) results in **acceptable** risks for the environment **provided** that the following precautionary measure is added to the the draft label (WG/GA):

NL: *Om verminderd functioneren van een Individuele Behandeling Afvalwater (IBA) bij toepassing van dit middel op de boerderij te voorkomen, dienen afvalresten die het middel bevatten geloosd te worden op de mestopslag of op de gemeentelijke riolering.*

EN: *To prevent the inhibition in functioning of an on-site wastewater treatment system (IBA), possible residues containing the product must be discharged to the slurry pit or to a municipal STP.*

- materials and equipment by dipping in accommodations and annexes for animals (PT03) results in **acceptable** risks for the environment **provided** that the following risk mitigation measure is added to the draft label (WG/GA):

NL*: Maak in het geval van desinfectie van materialen en gereedschappen in dierverblijfplaatsen middels dippen niet meer dan 10 L desinfectievloeistof per dag aan.*

EN: *Do not prepare more than 10 L disinfection solution on a daily basis for the disinfection of materials and equipment in accommodations and annexes for animals by dipping.*

- surfaces by spraying or foaming and materials and equipment by dipping in places where food or drinks are prepared, treated or stored (PT04) and disinfection of veterinary transport vehicles (PT03) results in **acceptable** risks for the environment **provided** that the following risk mitigation measure is added to the draft label (WG/GA):

NL: *Bij gebruik van dit middel in de voedselindustrie en bij desinfectie van transportmiddelen voor dieren is een additionele vetafscheider en slibvangput conform NEN-EN 1825-1 en 1825-2 en/of een biologische of chemische voorzuivering verplicht met afvoer op de gemeentelijke riolering.*

EN: *Application of this product in the food, feed and beverage industry, and for the disinfection of veterinary transport vehicles requires an additional sediment grease separation tank according to NEN-EN 1825-1 and 1825-2 and/or a biological or chemical pre-treatment connected to the municipal sewer.*

8 Conclusion

The applicant has proven that FORCE 7 under the proposed Legal Conditions for Use and the Directions for Use (WG/GA), is sufficiently effective and that no unacceptable risk is expected to human health, the person who uses the product and the environment.

9 Classification and labelling

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
ADBAC, DDAC, glutaraldehyde, isotridecanol, ethoxylated			
Pictogram:	GHS05	Signal word:	Danger
	GHS07		
	GHS08		
	GHS09		
H-statements:	H302	Harmful if swallowed.	
	H314	Causes severe skin burns and eye damage.	
	H317	May cause an allergic skin reaction.	
	H332	Harmful if inhaled.	
	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P260	Do not breathe dust/fume/gas/mist/vapours/spray.	
	P273	Avoid release to the environment.	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	P284	[In case of inadequate ventilation] wear respiratory protection.	
	P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].	
	P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
	P310	Immediately call a POISON CENTER/doctor/…	
	P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/...	
	P501	Dispose of contents/container to	
Supplemental Hazard information:	EUH071		

Child-resistant fastening obligatory?	**Not applicable**
Tactile warning of danger obligatory?	**Not applicable**

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	P342+P311 is assigned, as this sentence is highly recommended with the assigned H334.
Other:	Isotridecanol, ethoxylated needs to be declared as it contributes to the H302 classification.

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

10 References

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Database with monitoring data from pesticides in surface water obtained from regional water boards. http://www.bestrijdingsmiddelenatlas.nl
Lijst met probleemstoffen voor de bereiding van drinkwater uit oppervlaktewater, VEWIN, 2022 http://www.vewin.nl/probleemstoffen
Other
Regulation (EC) No 1005/2009 of the European Parliament and the Council of 16 September 2009 on substances that deplete the ozone layer.

Appendix I. Input parameters for environmental modelling

Parameter	Value	Remarks
	ADBAC	
molecular weight (g/mole)	359.6	Average value. 340.0 – 396.1 g/mol, depending on alkyl chain length C_{12} - C_{14} - C_{16}
melting point (°C)	150	Compound is a solid at environmental temperature. Start to decompose at 150°C.
vapour pressure at test temperature (Pa)	6.03E-04	
test temperature vapour pressure (°C)	20	
solubility at test temperature (mg/L)	431000	pH 6.5
test temperature solubility (°C)	20	
Henry constant (Pa × m3 × mol-1)	5.03E-07	Calculated
test temperature Henry constant (°C)	-	
octanol-water partition coefficient (L/kg)	-	deemed inaccurate (see Koc)
organic carbon-water partition coefficient (L/kg)	1640329	mean Koc (Agreed minutes – WGV2017_ENV_6-3/6-4_v2)
characterisation of biodegradability	readily biodegradable	
half-life for biodegradation in fresh water at 12°C (days)	15	Default half-life for compounds that are readily biodegradable according to the guidance on biocide legislation, Part B, volume IV as no degradation studies are available.
half-life for biodegradation in sediment at 12°C(days)	-	
half-life for biodegradation in soil at 12°C (days)	17.1	
rate constant for biodegradation in STP (/d)	not relevant	An OECD 3.03 STP simulation study demonstrated that ADBAC is effectively removed from waste water (99.8% removal).
half-life in air (hrs)	8.8	Estimated with AOPwin (OH timeframe 24 hrs/day, 0.5×10^6 OH radicals/cm^3)

Parameter	Value	Remarks
	DDAC	
molecular weight (g/mole)	362.1	
melting point (°C)	98.2	Compound is a solid at environmental temperature. Starts to decompose at 98.2°C.
vapour pressure at test temperature (Pa)	5.90E-6	
test temperature vapour pressure (°C)	20	
solubility at test temperature (mg/L)	500000	
test temperature solubility (°C)	20	
Henry constant (Pa m^3/ mol)	4.27E-9	
test temperature Henry constant (°C)	20	
octanol-water partition coefficient (L/kg)	-	
organic carbon-water partition coefficient (L/kg)	562314	
characterisation of biodegradability	readily biodegradable	
half-life for biodegradation in fresh water at 12°C (days)	15	Default half-life for compounds that are readily biodegradable according to the guidance on biocide legislation, Part B, volume IV as no degradation studies are available.
half-life for biodegradation in sediment at 12°C(days)	-	
rate constant for biodegradation in STP (/d)	not relevant	An OECD 3.03 STP simulation study demonstrated that ADBAC is effectively removed from waste water (99.8% removal).
half-life in air (hrs)	8.3	Estimated with AOPwin (OH timeframe 24 hrs/day, 0.5×106 OH radicals/cm^3)
half-life for biodegradation in soil at 12°C (days)	20.9	

Parameter	Value	Remarks
	Glutaraldehyde	
molecular weight (g/mole)	100.11	
melting point (°C)	-18	
vapour pressure at test temperature (Pa)	44	
test temperature vapour pressure (°C)	20	

Parameter	Value	Remarks
	Glutaraldehyde	
solubility at test temperature (mg/L)	513000	
test temperature solubility (°C)	21	
test temperature Henry constant (°C)	-	
octanol-water partition coefficient	0.4677	
organic carbon-water partition coefficient (L/kg)	326	
characterisation of biodegradability	readily biodegradable	
half-life for biodegradation in soil at 12°C (days)	30	Default value for readily biodegradable compounds
rate constant for biodegradation in STP (/h)	2.9	The tier 1 refinement considering the experimentally derived rate constant of 2.9 h-1 (at 15 °C) for the STP, as discussed in the Assessment Report for glutaraldehyde (2014) and corresponding corresponding to a half-life of 0.2 h.
half-life in air (hrs)	8.2	Estimated with AOPwin (OH timeframe 24 hrs/day, 0.5×10^{6} OH radicals/cm^{3})
Bioconcentration factor for fish (BCF_{fish})	1.41	
Bioconcentration factor for earthworm ($BCF_{earthwomr}$)	0.846	