16665 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 26 november 2021 is van

Huvepharma SA
Rue Jean Monnet 34 Zone industrielle d'Etriché
FR-49500 SEGRÉ-EN-ANJOU BLEU
Frankrijk

een aanvraag voor een toelating van de biocide (overgangsrecht) ontvangen voor het middel

Vulkan air

op basis van de werkzame stoffen glutaaraldehyde, alkyl (C12-16) dimethylbenzylammoniumchloride (ADBAC/BKC (C12-16)) en didecyldimethylammoniumchloride (DDAC)

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.

Dit besluit treedt in werking op de dag van bekendmaking in de Staatscourant.

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

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

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

2 WETTELIJKE GRONDSLAG

Besluit	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 of post@ctgb.nl.

Ede, 6 maart 2024

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

Drs. R.J.T. van Lint

Deze brief is elektronisch gegenereerd en daarom niet voorzien van een handtekening.

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BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20211746 TB
Type aanvraag:	toelating van de biocide (overgangsrecht)
Middelnaam:	Vulkan air
Formele registratiedatum: *	17 december 2021

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

2 Stofinformatie

Werkzame stof	Gehalte
glutaaraldehyde	12,15 %w/w
alkyl (C12-16) dimethylbenzylammoniumchloride (ADBAC/BKC (C12-16))	7,47 %w/w
didecyldimethylammoniumchloride (DDAC)	1,4 %w/w

De werkzame stof glutaaraldehyde is opgenomen in het review programma en is per 01/10/2016 voor de aangevraagde PT02, PT03 en PT04 geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

De werkzame stof ADBAC/BKC (C12-16) is opgenomen in het reviewprogramma maar nog *niet* geplaatst voor het aangevraagde PT02 op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.
De werkzame stof ADBAC/BKC (C12-16) is opgenomen in het review programma en is per 01/11/2022 voor de aangevraagde PT03 en PT04 geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

De werkzame stof DDAC is opgenomen in het reviewprogramma en is per 01/02/2024 voor de aangevraagde PT02 geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.
De werkzame stof DDAC is opgenomen in het review programma en is per 01/11/2022 voor de aangevraagde PT03 en PT04 geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

3 Toelatingsinformatie

Toelatingsnummer:	16665 N
Expiratiedatum:	1 maart 2034
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

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BIJLAGE II Etikettering van het middel Vulkan air

Professioneel	
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: Glutaaraldehyde, alkyl (C12-16) dimethylbenzylammoniumchloride en didecyldimethylammoniumchloride (DDAC)	
Pictogram	GHS05 GHS07 GHS08 GHS09
Signaalwoord	Gevaar
Gevarenaanduidingen	H302 + H332 Schadelijk bij inslikken en bij inademing. H314 Veroorzaakt ernstige brandwonden en oogletsel. H317 Kan een allergische huidreactie veroorzaken. 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. P280 Draag beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming/gehoorbescherming/... P284 Adembescherming dragen. P301 + P330 + P331 NA INSLIKKEN: de mond spoelen - GEEN braken opwekken. P303 + P361 + P353 BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken. Huid met water afspoelen/afdouchen. 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.

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BIJLAGE III WG/GA van het middel Vulkan air

A.

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van:

- Bacteriën (exclusief mycobacteriën en bacteriesporen), gisten en virussen (omkapselde en niet-omkapselde virussen)* door middel van spuiten op harde oppervlakken:
    - in ruimtes bestemd voor het verblijf van mensen, echter met uitzondering van ziekenhuizen en overige instellingen voor de gezondheidszorg;
    - die in contact komen met voedsel, diervoeder of de grondstoffen hiervoor;
- Bacteriën (exclusief mycobacteriën en bacteriesporen), gisten en virussen* door middel van spuiten op harde oppervlakken in ruimtes bestemd voor dieren echter met uitzondering van transportvoertuigen voor dieren;
- Bacteriën (exclusief mycobacteriën en bacteriesporen), gisten, schimmels en virussen (omkapselde en niet-omkapselde virussen)* door middel van verneveling op harde oppervlakken in ruimtes bestemd voor het verblijf van mensen, echter met uitzondering van ziekenhuizen en overige instellingen voor de gezondheidszorg en oppervlakken die in contact komen met voedsel, diervoeder of de grondstoffen hiervoor;
- Bacteriën (exclusief mycobacteriën en bacteriesporen), gisten en schimmels door middel van verneveling op harde oppervlakken in ruimtes bestemd voor dieren, echter met uitzondering van transportvoertuigen voor dieren.

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

Oppervlakken vooraf grondig reinigen met een geschikt reinigingsmiddel en vervolgens afspoelen met schoon water. Overtollig water verwijderen.

Algemene veiligheidsinstructie:
Bij mengen en laden van het product handschoenen, beschermende kleding en oog/gelaatbescherming dragen.

Desinfectie van harde oppervlakken via spuiten in ruimtes bestemd voor verblijf van mensen en op oppervlakken die in contact komen met voedsel of diervoeder.
Bereid een oplossing voor in water van Vulkan Air bij 0,6% (1:167). Spuit 100 ml/m^2 van de oplossing met een lagedruk- of automatische spuit op gereinigde oppervlakken. Laat 60 minuten inwerken. Vulkan Air kan worden aangebracht met schuimgeneratoren. Onbeschermde mensen en dieren mogen niet aanwezig zijn tijdens toepassing. Behandelde oppervlakken na behandeling afspoelen met drinkwater.

Dosering: 0.6% (gebruik per 1000 m^2 oppervlak 1,8 L Vulkan Air voor een oplossing van 300 L).
Minimale inwerktijd: 60 minuten voor bacteriën, gisten en virussen.

Bescherming bij toepassen: handschoenen, beschermende kleding en adembescherming (beschermingsfactor 10).

Desinfectie van harde oppervlakken via spuiten in ruimtes bestemd voor dieren.
Bereid een oplossing voor in water van Vulkan Air bij 0,8% (1:125). Spuit 100 ml/m^2 van de oplossing met een lagedruk- of automatische spuit op gereinigde oppervlakken. Laat 60 minuten inwerken.
Vulkan Air kan worden aangebracht met schuimgeneratoren. Onbeschermde mensen en dieren mogen niet aanwezig zijn tijdens toepassing.

Dosering: 0,8% (gebruik per 1000 m^2 oppervlak 0,8 L Vulkan Air voor een oplossing van 100 L)
Minimale inwerktijd: 60 minuten voor bacteriën, gisten en virussen.
Bescherming bij toepassen: handschoenen, beschermende kleding en adembescherming (beschermingsfactor 10).

Ruimtedesinfectie door koude verneveling in ruimtes bestemd voor mensen met uitzondering van oppervlakken die in contact komen met voedsel of diervoeder.
Gebruik 1 ml/m^3 Vulkan Air puur product, na volledige diffusie één uur inwerktijd. De ruimte moet worden afgesloten zonder aanwezigheid van dieren of mensen. Er moet naar maximale afdichting worden gestreefd. Behandel vanaf de toegangsdeur van het gebouw of van binnenuit (het dragen van een ademhalingsmasker is verplicht). Tijdens diffusie en inwerktijd de toegang blokkeren. Onbeschermde mensen en dieren mogen niet aanwezig zijn tijdens toepassing. Voor herbetreden dient de $AEC_{inhalation}$ van 0.0106 mg/m3 voor glutaaraldehyde gewaarborgd te worden met technische en organisatorische maatregelen (bijvoorbeeld met een sensor en/of minimale ventilatietijd van 2 uur bij een minimale ventilatie van 4 luchtverversingen per uur).

Dosering: 1 ml/m^3
Minimale inwerktijd: 1 uur voor bacteriën, gisten, schimmels en virussen.
Bescherming bij toepassen of in noodgeval wanneer de ruimte betreden moet worden: handschoenen, beschermende kleding en adembescherming (beschermingsfactor 20).

Ruimtedesinfectie door warme verneveling in ruimtes bestemd voor dieren met uitzondering van transportvoertuigen van dieren:
Gebruik 1,8 ml/m^3 Vulkan air puur product, na volledige diffusie drie uur inwerktijd. De ruimte moet worden afgesloten zonder aanwezigheid van dieren of mensen. Er moet naar maximale afdichting worden gestreefd. Behandel vanaf de toegangsdeur van het gebouw of van binnenuit (het dragen van een ademhalingsmasker is verplicht). Tijdens diffusie en inwerktijd de toegang blokkeren. Onbeschermde mensen en dieren mogen niet aanwezig zijn tijdens toepassing. Voor herbetreden dient de $AEC_{inhalation}$ van 0.0106 mg/m3 voor glutaaraldehyde gewaarborgd te worden met technische en organisatorische maatregelen (bijvoorbeeld met een sensor en/of minimale ventilatietijd van 2 uur bij een minimale ventilatie van 4 luchtverversingen per uur).

Dosering: 1,8 ml/m^3
Minimale inwerktijd: 3 uur bacteriën, gisten, schimmels en virussen.
Bescherming bij toepassen of in noodgeval wanneer de ruimte betreden moet worden: handschoenen, beschermende kleding en adembescherming (beschermingsfactor 40).

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BIJLAGE IV RISKMANAGEMENT

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1 Introduction

1.1 Applicant

Huvepharma SA
Rue Jean Monnet 34 Zone industrielle d'Etriché
FR-49500 SEGRÉ-EN-ANJOU BLEU
France

1.2 Active substance

Glutaraldehyde, alkyl (C12-16) dimethylbenzylammonium chloride (ADBAC/BKC (C12-16) and didecyldimethylammonium chloride (DDAC)

1.3 Product

Vulkan air

1.4 Function

Vulkan air is a disinfectant (PT02, 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 Vulkan air is the control of:

- bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses (enveloped and non-enveloped viruses) by spraying on:
    - Hard surfaces and materials in rooms where people reside excluding hospitals and other institutes for health care (PT02);
    - Hard surfaces and materials in places where food and drinks are prepared, treated or stored (PT04).
- bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses by spraying on hard surfaces and equipment for animals including transport-vehicles (PT03);
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses (enveloped and non-enveloped viruses) by cold and hot fogging on;
    - Hard surfaces and materials in rooms where people reside excluding hospitals and other institutes for health care (PT02);
    - Hard surfaces and materials in places where food and drinks are prepared, treated or stored (PT04).
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses by cold and hot fogging on hard surfaces and equipment for animals excluding transport-vehicles (PT03).

The product is intended for professional use.

1.7 Packaging details

	Material	Size / content	Other information
Professional use	HDPE	1 L	Canister
	HDPE	5 L	Canister
	HDPE	20 L	Canister
	HDPE	200 L	Canister
	HDPE	1000 kg	IBC

2 Identity

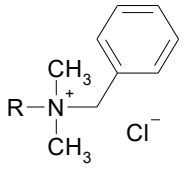
2.1 Identity of the active substance

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 final CAR is available for PT 1 and PT 2 (eCA Italy, February 2022).

The list of endpoints presented below is taken from the final CAR (PT1, February 2022, eCA Italy)

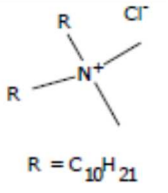
Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Quaternary ammonium compounds, benzyl-(C12-16)-alkyldimethyl, chlorides
CAS No	68424-85-1
EC No	270-325-2
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	972 g/kg (dry weight)
Identity of relevant impurities 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)
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 final CAR is available for PT 1 and 2 (February 2022 RMS IT). No CAR is available yet for PT 6, 10, 11 and 12.

The list of endpoints presented below is taken from the final CAR (PT1, February 2022, 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)	908 g/kg (dry weight)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{22}H_{48}N.Cl$
Molecular mass	362.1 g/mol
Structural formula	

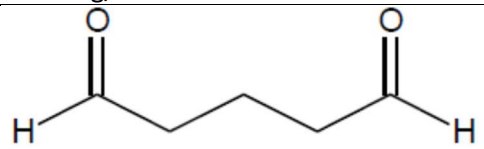
2.1.3 Glutaraldehyde

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	Vulkan air
Formulation type	SL
Content active substance	ADBAC: 7.47 % w/w DDAC: 1.4 % w/w Glutaraldehyde: 12.15 % w/w

Packaging information:

	Material	Size / content	Other information
Professional use	HDPE	1 L	Canister
	HDPE	5 L	Canister
	HDPE	20 L	Canister
	HDPE	2000 L	Canister
	HDPE	1000 kg	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	Green limpid solution
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	No data provided. Not flammable based on the composition.
pH 1% solution	neat pH (20°C) = 2.8 pH (1% solution) = 3.39 acidity = 1.97 % 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	32.1mN/m (25°C) for highest in-use concentration of 1.4% w/w
Viscosity	2.0 mm^2/s (40°C) 3.5 mm^2/s (20°C)
Relative density	1.070
Storage stability/Shelf life/Packaging	Claim 3 years (only study plan provided, study will be finished in 01/2023) **<u>8 weeks at 40°C, in HDPE</u>** **ADBAC concentration:** t0 = 7.7 % w/w t8 weeks = 7.6 % w/w **DDAC concentration:** t0 = 1.4 % w/w t8 weeks = 1.4 % w/w **Glutaraldehyde concentration:** t0 = 12.6% w/w t8 weeks = 11.4 % w/w **Appearance of the packaging:** t0 and t 8 weeks = HDPE drums with no cracks, leakage, or ballooning. **Appearance of the biocidal product:** t0 and t8 weeks = Green limpid solution **neat pH:** t0 and t8 weeks = 2.7 **1% solution pH:** t0 and t8 weeks = 3.39 **Acidity:** t0 = 1.97 % w/w expressed as H_2SO_4 t8 weeks = 2.04 % w/w expressed as H_2SO_4 **Density:** t0 = 1.070 t8 weeks = 1.069 **Dilution stability (CIPAC MT 41)** t0 and 8 weeks = no trace of sediment 30 min after dilution in water **Persistent foaming (CIPAC MT 47.2)** t0 and 8 weeks = >60mL Based on the available data a shelf life of 2 years in HDPE for Vulkan Air is supported.

	CIPAC MT 39.3: 7 days at 0°C = sample is not frozen if the sample is thawed at room temperature no presence of sediment, phase differentiation or crystallization was observed.
Technical properties	**Dilution stability (CIPAC MT 41)** no trace of sediment 30 min after dilution in water **Persistent foaming (CIPAC MT 47.2)** >60mL Since P280 is already assigned, no further action is required.
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 2 years in HDPE.

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 (ADBAC) • HPLC (DDAC) • HPLC (Glutaraldehyde)

4.2 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements

None.

5 Efficacy

5.1 Function

Vulkan air is a disinfectant based on Alkyl (C12-16) dimethylbenzylammonium chloride (7.47% w/w), didecyldimethylammonium chloride (1.4% w/w) and glutaraldehyde (12.15% w/w).

5.2 Field of use envisaged

The proposed field of use of Vulkan air is the control of:

- bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses (enveloped and non-enveloped viruses) by spraying on:

  - Hard surfaces and materials in rooms where people reside excluding hospitals and other institutes for health care (PT02);
  - Hard surfaces and materials in places where food and drinks are prepared, treated or stored (PT04).
- bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses by spraying on hard surfaces and equipment for animals including transport-vehicles (PT03);
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses (enveloped and non-enveloped viruses) by cold and hot fogging on;
  - Hard surfaces and materials in rooms where people reside excluding hospitals and other institutes for health care (PT02);
  - Hard surfaces and materials in places where food and drinks are prepared, treated or stored (PT04).
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses by cold and hot fogging on hard surfaces and equipment for animals excluding transport-vehicles (PT03).

These uses are included in PT02, 03 and 04.

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

38 studies were provided of which 23 were used in this assessment. These are summarised in Table 1. One study was not performed according a relevant test protocol and without a required test organism and therefore considered not relevant. Fourteen other studies were performed with test conditions irrelevant for the claims made in the dossier and are therefore disregarded. Some of the studies assessed were performed with another formulation. The applicant has declared that this formulation is identical to the formulation of Vulkan air.

Table 1. Summary of studies assessed.

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Bacteria (excluding mycobacteria and bacterial spores)			
EN 1276 (2019) 2, 1	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	**Concentration:** 0.05, 0.1, 0.2, 0.3% **Interfering substances:** 0.3g/l of bovine albumin **Contact time:** 5 min **Temperature:** 20°C	**LogR:>5.11:** 0.2% Clean 5 min 20°C
EN 13697 (2015 +A1 2019) 2, 2	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	**Concentration:** 0.05, 0.1, 0.2, 0.3% **Interfering substance:** 0.3g/l of bovine albumin **Contact time:** 5 min **Temperature:** 20°C	**LogR:>4.90**: 0.2% Clean 5 min 20°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 17272 (2020) 2, 2	*Enterococcus hirae* *Staphylococcus aureus* *Pseudomonas aeruginosa* *Proteus hauseri* *Escherichia coli*	**Concentration:** 0.75 ml/m^3 **Interfering substances:** 3g/l of bovine albumin **Application device:** Electric aerosol applicator (cold fogging) **Contact time:** 1 hour **Enclosure size:** 30.87 m^3 **Relative humidity:** 50-75% **Temperature:** 20°C	**LogR:>5:** 0.75 ml/m^3 Clean 20°C 1 hour
Field test 3	*Staphylococcus aureus* *Enterococcus hirae*	**Concentration:** 1 ml/m^3 **Interfering substances:** 3g/l of bovine albumin **Application device:** Thermo Nebulizer (hot fogging) **Contact time:** 60 min diffusion time 180 minutes contact time **Enclosure size:** 3630 m^3 **Temperature:** 7-10°C **Relative humidity:** 86%	**LogR:>5** 1 ml/m^3 Clean 180 min 10°C
EN 1656 (2019) 2, 1	*Pseudomonas aeruginosa* *Proteus vulgaris* *Staphylococcus aureus* *Enterococcus hirae*	**Concentration:** 0.05, 0.1, 0.2, 0.3, 0.5% **Interfering substances:** 3g/l of bovine albumin **Contact time:** 30 minutes **Temperature:** 10°C	**LogR:>5.22:** 0.5% Clean 30 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 1656 (2019) 2, 1	*Pseudomonas aeruginosa* *Proteus vulgaris* *Staphylococcus aureus* *Enterococcus hirae*	**Concentration:** 0.4, 0.5, 0.6, 0.7% **Interfering substance**: 3g/l of bovine albumin **Contact time:** 5 min **Temperature:** 10°C	**LogR:>5.08:** 0.6% Clean 5 min 10°C
EN 14349 (2012) 2, 2	*Pseudomonas aeruginosa* *Proteus vulgaris* *Staphylococcus aureus* *Enterococcus hirae*	**Concentration:** 0.05, 0.1, 0.3, 0.5, 0.7% **Interfering substances:** 3g/l of bovine albumin **Contact time:** 30 minutes **Temperature:** 10°C	**LogR:>4.68:** 0.5% Clean 30 min 10°C
EN 14349 (2012) 2, 2	*Pseudomonas aeruginosa* *Proteus vulgaris* *Staphylococcus aureus* *Enterococcus hirae*	**Concentration:** 0,4, 0.6, 0.8% **Interfering substance**: 3g/l of bovine albumin **Contact time**: 5 min **Temperature**: 10°C	**LogR:>4:** 0.6% Clean 5 min 10°C
EN 17272 (2019) 2, 2	*Pseudomonas aeruginosa* *Proteus vulgaris* *Staphylococcus aureus* *Enterococcus hirae*	**Application rate**: 1.5 ml/m3 (4.5 % product 1.2 mL/m³ (3.6 % product) 1.0 ml/m3 (3 % product) 0.8 ml/m3 (2.4 % product) **Diffusion time:** 3 minutes and 45 seconds **Application device**: Hurricane (Cold fogging) **Contact time:** 2 hours **Enclosure size:** 31.05 m3 **Temperature:** 10°C **Relative humidity**: 59% Interfering substance: 3g/l of bovine albumin	**LogR:>5:** 1.2 ml/m3 of 3.6% product 2 hours 10°C Clean **Test not valid as no correct distribution test was performed**

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Yeasts			
EN 1650 (2019) 2, 1	*Candida albicans*	**Concentration** 0.1, 0.2 and 0.3% **Interfering substances:** 0.3g/l of bovine albumin **Contact time:** 15 minutes **Temperature:** 20°C	**LogR:>4.03**: 0.2% Clean 15 min 20°C
EN 13697 (2015) 2, 2	*Candida albicans*	C**oncentration:** 0.3, 0.5, 0.7% **Interfering substances:** 3g/l of bovine albumin **Contact time:** 15 minutes **Temperature:** 20°C	**LogR:>3.71**: 0.5% Dirty 15 min 20°C
EN 13697 (2019) 2, 2	*Candida albicans*	C**oncentration:** 0.1, 0.2, 0.3% **Interfering substance:** 0.3g/l of bovine albumin **Contact time:** 15 min **Temperature:** 20°C	**LogR:>4.04**: 0.3% Clean 15 min 20°C
EN 17272 (2020) 2, 2	*Candida albicans*	**Concentration:** 1 ml/m^3 for yeast **Interfering substances:** 3g/l of bovine albumin **Application device:** Electric aerosol applicator (cold fogging) **Contact time:** 1hour **Enclosure size:** 30.87 m^3 **Relative humidity:** 50-75% **Temperature:** 20°C	**LogR:>5/4:** 1 ml/m^3 clean 20°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 1657 (2016) 2, 1	*Candida albicans*	**Concentration:** 0.1, 0.2 and 0.3% **Interfering substances:** 3g/l of bovine albumin **Contact time:** 30 minutes **Temperature:** 10°C	**LogR:>4.12:** 0.3% Clean 30 min 10°C
EN 1657 (2016) 2, 1	*Candida albicans*	**Concentration:** 0.01, 0.4, 0.6% **Interfering substance:** 3g/l of bovine albumin **Contact time:** 5 min **Temperature:** 10°C	**LogR:>4.38:** 0.4% Clean 5 min 10°C
EN 16438 (2014) 2, 2	*Candida albicans*	**Concentration:** 0.2, 0.3, 0.4% **Interfering substance:** 3g/l of bovine albumin **Contact time:** 60 min **Temperature:** 10°C	**LogR:>4.02**: 0.4% Clean 60 min 10°C
EN 16438 (2014) 2,2	*Candida albicans*	**Concentration:** 0.01, 0.4, 0.6% **Interfering substance**: 3g/l of bovine albumin **Contact time**: 5 min **Temperature:** 10°C	**LogR:>4.46**: 0.4% Clean 5 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 17272 (2019) 2, 2	*Candida albicans*	**Application rate**: 1.5 ml/m3 (4.5 % product 1.2 mL/m³ (3.6 % product) 1.0 ml/m3 (3 % product) **Diffusion time:** 3 minutes and 45 seconds **Application device**: Hurricane (Cold fogging) **Contact time:** 2 hours **Enclosure size:** 31.05 m3 **Temperature:** 10°C **Relative humidity**: 59% **Interfering substance:** 3g/l of bovine albumin	**LogR:>5:** 1.5 ml/m3 of 4.5% product 2 hours 10°C Clean **Test not valid as distribution test is missing**
Fungi			
Field test	*Aspergillus niger*	**Concentration:** 1 ml/m^3 **Interfering substances:** 3 g/l of bovine albumin **Application device:** Thermo Nebulizer (hot fogging) **Contact time:** 60 min diffusion time 180 minutes contact time **Enclosure size:** 3630 m^3 **Temperature:** 7-10°C **Relative humidity**: 86%	**LogR:>3** 1 ml/m^3 Clean 180 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 17272 (2020) 2, 2	*Aspergillus brasiliensis*	**Concentration:** 1 ml/m^3 **Interfering substances:** 3g/l of bovine albumin **Application device:** Electric aerosol applicator (cold fogging) **Contact time:** 1 hour **Enclosure size:** 30.87 m^3 **Relative humidity:** 50-75% **Temperature:** 20°C	**LogR:>5** 1 ml/m^3 clean 20°C
EN 17272 (2019) 2, 2	*Aspergillus brasiliensis*	**Application rate**: 1.5 ml/m3 (4.5 % product 1.2 mL/m^3 (3.6 % product) 1.0 ml/m3 (3 % product) **Diffusion time:** 3 minutes and 45 seconds **Application device**: Hurricane (Cold fogging) **Contact time:** 2 hours **Enclosure size:** 31.05 m3 **Temperature:** 10°C **Relative humidity**: 59% **Interfering substance:** 3g/l of bovine albumin	**LogR:>5:** 1.5 ml/m3 of 4.5% product 2 hours 10°C clean **Test not valid as the distribution test is not correct**

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Viruses / Bacteriophages			
EN 14675 (2015) 2, 1	*Bovine Enterovirus Type 1 (ECBO)*	**Concentration:** 0.4% 0.6% 0.8% 1 % **Interfering substances:** 3g/l of bovine albumin **Contact time:** 30 minutes **Temperature:** 10°C	**LogR:>4**: 0.8% Clean 30 min 10°C
EN 14675 (2015) 2, 1	*Bovine enterovirus*	**Concentration:** 0.8, 1, 1.2% **Interfering substance**: 3g/l of bovine albumin **Contact time:** 5 min **Temperature:** 10°C	**LogR:>4:** 0.8% Clean 30 min 20°C LogR > 4
EN 14476 (2019) 2, 1	*Adenovirus type 5* *Murine norovirus* *Poliovirus type 1*	**Concentration** 0.2, 0.3, 0.5, 0.6 % **Interfering substances:** 0.3 g/l of bovine albumin **Contact time:** 60 minutes **Temperature** 20°C	**LogR:>4:** 0.6% Clean 60 min 20°C
EN 16777 (2018) 2, 2	*Adenovirus type 5* *Murine norovirus*	**Concentration:** 0.3, 0.5 and 0.6% **Interfering substances:** 0.3 g/l of bovine albumin **Contact time:** 60 minutes **Temperature:** 20°C	**LogR:>4:** 0.5% Clean 60 min 20°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 17272 (2020) 2, 2	*Adenovirus* *Murine norovirus*	**Concentration:** 0.75 ml/m^3 **Interfering substances:** 0.3 g/l of bovine albumin **Application device:** Hurricane system (cold fogging) **Contact time** 1 hour **Enclosure size:** 36 m^3 **Relative humidity:** 59% **Temperature:** 20°C	**LogR:>4:** 0.75ml/m^3 Clean 1 h 20°C
EN 17122 (2019) 2, 2	*Porcine parvovirus*	**Concentration:** 0.6, 0.8, 1% **Interfering substance:** 3g/l of bovine albumin **Contact time:** 60 min **Temperature:** 10°C	**LogR:>4:** 0.8% Clean 60 min 10°C
EN 17122 (2019) 2, 2	*Porcine parvovirus*	**Concentration**: 0.8, 1.0, 1.2% **Interfering substance:** 3g/l of bovine albumin **Contact time:** 5 min **Temperature:** 10°C	**LogR:5.08** 0.8% Clean 5 min 10°C

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
EN 17272 (2019) 2, 2	Porcine parvovirus	**Application rate**: 1.8 ml/m3 (45.4 % product 1.5 mL/m³ (4.5 % product) 1.2 ml/m3 (3.6 % product) **Diffusion time:** 3 minutes and 45 seconds **Application device**: Hurricane (Cold fogging) **Contact time:** 2 hours **Enclosure size:** 31.05 m3 **Temperature:** 10°C **Relative humidity**: 66% **Interfering substance:** 3g/l of bovine albumin	**LogR:>5** 1.8 ml/m3 of 5.4% product 2 hours 10°C Clean **Test not valid as no correct distribution test was performed**

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

PT2 and PT4

The available information was sufficient to evaluate the efficacy of Vulkan air for control of bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses, considering evaluation is done under article 121 of the WGB.
The studies show that Vulkan air complies with the criteria for log reduction for disinfectants for bacteria (excluding mycobacteria and bacterial spores), yeast and viruses for use on hard surfaces disinfection by spraying, when used in accordance with the instructions described on the WG/GA.
The studies show that Vulkan air complies with the criteria for log reduction for disinfectants for bacteria (excluding mycobacteria and bacterial spores), yeast, fungi and viruses for use on hard surfaces disinfection by cold fogging, when used in accordance with the instructions described on the WG/GA. For the claim against hot fogging no efficacy data is provided with conditions relevant for use in PT2 and PT4 area's and is thus not substantiated for efficacy.

PT3

The available information was sufficient to evaluate the efficacy of Vulkan air for control of bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses, considering evaluation is done under article 121 of the WGB.
The studies show that Vulkan air complies with the criteria for log reduction for disinfectants for bacteria (excluding mycobacteria and bacterial spores), yeast and viruses for use on hard surfaces disinfection by spraying, when used in accordance with the instructions described on the WG/GA.
The studies show that Vulkan air complies with the criteria for log reduction for disinfectants for bacteria (excluding mycobacteria and bacterial spores), yeast and fungi for use on hard surfaces disinfection by hot fogging, when used in accordance with the instructions described on the WG/GA.
The studies show that Vulkan air does not comply with the criteria for log reduction for disinfectants for viruses by hot fogging and for bacteria (excluding mycobacteria and bacterial spores), yeast, fungi and viruses by cold fogging.

There is no valid simulated use test for viruses to demonstrate efficacy by cold fogging as the distribution test is not correct. For hot fogging viruses cannot be tested in the field trial but as there is no valid data in a simulated use test by hot or cold fogging efficacy against viruses by fogging is not substantiated. The simulated use test for cold fogging with bacteria, yeast and fungi does not contain a correct distribution test and therefore it cannot be determined that the test is valid and thus efficacy is not substantiated for cold fogging.

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. For the group of quaternary ammonium compounds, resistances at sublethal and subbiocidal levels due to active transport by efflux pumps have been reported. The Health Council of the Netherlands indicated quaternary ammonium compounds as active ingredients to which intrinsic resistance and acquired resistance occurs, and for which it was demonstrated that acquired resistance was transferable. In addition, cross-resistance with other disinfectants and co-resistance with resistance to antibiotics has been observed.

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

- bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses (enveloped and non-enveloped viruses) by spraying on hard surfaces and materials in rooms where people reside excluding hospitals and other institutes for health care, in places where food and drinks are prepared, treated or stored;
- bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses by spraying on hard surfaces and equipment for animals including transport vehicles;
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses (enveloped and non-enveloped viruses) by cold fogging on hard surfaces and materials in

rooms where people reside excluding hospitals and other institutes for health care, in places where food and drinks are prepared, treated or stored;
- bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi by hot fogging on hard surfaces and equipment for animals excluding transport vehicles for animals.

is **non**-effective in controlling;
- viruses by hot fogging on hard surfaces and equipment for animals;
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses by cold fogging on hard surfaces and equipment for animals.
- bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and viruses by hot fogging on hard surfaces and materials in rooms where people reside excluding hospitals and other institutes for health care, in places where food and drinks are prepared, treated or stored.

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
$AEL_{long-term}$	Not relevant		
$AEL_{medium-term}$	Not relevant		
$AEL_{short-term}$	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 AECinhalation 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 PT3 and 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 x 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:	**US ISC** **In vitro:** 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). **In vivo:** Chromosomal aberration test in rat bone marrow – negative. **EQC** 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	**US ISC** Rat/none Mouse/none **EQC** Rat/none **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** DDAC was not found to be carcinogenic **(US ISC; EQC)**
Relevant NOAEL/LOAEL	**US ISC** None **EQC** 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** 1. 10% (for water dilutions only) 2. 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 AR is available for PT2, 3, 4, 6, 11 and 12 (September 2014). The List of Endpoints below is taken from this AR, in which the R-phrases are replaced with the corresponding H-statements according to CLP.

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	1. NOAEL 15 mg/kg bw/day 2. LOAEL 3.5 mg/kg bw/day 3. NOAEL 3.6 mg/kg bw/day 4. 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

Vulkan air is a liquid concentrate and contains 7.47% ADBAC, 1.4% DDAC and 12.15% glutaraldehyde as active substances. The proposed field of use of Vulkan air is as disinfectants for surfaces (PT2), veterinary hygiene (PT3) and in places where food or drink is prepared, treated or stored (PT4).

Vulkan Air can be applied by cold/hot fogging or spraying. The maximum dosage for fogging application is 1.8 mL Vulkan air per m3. A dilution of 0.8% is used for low pressure spraying application for PT3 application and 0.6% for surface disinfection for PT2 and PT4 applications. For the risk assessment the dilution described for PT3 application is used as a worst case scenario, resulting in the following concentrations: 0.060% ADBAC, 0.011% DDAC, and 0.097 % glutaraldehyde.

The formulation Vulkan air 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 fogging, foaming and spraying using Vulkan air.

The vapour pressure of ADBAC and DDAC is very low (6.03 x 10^{-4} Pa at 20°C for ADBAC, 5.9x10^{-6} Pa at 20°C for DDAC), the Henry's law constant is very low (5.03 x 10^{-7} Pa x m3/mol at 20°C for ADBAC, 4.27E^{-09} Pa m3/mol at 20°C for DDAC), indicating poor partitioning from aqueous solution. Therefore, respiratory exposure to ADBAC and DDAC to vapour is considered to be negligible and only dermal exposure is possible. During application by spraying, inhalation exposure to ADBAC and DDAC in aerosol may still occur.
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°C).

As Vulkan air 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 Vulkan air 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 Vulkan air by spraying/foaming and fogging, 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 Vulkan Air 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

The Technical Agreements for Biocides (TAB, 9 November 2018) and WG-III-2016 states that systemic dermal and oral route is not necessary for exposure to corrosive concentrations as exposure will be negligible as appropriate PPE and RMM will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances.
The undiluted product of Vulkan air is classified with H314, and as such can cause local effects after dermal and eye exposure. Therefore, the use of personal protective equipment (gloves, protective cloths, eye/face protection) is prescribed during mixing and loading for the professional user and the systemic dermal or oral route will not have to be assessed. However, systemic inhalation route should be performed if inhalation exposure is possible.

The in-use dilution of 0.8% of Vulkan air is not considered corrosive to skin and eye according to CLP principles, therefore the systemic dermal exposure route should be assessed.

Application by Spraying, including mixing and loading
Systemic exposure

To estimate systemic dermal and respiratory, and local respiratory exposure to glutaraldehyde during the application of the in-use dilution of Vulkan air by various spraying applications, Spraying Model 1 is considered to be applicable as it is the most worst case scenario.

The concentration glutaraldehyde in the in-use solution is 0.097%. The indicative exposure values are 181 mg/min for hand exposure without protective gloves, 10.7 mg/min for hand exposure inside protective gloves, 92 mg/min for body exposure and 104 mg/m3 for respiratory exposure. The exposure duration for professional users is considered to be 2 hours/day. The dermal absorption value of glutaraldehyde is 10% according to the CAR. The results of exposure estimates are presented in table below.

Table T.1 Internal professional operator exposure to glutaraldehyde and risk assessment for the use of Vulkan air during mixing, loading and spraying of a 0.097% in-use dilution (0.8% 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	0.0530	0.014	3.78
Respiratory	0.0042	0.014	0.30
Total	0.0572	0.014	4.08
Mixing, loading and spraying[3], with PPE[4]			
Dermal	0.0039	0.014	0.28
Respiratory	0.0042	0.014	0.30
Total	0.0081	0.014	0.58

[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.

The exposure estimates were also calculated with spraying model 2, as there is a variety of spraying applications of the product. The use of PPE is also required for safe use of Vulkan air during spray application, based on the calculations using the default values of this model.

Local effects
Local dermal exposure to ADBAC, DDAC and glutaraldehyde can occur during mixing and loading of Vulkan air and during application by spraying.
During mixing and loading, the professional user is dermally exposed to the concentrate (containing 7.47% ADBAC, 1.4% DDAC and 12.15% w/w glutaraldehyde), and during the application the professional user is dermally exposed to the in-use dilution of Vulkan air.
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 active substances is exceeded. The combined concentration of ADBAC and DDAC in the in-use dilution (0.06% and 0.011% = 0.071%) is lower than the $NOAEC_{local\ dermal}$ of 0.6%. The concentration of glutaraldehyde in the in-use dilution (0.097%) does not exceed the $NOAEC_{local\ dermal}$ of 0.2% for glutaraldehyde . 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 0.06% and 0.011%, the concentration in air of 0.06 mg/m^3 is calculated for ADBAC and 0.011 mg/m^3 for DDAC. The concentrations combined are below the $AEC_{local\ inhalation}$ of 0.25 mg/m^3 for ADBAC and DDAC. Considering the concentration of glutaraldehyde of 0.097%, this corresponds to a concentration of glutaraldehyde of 0.10 mg/m^3 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 0.097% glutaraldehyde in the in-use dilution. An RPE device with a protection factor of 10 is required, based on the calculated glutaraldehyde / AEC (0.10 mg/m^3 / 0.0106 mg/m^3 = 9.4 protection factor). This also applies for spraying applications using spraying model 2. Based on a indicative inhalation value of 76 mg biocidal product/m^3 the concentration of glutaraldehyde would be 0.07 mg/m^3, thus also exceeding the $AEC_{inhalation}$ for long

term-exposure, with a calculated protection factor of 6.6 an RPE device with a protection factor of 10 is also required. Since RPE is needed for safe use, the sentence “Use respiratory protective equipment (APF 10) during application via spraying/foaming/fogging” 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 for the application by spraying. In addition, eye/face protection is prescribed during mixing and loading due to the corrosive properties of the undiluted product.

Exposure by fogging
Vulkan air may be applied to surfaces by fogging. The applicant stated that the product is manually loaded into the fogging apparatus. Based on the corrosive properties of Vulkan air, gloves, coverall and eye/face protection is prescribed for mixing and loading.
Fogging can either be started from the entrance door, in this scenario no exposure to the professional user is expected. However, it is also prescribed that it can be started within the room. In that case, the conclusion from the estimation by spraying will apply: gloves, coverall and respiratory protection is needed. Also, if the professional user needs to enter the area during treatment in emergency situations (for example the apparatus used for the fumigation is not working properly), than the professional user could be respiratory and dermally exposed to unknown concentration of the active substances. Therefore, the wearing of protective personal equipment and suitable respiratory protection equipment in emergency situations is added to the WG/GA.” Furthermore, the instructions for use include a restriction that no persons or animals are allowed to be present in the room while the room is treated. After the treatment, the room is released after 2 hours of ventilation. To justify a re-entry delay of 2 hours in the treated room for professionals without respiratory equipment, an estimation of the air concentration of glutaraldehyde after the application by fogging (and afterwards, ventilation) in the room is provided by the applicant.

Thus, a first sub-scenario was modelled to establish the concentration in the air at the end of fogging application due to evaporation from the surfaces receiving mists/aerosols. Consexpo web was used to model the evaporation of glutaraldehyde. Additionally, the level in glutaraldehyde was estimated based on the ventilation rates for animal housings (see values from Table 53 - Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017). Based on the worst case ventilation rates of animal houses the ventilation time of 2 hours is not sufficient. Therefore, the refinement was checked to set the minimal necessary ventilation rate. Based on this a minimal ventilation rate of 4 times/hour was considered necessary, and the following sentence will be added to the WG/GA: “For re-entry, the undercut of $AEC_{inhalation}$ of 0.0106 mg/m3 for glutaraldehyde air concentration shall be ensured with technical and organisational measures (e.g. sensor and/or a 2 hours-ventilation period with a minimum ventilation rate of 4 times/hour).”

Local effects
The recommended application dose for fogging is either 1.8 mL of pure product/m³ or 1 mL/m^3, depending on the type of fogging. The product is not diluted and therefore it contains 7.47% ADBAC, 1.4% DDAC and 12.15% w/w glutaraldehyde. Assuming a relative density of 1.070 g/mL this leads to the following concentrations: ADBAC and DDAC combined are 0.17 mg/m^3 and 0.09 mg/m^3, in product applications of 1.8 ml/m^3 and 1 ml/m^3, respectively. These concentrations do not exceed the $AEC_{local\ inhalation}$ of 0.25 mg/m^3 for ADBAC and DDAC. Glutaraldehyde is present in a concentration of 0.234 mg/m^3 and 0.130 mg/m^3, in product applications of 1.8 ml/m^3 and 1 ml/m^3, respectively. As these concentrations exceed the $AEC_{inhalation}$ for long-time exposure of 10.6 µg/m^3 for glutaraldehyde, calculations are made to determine the protection factor required of the RPE device. For a product application with a concentration of 1.8 ml/m^3 a protection factor of 40 is required (0.234 mg/m^3 / 0.0106 mg/m^3 = 22.1 protection factor). For a product application with a concentration of 1 ml/m^3 a protection factor of 20 is required (0.130 mg/m^3 / 0.0106 mg/m^3 = 12.3 protection factor).

In conclusion, adverse systemic and local respiratory effects after exposure to glutaraldehyde using Vulkan air are not expected for protected (gloves, protective clothing, suitable respiratory protective equipment) professional user for all in the WG/GA described applications. The necessary protection factors are included in the WG/GA per type of application.

6.3.2 Non-professional users, including the general public
The formulation Vulkan air 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 PT2 and PT3 uses, no instructions are given concerning rinsing after treatment, meaning that residue of the active substances may be found on the treated surfaces. Children may be exposed when touching treated surfaces. Animals transported may be dermally and orally exposed to ADBAC, DDAC and glutaraldehyde by touching or licking the surfaces disinfected with Vulkan air.

For local effects the sum of the concentrations of ADBAC (0.06%) and DDAC (0.011%) in the in-use solution of Vulkan air is lower than the $NOAEC_{local\ dermal}$ (0.6%). In addition, the concentration of glutaraldehyde (0.097%) 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.

<u>*Estimated exposure of an infant, due to contact with the treated area*</u>
The scenario is based on an infant (values from HEAdhoc recommendation 14), contacting treated surface and putting their hands in its mouth. During contact time (as indicated in the WG/GA) children can touch the surface and put their hands in their mouths, leading to oral exposure. The dosage is 0.856 mg product/cm2, based on 100 ml/m^2 product use (as described in the WG/GA), a relative density of 1.070 g/mL and an in-use dilution of 0.8% product, containing 0.071% ADBAC + DDAC. The estimated dosage active substance is therefore 0.00061 mg ADBAC+DDAC/cm^2.

For the calculation of the dermal exposure of a child, due to contact with the treated area the assumptions stated in the User Guidance are followed
Active substance residue on surface: 0.00061 mg a.s. /cm^2.
Hand surface area (palms and back of both hands): 196.8 cm^2.
It is assumed that 20 % of the hand (39.36 cm^2) is contaminated at 100 % surface concentration
Total amount of ADBAC+DDAC on the hands: 0.00061 (mg/cm^2) x 39.36 (cm^2) = 0.024 mg ADBAC+DDAC
It is assumed that 10 % of the total exposure that ends up on the skin of a child is taken in orally due to hand-mouth contact (Bremmer et al, 2006).

Oral exposure due to hand mouth contact 0.1 x 0.024 (mg) = 0.0024 mg ADBAC+DDAC / day
Body weight of an infant: 8 kg (HEAdhoc rec. 14)
Oral absorption: 10% (ADBAC+DDAC CAR, LoEP)
Internal oral exposure to ADBAC+DDAC: 0.0024 (mg/day) x 10% (oral absorption) / 8 kg = $3.0x10^{-5}$ mg a.s. /kg bw/day.
Based on the calculated worst case scenario, the exposure of the toddler is lower than the ADI (0.12 mg/kg bw/day). Therefore, no adverse health effects are expected via oral exposure to ADBAC and DDAC by infants touching a treated surface and putting their hands in their mouths.

<u>*Indirect exposure of animals*</u>

However, for PT3 uses, no instructions are given concerning rinsing after treatment, 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 Vulkan air.

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 100 mL/m^2, glutaraldehyde residue is calculated to be 10.38 mg per m^2 (100 mL/m^2 x 1.070 g/mL x 0.097% 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% ÷ 10.38 mg glutaraldehyde/m^2 = 2.7 m^2 =27000 cm^2

It is unlikely that a lamb licks a disinfected surface of 27000 cm^2 . Therefore, the risk for the animals due to the secondary exposure to glutaraldehyde contained in Vulkan air is considered acceptable.

In conclusion, 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 Vulkan air.

As concern has been identified for the unprotected professional users applying the formulation by spraying or fogging, adverse effects after respiratory exposure of bystanders and 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, the following sentence will be added to WG/GA: “No people and animals may be present in the facilities during the treatment”.

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

6.3.4 Combined exposure

The formulation Vulkan air 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 PPE (gloves and coverall) and RPE are prescribed based on the risk assessment of the systemic effects of glutaraldehyde, the local effects due to dermal and inhalation exposure to the three active substances is not further 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, and suitable respiratory equipment) professional user after dermal and respiratory exposure to ADBAC, DDAC and glutaraldehyde as a result of the

application of Vulkan air, when used in accordance to the WG/GA. The required protection factor for the respiratory equipment will be specified for each application where it's required for safe use.

Due to the corrosive properties of the undiluted product, additional eye/face protection is prescribed for the professional user when mixing and loading the product.

For the application by fogging the following sentences need to be included in the WG/GA: "If a treatment area in which fogging takes place needs to be entered due to emergency situation, wear suitable protective personal equipment and suitable respiratory protection equipment." And "For re-entry, the undercut of $AEC_{inhalation}$ of 0.0106 mg/m^3 for glutaraldehyde air concentration shall be ensured with technical and organisational measures (e.g. sensor and/or a 2 hours-ventilation period with a minimum ventilation rate of 4 times/hour)."

In order to avoid possible bystander and animal exposure during the treatment, the following sentence will be added to WG/GA: "No people and 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 Vulkan air.

7 Environment

7.1 Introduction

Authorisation is requested for the product Vulkan air containing alkyl (C12-16) dimethylbenzyl ammonium chloride, hereafter referred to as ADBAC, didecyldimethylammoniumchloride, hereafter referred to as DDAC, and glutaraldehyde as active substances. The biocidal product concerns a general disinfectant (PT02), 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)	Dilution product for spraying	Dose
Disinfection of surfaces and volumes not in contact with food for humans or animals by spraying or nebulization, with the exception of health care facilities (PT02)	ADBAC: 74.7 DDAC: 14 Glutaraldehyde: 121.5	0.6% v/v	Spraying: 100 mL diluted product/m^2 nebulization: 1 mL pure product /m^3
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by spraying or nebulization (PT03)		0.8% v/v	Spraying: 100 mL diluted product/m^2 nebulization: 1.8 mL pure product/m^3
Disinfection of the interior and exterior of vehicles used for animal transportation by spraying (PT03)			Spraying: 100 mL diluted product/m^2
Disinfection of surfaces and volumes by spraying or nebulization in places where food or drinks are prepared, treated or stored (PT04)		0.6% v/v	Spraying: 100 mL diluted product/m^2 nebulization: 1 mL pure product /m^3

7.2 Product related studies

The exposure assessment is based on data for the active substances. 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 included in the Union list of approved substances for PT1 (Regulation (EU) 2023/680), PT3 and 4 (Regulation (EU) 2021/1063) and 8 (Directive 2013/7/EU) with approval dates 01/07/2024 (PT1), 01/11/2022 (PT3 and 4) and 01/02/2015 (PT8). Approval of ADBAC for PT 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 PT1, 2, 3, 4, 6, 10, 11, 12 (RMS is IT). DDAC is 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). DDAC is also included in the Union list of approved substances for PT1 and 2 (Commission implementing regulation (EU) 2022/1991) with approval date 01/02/2024.The environmental risk assessment is based on the list of endpoints as published in the assessment reports for PT1 and 2 which are available on ECHA's website.

Glutaraldehyde is notified for inclusion for PT 1, 2, 3, 4, 6, 11, 12 and 13. Glutaraldehyde is approved for PT2, 3, 4, 6, 11 and 12 under BPR (Directive 2015/1759 with approval date 01/10/2016). Glutaraldehyde is not approved for PT1 and 13 (Decision 2014/227/EU). The environmental risk assessment is based on the list of endpoints as published in the assessment reports which are available on ECHA's website.

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
Disinfection of surfaces and volumes not in contact with food for humans or animals by spraying or nebulization, with the exception of health care facilities (PT02)	++	+	+	-	++
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by spraying or nebulization (PT03)	++	+	+	+	++
Disinfection of the interior and exterior of vehicles used for animal transportation by spraying (PT03)	++	+	+	-	++
Disinfection of surfaces and volumes by spraying or nebulization 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 when used by spraying or pure when used by nebulization. The working solution or pure product is used for disinfection of surfaces and volumes.

When the product is used for disinfection of surfaces by spraying or nebulization in livestock farming buildings (PT03), rinse water and residues in buckets are released via manure or waste water. Sewage sludge or manure can subsequently be 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 the 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.

Release to the sewer is the main emission pathway for disinfection of surfaces and volumes by spraying or nebulization in places where food or drinks are prepared, treated or stored (PT04) and for disinfection of surfaces and volumes not in contact with food for humans or animals by spraying or nebulization, with the exception of health care facilities (PT02). Residues left on the surfaces are rinsed with clean water afterwards or prior to the next disinfection event when wet cleaning prior to disinfection is prescribed. Additionally, left-overs of diluted product in buckets 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.

Emission to air is likely when the product is applied by spraying or nebulization. Spray drift may deposit on nearby soils or surface water. Additionally, emission to air and subsequent emission to soils may occur during sewage treatment where sewage sludge is aerated.

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 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 emission to effluent was calculated with Simple Treat 4.0 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 assessment was made for the highest dose only. 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 and volumes not in contact with food for humans or animals by spraying or nebulization, with the exception of health care facilities (PT02)
PECs were calculated in accordance with the ESD for PT02; the scenario for disinfectants used in industrial premises. For this scenario default values were used for number of disinfections per day and the size of the treated surface area (spraying) or volume (nebulization). The applied volume is in accordance with agreement ENV 52.

The scenario requires an amount of product applied per m^2 for spraying and per m^3 for nebulization. For spraying an amount of 100 mL diluted (0.6%) product per m^2 and for nebulization an amount of 1 mL pure product per m^3 is required according to the applicant.
It was assumed that 100% of the product applied will be removed during rinsing after use and therefore the fraction of substance disintegrated during or after application (F_{dis}) was set to zero (default).

Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by spraying or nebulization (PT03)
PECs 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. However, the stables' volumes were taken from the ESD for PT18 in case of application by nebulization. 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. For emission to the STP, only calculations were performed for the worst-case animal category which is turkeys in free range with litter floor (i1 = 16).

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 considered by using half-lives of 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.

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.
Based on the reactivity of glutaraldehyde in slurry/manure a residual fraction (Fresidue) of 0.01% according to the Assessment Report of glutaraladehyde for PT03 is applied for calculation of the PECs for soil and groundwater.

For spraying an amount of 100 mL diluted (0.8%) product per m^2 and for nebulization an amount of 1.8 mL pure product per m^3 is required according to the applicant.

Disinfection of animal transport vehicles (PT03)
PECs 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 and TAB agreement ENV 253 regarding interior and exterior surfaces. For spraying an amount of 100 mL diluted (0.8%) product per m^2 is required according to the applicant.

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 195 set to 70% for ADBAC and DDAC being hydrophobic compounds and 90% for glutaraldehyde that disappears rapidly by abiotic degradation.

Disinfection of surfaces and volumes by spraying or nebulization in places where food or drinks are prepared, treated or stored (PT04)
For the PT04 applications, 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. Application by spraying was assessed in accordance with the surfaces as prescribed in the ESD, but application by nebulization with TAB agreement ENV 66.
For spraying an amount of 100 mL diluted (0.6%) product per m^2 and for nebulization an amount of 1 mL pure product per m^3 is required according to the applicant.
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.

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			6.81 mg/kg dwt 1.48 mg/kg wwt	Experimental value is available but the lowest PNEC is derived from $PNEC_{water}$ using equilibrium partitioning method.
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			6.19 mg/kg dwt 1.35 mg/kg wwt	Experimental value is available but the lowest PNEC is derived from $PNEC_{water}$ using equilibrium partitioning method.
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. Therefore, in line with the Assessment Report for glutaraldehyde (2014), an assessment for sediment is not performed.

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 the disinfection of surfaces and volumes not in contact with food for humans or animals, with the exception of health care facilities (PT02). In Table E.5 PEC and PEC/PNEC ratios for micro-organisms in the STP and freshwater indirectly exposed due to the disinfection of livestock farming buildings (including water and feed troughs in animal housing) and the interior and exterior of vehicles used for animal transportation (PT03) are presented. For the disinfection of surfaces and volumes in places where food or drinks are prepared, treated or stored (PT04) these results are presented in Table E.6.

Table E.4 PEC and PEC/PNEC ratios for micro-organisms in the STP and freshwater indirectly exposed due to the disinfection of surfaces and volumes not in contact with food for humans or animals, with the exception of health care facilities (PT02)

	STP		**Fresh water**		**Sediment**	
	PEC (mg/L)	**PEC/PNEC**	**PEC (mg/L)[1]**	**PEC/PNEC**	**PEC (mg/kg ww)**	**PEC/PNEC**
Disinfection of surfaces not in contact with food for humans or animals by <u>spraying</u>, with the exception of health care facilities (PT02)						
ADBAC	4.48E-05	<0.001	1.30E-06	0.003	4.62E-02	0.031
DDAC	8.40E-06	<0.001	4.56E-07	<0.001	5.57E-03	0.004
Glutaraldehyde	7.95E-04	0.002	7.94E-05	0.032	-	-
Total	-	0.004	-	0.036	-	0.035
Disinfection of volumes not in contact with food for humans or animals by <u>nebulization</u>, with the exception of health care facilities (PT02)						
ADBAC	2.99E-04	0.004	8.63E-06	0.021	3.08E-01	0.208
DDAC	5.60E-05	<0.001	3.04E-06	0.003	3.71E-02	0.028
Glutaraldehyde	5.30E-03	0.01	5.29E-04	0.212	-	-
Total	-	0.015	-	0.236	-	0.236

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

Table E.5 PEC and PEC/PNEC ratios for micro-organisms in the STP and freshwater indirectly exposed due to the disinfection of livestock farming buildings (including water and

feed troughs in animal housing) and the interior and exterior of vehicles used for animal transportation (PT03)

	STP		Fresh water		Sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)[1]	PEC/PNEC	PEC (mg/kg ww)	PEC/PNEC
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by spraying (PT03)[2]						
ADBAC	9.61E-05	0.001	2.78E-06	0.007	9.90E-02	0.067
DDAC	1.80E-05	<0.001	9.77E-07	<0.001	1.19E-02	0.009
Glutaraldehyde	1.70E-03	0.003	1.70E-04	0.068	-	-
Total	-	0.005	-	0.076	-	0.076
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by nebulization (PT03)[2]						
ADBAC	3.36E-04	0.004	9.71E-06	0.023	3.46E-01	0.234
DDAC	6.30E-05	<0.001	3.42E-06	0.003	4.18E-02	0.031
Glutaraldehyde	5.96E-03	0.012	5.96E-04	0.238	-	-
Total	-	0.017	-	0.264	-	0.265
Disinfection of the interior and exterior of vehicles used for animal transportation by spraying (PT03)						
Mammal transport						
ADBAC	1.20E-03	0.015	3.45E-05	0.083	1.23E+00	0.832
DDAC	2.24E-04	0.002	1.22E-05	0.011	1.49E-01	0.110
Glutaraldehyde	9.42E-04	0.002	9.41E-05	0.038	-	-
Total	-	0.019	-	0.132	-	0.942
Poultry transport						
ADBAC	7.01E-04	0.009	2.03E-05	0.049	7.22E-01	0.488
DDAC	1.31E-04	<0.001	7.12E-06	0.006	8.71E-02	0.065
Glutaraldehyde	5.52E-04	0.001	5.52E-05	0.022	-	-
Total	-	0.011	-	0.077	-	0.553

[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.

Table E.6 PEC and PEC/PNEC ratios for micro-organisms in the STP and freshwater indirectly exposed due to the disinfection of surfaces 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 surfaces by spraying in places where food or drinks are prepared, treated or stored (PT04)						
without on-site treatment						
ADBAC						
large scale canteens	8.96E-05	0.001	2.59E-06	0.006	9.24E-02	0.062
slaughterhouses	4.48E-04	0.006	1.30E-05	0.031	4.62E-01	0.312
combined	5.38E-04	0.007	1.55E-05	0.037	5.54E-01	0.374
DDAC						
large scale canteens	1.68E-05	<0.001	9.11E-07	<0.001	1.11E-02	0.008
slaughterhouses	8.40E-05	<0.001	4.56E-06	0.004	5.57E-02	0.041
combined	1.01E-04	<0.001	5.47E-06	0.005	6.68E-02	0.050
Glutaraldehyde						
large scale canteens	1.59E-03	0.003	1.59E-04	0.064	-	-
slaughterhouses	7.95E-03	0.016	7.94E-04	0.318	-	-
combined	9.54E-03	0.019	9.53E-04	0.381	-	-
Total						
large scale canteens	-	0.004	-	0.071	-	0.070

	STP		Fresh water		Sediment	
	PEC (mg/L)	**PEC/PNEC**	**PEC (mg/L)[1]**	**PEC/PNEC**	**PEC (mg/kg ww)**	**PEC/PNEC**
slaughterhouses	-	0.023	-	0.353	-	0.353
combined	-	0.027	-	0.423	-	0.424
with on-site treatment						
ADBAC						
large scale canteens	2.69E-05	<0.001	7.77E-07	0.002	2.77E-02	0.019
slaughterhouses	1.34E-04	0.002	3.89E-06	0.009	1.39E-01	0.094
combined	1.61E-04	0.002	4.66E-06	0.011	1.66E-01	0.112
DDAC						
large scale canteens	5.04E-06	<0.001	2.73E-07	<0.001	3.34E-03	0.002
slaughterhouses	2.52E-05	<0.001	1.37E-06	0.001	1.67E-02	0.012
combined	3.02E-05	<0.001	1.64E-06	0.001	2.01E-02	0.015
Glutaraldehyde						
large scale canteens	1.59E-04	<0.001	1.59E-05	0.006	-	-
slaughterhouses	7.95E-04	0.002	7.94E-05	0.032	-	-
combined	9.54E-04	0.002	9.53E-05	0.038	-	-
Total						
large scale canteens	-	0.001	-	0.008	-	0.021
slaughterhouses	-	0.004	-	0.042	-	0.106
combined	-	0.004	-	0.050	-	0.127
Disinfection of volumes by <u>nebulization</u> in places where food or drinks are prepared, treated or stored (PT04)						
without on-site treatment						
ADBAC						
large scale canteens	4.48E-04	0.006	1.30E-05	0.031	4.62E-01	0.312
slaughterhouses	3.74E-03	0.048	1.08E-04	0.26	3.85E+00	**2.6**
combined	4.18E-03	0.054	1.21E-04	0.291	4.31E+00	**2.91**
DDAC						
large scale canteens	8.40E-05	<0.001	4.56E-06	0.004	5.57E-02	0.041
slaughterhouses	7.00E-04	0.005	3.80E-05	0.035	4.64E-01	0.344
combined	7.84E-04	0.006	4.25E-05	0.039	5.20E-01	0.385
Glutaraldehyde						
large scale canteens	7.95E-03	0.016	7.94E-04	0.318	-	-
slaughterhouses	6.62E-02	0.13	6.62E-03	**2.65**	-	-
combined	7.42E-02	0.145	7.41E-03	**2.97**	-	-
Total						
large scale canteens	-	0.023	-	0.353	-	0.353
slaughterhouses	-	0.183	-	**2.95**	-	**2.94**
combined	-	0.205	-	**3.30**	-	**3.30**
with on-site treatment						
ADBAC						
large scale canteens	1.34E-04	0.002	3.89E-06	0.009	1.39E-01	0.094
slaughterhouses	1.12E-03	0.014	3.24E-05	0.078	1.15E+00	0.78
combined	1.25E-03	0.016	3.63E-05	0.087	1.29E+00	0.874
DDAC						
large scale canteens	2.52E-05	<0.001	1.37E-06	0.001	1.67E-02	0.012
slaughterhouses	2.10E-04	0.002	1.14E-05	0.01	1.39E-01	0.103
combined	2.35E-04	0.002	1.28E-05	0.012	1.56E-01	0.116

	STP		Fresh water		Sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)[1]	PEC/PNEC	PEC (mg/kg ww)	PEC/PNEC
Glutaraldehyde						
large scale canteens	7.95E-04	0.002	7.94E-05	0.032	-	-
slaughterhouses	6.62E-03	0.013	6.62E-04	0.265	-	-
combined	7.42E-03	0.015	7.41E-04	0.297	-	-
Total						
large scale canteens	-	0.004	-	0.042	-	0.106
slaughterhouses	-	0.029	-	0.353	-	0.883
combined	-	0.033	-	0.396	-	0.990

The total PEC/PNEC values are all below the trigger value of 1 for the following applications:

- disinfection of surfaces not in contact with food for humans or animals by spraying or nebulization with the exception of health care facilities (PT02);
- disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by spraying or nebulization (PT03);
- disinfection of surfaces by spraying in places where food or drinks are prepared, treated or stored (PT04).

For the disinfection of surfaces in places where food or drinks are prepared, treated or stored (PT04) the total PEC/PNEC values for STP, water and/or sediment are all below the trigger value of 1 for disinfection by spraying without or without on-site pre-treatment but not for disinfection by nebulization without on-site pre-treatment. 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 for disinfection by nebulization 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.*

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 PT02 and PT03. The cumulative risk assessment was only made for sediment as the highest PEC/PNEC ratios were observed for this compartment. The results of the cumulative risk assessment are summarised in Table E.7.

Table E.7 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 volumes not in contact with food for humans or animals by nebulization, with the exception of health care facilities (PT02)	0.236	0.236
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by nebulization (PT03)	0.265	0.265
Disinfection of the interior and exterior of vehicles used for animal transportation by spraying (PT03) *Mammal transport*	0.942	0.942
Disinfection of volumes by nebulization in places where food or drinks are prepared, treated or stored (PT04)	**3.30**	0.990
Total	**4.74**	**2.43**

Simultaneous exposure from the intended uses as disinfectant for surfaces and volumes not in contact with food for humans or animals, with the exception of health care facilities (PT02), disinfectant for livestock farming surfaces and buildings (including water and feed troughs in animal housing) (PT03) and disinfectant for surfaces and volumes 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 sediment through direct release to the sewer is >1 irrespective of on-site pre-treatment of waste water. Consequently, aggregated emission results in unacceptable risks for sediments being the most vulnerable environmental compartment.

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 in Dutch surface water.

7.6.1.4 Surface water intended for the abstraction of drinking water

Biocidal products with the active substance ADBAC, DDAC and glutaraldehyde have been on the market for more than three years. The existing active substances ADBAC, DDAC and glutaraldehyde 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 (2023). 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 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 livestock farming surfaces and buildings (including water and feed troughs in animal housing) (PT03) is presented in Table E.8.

Table E.8 PEC_{soil} values and PEC/PNEC ratios for soils due to the disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) (PT03)

	Grassland		Arable land	
	PEC (mg/kg wwt)	**PEC/PNEC**	**PEC (mg/kg wwt)**	**PEC/PNEC**
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by spraying (PT03)				
ADBAC				
Dairy cattle	3.80E-04	<0.001	6.72E-04	<0.001
Beef cattle	5.44E-03	0.008	5.53E-03	0.008
Pig farming	4.68E-03	0.007	4.79E-03	0.007
Poultry, including duck farming	5.40E-03	0.008	9.54E-03	0.014
Poultry, excluding duck farming	3.01E-03	0.004	3.10E-03	0.004
DDAC				
Dairy cattle	7.60E-05	<0.001	1.26E-04	<0.001
Beef cattle	1.09E-03	<0.001	1.04E-03	<0.001
Pig farming	9.35E-04	<0.001	8.98E-04	<0.001
Poultry, including duck farming	1.08E-03	<0.001	1.79E-03	0.001
Poultry, excluding duck farming	6.01E-04	<0.001	5.81E-04	<0.001
Glutaraldehyde				
Dairy cattle	7.58E-08	<0.001	1.09E-07	<0.001
Beef cattle	1.08E-06	<0.001	8.99E-07	<0.001
Pig farming	9.32E-07	<0.001	7.80E-07	<0.001
Poultry, including duck farming	1.08E-06	<0.001	1.55E-06	<0.001
Poultry, excluding duck farming	6.00E-07	<0.001	5.04E-07	<0.001
Total				
Dairy cattle	-	0.003	-	0.003
Beef cattle	-	0.010	-	0.010
Pig farming	-	0.009	-	0.009
Poultry, including duck farming	-	0.010	-	0.016
Poultry, excluding duck farming	-	0.006	-	0.006
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by nebulization (PT03)				
ADBAC				
Dairy cattle	2.55E-03	0.004	4.51E-03	0.006
Beef cattle	1.11E-02	0.016	1.13E-02	0.016
Pig farming	1.19E-02	0.017	1.22E-02	0.017
Poultry, including duck farming	1.87E-02	0.027	3.30E-02	0.047
Poultry, excluding duck farming	1.05E-02	0.015	1.08E-02	0.015
DDAC				
Dairy cattle	5.10E-04	<0.001	8.44E-04	<0.001
Beef cattle	2.22E-03	0.002	2.12E-03	0.002
Pig farming	2.37E-03	0.002	2.28E-03	0.002
Poultry, including duck farming	3.73E-03	0.003	6.18E-03	0.004
Poultry, excluding duck farming	2.09E-03	0.001	2.02E-03	0.001
Glutaraldehyde				
Dairy cattle	5.08E-07	<0.001	7.33E-07	<0.001

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Beef cattle	2.22E-06	<0.001	1.84E-06	<0.001
Pig farming	2.36E-06	<0.001	1.98E-06	<0.001
Poultry, including duck farming	3.72E-06	<0.001	5.37E-06	<0.001
Poultry, excluding duck farming	2.09E-06	<0.001	1.76E-06	<0.001
Total				
Dairy cattle	-	0.006	-	0.006
Beef cattle	-	0.019	-	0.019
Pig farming	-	0.020	-	0.020
Poultry, including duck farming	-	0.031	-	0.052
Poultry, excluding duck farming	-	0.017	-	0.017

The intended use as a disinfectant for livestock farming surfaces and buildings (including water and feed troughs in animal housing) by spraying or nebulization (PT03) results in an acceptable risk for the soil compartment as the PEC is well below the PNEC. Hence, the risk for soil organisms is considered acceptable for the intended uses.

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 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 (excluding bees) is considered not acceptable for the active substances for all intended uses.

7.6.2.3 Groundwater

Due to distribution of manure, transportation of the active substances to groundwater is expected. Table E.9 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.9 PECgw values due to the disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) (PT03)

	Concentration in porewater (µg/L)	
	1st Tier	
	Grassland	Arable land
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by spraying (PT03)		
ADBAC		
Dairy cattle	1.80E-06	3.18E-06
Beef cattle	2.57E-05	2.62E-05
Pig farming	2.21E-05	2.27E-05
Poultry, including duck farming	2.55E-05	4.51E-05
Poultry, excluding duck farming	1.42E-05	1.47E-05
DDAC		
Dairy cattle	1.28E-06	2.12E-06
Beef cattle	1.83E-05	1.74E-05
Pig farming	1.57E-05	1.51E-05
Poultry, including duck farming	1.82E-05	3.01E-05
Poultry, excluding duck farming	1.01E-05	9.79E-06

	Concentration in porewater (µg/L)	
	1st Tier	
	Grassland	Arable land
Glutaraldehyde		
Dairy cattle	2.97E-06	4.35E-06
Beef cattle	4.26E-05	3.58E-05
Pig farming	3.66E-05	3.10E-05
Poultry, including duck farming	4.22E-05	6.17E-05
Poultry, excluding duck farming	2.35E-05	2.01E-05
Total		
Dairy cattle	6.05E-06	9.65E-06
Beef cattle	8.66E-05	7.94E-05
Pig farming	7.44E-05	6.88E-05
Poultry, including duck farming	8.59E-05	1.37E-04
Poultry, excluding duck farming	4.78E-05	4.46E-05
Disinfection of livestock farming surfaces and buildings (including water and feed troughs in animal housing) by nebulization (PT03)		
ADBAC		
Dairy cattle	1.21E-05	2.13E-05
Beef cattle	5.26E-05	5.34E-05
Pig farming	5.61E-05	5.75E-05
Poultry, including duck farming	8.83E-05	1.56E-04
Poultry, excluding duck farming	4.96E-05	5.11E-05
DDAC		
Dairy cattle	8.58E-06	1.42E-05
Beef cattle	3.74E-05	3.56E-05
Pig farming	3.99E-05	3.84E-05
Poultry, including duck farming	6.28E-05	1.04E-04
Poultry, excluding duck farming	3.53E-05	3.41E-05
Glutaraldehyde		
Dairy cattle	1.99E-05	2.92E-05
Beef cattle	8.69E-05	7.31E-05
Pig farming	9.28E-05	7.87E-05
Poultry, including duck farming	1.46E-04	2.13E-04
Poultry, excluding duck farming	8.20E-05	6.99E-05
Total		
Dairy cattle	4.06E-05	6.47E-05
Beef cattle	1.77E-04	1.62E-04
Pig farming	1.89E-04	1.75E-04
Poultry, including duck farming	2.97E-04	4.73E-04
Poultry, excluding duck farming	1.67E-04	1.55E-04

The concentrations of the active substances ADBAC, DDAC and glutaraldehyde in pore water are all <0.1 µg/L. The standards for groundwater are met.

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). The standard for persistence in soils is therefore met.

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 and glutaraldehyde (as discussed in 7.6.3.1) indicate that indirect exposure of birds and mammals to ADBAC, DDAC, glutaraldehyde 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 and glutaraldehyde 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 substances 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.

7.7 Measures to protect the environment (risk mitigation measures)

No risk mitigation measures for the environment were proposed by the applicant. Simultaneous emission to the STP from the intended uses of the product for the disinfection of the interior and exterior of vehicles used for animal transportation by spraying (PT03) and the disinfection of volumes by nebulization in places where food or drinks are prepared, treated or stored (PT04) may result in unacceptable risks for the aquatic environment, therefore 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. When used in accordance with the legal Instructions for Use (WG/GA), Vulkan air complies with the environmental standards and is not expected to cause unacceptable risks to the environment. However, simultaneous emission to the sewer results in unacceptable risks for the sediment compartment, mainly caused by the use of the product for disinfection of the interior and exterior of vehicles used for animal transportation by spraying (PT03) and disinfection of volumes by nebulization in places where food or drinks are prepared, treated or stored (PT04) irrelated to the use of on-site pre-treatment of waste water. Therefore, the product application is only acceptable if the intended uses for disinfection of the interior and exterior of vehicles used for animal transportation by spraying (PT03) and disinfection of volumes by nebulization in places where food or drinks are prepared, treated or stored (PT04) are removed from the WG/GA.

7.9 Data requirements

There are no additional data required.

8 Conclusion

The applicant has proven that Vulkan air 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			
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.	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	P284	[In case of inadequate ventilation] wear respiratory protection.	
	P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.	
	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	Corrosive to the respiratory tract.	
Child-resistant fastening obligatory?			**Not applicable**
Tactile warning of danger obligatory?			**Not applicable**

Explanation:	
Pictogram:	-
H-statements:	As EUH071 is triggered, H335 should be omitted from the label (see labelling guidance p.32)
P-statements:	P342+P311 is assigned, as this sentence is highly recommended with the assigned H334.
Other:	EUH071 is triggered as the application is by e.g. spraying, all components that contribute to H332 classification are also classified with H314.

* 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, 2023 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/cm³)

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 m³/ 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	

Parameter	Value	Remarks
	DDAC	
molecular weight (g/mole)	362.1	
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/cm³)
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	
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 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/cm³)
Bioconcentration factor for fish (BCF_{fish})	1.41	
Bioconcentration factor for earthworm ($BCF_{earthwomr}$)	0.846	