Van: [redacted], [redacted] <[redacted]@odachterhoek.nl>
Verzonden: 20-11-2025 14:20
Aan: [redacted], [redacted] <[redacted]@odachterhoek.nl>
Onderwerp: Doorstuur FW: ForFarmers De Hoop; ZZS

Ha [redacted],

[redacted]

Met vriendelijke groet,
[redacted]

+316[redacted] | [redacted]@odachterhoek.nl

Omgevingsdienst Achterhoek

Adres: Hanzestraat 3, [redacted] Doetinchem

Postadres: Postbus 350, 7000 AJ Doetinchem

info@odachterhoek.nl | www.odachterhoek.nl

Omgevingsdienst Achterhoek

*Omgevingsdienst Achterhoek voert milieu- en specialistische omgevingstaken uit
voor de Achterhoekse gemeenten en de provincie Gelderland.*

Van: [redacted] <[redacted]@forfarmers.eu>
Verzonden: woensdag 19 november 2025 20:14
Aan: [redacted], [redacted] <[redacted]@odachterhoek.nl>
CC: [redacted] <[redacted]@reudink-bio.eu>; [redacted] <[redacted]@forfarmers.eu>
Onderwerp: FW: ForFarmers De Hoop; n.a.v. milieucontrole op 15 aug 2025

Geachte [redacted] beste [redacted],

Hierbij de beantwoording van de gestelde vragen.

1. Vraag blijkt achterhaald te zijn volgens de mailing van 7 november 2025. Eén en ander zou elkaar wel eens gekruist kunnen hebben in het digitale universum.

2) het document 5.6051.24.....pdf gaat in de op vloeistofdichte voorziening, ook de nummers 2.6081.23 gaan over de vloeistofdichte voorzieningen.

3. Er zijn al nieuwe rapporten, ik ga er vanuit dat die ook de lading dekken. De rapportage van drie jaar terug heb ik nog niet kunnen vinden. Is digitaal niet beschikbaar en ik zou dan in het papierenarchief moeten duiken. Als het expliciet nodig is dan doe ik dat uiteraard. Maar de vraag rijst wel wat het doel van de oude rapporten is.

4. Akkoord.

[redacted]

Ik hoop je hiermee voldoende te hebben geïnformeerd.

met vriendelijke groet,

[redacted]

[redacted]

T +31 (0)573 28 88 00 • **M** +316[redacted]

[redacted]@forfarmers.eu • www.forfarmers.nl

ForFarmers Nederland B.V.
Postbus 91 • NL-7240 AB Lochem
Kwinkweerd 12 • NL-7241 CW Lochem

Van: [redacted], [redacted] <[redacted]@odachterhoek.nl>
Verzonden: dinsdag 4 november 2025 11:02
Aan: [redacted] <[redacted]@forfarmers.eu>
Onderwerp: ForFarmers De Hoop; n.a.v. milieucontrole op 15 aug 2025

Geachte [redacted]

Op 15 augustus 2025 heb ik een milieucontrole uitgevoerd bij uw vestiging aan de [redacted] in [redacted] Daarover hebben we per e-mail gecorrespondeerd met onderstaande restpunten als resultaat.

1. De periodieke SCIOS-inspectie van de 2 CV's zou volgens uw opgave door Winkelman/Achterhoek Service zijn uitgevoerd op 22 sep 2025. Van deze inspectie beschikken wij niet over een keuringsverklaring en -rapport en ook is deze inspectie nog niet afgemeld in SCIOS in overeenstemming met Bal artikel 4.1329.

Ik verzoek u om een afschrift van de SCIOS-keuringsverklaring en het bijbehorende keuringsrapport aan ons toe te sturen wanneer u die voorhanden heeft.

Tevens verzoek ik u om contact op te nemen met de inspecteur m.b.t. het achterblijven van de afmelding bij SCIOS, ook de EBI van de gasleiding naar de fabriek van 22 mei 2024 dient nog te worden afgemeld in SCIOS.

2. In de BIC-rapportages van vloeistofdichte voorzieningen van 20 sep 2025 zijn bij de was-monsternameplaats en de tankplaats gebreken geconstateerd (scheuren in de vloer)

waarvoor herstelactie noodzakelijk is. Ik ontvang graag een bewijs van reparatie van de voorzieningen.

3. In uw e-mail van 1 oktober 2025 heeft u ons abusievelijk niet het gevraagde VVV-rapport van de was-monsternameplaats van 9 dec 2022 toegezonden maar een ander document.

T.b.v. een volledig beeld van de bodembeschermende voorziening verzoek ik u nogmaals om toezending van de genoemde keuringsrapportage van 9 dec 2022 met kenmerk

3.6258/22.

4. De aangetroffen IBC's met etiket UN3265 betreffen volgens uw opgave het 'product 19269: MFCA Liquid +', een bijtende zure organische vloeistof met bestanddelen octaan- en decaanzuur. Dit product is, zoals u aangaf, inderdaad geen ZZS.

Dat geldt niet voor het aangetroffen MS Megades NOVO dat wél een ZZS is.

In uw e-mail van 1 oktober jl. stelt u dat de concentratie ZZS in een mengsel zou bepalen of een stof al dan niet wordt beschouwd als ZZS maar dat is onjuist. In Bal artikel 5.22a zijn de criteria voor ZZS neergelegd en de door u genoemde concentratie is er daar niet één van.

Het bestanddeel glutaaraldehyde in MS Megades NOVO valt onder artikel 5.22a lid 2 onder a onder 2. Het staat op de kandidatenlijst, bedoeld in artikel 59 van de REACH-verordening.

MS Megades NOVO is zodoende een ZZS waarvoor de regels in Bal § 5.4.3. van toepassing zijn. Ik verzoek u om alsnog de als bijlage bij deze e-mail gaande vragenlijst ingevuld te retourneren en verder uitvoering te geven aan het gestelde in Bal § 5.4.3.

De gevraagde informatie ontvangen wij graag zo spoedig mogelijk maar uiterlijk op 21 november 2025.

Met vriendelijke groet,

[redacted]
Toezichthouder Milieu

06-[redacted] | [redacted]@odachterhoek.nl

Omgevingsdienst Achterhoek
Hanzestraat 3, [redacted] Doetinchem
info@odachterhoek.nl | www.odachterhoek.nl

Omgevingsdienst
Achterhoek

De Omgevingsdienst Achterhoek voert milieu- en specialistische omgevingstaken uit voor de Achterhoekse gemeenten en de provincie Gelderland.

VRAGENLIJST ZZS

Bal § 5.4.3. ZZS

	Vragen algemeen om te beoordelen of de ZZS vrij komt	
1	Sinds wanneer wordt met deze stof gewerkt?	Juni 2023
2	Is het gebruik van deze stof aangevraagd?	Nee. MS Megades Novo is een door het ctgb goedgekeurd desinfectiemiddel.
3	In welke processen wordt de stof toegepast?	Toegepast in oplossing. Als nevel gebruikt voor de desinfectie van vrachtwagen banden/wielkassen.
4	Zijn er emissies naar de lucht van deze stof?	Glutaaraldehyde heeft een lage damspanning. Lager dan het water waarin het wordt opgelost.
5	Zijn er emissies naar het riool van deze stof?	Overtollige nevel wordt afgevoerd naar het riool.
6	Opvragen van de veiligheidsinformatiebladen	MSDS beschikbaar.
7	Opvragen van het jaarverbruik van de stof	2023: 640L, 2024: 1240L, 2025: 880L.
	Vragen als de stof naar de lucht gaat	
8	Zijn er emissiemetingen uitgevoerd?	Nee
9	Gegevens over de toegepaste maatregelen om de emissies te verminderen bijvoorbeeld dat zo min mogelijk van de ZZS wordt toegepast?	Toegepast in oplossing volgens gebruiksvoorschriften ctgb en leverancier.
10	Gegevens over de toegepaste technische maatregelen om de emissies naar de lucht te zuiveren?	Geen.
	Vragen als de stof wordt geloosd op het riool	
11	Gegevens over de toegepaste maatregelen om de lozing van de ZZS op het riool te verminderen. Bijvoorbeeld dat zo min mogelijk van de ZZS wordt toegepast en dat er zo min mogelijk afvalwater ontstaat?	Direct op banden en wielkas verneveld. Hierdoor beperkt overtollig product. Gebruiksvoorschriften geven afvoer naar riool (en RWZI) aan.
12	Opvragen of technische maatregelen worden toegepast om de emissies op het riool te zuiveren? Het gaat hierbij een zuiveringsinstallatie dat afvalwater zuivert.	Gebruiksvoorschriften geven afvoer naar riool (en RWZI) aan met slibvang en vetafscheider.
	Vragen specifiek voor ZZS	
13	Is er een vermijdings- en reductieprogramma opgesteld?	Nee.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 9 februari 2017 is van

Schippers Europe B.V.
Postbus 122
5530 AC BLADEL

een aanvraag tot uitbreiding van een toelating (overgangsrecht) ontvangen voor het middel

MS Megades Novo

op basis van de werkzame stoffen Alkyl (C12-16) dimethylbenzylammoniumchloride (ADBAC/BKC) en glutaaraldehyde.

HET COLLEGE BESLUIT tot uitbreiding van de toelating van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

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

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

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

- 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.

4 Wijziging van de toelating

De toelating wordt op de volgende punten gewijzigd:
Het middel wordt uitgebreid met de toepassing:
"Desinfectie van oppervlakken welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor, echter met uitzondering van melkwinningsapparatuur op de boerderij."

Bezwaarmogelijkheid

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

Ede, 6 maart 2020

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

14896 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20170242 UB
Type aanvraag:	aanvraag tot uitbreiding van een toelating (overgangsrecht)
Middelnaam:	MS Megades Novo
Verzenddatum aanvraag:	9 februari 2017
Formele registratiedatum: *	1 maart 2017
Datum in behandeling name:	26 september 2017

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

2 Stofinformatie

Werkzame stof	Gehalte
Alkyl (C12-16) dimethylbenzylammoniumchloride	9,8 %
glutaaraldehyde	14,7 %

De werkzame stof Alkyl (C12-16) dimethylbenzylammoniumchloride (ADBAC/BKC (C12-16)) is opgenomen in het reviewprogramma maar voor de aangevraagde PT2 en PT3 nog niet geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

De werkzame stof glutaaraldehyde is per 1 oktober 2016 geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012 voor de aangevraagde PT2 en PT3.

3 Toelatingsinformatie

Toelatingsnummer:	14896 N
Expiratiedatum:	1 augustus 2025
Afgeleide of parallel:	wijziging middel (uitbreiding)
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Met water mengbaar concentraat

14896 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel MS Megades Novo

Professioneel gebruik

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
Alkyl (C12-16) dimethylbenzylammoniumchloride
glutaaraldehyde
mierenzuur

Pictogram	GHS05 GHS07 GHS08 GHS09
Signaalwoord	Gevaar
Gevarenaanduidingen	H302 Schadelijk bij inslikken. H314 Veroorzaakt ernstige brandwonden en oogletsel. H317 Kan een allergische huidreactie veroorzaken. H332 Schadelijk bij inademing. H334 Kan bij inademing allergie- of astmasymptomen of ademhalingsmoeilijkheden veroorzaken. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P260 Stof/rook/gas/nevel/damp/spuitnevel niet inademen. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P284 Adembescherming dragen. P303 + P361 + P353 BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken. Huid met water afspoelen/afdouchen. P304 + P341 NA INADEMING: bij ademhalingsmoeilijkheden het slachtoffer in de frisse lucht brengen en laten rusten in een houding die het ademen vergemakkelijkt. 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.
Aanvullende etiketelementen	EUH071 Bijtend voor de luchtwegen.

14896 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE III WG/GA van het middel MS Megades Novo

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van:

1. bacteriën (exclusief mycobacteriën en bacteriesporen), gisten en virussen in dierverblijfplaatsen en bijbehorende ruimten, inclusief transportmiddelen voor dieren.

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

2. bacteriën (exclusief mycobacteriën en bacteriesporen) en gisten op oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor, echter met uitzondering van melkwinningsapparatuur op de boerderij.

   Om in het waterlevende organismen te beschermen dienen resten die het middel bevatten te worden geloosd naar het riool met aansluiting op de RWZI.
   Bij afvoer naar een gemeentelijke RWZI is een vetafscheider en slibvangput conform NEN-EN 1825-1 en 1825-2 en/of een biologische of chemische voorzuivering verplicht.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

De te desinfecteren oppervlakken en materialen eerst grondig reinigen. Een daarbij eventueel gebruikt reinigingsmiddel goed afspoelen met schoon water.

1. **Desinfectie van oppervlakken in dierverblijfplaatsen en bijbehorende ruimten, inclusief transportmiddelen voor dieren:**

Het middel toepassen door middel van sprayen onder lage druk. Zorg dat oppervlakken vochtig blijven gedurende de gehele inwerktijd. Na afloop het middel grondig afspoelen.

Dosering: 0,75% (= 7,5 ml aanvullen met water tot 1 liter).
Minimale inwerktijd: 5 minuten.

Tijdens mengen/laden van het product geschikte handschoenen en coverall dragen.
Tijdens het aanbrengen van het schuim geschikte handschoenen, coverall en adembescherming dragen.

Tijdens het aanbrengen van het schuim mogen er geen onbeschermde personen of dieren aanwezig zijn.

2. **Desinfectie van oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor, echter met uitzondering van melkwinningsapparatuur op de boerderij:**

Het middel toepassen door middel van sprayen onder lage druk. Zorg dat oppervlakken vochtig blijven gedurende de gehele inwerktijd. Na afloop het middel grondig afspoelen.

Dosering: 0,25% (= 2,5 ml aanvullen met water tot 1 liter).
Minimale inwerktijd: 5 minuten.

Tijdens mengen/laden van het product geschikte handschoenen en coverall dragen.
Tijdens het aanbrengen van het schuim geschikte handschoenen en coverall dragen.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV

RISKMANAGEMENT

Contents

1 Introduction

1.1 Applicant

Schippers Europe B.V.
Postbus 122
5530 AC BLADEL

1.2 Active substances

Alkyl (C12-16) dimethylbenzylammonium chloride (ADBAC / BCK (C12-16)) and glutaraldehyde

1.3 Product

MS Megades Novo

1.4 Function

Disinfectant PT03 and PT04

1.5 Background to the application

This concerns an application for extension of an existing authorisation of a biocidal product.

1.6 Intended uses

MS Megades Novo is already authorised in the Netherlands under registration number 14896 N with the following area of use:

- control of bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses on surfaces in animal housing, including animal transportation vehicles (PT03).

Additional authorisation is requested for:

- control of bacteria (excluding mycobacteria and bacterial spores) and yeasts on surfaces and equipment in places where food and beverages are prepared and stored, excluding milking equipment on the farm (PT04);
- *control of bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on hatching eggs in hatcheries[1] (PT03)*

The product is intended for professional use only.

1.7 Packaging details

1, 5, 20, 25, 60, 200L in HDPE

2 Identity

2.1 Identity of the active substance

2.1.1 ADBAC

Common name	ADBAC (non-ISO)
Name in Dutch	Quaternaire ammoniumverbindingen, benzyl-C12-16-alkyldimethyl, chloriden
Chemical name	Quaternary ammonium compounds, benzyl-(C12-16)-alkyldimethyl, chlorides
CAS no	68424-85-1
EC no	270-325-2 [EINECS]

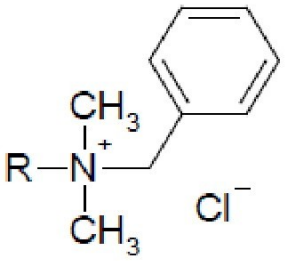
The active substance ADBAC is not yet included in the Union List of approved substances for PT3, 4. An AR for PT8 is available (June 2015, RMS IT). For PT 1, 2, 3 and 4 a first draft CAR is available (March 2012).

[1] This use was applied for was withdrawn in a later stage.

The List of Endpoints below is taken from AR on ADBAC PT8 (June 2015, RMS IT).

Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Quaternary ammonium compounds, benzyl-(C12-16)-alkyldimethyl, chlorides
CAS No	68424-85-1
EC No	270-325-2
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	**US ISC** 940 g/kg (dry weight) **EQC** 981 g/kg (dry weight)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{n+9}H_{2n+14}N.Cl$ (n = 12, 14, 16) Alkyl chain lengths distribution:

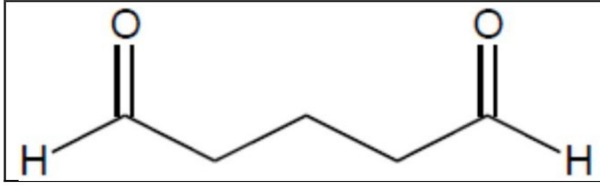
Chain Length	Range
C12	39 - 76%
C14	20 - 52%
C16	< 12%

Molecular mass	340.0 – 396.1 g/mol
Structural formula	 R = $C_{12}H_{25}$, $C_{14}H_{29}$ or $C_{16}H_{33}$

2.1.2 Identity of the active substance glutaraldehyde

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

Data on glutaraldehyde is taken from the List of Endpoints included in the Assessment Report (eCA) of September 2014, by RMS Finland. Confidential information is taken from List of Endpoints included in the Competent Authority Report (CAR) of June 2014, by RMS 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)	Maximum content of methanol in the substance as manufactured is 0.6% (wt) and the theoretical dry weight a maximum concentration of 1.2%, 12 g/kg was calculated. 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	MS Megades Novo
Formulation type	SL
Content active substance	Alkyl (C12-16) dimethylbenzyl ammonium chloride: 9.8% w/w Glutaraldehyde: 14.7% w/w

Packaging information:

	Material	Size / content	Other information
Professional use	HDPE	1, 5, 20, 25, 60, 200L	

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 active substance

3.1.1 ADBAC

The List of Endpoints below is taken from AR on ADBAC PT8 (June 2015, RMS IT).

Melting point (state purity)	**US ISC** The a.s. did not melt, but was observed to decompose starting at approximately 150°C (96.6%) **EQC** Melting range at atmospheric pressure of 28.9–30.2 °C (99.2%)
Boiling point (state purity)	**US ISC** The a.s. decomposed before melting (96.6%) **EQC** No boiling point at atmospheric pressure (1013 hPa). The test item decomposed at a temperature >160 °C (99.2%)
Thermal stability / Temperature of decomposition	**US ISC** > 150°C **EQC** > 160°C
Appearance (state purity)	**US ISC** Light beige solid (96.6%) **EQC** Crystalline, tenacious and sticky solid. Hygroscopic behaviour. White colour. Faint marzipan-like odour (94.4%)
Relative density (state purity)	**US ISC** D_4^{20} = 0.96 (96.6%) **EQC** D_4^{20} = 0.929 (94.4%)
Surface tension (state temperature and concentration of the test solution)	**US ISC** 31.3 mN/m at 20°C (test solution: 1 g/l aqueous solution) **EQC** 28.27 mN/m at 20 ± 0.5°C (test solution: 1.0 g/l aqueous solution) CMC: 0.5 g/L at 20 ± 0.5°C
Vapour pressure (in Pa, state temperature)	**US ISC** 6.03E-04 Pa @ 20°C (extrapolated) 8.57E-04 Pa @ 25°C (extrapolated) 4.22E-03 Pa @ 50°C (extrapolated) **EQC** < 1.5E-03 Pa @ 20°C (extrapolated) < 5.8E-03 Pa@ 25°C (extrapolated)
Henry's law constant (Pa m^3 mol^{-1})	**US ISC** 5.03E-07 Pa m^3 mol^{-1} at 20°C **EQC**

	< 1.15E-06 Pa m^3 mol^{-1} at 20°C
Solubility in water (g/l or mg/l, state temperature)	**US ISC** pH 5.5: 409 g/l at 20°C pH 6.5: 431 g/l at 20°C pH 8.2: 379 g/l at 20°C **EQC** 455 g/l in doubled distilled water at 20.0 ± 0.5 °C 444 g/l in acidic or basic solution at 20.0 ± 0.5 °C Solubility was found to be independent of temperature
Solubility in organic solvents (in g/l or mg/l, state temperature)	**US ISC** ethanol: > 250 g/l at 20°C isopropanol: > 250 g/l at 20°C n-octanol: > 250 g/l at 20°C **EQC** isopropanol: 549 g/l at 10°C; 568 g/l at 20°C; 586 g/l at 30°C n-octanol: 459 g/l at 20°C
Stability in organic solvents used in biocidal products including relevant breakdown products	**US ISC** Ethanol: Stable – < 5% loss over 2 weeks at 55 °C Isopropanol: Stable – < 5% loss over 2 weeks at 55°C (confirmed by supporting information) **EQC** Not required: no organic solvent is used in the representative biocidal product
Partition coefficient (log P_{OW}) (state temperature)	**US ISC** Not determined (EC methods A.8 not applicable for surfactants). Assessment by KOWWIN is inaccurate (software database very limited for surfactants). log POW could be roughly obtained from solubility in n-octanol and water. However, this calculation is of no use with regard to environmental fate and behaviour and secondary poisoning risk assessment (experimental BCF available) **EQC** 0.004 @ 20°C (calculated from individual solubilities in n-octanol and water)
Dissociation constant	Not applicable. The a.s. is fully dissociated in water
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	**US ISC** The UV/VIS absorption spectra were consistent with the assigned structure of the active substance. **EQC** No absorption above 290 nm in the neutral, acidic and basic media
Photostability (DT_{50}) (aqueous, sunlight, state pH)	**US ISC** The photolysis data available for DDAC are adequate for this active substance. The test substance is photolytically stable in absence of a photosensitising agent.

	EQC No absorption above 290 nm in UV spectrum
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not applicable: no adsorption above 290 nm in UV spectra
Flammability	Not flammable
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-ignition or relative self ignition temperature	No self-ignition was observed up to the maximum test temperature (≈400°C)

3.1.2 Glutaraldehyde

Data on glutaraldehyde is taken from the List of Endpoints included in the Assessment Report (eCA) of September 2014, by RMS Finland. Confidential information is taken from List of Endpoints included in the Competent Authority Report (CAR) of June 2014, by RMS Finland.

Melting point (state purity)	Peak maximum ca. -18 °C (BASF) -18 to -21.2 °C (50 % w/v) (Dow)
Boiling point (state purity)	101.5 °C at 987.1 hPa (ca. 50 g/100 g aqueous solution) (BASF) 100.7 °C at 1013 hPa (50 % w/v) (Dow)
Thermal stability / Temperature of decomposition	1.Peak: Onset temperature: 85 °C Peak temperature: 246 °C 2.Peak: Onset temperature: 330 °C Peak temperature: 385 °C (BASF) For Dow, there is no information, but this is not an absolute requirement in case the temperatures of melting and boiling have been determined, according to Guidance on information requirements.
Appearance (state purity)	Free flowing clear liquid (50 % solution) (BASF) Clear colourless liquid, sharp odour (50 % w/v) (Dow)
Relative density (state purity)	1.129 (50 % solution) (BASF, Dow)
Surface tension	ca. 68 mN/m at 20 °C (0.1 % solution)(BASF) 72.4 mN/m at 20 °C, (0.05 % solution) (Dow)
Vapour pressure (in Pa, state temperature)	44 Pa at 20 °C (BASF, Dow), 100 % GA
Henry's law constant (Pa m^3 mol^{-1})	0.0086 Pa×m^3/mol (calculated by RMS)
Solubility in water (g/l or mg/l, state temperature)	pH 5, 7, 9 (20.2+/- 0.1 °C): miscible (BASF) pH not measured: ≥ 51.3 g/100ml at 21 °C (Dow) Glutaraldehyde is not expected to ionize in water based on its chemical structure, therefore testing at different pH values was not considered necessary (Dow).

Solubility in organic solvents (in g/l or mg/l, state temperature)	Methanol: fully soluble 1,4-dioxane: fully soluble at 20 °C and at 30 °C (BASF) Isopropanol: fully soluble (≥ 51.3 g/100 ml) Acetone: fully soluble (≥ 51.3 g/100 ml) Ethyl acetate: 59 g/100 ml Dichloromethane: 70 g/100 ml n-hexane: 0.19 g/100 ml Toluene: 8.5 g/100 ml at 21 °C (Dow)
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable (organic solvents not used in biocidal products)
Partition coefficient (log P_{OW}) (state temperature)	pH 5 : -0.41 at 23 +/- 1 °C pH 9 : -0.80 at 23 +/- 1 °C pH 7 :-0.36 at 23 +/- 1 °C (BASF) pH not reported: -0.33 at 25 ºC (Dow)
Hydrolytic stability (DT_{50}) (state pH and temperature)	See Ch. 4: Fate and Behaviour in the Environment
Dissociation constant	Glutaraldehyde has no ionisable groups, and no ionisation/dissociation in water is expected.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Medium λ_{max} ε [nm] [l*mol-1*cm-1] neutral 234 14.9 neutral 282 5.9 acidic 234 14.5 acidic 282 6.1 basic 235 478.2 basic 283 22.3 max. at 234 nm. There are no peaks above 290 nm. The ε is below 10 at wavelengths of 290 nm or greater. (BASF,Dow)
Photostability (DT_{50}) (aqueous, sunlight, state pH)	See Ch. 4: Fate and Behaviour in the Environment
Quantum yield of direct phototransformation in water at Σ > 290 nm	See Ch. 4: Fate and Behaviour in the Environment
Flammability	Not flammable, 50% glutaraldehyde (BASF, Dow) Auto Ignition Temperature = 395 °C at 1002 – 1006 hPa (BASF)
Explosive properties	Not explosive (BASF, Dow)

3.2 Physical and chemical properties of the biocidal product

Appearance	Blue liquid
Explosive properties	Not explosive
Oxidative properties	Not oxidising
Autoflammability	No data, the product is expected not to be auto flammable
Flashpoint or Flammability	No data, flashpoint is expected to be >60°C
pH 1% solution	3.2 (1%)
Particle size distribution	Not applicable
Surface tension	Not applicable
Viscosity	1 mm^2/s (20°C)
Relative density	1.035
Storage stability/Shelf life/Packaging	Accelerated storage stability test were performed for 18 weeks at 30°C in glass. Tested parameters are: active substance content, physical state, odour, colour, pH and weight determination. All tested parameters remain within acceptable limits. The shelf life of the original product was determined during 30 months at 25°C in HDPE. Based on these data, a provisional shelf-life of 2 years is supported. In addition the stability was tested at 0°C for 7 days. The sample appearance and odour were tested. No phase separation or precipitation events were visible.
Technical properties	The product is a SL formulation. As the product is intended to foam no data are required.
Physical and chemical compatibility	Not applicable

3.3 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 is 2 years in HDPE

Data requirements

None.

4 Analytical methods for detection and identification

4.1 Analytical methods for the technical active substance

4.1.1 ADBAC

The List of Endpoints below is taken from AR on ADBAC PT8 (June 2015, RMS IT).

Technical as (principle of method)	**US ISC** HPLC with evaporative light scattering detection (ELSD). Confirmation by LC-MS **EQC** Analysis by RP-HPLC/DAD (confirmation of identity of each a.s. constituent by spectral match versus relevant standards)
Impurities in technical as (principle of method)	**US ISC** HPLC-ELSD (identification by LC-MS) Titration method IC coupled with conductivity detector; AAS Karl-Fischer titration and GC/FID for process solvents **EQC** RP-HPLC/MS-MS, with two ion transitions considered (one as quantifier, one as qualifier) GC-MS ICP-OES Karl-Fischer titration

4.1.2 Glutaraldehyde

Data on glutaraldehyde is taken from the List of Endpoints included in the Competent Authority Report (CAR) of June 2014, by RMS Finland.

Technical as (principle of method)	Potentiometric titration (BASF) HPLC-UV (Dow) Titration (Dow) For additional information required at product authorisation see Doc IIA and the Doc IIIAs.
Impurities in technical as (principle of method)	GC-MS-FID (BASF) Karl-Fisher titration (BASF) GC-TCD (Dow) IEC-CD (Dow) For additional information required at product authorisation see Doc IIA and the Doc IIIAs.

4.2 Analytical methods for analysis of the biocidal product

Preparation (principle of method)	ADBAC: HPLC-UV (264 nm) Glutaraldehyde: HPLC-UV (360 nm)

4.3 Residue analytical methods

4.3.1 ADBAC

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Wood treated with C12-16-ADBAC/BKC-containing biocidal products is not intended for and contains label restrictions against use in areas where food for human consumption is prepared, consumed or stored. Furthermore, the use of C12-16-ADBAC/BKC-based wood preservatives must exclude applications that may lead to

	contact with food and feedstuffs and contaminants thereof (e.g. application on wood crates for the storage or transport of food/feedingstuff)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Wood treated with C12-16-ADBAC/BKC-containing biocidal product is not intended for and contains label restrictions against use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is prepared, consumed or stored. Furthermore, the use of C12-16-ADBAC/BKC-based wood preservatives must exclude applications that may lead to contact with food and feedstuffs and contaminants thereof (e.g. application on wood crates for the storage or transport of food/feedingstuff)
Soil (principle of method and LOQ)	**EQC** Extraction with acetonitrile containing 1% TFA. After centrifugation and dilution with water, analysis by RP-HPLC/MS-MS (two mass transitions validated for each a.s. constituent). LOQ = 0.05 mg a.s./kg LOQ (for each individual constituent) =0.0167 mg/kg
Water (principle of method and LOQ)	**EQC** Samples over SPE cartridges. After drying, elution with acetonitrile : HPLC water (60:40, v/v) + 1% HCOOH. Analysis by RP-HPLC/MSMS (two mass transitions validated for each a.s. constituent). LOQ = 0.1 µg a.s./L LOQ (for each individual constituent) = 0.0133 µg/L
Air (principle of method and LOQ)	Not required. The a.s. is non-volatile nor expected to occur in air (representative products BQ-25 and BKC-50 are used in the following wood preservative treatment applications: automated dipping process, vacuum pressure process and spraying application in closed tunnel).
Body fluids and tissues (principle of method and LOQ)	Not required. The a.s. is neither toxic nor highly toxic

4.3.2 Glutaraldehyde

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Waived (BASF, Dow) The product is not intended to be added to food and feedstuffs or be used in facilities during food processing. Only by accident may trace amounts of glutaraldehyde be on the surface of food and feedstuffs. Due to evaporation, photodegradation and rapid reactions with proteins, only trace amounts would be expected even in the case of accident.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Waived (BASF, Dow). It is technically impossible at this time to analyse glutaraldehyde in animal tissues as the glutaraldehyde will react with the biological material, followed by rapid metabolisation and elimination.
Soil (principle of method and LOQ)	Waived, Persistence or accumulation of glutaraldehyde or its metabolites in soil is not expected (BASF) LC-MS/MS, 0.05 mg/kg (Dow) The method is not required since the DT50 < 3 days
Water (principle of method and LOQ)	GC-MS, LOQ = 0.05 µg/l (for drinking water and surface water) (BASF) LC-MS-MS, 0.1 µg/l (for drinking water and surface

	water) (Dow)
Air (principle of method and LOQ)	[HPLC/UV, 18 µg/m3 (BASF) HPLC/UV, 55.0 ng/sample (STS: 0.44 ppb or 1.8 µg/m3; LTS: 0.027 ppb or 0.11 µg/m3) (Dow)] It has been agreed that a new method will be submitted before product authorisation
Body fluids and tissues (principle of method and LOQ)	Rat blood: GC-MS, 20 ng/g (Dow) Body tissues: waived (BASF, Dow) It is technically impossible at this time to analyse glutaraldehyde in animal tissues as the glutaraldehyde will react with the biological material, followed by rapid metabolisation and elimination.

4.4 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements

None.

5 Efficacy

5.1 Function

MS Megades Novo is a disinfectant based on Alkyl (C12-16)dimethylbenzylammoniumchloride (9.8%, w/w) and glutaraldehyde (14.7%, w/w).

5.2 Field of use envisaged

MS Megades Novo is already authorised in the Netherlands under registration number 14896 N with the following area of use:

- control of bacteria (excluding mycobacteria and bacterial spores), yeasts and viruses on surfaces in animal housing, including animal transportation vehicles.

Additional authorisation is requested for:

- control of bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on hatching eggs in hatcheries[2];
- control of bacteria (excluding mycobacteria and bacterial spores) and yeasts on surfaces and equipment in places where food and beverages are prepared and stored, excluding milking equipment on the farm.

Only the new uses will be evaluated in this dossier.
These uses are included in PT03 and PT04.

The product is intended for professional use only.

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

Nine studies were provided of which eight are used in this assessment. These are summarised in Table 1. All studies assessed were performed with the formulation of application. One test was not used as the test was carried out with a test organism not relevant for the claim.

Table 1. Summary of studies assessed.

[2] This use applied for was withdrawn by the applicant as a response to additional requested information.

Test (version) Phase, step	**Test organism**	**Test parameters**	**Results***
Bacteria (excluding mycobacteria and bacterial spores)			
EN 1656 (2009 + AC 2010) 2,1	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Proteus vulgaris*	**Concentration (%):** 0.1%; 0.5%; 0.9% **Interfering substances:** 0.3 g/L BSA **Contact time:** 30 min. **Test temperature:** 30°C	**log R ≥ 5.47:** 0. 5 %; Clean 30 min; 30°C
EN 1276 (2009+AC 2010) 2, 1	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Escherichia coli*	**Concentration (%):** 0.25%; 0.5%; 0.75% **Interfering substances:** 3 g/L BSA **Contact time:** 5 min. **Test temperature:** 20°C	**log R ≥ 5.40:** 0.25 %; Clean 5 min; 20°C
EN 13697 (2015) 2,2	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Escherichia coli*	**Concentration (%):** 0.25%; 0.5%; 0.75% **Interfering substances:** 0.3 g/L BSA **Contact time:** 5 min. **Test temperature:** 20°C	**log R ≥ 5.35:** 0.25 %; Clean 5 min; 20°C
EN 16437 (2014) 2, 2	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Proteus vulgaris*	**Concentration (%):** 0.9%; 2% and 3% **Interfering substances:** 3 g/L BSA **Contact time:** 30 min. **Test temperature:** 30°C	**log R=5.06:** 2 %; Clean 30 min; 30°C
Yeasts			
EN 1650 (2008 + A1 2013) 2, 1	*Candida albicans*	**Concentration (%):** 0.25%; 0.5%; 0.75% **Interfering substances:** 0.3 g/L BSA **Contact time:** 5 min. **Test temperature:** 20°C	**log R>4.50:** 0.25 %; Clean 5 min; 20°C
EN 13697 (2015) 2, 2	*Candida albicans*	**Concentration (%):** 0.25%; 0.5%; 0.75% **Interfering substances:** 0.3 g/L BSA **Contact time:** 5 min. **Test temperature:** 20°C	**log R>4.59:** 0.25 %; Clean 5 min; 20°C
EN 1657 (2016) 2,1	*Candida albicans*	**Concentration (%):** 2%; 3%; 4% and 5% **Interfering substances:** 3 g/L BSA **Contact time:** 30 min.	**log R>4.50:** 2%; Clean 30 min; 30°C

Test (version) Phase, step	Test organism	Test parameters	Results*
		Test temperature: 30°C	
Fungi			
EN 1657 (2016) 2,1	*Aspergillus brasiliensis*	**Concentration (%):** 2%; 3%; 4% and 5% **Interfering substances:** 3 g/L BSA **Contact time:** 30 min. **Test temperature:** 30°C	**log R>4.46:** 3 %; Clean 30 min; 30°C

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

In addition several studies were provided to demonstrate the non-activity of the product without the active substances Alkyl (C12-16) dimethylbenzylammonium chloride and glutaraldehyde .
These studies are confidential and therefore not listed in the table above. The studies provided sufficient evidence to conclude that the co-formulants not add to the efficacy of MS Megades novo.

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

5.3.2 Evaluation of the label (WG/GA)
The applicant has provided a WG/GA in Dutch. This has been adapted to our standards.

5.4 Mode of action
Alkyl (C12-16) dimethylbenzylammonium chloride (ADBAC/BKC (C12-16)) is a cationic surfactant type active substance. Since it is surface active, it has fair wetting properties and reacts strongly with cell walls of micro-organisms. Its mode of action, therefore, is to destroy the cell walls by sticking on the exterior structures and by entering and disintegration 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.
The mode of action of glutaraldehyde is thought to differ according to the target organisms. Microbial cells are killed by cross-linking with primary amines located in the cell wall of the micro-organisms, sealing the outer layer of the bacterial cell surface and inactivating cell enzymes. In fungi, inhibition of germination, spore swelling, mycelial growth and sporulation has been demonstrated. In viruses, the main targets for glutaraldehyde are thought to be nucleic acid, proteins and envelope constituents. The established reactivity of glutaraldehyde with proteins suggests that the viral capsid or viral-specific enzymes are vulnerable to glutaraldehyde treatment.

5.5 Limitations on efficacy including resistance

5.5.1 General limitations
No limitations are mentioned.

5.5.2 Resistance
Given the combination of two active substances with different modes of action no resistance management strategy is necessary.

5.5.3 Resistance management strategies

No management strategy is necessary.

5.6 Overall conclusions of efficacy

Based on the data submitted and considering that the evaluation is done under article 121 of the WGB, it can be concluded that MS Megades Novo, when used in accordance with the proposed label (WG/GA), is effective in controlling

- bacteria (excluding mycobacteria and bacterial spores), yeasts and fungi on hatching eggs in hatcheries;
- bacteria (excluding mycobacteria and bacterial spores) and yeasts on surfaces and equipment in places where food and beverages are prepared and stored, excluding milking equipment on the farm.

6 Human toxicology

BKC

The active substance Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (BKC) is considered to be structurally identical to the substance benzyl-(C8-18)-alkyldimethyl, chlorides (ADBAC). The List of Endpoints below is taken from the combined LOEPs on ADBAC-BKC (BPC-11 June 2015) Where relevant, some additional remarks/information are given in italics.

List of endpoints

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	**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 can be considered approximately 10%, based on the administered dose eliminated via urine, bile and tissue residues, in two independent studies from the two applicants. The oral absorption value of 10 % at non-corrosive concentrations. **(US ISC; EQC)**
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%). The dermal absorption value has to be considered of 10 % at non-corrosive concentrations. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION**: 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 both tested concentrations (i.e., at non-corrosive concentrations) **(US ISC; EQC)**
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:** <2000 mg/kg bw **(Literature data provided by EQC)**

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 **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available, but expected to be corrosive **(US ISC; EQC)**
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. Rat study **(US ISC; EQC)** Mouse study **(US ISC)**

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)**
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 $C_{12\text{-}16}$-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 $C_{12\text{-}16}$-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	**0.3%**	2-week skin irritation study with rats **(US ISC)**
Oral NOAEC	Not data available	

Summary for systemic effects

Value	**Study**	**Safety**

			factor
$AEL_{long\text{-}term}$	Not relevant		
$AEL_{medium\text{-}term}$	Not relevant		
$AEL_{short\text{-}term}$	Not relevant		
ADI*	Not applicable		
ARfD	Not applicable		

* 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** $C_{12\text{-}16}$-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 $C_{8\text{-}18}$-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**

	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%. **(US ISC)**

Data requirements
No additional data requirements are identified.

Local respiratory effects and determination of local Acceptable Exposure Level (AEC_{local})
BKC is considered to be structurally identical to ADBAC. For ADBAC the primary effects are the local effects, hence for the risk assessment of ADBAC it is more relevant to take into account the concentration of the active substance on the skin than the dose expressed in mg/kg bw/day (systemic effects). Due to its corrosive properties, ADBAC produces local effects after a single exposure (skin and eye irritation) and repeated exposure (GI-tract irritation). Therefore local acceptable exposure levels (AEC_{local}) will be determined.

$NOAEC_{local\ dermal}$
In the 2-week skin irritation study with rats, no systemic effects were observed and the NOAEL for local effects has been set at 6 mg/kg bw/day (0.3% ADBAC).
Based on this the $NOAEC_{local\ dermal}$ is set at 0.3% ADBAC (see harmonised LOEPs).

$AEC_{local\ inhalation}$
Recent data on acute inhalation exposure to ADBAC indicate an LC_{50} value of 53 mg/m^3 in rats (4h nose only exposure)[1]. In addition, a NOAEC of 0.049 mg/m^3 was derived in an experiment where mice were exposed head only during 45 minutes. Effects included a concentration dependent decrease in tidal volume (>15%) and decreased respiratory rate at 0.23 mg/m^3 as well as an increase of inflammatory cells (neutrophils and alveolar macrophages in bronchial lavage fluid) at 19 mg/m^3)[2].
In the EPA RED document of ADBAC, an LC_{50} of > 54 mg/m^3 and < 510 mg/m^3 was reported. Furthermore, the EPA RED concluded that an inhalation AEC might be derived based on the NOAEL of 2.4 mg/kg bw/day based on hyperactivity and laboured breathing at 7.3 mg/kg bw/day in an oral developmental toxicity study in rabbits (also included in the endpoint list of ADBAC). However, local effects are not considered in this study, and therefore, this route-to-route extrapolation seems not appropriate.

Based on the available LC_{50} values and applying a safety factor of 100 based on the limited information available (only LC_{50}) with in addition a factor of 3 to account for extrapolation from lethal to non-lethal affects, the calculated AEC would be 0.18 mg/m^3. Taking the NOAEC of 0.049 mg/m^3 without an additional safety factor, the AEC for local effects after inhalation is set at 0.049 mg/m^3.

In view of the above considerations the $AEC_{local\ inhalation}$ is set at 0.049 mg/m^3 in a worst case approach.

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

List of endpoints

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

Rate and extent of oral absorption:	Approx. 37 to 51% for both sexes depending on dose level and method of calculation (measured as radioactivity of ^{14}C labeled GA). Oral absorption of 40% is proposed for estimating the systemic dose.

Rate and extent of dermal absorption:	10% is proposed based on the weight of evidence.
Distribution:	All organs and tissues (radioactive label).
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Rapid and almost complete, independent of sex
Toxicologically significant metabolite	Metabolites are poorly known, but non expected to be toxicologically significant.

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	77 mg/kg bw for pure substance; H301
Rabbit LD_{50} dermal	> 1000 mg/kg bw for pure substance; highly dependent on concentration
Rat LC_{50} inhalation	0.28 mg/L in male rats and 0.35 mg/L in female rats; H330
Skin irritation	Corrosive; Skin Corr. 1B, H314
Eye irritation	Corrosive; H314
Skin sensitisation (test method used and result)	Sensitizing; guinea pig maximization test; H317

Repeated dose toxicity (Annex IIA, point 6.3)

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

Genotoxicity (Annex IIA, point 6.6)

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

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	Large Granular Lymphocytic Leukaemia in female rats Testis Leydig cell adenomas in male rats

lowest dose with tumours	LGLL: 5.5 mg/kg wbd/ay (2-year oral study, not treatment related) Leydig cells: 3.5 mg/kg bw/day (2 year oral study)

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	1. Increased resorption rate, increased post-implantation losses, reduction in mean placental weights (teratogenicity study in rabbits) 2. Testes Leydig cell hyperplasia, cystic degeneration (2-year oral study in Wistar rats) 3. Testes consistency changes (2-year oral study in Fischer 344 rats) 4. Diffuse degeneration of the testes (1-year oral study in Wistar rats)
Lowest relevant reproductive NOAEL / LOAEL	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 NOEClocal dermal of 0.2% (without additional assessment factors) will be used.*

Data requirements
No additional data requirements are identified.

6.1 Human exposure assessment active substance

6.1.1 General aspects

MS Megades Novo is a liquid concentrate containing 9.8% ADBAC and 14.7% glutaraldehyde as active substances. MS Megades Novo has already been authorised in the Netherlands (14896 N) for PT3: use against bacteria, yeasts, fungi and viruses in animal housing facilities and adjacent areas.

The current application concerns an extension of use for MS Megades Novo for disinfection of surfaces and materials where feed is prepared, handled and stored (PT4) and disinfection of hatching-eggs (PT3).

The maximum dosage for the already authorised use is 0.75% MS Megades Novo in water (7.5 mL diluted to 1 L water), resulting in the maximal concentrations of ADBAC and glutaraldehyde of 0.07% and 0.11%, respectively. The maximum dosage for the current application for extension of use is 3% MS Megades Novo in water (30 mL diluted to 1 L water), resulting in the maximal concentrations of ADBAC and glutaraldehyde of 0.29% and 0.44%, respectively.

The formulation MS Megades Novo is intended for professional use only.

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

The professional user can be exposed to active substances ADBAC and glutaraldehyde during mixing and loading and application of MS Megades Novo via coarse spraying. As the vapour pressure of ADBAC is very low (6.03 x 10-4 Pa at 20 ºC), and its Henry's law constant is also very low (5.03 x 10-7 Pa x m3/mol at 20 ºC), indicating poor partitioning from aqueous solution, respiratory exposure to ADBAC is considered to be negligible. This is also shown by the following calculation:
The inhalation exposure to ADBAC during the application via coarse spraying was estimated using the Spraying Model 2 (User Guidance v.1, 2002, P. 30). The indicative value for inhalation exposure is 76 mg/m3. Considering the total concentration of ADBAC in the in-use dilution of MS Megades Novo of 0.44%, this corresponds to the total concentration of ADBAC in air of 0.33 mg/m3. This concentration is above the AEClocal inhalation of 0.049 mg/m3 for ADBAC. However, the AEClocal inhalation has been set based on the observed effects in the lungs of laboratory animals (effects on tracheobronchial and pulmonary regions), caused by exposure to particles/droplets in the thoracic (≤ 10 µm) and respirable range (≤ 4 µm). These particles are not expected to be formed during the application by coarse spraying. In addition, ADBAC is not volatile. Therefore no adverse effects are expected due to the respiratory exposure to ADBAC during the application by coarse spraying.
For glutaraldehyde both dermal and respiratory exposures are possible.
As the MS Megades Novo is intended for professional use only, oral exposure is considered negligible.

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

The formulation MS Megades Novo is intended for professional use only.

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

During application of the formulation MS Megades Novo by coarse spraying secondary respiratory bystander exposure may occur. However, this exposure is expected to be lower than direct exposure of a professional user applying the formulation by coarse spraying (PT3 and PT4). The applicant has indicated that the treated surfaces need to be washed thoroughly after the treatment (PT4). Based on this, secondary dermal exposure for the general public including children by touching treated surfaces is not envisaged. Similarly, no secondary exposure of animals by licking or touching treated surfaces is expected.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

The current classification and labelling of the formulation cannot be maintained since with the current extension of use also includes a modification of the composition. No studies with MS Megades Novo 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 *General*

The current application is an extension request of MS Megades Novo, which is currently authorised for surface disinfection in animal stables and annexes (PT03). The extension of the authorisation request includes the disinfection of surfaces and materials were feed is prepared, handled or stored (PT04) and to be used for the disinfection of hatching eggs in hatcheries (PT04).

6.3.2 *Professional users*

The current application includes the disinfection of surfaces and materials were feed is prepared, handled or stored (PT4) at a dosage of 0.25% MS Megades Novo for which mixing, loading and application by spraying is a relevant exposure scenario for the professional user.

The pH of the undiluted product does not trigger classification. Local dermal exposure to ADBAC and glutaraldehyde can occur during mixing and loading of MS Megades Novo and during application by coarse spraying. During mixing and loading, the professional user is dermally exposed to the concentrate (containing 9.8% w/w ADBAC and 14.7% w/w glutaraldehyde), and during the application the professional user is dermally exposed to the calculated maximum dosing of 0.25% MS Megades Novo (equal to 0.02% w/w ADBAC and 0.04% w/w glutaraldehyde).
For ADBAC the $NOAEC_{local\ dermal}$ of 0.3% will be considered, and for glutaraldehyde the $NOAEC_{local\ dermal}$ of 0.2% will be considered. For the exposure to the concentrated product, the $NOAEC_{local\ dermal}$ for both actives is exceeded. The exposure to the maximum calculated in-use dilution for both actives is below the $NOAEC_{local\ dermal}$. In conclusion, gloves and coverall are prescribed for the professional user during mixing and loading.

For glutaraldehyde both dermal and respiratory exposures are relevant to determine the systemic exposure, whereas for ADBAC only local risk characterisation is considered relevant.

To estimate systemic dermal and respiratory to glutaraldehyde during the application of the in-use dilution of MS Megades Novo MS by low pressure and coarse spraying, Spraying Model 1 is considered to be applicable. This model also includes mixing and loading step; therefore no separate assessment of mixing and loading was performed, as it is considered to be covered by Spraying Model 1. The concentration glutaraldehyde in the 0.25% MS Megades Novo in-use solution is 0.04%. The indicative exposure values are 181 mg/min for potential hand exposure, 92 mg/min for potential body exposure, 104 mg/m^3 for respiratory exposure. The exposure duration for professional users is considered to be 3 hours/day. To estimate the systemic dermal and respiratory exposure to glutaraldehyde during hand-held trigger spray the consumer spraying and dusting model 2 was used. Since this model does not contain a mixing and loading scenario, additional calculations were made using the Mixing and Loading Model 4. For mixing and loading, the indicative value of 0.01 ml-treatment for handling 1 L is used. As a 0.25% solution is used for disinfection in the food and feed area, meaning handling 1 L concentrate lead to a total of 400L in-use solution. This is considered worst case, and therefore only one mixing and loading per day is calculated. For the respiratory exposure during mixing and loading the ConsExpo model evaporation – constant rate was used. The results of exposure estimates are presented in the table below.

Table T1. Internal professional operator exposure to glutaraldehyde and risk assessment during spraying with 0.25% Megades Novo MS (PT4)

	Route	Estimated local exposure (mg/kg bw/day)	Systemic AEL (mg/kg bw/day)	%AEL[a]
Low pressure/ coarse spraying, including mixing/loading, no PPE[c]				
	Dermal[b]	0.033	0.014	234
	Respiratory	0.003	0.014	19
	Total	0.035	0.014	253
Low pressure/ coarse spraying, including mixing/loading, PPE (coverall and gloves)[c]				
	Dermal	0.002	0.014	17
	Respiratory	0.003	0.014	19
	Total	0.005	0.014	36
Hand-held trigger spraying, including mixing/loading, no PPE				

	Route	Estimated local exposure (mg/kg bw/day)	Systemic AEL (mg/kg bw/day)	%AEL[a]
Mixing/loading	Dermal[b, d]	0.003	0.014	21
	Respiratory[e]	0.003	0.014	21
Spraying[f]	Dermal[b]	0.0004	0.014	3
	Respiratory	<0.0001	0.014	<1
Mixing/loading and spraying	Total	0.0064	0.014	45

a The %AEL is calculated by dividing external exposure by external AEL, multiplied by 100
b A dermal absorption default value of 10% was used derived from the LOEP
c Exposure estimates were made using Spraying Model 1
d Exposure estimates were made using Mixing and Loading Model 4
e Exposure estimates were made using ConsExpo Web version , evaporation – constant rate
f Exposure estimates were made using Consumer spraying and dusting model 2, trigger spray

Based on this, adverse systemic and local effects after exposure to glutaraldehyde cannot be excluded for low pressure/ coarse spraying for the unprotected professional user. However, for the protected professional user wearing gloves and protective clothing the exposure to glutaraldehyde is considered acceptable. The exposure to glutaraldehyde during trigger spraying is considered acceptable for the unprotected user.

In addition to the use in the food and feed area, the current extension of use concerns the disinfection of eggs in hatcheries (PT3) at a dose of 3% MS Megades Novo. For this application, only mixing and loading is considered a possible exposure scenario as application is generally performed automatically. Moreover, during the original authorisation, spraying of a 3% formulation was not considered acceptable for the protected professional user wearing gloves, protective clothing, respiratory protective equipment. In order to avoid possible dermal and respiratory exposure during the treatment in egg hatcheries (PT3) by spraying, the following sentence will be added to WG/GA: “No people may be present in the facilities during the treatment”.

To estimate systemic dermal and respiratory to glutaraldehyde during mixing and loading of the produced intended for the use in egg hatcheries, Mixing and Loading model 7, pouring and pumping liquids is considered to be applicable. The concentration glutaraldehyde is 14.7% in MS Megades Novo. The indicative exposure values are 101 mg/min for potential dermal exposure and 0.94 mg/m^3 for respiratory exposure. The exposure duration for professional users is considered to be 10 min/day. The results are presented in Table 2.

Table T2. Internal professional operator exposure to glutaraldehyde and risk assessment during mixing and loading of a 3% Megades Novo MS formulation

	Route	Estimated local exposure (mg/kg bw/day)	Systemic AEL (mg/kg bw/day)	%AEL[a]
Mixing and loading, no PPE[c]				
	Dermal[b]	0.25	0.014	1768
	Respiratory	<0.001	0.014	3
	Total	0.25	0.014	1770
Mixing and loading, PPE (coverall and gloves)[c]				
	Dermal	0.002	0.014	18
	Respiratory	<0.001	0.014	3

	Route	Estimated local exposure (mg/kg bw/day)	Systemic AEL (mg/kg bw/day)	%AEL[a]
	Total	0.003	0.014	21

a The %AEL is calculated by dividing external exposure by external AEL, multiplied by 100
b A dermal absorption value of 10% was used derived from the LOEP
c Exposure estimates were made using Mixing and Loading model 7, pouring and pumping liquids

Based on this, adverse systemic and local effects after exposure to glutaraldehyde cannot be excluded for mixing and loading for the unprotected professional user. However, for the protected professional user wearing gloves and protective clothing the exposure to glutaraldehyde is considered acceptable. The use of these personal protective equipment is also considered necessary based on the local effects (see above).

6.3.3 Non-professional users, including the general public

The formulation MS Megades Novo is intended for professional use only.

6.3.4 Indirect exposure as a result of use

The applicant has indicated that treated surfaces need to be rinsed thoroughly with water after the treatment as PT4. Therefore no concern for secondary dermal exposure is expected. For the use of MS Megades Novo in hatcheries (PT3) rinsing with water is not recommended after eggs are treated. According to the proposed WG/GA, treated eggs can be left to dry, meaning that residue of the active substances may be found on the treated eggs. However, considering that hatching eggs are disinfected which are placed in a disinfection room, secondary exposure by persons other than the professional worker are considered unlikely. ADBAC is not volatile. Therefore no adverse effects are expected due to the respiratory exposure to ADBAC. Although secondary exposure to glutaraldehyde would be possible, the air in the disinfection room should be refreshed using a ventilation system after the eggs have dried. Therefore, respiratory exposure to both active substances is considered negligible. To avoid persons entering the room before ventilation, the following sentence will be added to WG/GA: “it is not allowed to enter the disinfected zone before the drying process and ventilation have been completed.”. Moreover, dermal exposure is considered negligible since the aim of disinfecting the eggs is to reduce the level of bacteria, yeast and fungal spores into the hatchery while touching the eggs might result in (re-)contamination of the eggs, and therefore when handling disinfected eggs it is assumed that gloves are worn. Nevertheless, dermal contact to residues by unprotected workers will be assessed.
The maximum concentration of MS Megades Novo to be used in egg hatcheries is 3%. The re-entry time to allow surfaces to dry is 20 minutes, therefore the professional user can be dermally exposure to residues on dry eggs. Taking into account that the transfer coefficient of dried liquid from different types of surfaces is 18% (TNsG 2002, p. 204)this would result in the maximal concentrations of ADBAC and glutaraldehyde of 0.05% and 0. 07%, respectively. These values are below the NOEClocal dermal of 0.3% and 0.2% for ADBAC and glutaraldehyde, respectively. Therefore, no local effects are expected following the secondary exposure to MS Megades Novo at a maximum concentration of 3%. In addition to local effects, also systemic effects are possible following exposure to glutaraldehyde.

The dermal exposure was determined assuming that the product contains 0. 4% glutaraldehyde, that a layer of 0.01 cm is applied with a product density of 960 mg/cm^3, that 100% of the hand are contaminated as a worst case, that the transfer efficiency of dry product is 18% (TNsG 2002), and an area of the hand equal to 820 cm^2 (HEEG 2013). A dermal absorption of 10% was used which was derived from the list of endpoints for glutaraldehyde.

Table T1. Secondary exposure to glutaraldehyde and risk assessment

Route	**estimated internal exposure**	**systemic AEL**	**% AEL**

	(mg/kg bw/day)	(mg/kg bw/day)	
dermal	0.009	0.014	61

Based on the calculations made, the secondary exposure to glutaraldehyde by unprotected professional workers is considered acceptable. However, a sentence was added by the applicant on the WG/GA that gloves should be worn during activities with the trays in which the eggs can be placed, thus further reducing the dermal exposure.

The indirect secondary respiratory exposure as a result of use in the food and feed area by spraying was evaluated during the original authorization.

For secondary respiratory exposure of bystanders , a concern has been identified for professional users applying the formulation by coarse spraying in egg hatcheries using 3% MS Megades Novo. Therefore adverse effects after respiratory exposure of bystanders can also not be excluded. However, it is very unlikely that bystanders will be present during treatment in a disinfection room. Moreover, in order to avoid possible respiratory exposure during the treatment to the professional user, the following sentence will be added to WG/GA: “No people may be present in the facilities during the treatment”. This also prevents any potential secondary exposure to bystanders.

6.3.5 Combined exposure

The formulation MS Megades Novo is a mixture of 2 active substances. The combined toxicological effect of these two active substances was already evaluated during the original authorisation and it was concluded that as the risk assessment is based on local effects of both active substances, the principle of addition has been applied, as is also reflected in the classification of the formulations.

6.3.6 Substances of concern

The formulation MS Megades Novo does not contain potential substances of concern.

6.4 Overall conclusions for the aspect human health

Based on this risk assessment, it was concluded that no adverse health effects are expected for the protected (gloves and suitable protective clothing) professional user after dermal and respiratory exposure to ADBAC and glutaraldehyde as a result of the application of MS Megades Novo, when used in accordance to the WG/GA. Furthermore, to protect the professional user during the use of MS Megades Novo in egg hatcheries and to avoid possible bystander exposure during the treatment, the following sentences will be added to WG/GA: “No people may be present in the facilities during the treatment” and “it is not allowed to enter the disinfected zone before the drying process and ventilation have been completed.”.

Taken these restrictions into consideration, no adverse health effects are expected for the general public after dermal and respiratory exposure to ADBAC and glutaraldehyde by the use of MS Megades Novo.

The current classification and labelling of the formulation cannot be maintained since with the current extension of use also a modification of the composition was applied.

7 Environment

7.1 Introduction

MS Megades Novo containing alkyl dimethyl benzyl ammonium chloride (ADBAC) and glutaraldehyde as active substances is currently authorised (14896 N) for the disinfection of animal housing, including tools and equipment (PT03).
The current request for authorisation concerns an extension to disinfection of surfaces which can have direct contact with food, feed, or beverages excluding milking parlour systems on farms (PT04). The biocidal product is for professional use. The intended use (extension) is described in Table E.1.

Table E.1. Intended use (extension), dose, and use concentrations of the active substances.

Area of use envisaged	Concentration active substances in product (g/L)		Dosage product (mL/L water)	Use concentration active substances in diluted product (g/L)	
	ADBAC	Glutaraldehyde		ADBAC	Glutaraldehyde
Disinfection of surfaces which can have direct contact with food, feed, or beverages excluding milking parlour systems on farms by spraying (PT04)	100	147	2.5 mL/L water	0.25	0.37

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. The data for the active substances applied in the current risk assessment are presented in appendix I.

7.3 Environmental exposure assessment

7.3.1 Chemistry and/or metabolism

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. A monitoring study (Clara *et al*, 2007) conducted in nine Austrian sewage treatment plants (STPs) demonstrated that quaternary ammonium compounds are effectively removed from waste water (98.5% removal). Metabolites of ADBAC are not formed > 10% in all environmental compartments.

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.

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. The adsorption is considered to be irreversible as no desorption could be observed in the test.

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

7.3.2 Distribution in the environment

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

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

Main scenario	Environmental compartments exposed				
	STP	Freshwater[1]	Saltwater[1]	Soil[2,3]	Air
Disinfection of surfaces which can have direct contact with food, feed, or beverages excluding milking parlour systems on farms by spraying (PT04)	++	+	-	-	- (Q)

++ Compartment directly exposed, + Compartment indirectly exposed, (Q) Qualitative assessment, depending on application, 1 Including sediment, 2 Including groundwater, and soil invertebrates and arthropods, 3 In the Netherlands, surplus sludge of public STPs is not applied for fertilization and soil improvement of agricultural soil. Therefore, exposure of soil and groundwater via STP surplus sludge application is not part of the risk assessment.

After the application of the product on surfaces the remaining product will mostly end up in the sewer after cleaning the treated surfaces. Residues that are released to the sewer can enter the aquatic environment via an STP. Application of sewage sludge as a soil fertiliser 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.
Food and drink industries are equipped with air filter systems to prevent release of odour and microbes to the outside air. Thus, the biocide emission to outside air is limited.

7.3.3 Predicted environment concentration calculations

7.3.3.1 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, volume IV (distribution in the environment), and the model SimpleTreat (concentrations for micro-organisms in a STP and the STP's effluent) by using the default values for parameters, unless otherwise noted. Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substances are added are disposed as solid waste and usually incinerated. Possible pH effects on the environment were not considered, because the STP and receiving compartments are expected to have sufficient buffering. The applied methods are explained below. The risk assessment is based on the active substance's physical-chemical properties as listed in appendix I and the concentrations as listed in Table E.1.

Monitoring data demonstrated that STPs effectively remove ADBAC and other quaternary ammonium compounds from waste water (Clara et al., 2007). Concentrations in surface water of ADBAC and DDAC were therefore based on monitoring data (98.5% removal) instead of the distribution over sewage sludge, air, and water by SimpleTreat.

Because sewage sludge is not applied as a soil fertiliser in The Netherlands, emission to soils is negligible. No PECs were therefore calculated for soils and groundwater for this type of use.

7.3.3.2 Disinfection of surfaces which can have direct contact with food, feed, or beverages excluding milking parlour systems on farms (PT04)

Predicted environmental concentrations (PECs) were calculated according to the exposure scenarios described in the ESD for PT04 (final draft, January 2011) by applying the scenarios for large scale catering kitchens, canteens and slaughterhouses. 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). However, not all food processing facilities will have a grease and sediment separation tank. Therefore the risks have been calculated without a sediment and grease separation tank. The effect of the grease separation is a 90% reduction in the emission to the STP.

7.4 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, volume IV. The PNECs based on the ecotoxicological data applied for the current risk assessment are presented in **Fout! Verwijzingsbron niet gevonden.**.

Table E.3. Predicted no-effect concentrations for ADBAC 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)
fresh water	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). Daphnias are most sensitive
sediment	NOEC: 520 mg/kg dwt	100	1.13 mg/kg wwt	*Chironomus tentans* study
soil	EC_{10}: 74 mg/kg wwt	100	0.74 mg/kg wwt	C12-16-ADBAC was tested on soil dwelling invertebrates, micro-organisms and plants. Soil micro-organisms are most sensitive
Glutaraldehyde				
STP	EC_{50}: 51 mg/L	100	0.51 mg/L	EC_{50} from a respiration inhibition study
fresh water	NOEC: 0.025 mg/L	10	2.5 µg/L	Three trophic levels. Based on the lowest NOEC for algal growth inhibition
sediment	No studies available. Emission to sediment is not expected considering glutaraldehyde's low hydrophobicity (Log K_{ow} is -0.33)			
soil	EC_{10}: 9.2 mg/kgwwt	50	0.184 mg/kg wwt	Carbon transformation test. PNEC is based on initial concentrations.

Note that data on sediment organisms is not available for glutaraldehyde and therefore have to be derived from aquatic data by applying equilibrium partitioning. However, $PEC_{sediment}$ is also derived by using equilibrium partitioning from $PEC_{freshwater}$ and therefore the ratio PEC:PNEC for freshwater covers that of sediment as well. Calculation of $PEC_{sediment}$ is therefore not included in the current risk assessment. However, adsorption to sediment is not expected as the active substance is not hydrophobic.

7.5 Risk characterisation for the environment

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

7.5.1 Aquatic compartment (incl. sediment) and STP

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

The risk characterisation for the aquatic compartment (freshwater and sediment) indirectly exposed via a STP are presented in
Table E.**4**.

The risks are based on disinfection of surfaces in slaughterhouses and large canteens where waste water is treated in a grease and sediment separation tank before being discharged to the sewer. These facilities are mandatory at slaughterhouses (Besluit algemene regels voor inrichtingen milieubeheer). An additional removal of 90% in the STP is therefore included.

Table E.4. PEC and PEC/PNEC ratios for micro-organisms in the STP and freshwater indirectly exposed due to disinfection of surfaces which can have direct contact with food, feed, or beverages excluding milking parlour systems on farms (PT04)

	STP		Fresh water		Sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)[1]	PEC/PNEC	PEC (mg/L)	PEC/PNEC
ADBAC						
Disinfection of surfaces which can have direct contact with food, feed, or beverages excluding milking parlour systems on farms (PT04)						
Without on-site-pre-treatment						
large scale canteens	3.75E-04	0.005	7.52E-06	0.018	4.35E-01	0.385
slaughterhouses	1.88E-03	0.024	3.76E-05	0.091	2.17E+00	**1.92**
combined	2.25E-03	0.029	4.51E-05	0.109	2.61E+00	**2.31**
With on-site-pre-treatment						
large scale canteens	3.75E-05	<0.001	7.52E-07	0.002	4.35E-02	0.038
slaughterhouses	1.88E-04	0.002	3.76E-06	0.009	2.17E-01	0.192
combined	2.25E-04	0.003	4.51E-06	0.011	2.61E-01	0.231
Glutaraldehyde						
Disinfection of surfaces which can have direct contact with food, feed, or beverages excluding milking parlour systems on farms (PT04)						
Without on-site-pre-treatment						
large scale canteens	4.56E-03	0.009	4.56E-04	0.182	3.59E-03	0.182
slaughterhouses	2.28E-02	0.045	2.28E-03	0.911	1.79E-02	0.911
combined	2.74E-02	0.054	2.73E-03	**1.09**	2.15E-02	**1.09**
With on-site-pre-treatment						
large scale canteens	4.56E-04	<0.001	4.56E-05	0.018	3.59E-04	0.018
slaughterhouses	2.28E-03	0.004	2.28E-04	0.091	1.79E-03	0.091
combined	2.74E-03	0.005	2.73E-04	0.109	2.15E-03	0.109
Total both active substances (without on site-pre-treatment)	2.97E-02	0.08	2.78E-03	**1.20**	2.63E+00	**3.4**
Total both active substances (with on site-pre-treatment)	2.97E-03	0.01	2.78E-04	0.12	2.63E-01	0.3

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

The application of MS Megades Novo results in unacceptable risks as PEC:PNEC >1 in the freshwater and sediment compartment as ADBAC is highly adsorptive. A PEC:PNEC ratio above one is acceptable provided that the slaughterhouses' and large scale canteens' waste water is led through a grease separation tank prior to discharge to the sewer. A risk mitigation will be added to the WG/GA.

7.5.1.2 Monitoring data (surface water)

Dutch water boards have a well-established programme for monitoring pesticide contamination of surface waters for which the results are publicly available on-line (www. bestrijdingsmiddelenatlas.nl). Here, monitoring data are processed in a graphic format aiming to provide an insight into measured pesticide contamination of Dutch surface waters against

environmental standards. The Pesticide Atlas was used to evaluate measured concentrations of pesticides in Dutch surface water, but no data are available regarding the presence of the active substances ADBAC and glutaraldehyde in Dutch surface water.

7.5.1.3 Surface water intended for the abstraction of drinking water

Biocidal products with the active substances ADBAC and glutaraldehyde have been on the market for more than three years. The existing active substances 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 (2015). In addition, ADBAC and glutaraldehyde are not included in the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010), but the RIVM recommends to include quaternary ammonium compounds in general. 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 no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. Thus the standards for surface water destined for the production of drinking water are met.

7.5.2 Terrestrial compartment

7.5.2.1 Soil organisms

For the intended use of the product, emission of the active substance to soil is not expected. Direct exposure is negligible for bees as the product is used indoors. The exposure of non-target arthropods and soil organisms (including bees) to the active substances is therefore deemed negligible. Hence, the risk for soil organisms and non- target arthropods (including bees) is considered acceptable for the intended uses.

7.5.2.2 Non-target arthropods (including bees)

The risk assessment to arthropods is considered to be similar to soil organisms due to their direct contact with soils. The standards for soil arthropods are therefore met. Because the active substances are expected to have a non-systemic mode of action, secondary exposure of bees through pollen is considered negligible. Hence, the risk for bees is considered acceptable for the active substances.

7.5.2.3 Groundwater

Assessment of the drinking water criterion defines that the concentration of the active substances and the relevant metabolites in groundwater for the preparation of drinking water needs to be < 0.1µg/L. In The Netherlands, the application of sewage sludge as a soil fertilizer is not foreseen. Therefore, no biocides are discharged to the soil compartment along with sewage sludge. Direct emission to soils is not foreseen as well as residues are predominantly discharged to the sewer. Therefore, application of the product according to the instructions of use will not result in unacceptable risks for the groundwater compartment.

7.5.2.4 Persistence in soil

The half-lives of ADBAC and glutaraldehyde in soils (see appendix I) do not exceed the criteria for persistence in soils (180 days). The standard for persistence in soils is therefore met.

7.5.3 Non compartment specific effects relevant to the food chain

7.5.3.1 Bioconcentration

ADBAC is a surfactant and therefore a normal K_{ow} could not be established. An experimental BCF (whole fish) is determined at 79 L/kg, indicating that ADBAC has a low potential for bioaccumulation.

As the log K_{ow} of glutaraldehyde is < 3 (see appendix I) and the active substance is not highly adsorptive (K_{oc} <20000 L/kg in sediment and/or 50000 L/kg in soils), bioconcentration is not expected

according to the trigger values presented in the guidance on biocide legislation, Part B, volume IV. The risk for bioconcentration of the proposed uses is therefore considered not relevant. The standards for bioconcentration are met and no further assessment of secondary poisoning is deemed necessary.
Hence the product meets the standards for bioaccumulation.

7.5.3.2 Primary and secondary poisoning of birds and mammals
The low BCFs (see above) indicate that the risk for birds and mammals is low regarding secondary poisoning. Hence the product meets the standards for the risk to birds and mammals. Primary poisoning is not expected for the intended uses.

7.5.4 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 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 the following half-lives in air (OH timeframe 24 hrs/day, 0.5×10^6 OH radicals/cm^3):

- ADBAC: 8.8 hours
- Glutaraldehyde: 8.2 hours

The calculated half-lives are below the trigger of 2 days, which is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. The environmental risk to air is therefore considered acceptable.

7.6 Measures to protect the environment (risk mitigation measures)
The following risk mitigation for the authorised application (14896 N)) of MS Megades Novo for the disinfection of animal housing, including tools and equipment (PT03) was already included in the WG/GA:
EN: To prevent the inhibition in functioning of an on-site wastewater treatment system (IBA), possible residues containing the product must be discharged to the slurry pit.

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

No new risk mitigation measures where proposed by the applicant. No risks were identified for the aquatic compartment provided that an extra on-site STP for the disinfection of surfaces which can have direct contact with food, feed, or beverages excluding milking parlour systems is taken into account. Therefore additional measures to protect the environment (restrictions and risk mitigation measures) are required (see next section).

7.7 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), MS Megades Novo complies with the environmental standards and will not cause unacceptable effects to the environment provided that waste water coming from food and feed industries, kitchens, canteens, etc. is led through a grease separation tanks prior to final discharge to the sewer. The following risk mitigation measure must be additionally added to the WG/GA:

> EN: To protect water living organisms, residues containing the product should be discharged to the sewer connected to the STP. When discharged to a municipal STP the sewer connection must be preceded by a sediment grease separation tank conform NEN-EN 1825-1 and 1825-2 and/or a biological or chemical pre-treatment.

NL: Om in het waterlevende organismen te beschermen dienen resten die het middel bevatten te worden geloosd naar het riool met aansluiting op de RWZI. Bij afvoer naar een gemeentelijke RWZI is een vetafscheider en slibvangput conform NEN-EN 1825-1 en 1825-2 en/of een biologische of chemische voorzuivering verplicht.

7.8 Data requirements

There are no additional data required.

8 Conclusion

The applicant has proven that MS Megades Novo 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

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Glutaraldehyde (111-30-8), alkyl dimethylbenzyl ammonium chloride (68424-85-1), formic acid (64-18-6)			
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.	
	P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].	
	P304+P341	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/...
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 the product is assigned with EUH071, H335 is omitted in accordance to the labelling guidance.
P-statements:	P-statements proposed by the applicant were granted. Based on the risk assessment gloves, coverall and respiratory equipment are assigned.
Other:	-

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

10 References

Bakker, J. Biociden in oppervlaktewater voor drinkwaterproductie, National Institute of Public Health and the Environment, RIVM report [redacted], 2010, Bilthoven, The Netherlands.
Clara, M., Scharf, S., Scheffknecht, C., and Gans, O. 2007. Occurrence of selected surfactants in untreated and treated sewage. Water Research 41, 4339-4348
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, 2015 http://www.vewin.nl/probleemstoffen
Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, JRC Scientific and Technical Reports, Report nr. EUR 25116 EN, Publications Office of the European Union, Luxembourg, 2011
Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, JRC Scientific and Technical Reports, Report nr. EUR 25117 EN, Publications Office of the European Union, Luxembourg, 2011
Regulation (EC) No 1005/2009 of the European Parliament and the Council of 16 September 2009 on substances that deplete the ozone layer.
Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017.

Appendix I. Input parameters for 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)	2658607	The average Koc for sand, sandy loam, clay loam, silt loam.
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)	76	
half-life for leaching from soil (days)		
rate constant for biodegradation in STP (/d)	not relevant	Data for ADBAC is available demonstrating that an STP effectively removes 98.5% of the active ingredients from the waste water (monitoring study for several municipal STPs, Clara et al., Water Research 41, 4399-4348).
half-life in air (hrs)	8.8	Estimated with AOPwin (OH timeframe 24 hrs/day, 0.5×106 OH radicals/cm³)

parameter	value	remarks
	Glutaraldehyde	
molecular weight (g/mole)	100.11	
melting point (°C)	-33	Compound is a liquid at environmental temperature.
vapour pressure at test temperature (Pa)	44	Pure substance
test temperature vapour pressure (°C)	20	
solubility at test temperature (mg/L)	miscible ≥ 51.3 g/100ml	
test temperature solubility (°C)	20.2+/- 0.1 °C 21 °C	
Henry constant (Pa × m^3 × mol^{-1})	0.0086	calculated
test temperature Henry constant (°C)	-	

parameter	value	remarks
	Glutaraldehyde	
octanol-water partition coefficient (L/kg)	0.47	
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 (/d)	24	Default value for readily biodegradable compounds

Rijksinstituut voor Volksgezondheid
en Milieu
*Ministerie van Volksgezondheid,
Welzijn en Sport*

Ministerie van Infrastructuur en Waterstaat
Directie Veiligheid en Risico's

A. van Leeuwenhoeklaan 9
3721 MA Bilthoven
Postbus 1
3720 BA Bilthoven
www.rivm.nl

KvK Utrecht 30276683

T 030 274 91 11

F 030 274 29 71
info@rivm.nl

memo

Datum
12 februari 2019

Behandeld door
[redacted]
VSP/MSP

T 4706
[redacted]@rivm.nl

Toelichting over de ZZS-toets voor mengsels en stoffen met ZZS-bestanddelen

Introductie

Deze memo beschrijft de technische criteria om mengsels en stoffen die één of meerdere ZZS bevatten wel of niet als ZZS te behandelen. Deze criteria zijn afkomstig van de internationale wettelijke kaders die gebruikt worden voor de identificatie van ZZS.
Deze memo is relevant in het kader van het ZZS emissie beleid volgens het Activiteitenbesluit en de Activiteitenregeling[1].

Context

De REACH- en CLP-verordeningen (EG 1907/2006 en EG 1272/2008) en de definitie van Zeer Zorgwekkende Stoffen (ZZS) zijn de centrale uitgangspunten in deze toelichting. Uiteraard ligt de verantwoordelijkheid voor de identificatie van ZZS en dus ook voor de ZZS-toets in geval van mengsels en stoffen bij de bedrijven.
Deze memo beschrijft systematisch de inhoudelijke en technische uitgangspunten die nodig zijn voor deze ZZS-toets bij mengsels en stoffen waarmee bepaald kan worden of een mengsel of een stof, dat één of meerdere ZZS bevat, als ZZS behandeld moet worden.
De precieze uitwerking op, en praktische toepassing voor het vergunningverlenersproces is geen onderdeel van deze memo. Hiervoor wordt verwezen naar de infomil website (www.infomil.nl).

Definitie van mengsels en stoffen

De volgende definities van stoffen en mengsels worden gehanteerd onder de REACH- en CLP-verordeningen. Deze worden ook gehanteerd voor deze memo:

Mengsel: "een mengsel of oplossing bestaande uit twee of meer stoffen".

Stof: "een chemisch element en zijn verbindingen in de natuurlijke toestand of het resultaat van een vervaardigingsproces, met inbegrip van alle additieven die nodig zijn voor het behoud van de stabiliteit ervan en alle onzuiverheden ten gevolge van het

[1] Voor meer informatie zie: www.infomil.nl/onderwerpen/integrale/activiteitenbesluit/

toegepaste procedé, doch met uitzondering van elk oplosmiddel dat kan worden afgescheiden zonder dat de stabiliteit van de stof wordt aangetast of de samenstelling ervan wordt gewijzigd."
Er worden drie stoftypen gehanteerd[2]:

- stoffen met één hoofdbestandsdeel: Hier maakt dit ene bestanddeel minstens 80% van de stof uit. Dergelijke stoffen kunnen dus nog wel additieven, oplosmiddelen en andere componenten in lage gehaltes (onzuiverheden) bevatten.
- stoffen met verscheidene bestanddelen: De stof bestaat uit meerdere hoofdbestanddelen. Elk hoofdbestanddeel is voor 10% tot 80% in de stof aanwezig. Ook in deze stoffen kunnen hiernaast ook additieven, oplosmiddelen en onzuiverheden aanwezig zijn.
- UVCB-stoffen: Dit zijn stoffen met onbekende of variabele samenstelling, complexe reactieproducten of biologische materialen[3]. UVCB-stoffen hebben veel verschillende bestanddelen, een aantal hiervan is mogelijk onbekend. De samenstelling kan wisselend of moeilijk te voorspellen zijn. Een voorbeeld van UVCB stoffen zijn vele aardolie- en steenkoolderivaten die op de ZZS lijst staan. De naamgeving van UVCBs is gebaseerd op de procesbeschrijving (bijvoorbeeld reactiemassa X…). Daarnaast is in de naam of in het veiligheidsinformatieblad vaak informatie over de belangrijkste (groepen van) bestanddelen beschikbaar (bijvoorbeeld groter dan x% aromatische koolwaterstoffen of y% benzeen). Regels voor de naamgeving van UVCBs staan in de REACH guidance.

Uit bovenstaande blijkt dat de term "stof" in de REACH systematiek per definitie ongelijk is aan een chemisch zuivere stof. Stoffen bevatten dus in de regel meerdere componenten of bestanddelen. Echter, deze stoffen zijn volgens de definities geen mengsels. Mengsels worden in een formuleringsstap gemaakt uit twee of meerdere stoffen zonder dat daarbij een chemische omzetting plaatsvindt. Mengsels zijn bijvoorbeeld shampoos of verf. Rekenregels die volgens de CLP-verordening gelden voor classificatie van mengsels zijn ook toepasbaar op stoffen met meerdere bestanddelen. Deze rekenregels zijn daarmee een belangrijke pijler onder deze memo. Binnen het REACH en CLP kader worden stoffen en mengsels, indien het afval betreft, uitgezonderd van de definitie voor stof en mengsel. Het ZZS emissiebeleid is ook van toepassing op emissies van afvalstomen met ZZS. Het is daarom noodzakelijk om te bepalen of een afvalstroom ZZS-bestanddelen bevat. Daarom kan deze memo ook gebruikt worden om te bepalen of een afvalstroom als ZZS behandeld moet worden[4].

Identificatie van ZZS

ZZS zijn stoffen (dit kunnen ook UVCB-stoffen zijn) waarvoor geldt dat ze aan de criteria voldoen zoals vastgelegd in artikel 57 van de REACH verordening. Deze stoffen staan op de ZZS-lijst van het RIVM (rvs.rivm.nl/zoeksysteem/ZZSlijst/Index) of

[2] Voor meer informatie zie: echa.europa.eu/nl/support/substance-identification
[3] UVCB = Unknown or variable composition, Complex reaction products, Biological materials
[4] Voor meer informatie over ZZS in afval: zie RIVM rapport 2017-0099

kunnen volgens zelfidentificatie als ZZS worden aangemerkt. Voor meer informatie: zie de RIVM website over identificatie van ZZS[5].
Op de ZZS lijst staan veel stoffen met in de naam het woord “mengsel”. Echter volgens de definities zijn dit meestal geen mengsels maar stoffen, omdat het, bijvoorbeeld, complexe reactieproducten en dus UVCBs zijn.

Algemene regel voor het behandelen van mengsels en stoffen met ZZS-bestanddelen

De wettelijke kaders die worden gebruikt voor de identificatie van ZZS (bijvoorbeeld CLP-, REACH- en POP-verordening) worden ook gebruikt om te bepalen of een mengsel of een stof met een ZZS-bestanddeel als ZZS behandeld moet worden..
Over het algemeen wordt, in lijn met de REACH- en CLP-verordening, een concentratiegrens van 0,1 gewichtsprocent (g/g) gebruikt. Dus dat wil zeggen dat mengsels en stoffen die één ZZS-bestanddeel bevatten in een concentratie van 0,1% of meer, zelf ook als ZZS moeten worden behandeld.

Hierbij moet worden opgemerkt dat de verschillende bovengenoemde wettelijke kaders echter ook uitzonderingen op deze concentratieregel kennen en dat deze uitzonderingen moeten worden meegenomen (zie hiervoor een voorbeeld op pagina 4). De kaders waarvoor uitzonderingen gelden, worden hieronder besproken. Als een ZZS volgens meerdere kaders is geïdentificeerd, geldt de meest strenge concentratiegrens voor dit ZZS-bestanddeel.

Stoffen van alle drie de stoftypen (zie Definitie van mengsels en stoffen) kunnen onzuiverheden bevatten die niet zijn meegewogen bij, bijvoorbeeld, de classificatie van een stof volgens de CLP-verordening. In het geval dat deze onzuiverheden ZZS zijn, dan gelden dezelfde regels als voor ZZS in mengsels[6].

Opmerkingen per wettelijk kader

REACH verordening
Voor SVHC stoffen[7] (SVHC = Substance of Very High Concern) wordt onder de REACH verordening over het algemeen een concentratiegrens van 0,1% gehanteerd met daarbij de uitzonderingen die al gelden volgens de CLP-verordening waar REACH naar verwijst zoals hieronder besproken. Voor sommige stoffen gelden volgens de REACH-verordening restricties vanwege eigenschappen die overeenkomen met de ZZS-criteria. Deze stoffen zijn daarom ook op de ZZS lijst geplaatst. In bijlage XVII van REACH staan concentratiegrenzen voor sommige van deze stoffen in mengsels. Als voorbeeld: voor polychloorterfenylen geldt dat deze voor niet meer dan

[5] www.rivm.nl/rvs/Stoffenlijsten/Zeer_Zorgwekkende_Stoffen/Identificatie_Zeer_Zorgwekkende_Stoffen
[6] Zie ook sectie 1.1.7.2. van de Europese handleiding voor toepassing van CLP-criteria: https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/
[7] Voor het verschil tussen ZZS en SVHC stoffen zie: http://www.rivm.nl/rvs/Stoffenlijsten/Zeer_Zorgwekkende_Stoffen/Identificatie_Zeer_Zorgwekkende_Stoffen

0,005% in mengsels mogen zitten. Deze grenzen moeten worden meegenomen bij het bepalen of een mengsel als ZZS moet worden behandeld.

CLP verordening
De fabrikant, formuleerder of importeur van een mengsel of een stof moet deze zelf classificeren volgens de regels van de CLP-verordening. Mengsels en stoffen met als classificatie de H-zinnen H340, H350 of H360[8] (CMR) moeten als ZZS worden behandeld. De indeling van een mengsel of stof door een fabrikant kunt u terugvinden op het op het Veiligheidsinformatieblad (VIB of Safety Data Sheet (SDS) in het Engels).

De CLP-verordening kent uitzonderingen op de algemene concentratiegrens van 0,1 %(g/g). Als voorbeeld: benzo-a-pyreen heeft een specifieke concentratiegrens die afwijkt van 0,1%. Dat wil zeggen dat, indien een stof of mengsel het ZZS-bestanddeel benzo-a-pyreen bevat in een concentratie die groter of gelijk is dan 0,01%, de stof of het mengsel zelf ook als ZZS behandeld dient te worden. Er zijn ook stoffen met een hogere algemene of specifieke concentratiegrens, bijvoorbeeld stoffen die giftig zijn voor de voortplanting waarvoor een algemene concentratiegrens voor indeling van mengsels van 0,3% geldt. Men wordt geadviseerd voor bestanddelen in mengsels en stoffen de volgende stappen van de CLP-verordening te volgen:

1) controleer in CLP Annex I de algemene concentratiegrens voor indeling van mengsels voor de betreffende gevaarsklasse/categorie.
2) controleer in CLP Annex VI (of via de C&L inventaris op de ECHA website) of voor het betreffende bestanddeel en betreffende gevaarsklasse/categorie een specifieke concentratiegrens geldt. Een specifieke concentratiegrens voor een gevaarsklasse/categorie gaat voor de algemene concentratiegrens van deze gevaarsklasse.
3) Als het ZZS-bestanddeel aan meerdere ZZS criteria voldoet, dan is de laagste specifieke concentratiegrens geldend.

Sommige UVCBs op Annex VI van de CLP verordening hebben een voetnoot die stelt dat indien het gehalte van een bepaald bestanddeel in de UVCB lager is dan een aangegeven percentage (bijvoorbeeld minder dan 0.1% benzeen), deze UVCB niet als Carc. 1b of Muta. 1b geclassificeerd hoeft te worden. Als aan deze voetnoot wordt voldaan sluit dit echter niet uit dat dat de UVCB dan nog wel als, bijvoorbeeld, Repr. 1b geclassificeerd kan zijn of dat deze PBT bestanddelen bevat. Het bedrijf moet daarom wel aantonen dat de UVCB ook niet aan de andere ZZS-criteria voldoet.

POP verordening
Voor veel stoffen in de POP-verordening gelden eveneens concentratiegrenzen die afwijken van de algemene concentratiegrens van 0,1%. Deze concentratiegrenzen worden gegeven in bijlage IV van de POP-verordening en moeten worden meegenomen bij het bepalen of een mengsel of stof als ZZS moet worden behandeld.

[8] Op oude VIBs kunnen ook de R-zinnen R45, R46, R49, R60 of R61 zijn gebruikt.

Let op: Veel stoffen op Bijlage I van de POP-verordening (deze zijn allemaal ZZS) mogen helemaal niet meer gebruikt worden en ook niet meer in mengsels of artikelen zitten. Gebruik van mengsels met deze stoffen mag volgens deze verordening niet meer vergund worden.

Hoe nu om te gaan indien het mengsel of de stof meerdere ZZS-bestanddelen bevat?

Mengsels en stoffen kunnen ook meerdere ZZS-bestanddelen bevatten die individueel allemaal onder de concentratiegrens zitten, maar bij elkaar opgeteld wel boven de grens van 0,1% komen. Moet het mengsel of stof dan wel of niet als ZZS worden behandeld? Om deze vraag te beantwoorden moet men zich realiseren dat deze ZZS-bestanddelen op basis van verschillende gevaarscriteria als ZZS kunnen worden aangemerkt. Denk hierbij aan de criteria zoals beschreven in artikel 57 van REACH: C (carcinogeen), M (mutageen), R (reprotoxisch) in categorie 1A of 1B of PBT (persistent, bioaccumulerend en toxisch) en vPvB (*very peristent* en *very bioaccumulative*). Omdat de toxicologische effecten en/of werkingsmechanismen van de ZZS-bestanddelen, die bij deze gevaren horen, van elkaar kunnen verschillen, en omdat concentratiegrenzen voor ZZS per gevaarsklasse verschillen, kunnen de verschillende concentraties van de ZZS-bestanddelen, aanwezig in het mengsel of de stof, niet zonder meer bij elkaar opgeteld worden[9]. Daarom kunnen vanuit wetenschappelijk oogpunt concentraties van ZZS-bestanddelen die volgens hetzelfde gevaarscriterium als ZZS zijn aangemerkt alleen bij elkaar worden opgeteld als deze geacht worden via hetzelfde werkingsmechanisme te werken.

Als voorbeeld: twee ZZS-bestanddelen die schadelijk zijn voor de voortplanting (R) waarbij de ene ZZS-bestanddeel schadelijk is voor de vruchtbaarheid en het andere ZZS-bestanddeel schadelijk voor het ongeboren kind. Omdat ze een ander werkingsmechanisme hebben, kunnen ze niet bij elkaar worden opgeteld.

Dit is in het algemeen niet altijd eenduidig vast te stellen, in geval van onduidelijkheid dient het bedrijf een gecertificeerde toxicologisch expert te raadplegen. Uit voorzorg kan worden overwogen om de concentraties van de ZZS bij elkaar op te tellen, zolang niet is vastgesteld dat de toxicologische effecten en/of werkingsmechanismen van de ZZS in het mengsel verschillend zijn.

Verantwoordelijke voor de ZZS-toets

Zoals hierboven al genoemd, kan het VIB als bron worden gebruikt om informatie te verkrijgen over de CLP classificatie van het mengsel of stof en ook om te bepalen welke gevaarlijke bestanddelen zich in het mengsel of de stof bevinden. Echter het bedrijf is er uiteindelijk verantwoordelijk voor dat de ZZS-toets voor het mengsel naar volledigheid wordt uitgevoerd.

Aansluiting bij ABM voor water

De ABM (Algemene Beoordelings Methodiek) wordt gebruikt binnen het algemene waterkwaliteitsbeleid om de waterbezwaarlijkheid van stoffen en mengsels vast te

[9] Informatie over het groeperen van stoffen vindt u op de website van ECHA (https://echa.europa.eu/nl/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across), en voor meer details over het omgaan met mengseltoxiciteit zie RIVM rapport 2016-0162.

stellen. In dit kader wordt het VIB geraadpleegd en wordt de concentratiegrens van 0,1% gehanteerd. Daarmee zijn de ABM en bovenstaand voorstel goed met elkaar in overeenstemming.

Actueel WG/GA van het middel MS Megades Novo, 14896 N

6 maart 2020

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van:

1. bacteriën (exclusief mycobacteriën en bacteriesporen), gisten en virussen in dierverblijfplaatsen en bijbehorende ruimten, inclusief transportmiddelen voor dieren.

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

2. bacteriën (exclusief mycobacteriën en bacteriesporen) en gisten op oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor, echter met uitzondering van melkwinningsapparatuur op de boerderij.

   Om in het waterlevende organismen te beschermen dienen resten die het middel bevatten te worden geloosd naar het riool met aansluiting op de RWZI.
   Bij afvoer naar een gemeentelijke RWZI is een vetafscheider en slibvangput conform NEN-EN 1825-1 en 1825-2 en/of een biologische of chemische voorzuivering verplicht.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

De te desinfecteren oppervlakken en materialen eerst grondig reinigen. Een daarbij eventueel gebruikt reinigingsmiddel goed afspoelen met schoon water.

1. **Desinfectie van oppervlakken in dierverblijfplaatsen en bijbehorende ruimten, inclusief transportmiddelen voor dieren:**

Het middel toepassen door middel van sprayen onder lage druk. Zorg dat oppervlakken vochtig blijven gedurende de gehele inwerktijd. Na afloop het middel grondig afspoelen.

Dosering: 0,75% (= 7,5 ml aanvullen met water tot 1 liter).
Minimale inwerktijd: 5 minuten.

Tijdens mengen/laden van het product geschikte handschoenen en coverall dragen.
Tijdens het aanbrengen van het schuim geschikte handschoenen, coverall en adembescherming dragen.

Tijdens het aanbrengen van het schuim mogen er geen onbeschermde personen of dieren aanwezig zijn.

2. **Desinfectie van oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor, echter met uitzondering van melkwinningsapparatuur op de boerderij:**

Het middel toepassen door middel van sprayen onder lage druk. Zorg dat oppervlakken vochtig blijven gedurende de gehele inwerktijd. Na afloop het middel grondig afspoelen.

Dosering: 0,25% (= 2,5 ml aanvullen met water tot 1 liter).
Minimale inwerktijd: 5 minuten.

Tijdens mengen/laden van het product geschikte handschoenen en coverall dragen.
Tijdens het aanbrengen van het schuim geschikte handschoenen en coverall dragen.

Toelichting grondslagen

In dit document kunt u secties vinden die onleesbaar zijn gemaakt. Deze informatie is achterwege gelaten op basis van de Wet open overheid (Woo). De letter die hierbij is vermeld correspondeert met de bijbehorende grondslag in onderstaand overzicht.

J Art. 5.1 lid 2 sub e

Het belang van de openbaarmaking van deze informatie weegt niet op tegen het belang van de eerbiediging van de persoonlijke levenssfeer van betrokkenen