ctgb

Het College voor de Toelating van gewasbeschermingsmiddelen en biociden,

Beslissende op het bezwaar van 9 januari 2019 van Christeyns B.V. (hierna te noemen: bezwaarde), door het College voor de toelating van gewasbeschermingsmiddelen en biociden (hierna te noemen: het College of het Ctgb) ontvangen op 11 januari 2019, gericht tegen het besluit van het College van 28 december 2018 tot afwijzing van de aanvraag voor de biocide Mida Foam 196 Fl, een middel op basis van de werkzame stof actief chloor gevormd uit natriumhypochloriet.

Het bezwaar is geregistreerd onder nummer 2019-04.

1. De procedure

Op 11 oktober 2017 heeft bezwaarde een aanvraag ingediend voor de toelating van de biocide op basis van niet geplaatste stoffen (overgangsrecht) voor het middel Mida Foam 196 Fl.

Bij besluit van 28 december 2018 (hierna te noemen: het bestreden besluit) heeft het College besloten de aanvraag van 11 oktober 2017 af te wijzen. Het College heeft besloten dat de fysische en chemische eigenschappen van het middel niet konden worden vastgesteld voor wat betreft de houdbaarheid van het middel, waardoor ze voor juist gebruik en adequate opslag van het middel niet aanvaardbaar worden geacht. Daarnaast kan de werkzaamheid niet worden vastgesteld voor verouderd product.

Bezwaarde heeft tegen dit besluit bezwaar gemaakt bij brief van 9 januari 2019. Deze brief is door het College ontvangen op 11 januari 2019. Het bezwaarschrift is opgesteld in de Engelse taal.

Bij brief van 14 januari 2019 heeft het College bezwaarde verzocht om voor 12 februari 2019 een Nederlandse vertaling van het bezwaarschrift toe te sturen, omdat het College een Nederlandse vertaling noodzakelijk acht voor een goede behandeling van het bezwaarschrift.

Op 6 maart 2019 heeft het College uw bezwaarschrift kennelijk niet-ontvankelijk verklaard nu het College in de veronderstelling verkeerde dat de Nederlandse vertaling van het bezwaarschrift ontbrak.

Op 12 maart 2019 heeft u het College er op gewezen dat tijdig een Nederlandse vertaling van het bezwaarschrift is toegestuurd.

Bij brief van 3 april 2019 heeft de voorzitter van het College bevestigd dat deze Nederlandse vertaling inderdaad tijdig is ontvangen en wordt teruggekomen op het besluit van 6 maart 2019. Uw bezwaarschrift wordt ontvankelijk geacht en in behandeling genomen.

2. Beoordeling van de ontvankelijkheid

Ingevolge artikel 1:2, eerste lid, Algemene wet bestuursrecht (hierna te noemen: Awb) wordt onder belanghebbende verstaan: degene wiens belang rechtstreeks bij een besluit is betrokken. Bezwaarde is de geadresseerde van het bestreden besluit en is derhalve als belanghebbende aan te merken.

Het bezwaar is, conform artikel 6:4 Awb, ingediend bij het bestuursorgaan dat het primaire besluit heeft genomen. Daarnaast is het bezwaar gericht tegen een appellabel besluit en is voldaan aan de vormvereisten van artikel 6:5 Awb. Bovendien heeft bezwaarde het bezwaarschrift, conform artikel 6:7 Awb, tijdig ingediend. Gelet op het bovenstaande is bezwaarde ontvankelijk.

3. Samenvatting van het bezwaarschrift

Bezwaarde kan zich niet verenigen met het bestreden besluit. Bezwaarde stelt dat Mida Foam 196 Fl zeer gelijkwaardig is aan een PT4 biocide middel dat reeds is toegelaten (Akzo Nobel natriumhypochloriet 12.5-15% met toelatingsnummer 13693) door het Ctgb. Dit toegelaten product heeft volgens bezwaarde hetzelfde gebruik en eveneens natrium hypochloriet als enige werkzame stof. De stabiliteit van het toegelaten middel is slechts 1 maand, hetgeen minder is dan de aangetoonde stabiliteit van Mida Foam 196 Fl van 2 maanden.

Bezwaarde geeft aan dat er geen enkele aanwijzing in de Europese richtlijnen voor biociden is dat een minimale houdbaarheid vereist is voor de toelating van biociden en bezwaarde stelt derhalve dat er geen objectieve wettelijke basis is voor het afwijzen van een toelating op basis van een korte houdbaarheid.

Tot slot geeft bezwaarde aan dat het gelijkheidsbeginsel is geschonden omdat hij als rechtsonderhorige in gelijke omstandigheden op een ongelijke wijze worden behandeld ten aanzien van andere rechtsonderhorige.

4. Overwegingen

Het gelijkheidsbeginsel
Bezwaarde beroept zich op artikel 1 van de Grondwet, de algemene beginselen van behoorlijk bestuur en artikel 3.3 van het Verdrag betreffende de werking van de Europese Unie (VWEU). Opgemerkt zij dat laatst genoemd artikel niet bestaat. Duidelijk is echter dat bezwaarde een beroep doet op het gelijkheidsbeginsel. Het gelijkheidsbeginsel houdt in dat gelijke gevallen gelijk behandeld worden en ongelijke gevallen ongelijk naar de mate waarin zij verschillen. Het discriminatieverbod is één aspect hiervan.

Het middel Akzo Nobel natriumhypochloriet 12.5-15% met toelatingsnummer 13693, waaraan bezwaarde refereert, is een toelating onder het zogenoemde gedifferentieerd handhavingsbeleid biociden.[1] In 2009 is geconstateerd dat een groot aantal producten met een biocideclaim om verschillende redenen op de Nederlandse markt waren zonder de vereiste toelating. Om bedrijven die biocideproducten reeds voor 1 januari 2009 zonder toelating op de markt hadden gebracht een kans te geven om alsnog een toelating te verkrijgen, is destijds het ministerie van VROM gestart met het zogenoemde gedifferentieerd handhavingsbeleid biociden. In het kader van dit beleid heeft het Ctgb een aanvraagprocedure opgezet om aanvragen voor de toelating van biociden zonder toelating (BZT) te beoordelen en af te handelen.

[1] Dit beleid is op 23 februari 2009 in een brief aan de Tweede Kamer uiteen gezet (TK 2008–2009, 27 858, nr. 75).

Het gedifferentieerd handhavingsbeleid bestond uit een combinatie van handhaven van niet onder het beleid vallende biociden en een versnelde en vereenvoudigde aanvraagafhandeling door het Ctgb. Dit betekent dat het middel waaraan bezwaarde refereert een versnelde en vereenvoudigde aanvraagafhandeling heeft doorlopen.

Het door bezwaarde aangevraagde middel heeft de reguliere procedure doorlopen. De reguliere procedure verschilt dermate van de procedure die gevolgd werd in het kader van het gedifferentieerd handhavingsbeleid dat niet gesproken kan worden over gelijke gevallen.

Het College heeft bij de toelating van het middel Akzo Nobel natriumhypochloriet 12.5-15% met toelatingsnummer 13693 immers een ander beleid gevoerd. Het gelijkheidsbeginsel betekent dat binnen één beleid gelijke gevallen gelijk moeten worden behandeld. Nu hier geen sprake van is, kan het beroep van bezwaarde op het gelijkheidsbeginsel niet slagen.

Daar komt bij dat de middelen niet identiek zijn. De werkzame stof gehaltes tussen beide middelen zijn niet gelijk. Daarnaast bevatten de middelen ook niet allemaal dezelfde co-formulanten. De co-formulanten die wel in beide middelen aanwezig zijn verschillen in gehalte.

Er kan dus niet gesproken worden van een exact gelijk geval. Het beroep van bezwaarde op het gelijkheidsbeginsel slaagt dan ook niet.

Minimale houdbaarheid
Bezwaarde geeft aan dat er geen enkele aanwijzing in de Europese richtlijnen voor biociden is dat een minimale houdbaarheid vereist is voor de toelating van biociden en bezwaarde stelt derhalve dat er geen objectieve wettelijke basis is voor het afwijzen van een toelating op basis van een korte houdbaarheid.

Voor de toelating van een biocide bestaat geen minimale houdbaarheid. Echter dient het Ctgb wel een houdbaarheid vast te stellen. Bezwaarde heeft in het aanvraagformulier een houdbaarheidsclaim gedaan. Deze claim was onvoldoende onderbouwd en het Ctgb heeft de aanvraag derhalve terecht afgewezen. Naar aanleiding van de in bezwaar geleverde onderbouwing heeft het College op basis van alle beschikbare data in dit specifieke dossier en met het oog op de door het College uitgevoerde beoordeling ten tijde van het primaire besluit, in dit specifieke geval een houdbaarheid van 2 maanden vastgesteld.

5. Afzien van horen

Met inachtneming van artikel 7:3, aanhef en onder e, van Awb ziet het College af van de mogelijkheid bezwaarde te horen.

6. Besluit op het bezwaarschrift

Het College besluit, na heroverweging van het bestreden besluit als bedoeld in artikel 7:11 Awb en in het kader van de integrale heroverweging, dat het bezwaar gegrond is. Het bestreden besluit komt derhalve te luiden als voorzien in de bijlage bij dit besluit.

Een ieder wiens belang rechtstreeks bij dit besluit is betrokken, kan op grond van ***artikel 4 van Bijlage 2 bij de Awb*** *tegen dit besluit binnen 6 weken na bekendmaking van het besluit beroep instellen bij het* ***College van Beroep voor het bedrijfsleven, Postbus 20021, 2500 EA 's-Gravenhage.*** *Het beroepschrift moet op grond van artikel 6:5 Awb zijn ondertekend en bevat tenminste de naam en het adres van de indiener, de*

dagtekening, de omschrijving van het besluit waartegen het beroep is gericht, de gronden waarop het beroepschrift rust en zo mogelijk een afschrift van het besluit. Van de indiener van het beroepschrift wordt griffierecht geheven door de griffier van het College van Beroep voor het bedrijfsleven (hierna: het CBb). Nadere informatie over de hoogte van het griffierecht en de wijze van betalen wordt door de Griffie van het CBb verstrekt.

Ede, 27 januari 2021

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN ,

Ir. J.F. de Leeuw
(voorzitter)

16112 N

ctgb

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 11 oktober 2017 is van

Christeyns B.V.
Lireweg 12
2153 PH NIEUW-VENNEP

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

Mida Foam 196 FI

op basis van de werkzame stof actief chloor gevormd uit natriumhypochloriet.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

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

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

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

- 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.

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

Ir. J.F. de Leeuw

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20171793 TB (20201636 TB t.b.v. administratieve afhandeling)
Type aanvraag:	toelating van de biocide op basis van niet geplaatste stoffen (overgangsrecht)
Middelnaam:	Mida Foam 196 FI
Verzenddatum aanvraag:	9 oktober 2017
Formele registratiedatum: *	23 oktober 2017
Datum in behandeling name:	28 augustus 2018

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

2 Stofinformatie

Werkzame stof	Gehalte
natriumhypochloriet	5,2 % (ALS ACTIEF CHLOOR)

De werkzame stof actief chloor gevormd uit natriumhypochloriet is opgenomen in het reviewprogramma voor het gevraagde PT04 en is op 1 januari 2019 geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

3 Toelatingsinformatie

Toelatingsnummer:	16112 N
Expiratiedatum:	1 december 2030
Afgeleide of parallel:	n.v.t. (nieuw middel)
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Met water mengbaar concentraat

Uiterste gebruiksdatum:
2 maanden na productiedatum

16112 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Mida Foam 196 FI

Professioneel gebruik

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: natriumhydroxide

Pictogram	GHS05 GHS09
Signaalwoord	Gevaar
Gevarenaanduidingen	H290 Kan bijtend zijn voor metalen. H314 Veroorzaakt ernstige brandwonden en oogletsel. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P260 Stof/rook/gas/nevel/damp/spuitnevel niet inademen. P280 Draag beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming/gehoorbescherming/... P303 + P361 + P353 BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken. Huid met water afspoelen/afdouchen. P305 + P351 + P338 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. P310 Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen.
Aanvullende etiketelementen	EUH031 Vormt giftig gas in contact met zuren.

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HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE III WG/GA van het middel Mida Foam 196 FI

A.

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van bacteriën (exclusief mycobacteriën en bacteriesporen), gisten, schimmels en bacteriofagen op oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor, echter met uitzondering van zuigelingen- en opvolgvoeding en babyvoeding.

Het middel mag uitsluitend worden toegepast met behulp van schuimreinigerinstallaties.

Onbeschermde personen dienen niet aanwezig te zijn in de ruimten waar de behandeling plaatsvindt.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.

GEBRUIKSAANWIJZING

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

Mida Foam 196 FI op de te desinfecteren oppervlakken aanbrengen door middel van schuimtoepassing, bij een temperatuur van 20 °C.

Bij het desinfecteren zoveel vloeistof gebruiken, dat de oppervlakken gedurende de gehele inwerktijd nat blijven.

Behandelde oppervlakken dienen na de inwerktijd grondig met schoon water te worden nagespoeld.

Dosering: 6% (60 ml middel per liter water).

Minimale inwerktijd:
- voor bestrijding van bacteriën, gisten en schimmels: 15 minuten
- voor bestrijding van bacteriofagen: 20 minuten

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV

RISKMANAGEMENT

Contents

1 Introduction

1.1 Applicant

Christeyns B.V.
Lireweg 12
2153 PH NIEUW-VENNEP

1.2 Active substance

active chlorine released from sodium hypochlorite

1.3 Product

Mida Foam 196 FI

1.4 Function

Mida Foam 196 FI is a disinfectant (PT04).

1.5 Background to the application

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

1.6 Intended uses

The proposed field of use of Mida Foam 196 FI is the control of bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and bacteriophages on surfaces that may come into contact with food and feed.

The product is intended for professional use.

1.7 Packaging details

5, 10, 20, 200, 1000L in HDPE container

2 Identity

2.1 Identity of the active substance

Common name	Sodium hypochlorite (non-ISO)
Name in Dutch	Natriumhypochloriet
Chemical name	Sodium hypochlorite
CAS no	7681-52-9
EC no	231-668-3

The active substance active chlorine released form sodium hypochlorite is included in the Union list of approved substance of Regulation (EU) 528/2012 for PT 1-2-3-4-5. The approval came into force on 1 January 2019. An AR is available (eCA Italy, January 2017). For PT 11-12 the substance is under review.

The list of endpoints below is taken from the AR (eCA Italy, January 2017).

Chemical name (IUPAC)	Sodium hypochlorite
Chemical name (CA)	Hypochlorous acid, sodium salt
CAS No	7681-52-9
EEC No	231-668-3
Other substance No.	017-011-00-1 (Index number)

Purity of the active substance as manufactured (g/kg or g/l)	Aqueous solution with an active chlorine concentration ≤180 g/kg ([14]), in compliance with the EN 901:2013
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Sodium chlorate (relevant impurity): ≤5.4% of the active chlorine Sodium hydroxide (additive)
Molecular formula	ClHO.Na
Molecular mass	74.44 g/mol
Structural formula	Na^+ Cl—O^-

(14) Due to its instability as a pure salt, sodium hypochlorite is manufactured and handled only as aqueous solution, with a pH value greater than 11 at 20°C. Solutions are kept alkaline in order to decrease the degradation rate of the hypochlorite to chloride and chlorate.
Sodium hypochlorite is determined by a titrimetric method. Results are typically expressed as available (active) chlorine using by convention the molecular weight of elemental chlorine in calculations, but they can be converted into sodium hypochlorite by applying a conversion factor of 1.05 (MW_{NaOCl}/MW_{Cl2} = 74.44/70.91).

2.2 Identity of the biocidal product

Name	Mida Foam 196 FI
Formulation type	SL
Content active substance	5.2 %w/w active chlorine

Packaging information:

	Material	Size / content	Other information
Professional use	HDPE	5 L	container
	HDPE	10 L	container
	HDPE	22 kg (20 L)	container
	HDPE	220 kg (200 L)	container
	HDPE	1050 kg (1000 L)	container

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

The list of endpoints below is taken from the AR (eCA Italy, January 2017).

Melting point (state purity)	-28.9 ± 0.5 °C (24.3 % available chlorine)
Boiling point (state purity)	Water evaporated when heating the sodium hypochlorite aqueous solution (24.3% w/w active chlorine), white crystals were observed on the bottom of the test vessel
Temperature of decomposition	Not determined, since sodium hypochlorite in its pure form is highly unstable

Appearance (state purity)	Yellow limpid liquid (24.3% w/w active chlorine), with faint chlorinous odour (according to EN 901:2013)
Relative density (state purity)	$D^{21.2}_4$ = 1.300 ± 0.001 (24.3% w/w active chlorine)
Surface tension	82.4 ± 0.8 mN/m at 20.2-20.3 °C (24.3% w/w active chlorine)
Vapour pressure (in Pa, state temperature)	ca. 2.5 x 10^3 Pa at 20°C for sodium hypochlorite aqueous solutions (according to EN 901:2003). At pH >11 the hypochlorite anion is the predominant species. As an ionic species, the hypochlorite anion has high water solubility and is unlikely to evaporate from the aqueous solution. Thus, it can be assumed that the hypochlorite anion has a vapour pressure significantly less than 10^{-5} Pa
Henry's law constant (Pa m^3 mol^{-1})	Not derived for sodium hypochlorite (expected to be negligible, based on vapour pressure and solubility in water). For the purpose of risk assessment only, a HLC of 0.11 Pa m^3 mol^{-1} at 20°C is considered for hypochlorous acid, which is the only volatile chlorine species present at the equilibrium at in-use pH values under PT2
Solubility in water (g/l or mg/l, state temperature)	26 g sodium hypochlorite/100 g H2O at 0°C (CRC Handbook of Chemistry and Physics)
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	Not relevant. Sodium hypochlorite is not used in organic solvents, due to its nature as a strong oxidant
Stability in organic solvents used in biocidal products including relevant breakdown products	Not relevant. Sodium hypochlorite is not used in organic solvents, due to its nature as a strong oxidant
Partition coefficient (log P_{OW}) (state temperature)	Not required for inorganic substances such as sodium hypochlorite
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	In water, sodium hypochlorite hydrolyses according to: $NaClO + H_2O \leftrightarrow Na^+ + HClO + OH^-$ $K_{hydrolysis}(ClO^-) = K_w/K_a$ where Ka(HClO)= 3.5 x 10^{-8} mol/dm^3 at 20°C Further, the hypochlorous acid (HClO) participates in the following equilibrium: $HClO + H_3O+ + Cl^- \leftrightarrow Cl_2 + 2H_2O$ $K_{hydrolysis}(Cl_2)$ = 3.2 x 10^{-4} mol/dm^3 at 20°C
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Not determined, since sodium hypochlorite in its pure form is highly unstable
Flammability or flashpoint	Flash-point > 110°C (24.3% w/w active chlorine) Sodium hypochlorite solutions are not known to spontaneously ignite when exposed to air

	or to emit flammable gases
Explosive properties	New test for explosives according to the UN Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria needs to be provided (at the maximum available concentration of sodium hypochlorite in water), at the latest six months before the date of approval
Oxidising properties	New test for oxidising liquids according to the UN Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria needs to be provided (at the maximum available concentration of sodium hypochlorite in water), at the latest six months before the date of approval
Auto-ignition or relative self-ignition temperature	Not required for liquids non flammable in air such as sodium hypochlorite aqueous solutions

3.2 Physical and chemical properties of the biocidal product

Appearance	Clear, non-viscuous and yellow-green coloured liquid, with a chlorous odour like disinfectant. The liquid is slight foaming and interspersed with small bubbles.
Explosive properties	Not explosive
Oxidative properties	No oxidative properties
Autoflammability	Not autoflammable
Flashpoint or Flammability	Not flammable. Based on the composition it is not expected that the product is flammable.
pH 1% solution	12.3 ± 0.5 (1 %); 13.5 ± 0.5 (100 %) Based on the high pH the product is classified as corrosive to metals (H290).
Particle size distribution	Not applicable
Surface tension	Not applicable
Viscosity	Not applicable
Relative density	1.191
Storage stability/Shelf life/Packaging	Claimed: 2 months. A long term stability study at ambient temperature (20 °C) was performed over a period of 12 months in containers (polyethylene 1 L). Appearance (physical state, colour and odour), stability of the original container, weight change of the test item containers, content of active chlorine, pH value, alkalinity and relative density were determined. The content of the active ingredient decreased with more than 10 % after the first 3 months of storage (from 5.85 % w/w initially to 3.96 % w/w after 6 months and to 3.04 % w/w after 12 months of storage). pH and relative density remained stable. Alkalinity decreased from 9.51 to 8.7 after 6 months and to 8.22 after 12 months of storage.

	The decrease of the % sodium hypochlorite is 32% after 6 months. According to the BPR guidance, where the degradation of the active content is >10%, or in cases where a decrease of <10% may impact on the efficacy and/or the risk assessment, then a justification for the acceptability of the decrease should be provided. Efficacy tests with an aged product have not been performed. . The first point at which the active substance content was determined in the shelf life study is 3 months. The data indicates that, by interpolation of all five measured concentrations (0, 3, 6, 9 and 12 months) using 1st order correlation, the product is sufficiently stable for at least 2 months, with an acceptable margin (degradation <10%). Therefore, a 2 months shelf-life is accepted in this case. Chlorate concentrations were determined for a fresh and aged sample (6 months). The concentrations were 2.89 g/L for the fresh sample and 16.7 g/L for the aged sample. This data is used to support the toxicological risk assessment.
Technical properties	persistent foaming: No data available. This is acceptable as the product is intended to produce foam. dilution stability: No data available. Based on the composition the product is expected to be stable.
Physical and chemical compatibility	Not intended to be used together with other biocidal products.

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.

The provided data support a shelf-life of 2 months in (HD)PE containers.

Data requirements

None

4 Analytical methods for detection and identification

The list of endpoints below is taken from the AR (eCA Italy, January 2017).

4.1 Analytical methods for the technical active substance

Technical as (principle of method)	Active chlorine (a.s.): Iodometric titration LOQ = 0.5% w/w as sodium hypochlorite (corresponding to 0.48% w/w as active chlorine). Results expressed as active chlorine can be converted into sodium hypochlorite by applying a conversion factor of 1.05
Impurities in technical as (principle of method)	Fully-validated analytical methods are to be provided to the eCA-IT at the latest six months before the date of approval

4.2 Analytical methods for analysis of the biocidal product

Preparation (principle of method)	Active chlorine: redox titration (iodometric)

4.3 Residue analytical methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	In principle, under PT4 fully-validated analytical methods for residues of both the active chlorine (HClO/ClO–) and the relevant metabolite chlorate (ClO3 –) are requested for monitoring purposes in various matrices and for the estimation of human and animal exposure. Nevertheless, active chlorine degrades rapidly in contact with food/feed matrices, hence the request cannot be met, but for chlorate only. Methods should be submitted at the latest six months before the active substance approval
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	In principle, under PT4 fully-validated analytical methods for residues of both active chlorine (HClO/ClO–) and the relevant metabolite chlorate (ClO3 –) are requested for monitoring purposes in various matrices and for the estimation of human and animal exposure. Nevertheless, active chlorine degrades rapidly in contact with food/feed matrices, hence the request cannot be met, but for chlorate only. Methods should be submitted at the latest six months before the active substance approval
Soil (principle of method and LOQ)	Not required. Active chlorine ($HClO/ClO^-$) reacts rapidly with organic matter
Water (principle of method and LOQ)	Drinking water: fully-validated analytical methods need to be provided for monitoring purposes for both the active chlorine ($HClO/ClO^-$) and the relevant metabolite chlorate (ClO_3^-), at the latest six months before the date of approval Surface water: Not required. Active chlorine ($HClO/ClO^-$) reacts rapidly with organic matter
Air (principle of method and LOQ)	Not required. In case of accidental release of chlorine, analytical methods for the monitoring of chlorine in workplace air (a, b) are available: a) OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; Smith & Cochran Spectrophotometric determination of Free Chlorine in Air using Sulphamic acid/Tri-iodide procedure - Anal Chem 1986 Vol 58 pp 1591-1592 b) OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; NIOSH free chlorine in air 01.01.75; ISO 7392/2 Water quality – Determination of free and total chlorine Part 2 Colorimetric method using DPD for routine control purposes 15.10.85
Body fluids and tissues (principle of method and LOQ)	Not required. Active chlorine ($HClO/ClO^-$) reacts rapidly with organic matter In case of accidental release of gaseous chlorine, analytical methods available for the monitoring of chlorine in workplace air are meaningful for monitoring human exposure (see "Air" above).

The remaining issues with regard to the impurities in the active substance and monitoring of chlorate have been addressed. An evaluation of post-approval data was made available by the eCA Italy and uploaded to S-CIRCABC on 5 June 2019.

4.4 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements

None.

5 Efficacy

5.1 Function

Mida Foam 196 FI is a disinfectant based on 5.45% w/w sodium hypochlorite , corresponding to 5.2% active chlorine.

5.2 Field of use envisaged

The proposed field of use of Mida Foam 196 FI is the control of bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and bacteriophages on surfaces that may come into contact with food and feed.

These uses are included in PT04.

The product is intended for professional use.

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

Fifteen studies were provided and used in this assessment. These are summarised in Table 1. Some of the studies assessed were performed with another formulation. The applicant has declared that this formulation is similar to the formulation of Mida Foam 196 FI. All tests were conducted on freshly prepared formulation unless otherwise noted.

Table 1. Summary of studies assessed

Test (version) Phase, step	Test organism	Test parameters	Results*
Bacteria (excluding mycobacteria and bacterial spores)			
EN 1276 (2010) 2,1	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Escherichia coli*	**Concentration (%):** 0.3; 3.0; 6.0% **Interfering substances:** 3 g BSA/L **Contact time:** 5 min **Test temperature:** 20°C	**log R>5.11:** 3.0% Dirty 5 min 20°C
EN 1276 (2010) 2,1	*Salmonella typhimurum* *Campylobacter jejuni* *Listeria monocytogenes*	**Concentration (%):** 0.3; 3.0; 6.0% **Interfering substances:** 3 g BSA/L **Contact time:** 5 min **Test temperature:** 20°C	**log R>5.08:** 6.0% Dirty 5 min 20°C

Test (version) Phase, step	Test organism	Test parameters	Results*
EN 1276 (2012) 2,1	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Escherichia coli*	**Concentration (%):** 2.0% **Interfering substances:** 0.3 g BSA/L **Contact time:** 20 min **Test temperature:** 20°C	**log R>5.17:** 2.0% Clean 20 min 20°C
EN 13697 (2001) 2,2	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Escherichia coli*	**Concentration (%):** 0.1; 3.0; 4.0% **Interfering substances:** 3 g BSA/L **Contact time:** 5 min **Test temperature:** 20°C	**log R>4.90:** 3.0% Dirty 5 min 20°C
EN 13697 (2001) 2,2	*Salmonella typhimurum* *Campylobacter jejuni* *Listeria monocytogenes*	**Concentration (%):** 0.1; 3.0; 4.0; 6.0% **Interfering substances:** 3 g BSA/L **Contact time:** 5 min **Test temperature:** 20°C	**log R>6.02:** 4.0% Dirty 5 min 20°C
EN 13697 (2015) 2,2	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Escherichia coli*	**After six months of storage** **Concentration (%):** 1.0; 3.0; 5.0% **Interfering substances:** 0.3 g BSA/L or 8.5 g skimmed milk/L (*P. aeruginosa* only) **Contact time:** 20 min **Test temperature:** 20°C	*Aged product (6 months):* **log R>6.56:** 3.0% Clean 20 min 20°C
Yeasts			
EN 1650 (2013) 2,1	*Candida albicans*	**Concentration (%):** 0.3; 3.0; 6.0% **Interfering substances:** 3 g BSA/L **Contact time:** 15 min **Test temperature:** 20°C	**log R>4.24:** 3.0% Dirty 15 min 20°C
EN 1650 (2008) 2,1	*Candida albicans*	**Concentration (%):** 2.0% **Interfering substances:** 0.3 g BSA/L **Contact time:** 20 min **Test temperature:** 20°C	**log R>4.54:** 2.0% Clean 20 min 20°C

Test (version) Phase, step	**Test organism**	**Test parameters**	**Results***
EN 13697 (2001) 2,2	*Candida albicans*	**Concentration (%):** 0.05; 0.25; 3.0% **Interfering substances:** 3 g BSA/L **Contact time:** 15 min **Test temperature:** 20°C	**log R>5.12:** 0.25% Dirty 15 min 20°C
EN 13697 (2015) 2,2	*Candida albicans*	**After six months of storage** **Concentration (%):** 1.0; 3.0; 5.0% **Interfering substances:** 0.3 g BSA/L **Contact time:** 20 min **Test temperature:** 20°C	*Aged product (6 months):* **log R>5.77:** 1.0% Clean 20 min 20°C
		Fungi	
EN 1650 (2013) 2,1	*Aspergillus brasiliensis*	**Concentration (%):** 1.0; 2.0; 3.0% **Interfering substances:** 3 g BSA/L **Contact time:** 15 min **Test temperature:** 20°C	**log R>4.09** 2.0% Dirty 15 min 20°C
EN 1650 (2008) 2,1	*Aspergillus brasiliensis*	**Concentration (%):** 2.0% **Interfering substances:** 0.3 g BSA/L **Contact time:** 20 min **Test temperature:** 20°C	**log R>4.23:** 2.0% Clean 20 min 20°C
EN 13697 (2001) 2,2	*Aspergillus brasiliensis*	**Concentration (%):** 1.0; 2.0; 3.0% **Interfering substances:** 3 g BSA/L **Contact time:** 15 min **Test temperature:** 20°C	**log R>5.75:** 2.0% Dirty 15 min 20°C
EN 13697 (2015) 2,2	*Aspergillus brasiliensis*	**After six months of storage** **Concentration (%):** 1.0; 3.0; 5.0% **Interfering substances:** 0.3 g BSA/L or **Contact time:** 20 min **Test temperature:** 20°C	*Aged product (6 months):* **log R>5.59:** 3.0% Clean 20 min 20°C

Test (version) Phase, step	Test organism	Test parameters	Results*
Viruses / Bacteriophages			
EN 13610 (2003) 2,1	*Bacteriophage* P001 *Bacteriophage* P008 *Bacteriophage* F7/2	**Concentration (%):** 2.0% **Interfering substances:** 10 g whey/L **Contact time:** 20 min **Test temperature:** 20°C	**log R>4.04:** 2.0 % Clean 20 min 20°C

* For phase 2, step 1 and step 2 studies the most challenging test conditions resulting in the required lg reduction are given
The available information was sufficient to evaluate the efficacy of Mida Foam 196 FI for control of bacteria (excluding mycobacteria and bacterial spores), fungi, yeast and bacteriophages considering evaluation is done under article 121 of the WGB.

Also after additional questions during evaluation, not sufficient data are available with aged product. As a result only efficacy with fresh product could be evaluated. This is sufficient to authorize the product with a shelf life claim of 2 months.

Initially a dose differentiation is claimed for bacteria (different dose for standard bacteria and for specific bacteria for PT04 area) and for aged versus fresh product. Both differentiations are not acceptable. After additional questions during evaluation, the applicant agreed to drop the dose differentiation for age of the product, but still included a dose differentiation for different bacterial species. This differentiation cannot be accepted. In addition, the applicant adapted the claimed doses to maximum 6% for bacteria, and a dose of 0.25% - 2% against yeast, fungi and bacteriophages (dose depending on the claimed organism).
Bactericidal efficacy: efficacy is demonstrated with fresh product against bacteria (including specific bacteria species for PT04 area) at a dose of 6% at high level soiling conditions and a contact time of 5 minutes.
Yeasticidal efficacy: efficacy against yeasts is demonstrated with fresh product at a dose of 2%, a contact time of 20 minutes and low level soiling conditions, or 3% at a contact time of 15 minutes and high level soiling conditions. This is higher than the claimed dose of 0.25%.
Fungicidal efficacy and efficacy against bacteriophages: for fungi and bacteriophages sufficient efficacy was demonstrated with fresh product at the claimed dosages (i.e. 2%) and application conditions.
Note that it is not possible for optional organisms to claim dose rates that are lower than the dose rate for mandatory organisms (bacteria and yeast).

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. The dose differentiation for specific bacteria has been removed. The dose differentiation for fungi and bacteriophages has been removed, as the dosages required for optional organisms cannot be lower than the dosages required for mandatory organisms.

5.4 Mode of action

In water, sodium hypochlorite ionizes to produce Na^+ and the hypochlorite ion, OCl^-, which establishes an equilibrium with hypochlorous acid (HOCl). Between pH 4 and 7, chlorine exists predominantly as HClO, the active moiety, whereas above pH9, OCl_2 predominates.
Chlorine Releasing Agents (CRAs) are highly active oxidizing agents and thereby destroy the cellular activity of proteins; potentiation of oxidation may occur at low pH, where the activity of CRAs is maximal, although increased penetration of outer cell layers may be achieved with CRAs in the unionized state. Hypochlorous acid has long been considered the active moiety responsible for bacterial inactivation by CRAs, the OCl_2 ion having a minute effect compared to undissolved HOCl.

Deleterious effects of CRAs on bacterial DNA that involve the formation of chlorinated derivatives of nucleotide bases have been described. Hypochlorous acid has also been found to disrupt oxidative phosphorylation and other membrane-associated activity.

5.5 Limitations on efficacy including resistance

5.5.1 General limitations
No limitations are mentioned.

5.5.2 Resistance
Although different species vary in their sensitivity to hypochlorite, development of acquired resistance is not expected. Sodium hypochlorite is a reactive biocide which attacks and inactivates microbial cells in many ways, reacting with a wide range of molecules in the cell wall and cell interior and degrading or destroying the cell completely. Secondly, being reactive, hypochlorite is also rapidly decomposed on contact with organic matter during use such that organisms are not exposed to active residual. For the same reasons cross-resistance is not to be expected, nor has been observed.

5.5.3 Resistance management strategies
No management strategies are necessary as acquired resistance to active chlorine is not expected due to its reactive nature and unspecific mode of action.

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 Mida Foam 196 FI, when used in accordance with the proposed label (WG/GA), is effective in controlling bacteria (excluding mycobacteria and bacterial spores), yeasts, fungi and bacteriophages on surfaces that may come into contact with food and feed.

6 Human toxicology

Active chlorine released from sodium hypochlorite

This assessment is based on the List of Endpoints (LoEP) from the final CA-report for which Italy is the Reporting Member State.

List of Endpoints

In water, sodium hypochlorite dissociates into the sodium cation (Na^+) and hypochlorite anion (ClO^-), which is characterised by its well-known irritating/corrosive effects. Further, hypochlorite is in equilibrium with hypochlorus acid (HClO) and chlorine (Cl_2). The remaining sodium cation is a physiologically-essential element and required in the intermediary metabolism. Hence, it cannot be regarded as a typical xenobiotic when entering the body.
Since in aqueous solutions, sodium hypochlorite (NaOCl) and chlorine share the same anion (ClO^-) and, thus, release the very same active substance (i.e. active chlorine, thought to consist of hypochlorite, hypochlorous acid and chlorine in equilibrium), read-across is possible for all the toxicological end-points.

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	The BPC TOX-WGIII-2016 agreed that human health effects are primarily due to the local mode of action of hypochlorite and potential systemic effects are secondary to its direct irritating reactivity Consequently, oral absorption of sodium hypochlorite is not relevant Regarding oral absorption of sodium ions, high sodium intakes are not expected to be associated with severe health effects as sodium ions are natural physiological metabolites
Rate and extent of dermal absorption*:	The BPC TOX-WGIII-2016 agreed that human health effects are primarily due to the local mode of action of hypochlorite and potential systemic effects are secondary to its direct irritating reactivity Consequently, dermal absorption of sodium hypochlorite is not relevant
Distribution:	The BPC TOX-WGIII-2016 agreed that human health effects are primarily due to the local mode of action of hypochlorite and potential systemic effects are secondary to its direct irritating reactivity In water, different chlorine species are available. The final metabolites in physiological systems are most likely the sodium and chloride ion, which are physiologically essential metabolites
Potential for accumulation:	The BPC TOX-WGIII-2016 agreed that human health effects are primarily due to the local mode of action of hypochlorite and potential systemic effects are secondary to its direct irritating reactivity Due to the high reactivity of chlorine species, no potential for accumulation is expected
Rate and extent of excretion:	After exposure towards [^{36}Cl]-hypochlorus acid, no radioactivity was detected in expired air throughout the 96 h study Excretion mainly through urine as chloride (36.43% + 5.67 of the administered dose after 96 h) Excretion through faeces 96h after exposure (14.8% + 3.7 of the administered dose after 96 h) The total recovery was slightly higher than 50% The final metabolites in physiological systems are the sodium and chloride ion, which are physiologically essential metabolites
Toxicologically significant metabolite(s)	None

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

Acute toxicity	
Rat LD_{50} oral	LD_{50}>2000 mg avCl/kg bwNo classification for acute toxicity (oral) warranted
Rat LD_{50} dermal	LD_{50}>2000 mg avCl/kg bw No classification for acute toxicity (dermal) warranted
Rat LC_{50} inhalation	$LC_{50(1h)}$>10.5 mg avCl/L Regulation (EC) 1272/2008 (CLP) requires conversion of existing inhalation toxicity data which have been generated using a 1-hour testing exposure to 4-hour exposures. As hypochlorite exerts only local effects at the side of first contact, such conversion is not considered necessary No classification for acute toxicity (inhalation) warranted
Skin corrosion/irritation	With sodium hypochlorite solutions ≥5% avCl, skin irritating properties were shown Sodium hypochlorite is classified as Skin Corr. 1B, H314, according to Annex VI, Regulation (EC) 1272/2008 (harmonised classification)
Eye irritation	With sodium hypochlorite solutions ≥5% avCl, eye irritation properties were shown Sodium hypochlorite is classified as Skin Corr. 1B, H314, according to Annex VI, Regulation (EC) 1272/2008 (harmonised classification), covering also eye irritation effects
Respiratory tract irritation	Sodium hypochlorite can be expected to be irritant to the respiratory tract due to the corrosive character of the substance. According to the Guidance on the Application of the CLP Criteria (Version 4.1, 2015, Chapter 3.8.2.5), a classification for corrosivity is considered to implicitly cover the potential to cause RTI. Consequently, no additional classification is required
Skin sensitisation (test method used and result)	Three skin sensitisation studies in guinea pigs (Buehler test) with sodium hypochlorite showed no sensitising properties No classification for skin sensitisation warranted

Respiratory sensitisation (test method used and result)	As there are no indications for skin sensitising potential of sodium hypochlorite, no potential for respiratory sensitisation is expected

Repeated dose toxicity

Short term

Species / target / critical effect	Rats (oral, inhalation)/local irritation at site of first contact, no systemic effects
Relevant oral NOAEC / LOAEC	LOAEC: not detected NOAEC: >7500 ppm avCl
Relevant dermal NOAEC / LOAEC	No dermal repeated dose studies are available for sodium hypochlorite Human data is available for sodium hypochlorite (see below)
Relevant inhalation NOAEC / LOAEC	No inhalation repeated dose study is available for sodium hypochlorite Read-across to chlorine:LOAEC: 3.0 ppm equivalent to 9.0 mg/m^3 NOAEC: 1.0 ppm equivalent to 3.0 mg/m^3

Subchronic

Species/ target / critical effect	Rats, mice and monkeys (oral, inhalation)/local irritation at site of first contact, no systemic effects
Relevant oral NOAEC / LOAEC	LOAEC: 0.2% avCl NOAEC: between 0.02% avCl (highest dose tested) and 0.1 % avCl
Relevant dermal NOAEC / LOAEC	No dermal repeated dose studies are available for sodium hypochlorite Human data is available for sodium hypochlorite (see below)
Relevant inhalation NOAEC / LOAEC	No inhalation repeated dose studies are available for sodium hypochlorite Read-across to chlorine: LOAEC: 2.3 ppm avCl (6.9 mg/m^3 avCl) NOAEC: 0.5 ppm avCl (1.5 mg/m^3 avCl)

Long term

Species/ target / critical effect	Rats and mice (oral, inhalation)/local irritation at site of first contact, no systemic effects
Relevant oral NOAEC / LOAEC	LOAEC: 0.2% avCl NOAEC: between 0.0275 % avCl (highest dose tested) and 0.1 % avCl

Relevant dermal NOAEC / LOAEC	No dermal repeated dose studies are available for sodium hypochlorite Human data is available for sodium hypochlorite (see below)
Relevant inhalation NOAEC / LOAEC	No inhalation repeated dose studies are available for sodium hypochlorite Read-across to chlorine: LOAEC: 0.4 ppm avCl (1.2 mg/m³) NOAEC: <0.4 ppm avCl (<1.2 mg/m³)

Genotoxicity

Hypochlorite solutions show sporadic equivocal/positive results in *in vitro* assays (three Ames tests, cytogenetic assay in mammalian cells) which is due to the ability to generate reactive oxygen species and to induce DNA damage. Standard *in vivo* studies (two micronucleus tests, bone marrow aberration assay, DNA damage in renal tissue) were negative. A non-standard germ cell assay was equivocal. The biological relevance of any result from an *in vivo* study is questionable in view of uncertainty of the availability of the test substance at the target organ Weight of evidence indicates no concern of mutagenic/genotoxic potential *in vivo*

Carcinogenicity

Species/type of tumour	Rat and mouse; there were no treatment related increases in non-neoplastic lesions or tumour incidence
Relevant NOAEC/LOAEC	Studies performed with sodium hypochlorite (oral): LOAEC: 0.2% avC NOAEC: between 0.0275 % avCl (highest dose tested) and 0.1 % avCl Read-across to chlorine (inhalation): LOAEC: 0.4 ppm avCl (1.2 mg/m³) NOAEC: <0.4 ppm avCl (<1.2 mg/m³)

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	No indication of prenatal developmental toxicity, however test concentration too low
Relevant maternal NOAEC	NOAEC: >100 mg/L avCl
Relevant developmental NOAEC	NOAEC: ≥100 mg/L avCl

Fertility

Species/critical effect	No indication for influence on fertility, however test concentration too low
Relevant parental NOAEL	NOAEL: ≥5 mg/kg/bw/d
Relevant offspring NOAEL	NOAEL: ≥5 mg/kg/bw/d
Relevant fertility NOAEL	NOAEL: ≥5 mg/kg/bw/d

Neurotoxicity

Species/ target/critical effect	No neurotoxicity studies available; studies are waived due to lack of evidence of a neurotoxic effect from other acute, subacute, subchronic and chronic studies

Developmental Neurotoxicity

Species/ target/critical effect	No developmental neurotoxicity studies available; studies are waived as the structure of sodium hypochlorite is not related to known neurotoxic substances

Immunotoxicity

Species/ target/critical effect	No immunotoxicity studies available

Developmental Immunotoxicity

Species/ target/critical effect	No developmental immunotoxicity studies available

Other toxicological studies

Tissue toxicity of sodium hypochlorite solutions in female guinea pigs after dermal exposure towards 0.1 or 0.5% sodium hypochlorite solution: 15% decrease in basal cell viabilities after 2 weeks of treatment at 0.5%, morphological changes in cells after 7 and 14 days of treatment at 0.5% and 14 days at 0.1%. It was concluded that a 0.1% solution of sodium hypochlorite could be used for long-term maintenance of the wound due to the relatively low toxicity

Whole body exposure of mice (except head) with aqueous solutions of hypochlorous acid (1, 10, 100, 300, 1000 ppm) and sodium hypochlorite (1000 ppm) for 10 minutes daily on 4 consecutive days: dose-related response to hypochlorous acid (pH 6.5) treatment, the minimally effective dose being 100 ppm, skin thickness (interfollicular epidermis) and the number of cells (total and basal) increased, sodium hypochlorite solution (pH 8.5) showed similar effects at 1000 ppm. NOAEL at 10 ppm sodium hypochlorite

Effect of sodium hypochlorite solutions on skin of guinea-pigs) at 0.125% daily for 1, 2, 4 and 8 weeks: no treatment related effects on the parameters measured (e.g. number of epidermal cells, area of epidermis, area of papillary layer)

Medical/human data

A huge set of human data on "hypochlorite bleaches" and chlorine gas is available.

<u>Oral exposure towards hypochlorite solutions</u>

Accidental human data reported for ingestion and parenteral route; recovery is expected rapid and without any permanent health consequences.

No indications of chronic toxicity in humans following exposure to sodium hypochlorite reported in the literature.

Some studies reported small relative risks for colon and bladder cancer incidence for population consuming chlorinated drinking water for long periods of time, however, studies refer to DBPs, are equivocal or insufficient to establish a causal relationship, are of poor quality, incomplete and prone to confounding factors.

<u>Dermal exposure towards hypochlorite solutions</u>

Patch test on intact human skin: solutions ≥5% avCl irritant

Patch test on human skin in dermatitis patients: weak to moderate irritation with 2% NaOCl; no irritation with 1 % NaOCl

Accidental spillage of hypochlorite bleach into the eyes expected to cause slight, temporary discomfort, which subsides within a short period of time or after rinsing with water

Dermatological case studies (poorly reported and not fully conclusive) indicate a few isolated cases of allergic contact sensitization

<u>Inhalation of chlorine gas</u>

Human volunteer repeated dose study: *Sensory irritation and a transient impairment in lung function* at 1.0 ppm corresponding to 3.0 mg/m^3 chlorine (LOAEC), *only trivial changes of lung function parameters* at 0.5 ppm corresponding to 1.5 mg/m^3 chlorine (NOAEC)

Human volunteer repeated dose study: No significant effects in respiratory function nasal lavage fluid parameters at 0.5 ppm corresponding to 1.5 mg/m^3 chlorine (NOAEC)

Several reports on accidental exposure to chlorine are available. Depending on chlorine concentrations signs of toxicity: dyspnea and coughing, irritation of the throat and eyes, headache, temporary changes in lung function, cytopathological features and tracheobronchial congestions

Summary

	Value	Study	Safety factor
ADI (chlorate)	3 µg chlorate/kg bw	based on the TDI for perchlorate (derived from human observations) according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135)	-
ARfD (chlorate)	36 µg chlorate/kg bw	based on human 12-wks repeated dose oral (drinking water) clinical study according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135	-
$NOAEC_{oral}$	1000 ppm avCl (0.1 % avCl)	rat 90-d subchronic repeated dose oral (drinking water) study rat 104-wks chronic repeated dose oral (drinking water) study	1
$NOAEC_{dermal}$	1% avCl	human (dermatitis patients) 48 h-patch test study	1
$NOAEC_{inhalation}$ (chlorine)	0.5 ppm avCl (1.5 mg avCl/m^3)	monkey 52-wks subchronic repeated dose inhalation study human volunteer single dose inhalation study (4-8 h) human volunteer repeated dose inhalation study (3 d, 6 h/d)	3.2 (intra-species toxicodynamic factor)
$AEC_{inhalation}$ (NaOCl)	No repeated dose inhalation toxicity study on NaOCl is available. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an $AEC_{inhalation}$ based on chlorine data (please see above) $AEC_{inhalation}$ (NaOCl) = 0.5 mg avCl/m^3		
$AEC_{inhalation}$ (HClO)	No repeated dose inhalation toxicity study on HClO is available since HClO does not exist as such but is only formed in aqueous solutions of chlorine. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an $AEC_{inhalation}$ based on chlorine data (please see above) $AEC_{inhalation}$ (HClO) = 0.5 mg avCl/m^3		

MRLs

Relevant commodities	Not relevant for substances such as NaOCl which act by a local mode of action only For chlorate (stable relevant metabolite), no MRL was set*

* In NL Dutch intervention values are set, see https://www.nvwa.nl/onderwerpen/inspectieresultaten-bestrijdingsmiddelen-in-voedingsmiddelen/wettelijke-normen-resten-bestrijdingsmiddelen-in-voedingsmiddelen/interventiewaarden-voor-chloraat-in-levensmiddelen

These intervention values remain applicable until new MRLs are set by the European Commission.

Reference value for groundwater

According to BPR Annex VI, point 68	0.1 µg/L

Local effects
Sodium hypochlorite is a corrosive substance, local effects were observed after single and repeated oral and dermal exposure. Based on the observed local effects, and secondary local effects, a full risk assessment for systemic toxicity is not considered necessary.

Data requirements active substance
No additional data requirements are identified.

6.1 Human exposure assessment active substance

6.1.1 General aspects
Mida Foam 196 FI is a concentrated liquid and contains active chlorine released from sodium hypochlorite as active substance (5.2% w/w expressed as active chlorine). The proposed field of use of Mida Foam 196 FI is a surface disinfectant in food industry (PT4).

The formulation Mida Foam 196 FI is for professional use.

6.1.2 Identification of main paths of professional exposure towards active substance from its use in biocidal product
The formulation is diluted to up to 6% in water before use (max 0.312% w/w sodium hypochlorite expressed as active chlorine) manually and applied using foaming equipment. Therefore, the professional user can be dermally and respiratory exposed to chlorine species during mixing and loading and application. The treated surfaces will be rinsed with drinking water.

As Mida Foam 196 FI is intended for professional use only, oral exposure is considered negligible.

Sodium hypochlorite does not exist as a pure substance, but only in the form of aqueous solutions. When diluted in water, sodium hypochlorite is partly transformed into hypochloric acid (HOCl), depending on the pH of the solution. Under acidic conditions, hypochloric acid can decompose with the liberation of free chlorine:

$$HOCl + H^+ + Cl^- \leftrightarrow Cl_2 + H_2O$$

According to the CAR at the alkaline pH, which is the case for undiluted Mida Foam 196 FI (pH 13.5±0.5), equilibrium is shifted to OCl^- and no chlorine gas is formed. Only a small amount of hypochloric acid will be combined with organic matter present on surface and the amount of chlorine evaporating into the ambient air is considered negligible. However, upper airway exposure to aerosols during loading cannot be excluded and therefore the associated risk needs to be considered.

6.1.3 Identification of main paths of non-professional exposure towards active substance from its use in biocidal product
The formulation Mida Foam 196 FI is to be used by professionals only.

6.1.4 Indirect exposure as a result of use of the active substance in biocidal product
Bystanders may be exposed to chlorine species dermally and respiratory if they are present in the same room as Mida Foam 196 FI is handled.

Sodium hypochlorite is a highly reactive substance which reacts immediately with organic matter at the site of first contact. The WG/GA states that the system needs to be rinsed with water after treatment, however chlorate residues may still be relevant as chlorate is considered a stable metabolite (BCP APCP-WGII-2016). Therefore, secondary dietary exposure of the general public to chlorate residues cannot be excluded.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

No studies with Mida Foam 196 FI have been submitted and the classification and labelling of the formulation has been prepared based on the calculation method described in Annex I of Regulation 1272/2008/EC.

6.2.2 Data requirements formulated product

No additional data requirements are identified.

6.3 Risk characterisation for human health

6.3.1 Professional users

As for sodium hypochlorite systemic effects are considered to be secondary to local effects, the risk assessment will be based on local effects.

Mixing and loading

Professional users make the in-use concentration of up to 6% (max 0.312% w/w sodium hypochlorite expressed as active chlorine) before application. Therefore, the professional user can be dermally and respiratory exposed to chlorine species during mixing and loading. The active chlorine concentration in the undiluted formulation is 5.2% for Mida Foam 196 FI, which is higher than the dermal NOAEC value of 1%. Also, due to the high pH the formulation is classified to be skin corrosive (Cat 1). Therefore, the use of gloves, eye protection and suitable protective clothing is prescribed during the mixing and loading operation.

To estimate potential respiratory exposure to chlorine during mixing and loading, Mixing and Loading Model 7 for liquids can be used (HEAd hoc recommendation no. 6). The model gives the indicative respiratory exposure of 0.94 mg biocidal product/ m^3, corresponding to a concentration of 0.049 mg sodium hypochlorite/m^3 expressed as active chlorine (5.2% w/w). This is below the respective $AEC_{inhalation}$ of 0.5 mg/m^3. The resulting risk index is (0.049/0.5=) 0.10.

Application by foaming

Professional user can be dermally and respiratory exposed to chlorine species during application by foaming. The active chlorine concentration in the working solution is up to 0.312%, which is below the dermal NOAEC value of 1%. However, due to the high pH the formulation (12.3±0.5 at 1% dilution) also the diluted working solution is considered to be skin corrosive (Cat 1). Therefore, the use of gloves, eye protection and suitable protective clothing is prescribed during the foaming application.

To estimate potential respiratory exposure to chlorine during foaming application, Spraying Model 1 for liquids is used (HEAd hoc recommendation no. 6). The model gives the indicative respiratory exposure of 104 mg biocidal product/m^3, corresponding to a concentration of up to 0.32 mg sodium hypochlorite/m^3 expressed as active chlorine (0.312% w/w). This is below the respective $AEC_{inhalation}$ of 0.5 mg/m^3. The resulting risk index is (0.32/0.5=) 0.65.

In conclusion, no adverse effects are expected for protected (gloves, eye protection and suitable protective clothing) professional users from exposure to sodium hypochlorite by application of Mida Foam 196 FI during mixing and loading and application by foaming.

6.3.2 Non-professional users, including the general public
The formulation Mida Foam 196 FI is to be used by professionals only.

6.3.3 Indirect exposure as a result of use
Bystanders may be respiratory and dermally exposed to Mida Foam 196 FI. For the professional users PPE (gloves, eye protection, and protective clothing) is prescribed. Therefore, unprotected bystanders should be kept away from the room where a disinfection takes place to prevent accidental dermal exposure. To keep unauthorised persons from entering the treatment area, the product label should carry the phrase "Unprotected persons should be kept out the treatment areas".

Dietary risk assessment and disinfectant by-products assessment
Sodium hypochlorite is a highly reactive substance which reacts immediately with organic matter and decomposes to sodium chloride. The BPC APCP-WGII-2016 concluded that chlorate residues may still be relevant as chlorate is considered a stable metabolite. Sodium chlorate is a by-product of the manufacturing process and is formed during degradation (e.g during storage). Thus, chlorate may represent a worst-case for sodium hypochlorite residues.

The product is used in food and beverage industries and residual amount of chlorate may be transferred to foodstuffs, beverages and raw materials. The applicant has submitted a residue test conducted at a customer who is using Mida Foam 196 FI in practice. In this test the formulation was diluted to 1.96% and was applied on a double screw. Application on a double screw was considered to represent the worst case. Because the screw does not rotate during disinfection the operator needs to move around and apply more product than for other objects (e.g. flat surfaces) to ensure that the surface is completely covered with the diluted solution. After disinfection the surface of double screw was rinsed off twice. The second rinse water contained 0.029 mg chlorate/kg. Considering that the current application for Mida Foam FI 196 concerns in-use concentration of 6% instead of 1.96% as used in the residue test, the chlorate concentration in second rinse water is estimated to be 0.089 mg/kg when Mida Foam FI 196 is used in accordance with the proposed WGGA.

There is no MRL set for chlorate at the EU level. Therefore the default MRL of 0.01 mg/kg is applicable according to the Regulation 396/2005. However this value is so low that even without the use of a plant protection product the MRL is exceeded. Therefore since 2014 the Dutch intervention MRLs are set for chlorate in the Netherlands. The MRL is set to be between 0.1 and 0.25 mg/kg, except for baby food. For baby food the MRL of 0.01 mg/kg is applied in accordance with the Commission Directive 2006/125/EC and 2006/141/EC. The Dutch intervention MRLs will remain effective until the European Commission's has established new MRLs for chlorate.

Because the chlorate concentration in the second rinse water is estimated to be lower than 0.1 mg/kg but higher than 0.01 mg/kg, an exceedance of chlorate level above MRL cannot be excluded in baby food. Thus, the use of Mida Foam FI 196 can be authorised for food industry with the exemption for the production of baby food.

6.3.4 Combined exposure
Mida Foam 196 FI contains only one active substance and it is not described that it should be used in combination with other formulations.

6.3.5 Substances of concern
One co-formulant was identified as substance of concern contributing to the classification of Mida Foam 196 FI as Skin Corr Cat 1 (H314). According to the SoC guidance (Ca-Nov14doc.5.11) this SoC falls into band B, for which qualitative exposure and risk assessment to determine whether P-

sentences associated with concerned H-statements are sufficient or whether other risk mitigation measures should be applied.

As appropriate PPEs (gloves, eye protection and suitable protective clothing) are prescribed when handling the undiluted product, no adverse effects are expected from the exposure to the SoC. Further risk assessment for the identified SoC is not considered necessary.

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, eye protection and suitable protective clothing) professional user after dermal and respiratory exposure to active chlorine generated from sodium hypochlorite as a result of the application of Mida Foam 196 FI, when used in accordance with the WG/GA.

Adverse effects for unprotected bystanders could not be excluded. To keep unauthorised persons from entering the treatment area, the product label should carry the phrase "Unprotected persons should be kept out the treatment areas".

Regarding dietary exposure of the general public, concentrations of a metabolite chlorate may exceed the MRL in baby food. Therefore the use of Mida Foam FI 196 can be authorised for food industry with the exemption for the production of baby food.

7 Environment

7.1 Introduction

Authorisation is requested for the product Mida Foam 196 FI containing sodium hypochlorite as the active substance. The biocidal product concerns a disinfectant for food and feed areas (PT04). The product is for professional use. The intended uses are described in Table E.1.

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

Area of use envisaged	Concentration active substance in product	Dose	Use concentration active substance
Disinfection of surfaces in direct contact with food or feed (PT04)	59.8 g/L (sodium hypochlorite)	20-90 mL per L water	1.38-6.19 g/L (sodium hypochlorite)*

* based on a density of 1150 kg/m^3 of the product

The diluted product is subsequently applied on the surfaces to be disinfected by foaming. The applicant indicates that an amount of 200 mL diluted product applied per m^2 can be considered worst-case.

7.2 Product related studies

The exposure assessment is based on data for the active substance. There are no fate or ecotoxicity data available for the product.

7.3 Environmental exposure assessment

7.3.1 Chemistry and/or metabolism

Sodium hypochlorite is gaseous chlorine (Cl_2) in a solution of sodium hydroxide (NaOH). Chlorine will be present as a gas, hydrochloric acid (HOCl), or hypochlorite (OCl^-), depending on the pH. The biocidal principle of sodium hypochlorite is based on hydrochloric acid, which is a strong oxidiser. Above pH 11 the biocidal aim of sodium hypochlorite is strongly decreased as chlorine is only present

as hypochlorite. In strongly diluted solutions hydrochloride acid decomposes into chlorine and oxygen, a chemical reaction that is accelerated by light and the presence of metals.
Free available chlorine can be built in organic matter forming chlorinated organic micro pollutants.

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. Emissions from active substances 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[1]	Freshwater[2]	Saltwater[2]	Soil[3]	Air
Disinfection of surfaces in direct contact with food or feed (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.

The diluted product is subsequently applied on the surfaces to be disinfected by spraying, foaming or soaking. Because surfaces are rinsed with clean water afterwards or wet cleaned when necessary, residues are released to the sewer along with the waste water. Surplus fluids are discharged to the sewer as well. The active substance therefore enters the aquatic environment via the sewage treatment plant (STP). In order to fulfil the requirements set by the local water boards regarding lipids and fats, and biological oxygen demand (BOD) , waste water from food, feed, and beverage industries is usually purified in grease and sedimentation separation tanks prior to discharge to the sewer. Such systems are however not required for other industrial areas, but additional purification of waste water prior to release to the sewer may take place as well.

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.
Considering that the product is not volatile, emission to air is assumed negligible.

Due to the active substances' chemical properties, the assessment will be performed qualitatively. Possible pH effects on the environment were not considered, because the receiving compartments are expected to have sufficient buffering.

7.4 Risk characterization for the environment

7.4.1 Aquatic compartment (incl. sediment) and STP

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

Hypochlorite is a very reactive compound. During and after use of the product the concentration strongly decreases when hypochlorite reacts through a chain of reactions, thereby forming chlorine. Residues will react with organic matter present in the pipeline system that discharges to the STP. The wastewater discharged to the sewer system will contain very low or no hypochlorite, hypochloric acid or free chlorine because of the degradation processes that occur in the sewer system. The

remaining fraction of residues will be removed in the STP. Therefore, no unacceptable risks for micro-organisms in the STP and organisms in the aquatic compartment are expected.
Conclusively, the proposed applications when used in compliance with the legal directions for use (WG/GA) meet the standards for aquatic organisms, sediment organisms and micro-organisms in the STP.

7.4.1.2 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 sodium hypochlorite or active chlorine in Dutch surface water.

7.4.1.3 Surface water intended for the abstraction of drinking water
Biocidal products with the active substance hypochlorite (and active chlorine) have been on the market for more than three years. The existing active substance is 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, the active substance is not included in the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010). Considering this the Ctgb concludes that there are in this case insufficient indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. Thus the standards for surface water destined for the production of drinking water are met.

7.4.2 Terrestrial compartment

7.4.2.1 Soil organisms
For the intended use of the product, direct and indirect 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 substance is therefore deemed negligible. Hence, the risk for soil organisms and non- target arthropods (including bees) is considered acceptable for the intended uses.

7.4.2.2 Groundwater
Assessment of the drinking water criterion defines that the concentration of the active substance and the relevant metabolites in groundwater for the preparation of drinking water needs to be <0.1 µg/L. Considering the application of the product, emission routes to the environment, and the biochemical profile of the active substance, environmental concentrations in soil and soil pore water are expected to be low. Leaching and concentrations in shallow groundwater will be negligible. Therefore, the risk for groundwater is considered acceptable.

7.4.2.3 Persistence in soil
Sodium hypochlorite is chemically instable and a highly reactive oxidant. The proposed use will not result in exposure of soil. Therefore standards for persistence in soil are met.

7.4.3 Non compartment specific effects relevant to the food chain

7.4.3.1 Bioconcentration

The risk for bioconcentration in aquatic organisms is considered low for the active substance, as the log K_{ow} is < 3 (-0.87). Bioconcentration and biomagnification is not expected (conform the biomagnification trigger value proposed for K_{ow} in the Guidance on biocide legislation, Part B+C,

volume IV) and the risk for bioconcentration for the proposed use is therefore considered acceptable.

7.4.3.2 Primary and secondary poisoning of birds and mammals
The concentration of sodium hypochlorite in waste water will be negligible after discharge to surface water because of the degradation processes that occur in the sewer system and the STP.
Direct exposure of birds and mammals to the product is not expected and primary poisoning of birds and mammals is not considered relevant. Indirect exposure through the consumption of aquatic or soil organisms is also not considered relevant. As direct and indirect exposure of birds and mammals to the active substance or contaminated aquatic and terrestrial organisms is expected to be negligible, the risk for the primary and secondary poisoning is considered acceptable.

7.4.4 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 sodium hypochlorite (and active chlorine) contribute to depletion of the ozone layer as the compounds are not listed as 'controlled substance' according to Annex I of Regulation (EC) No 1005/2009 of the European Parliament. In addition, although the volatilization of chlorine gas depends on the pH, volatilization is expected to be very low. The calculated half-life is 2750 hours and long distance transport seems likely. However, it is not expected that this will result in unacceptable risks as the active substance is quickly oxidised once entering the sewer system and not volatile resulting in a negligible emission from the STP during sewage treatment. The environmental risk to air are therefore considered acceptable for the substance.

7.5 Measures to protect the environment (risk mitigation measures)

The applicant did not include any risk mitigation measures for the environment in the draft WG/GA and PGB-PUB. Additional risk mitigation measures are not required, considering that risks to the environment are acceptable for the intended uses.

7.6 Overall conclusion for the aspect Environment

An authorisation of a biocide in The Netherlands is only possible when the risks related to the product application are acceptable. When used in accordance with the legal Instructions for Use (WG/GA), Mida Foam 196 FI complies with the environmental standards and will not cause unacceptable effects to the environment. No risk mitigation measures are necessary.

7.7 Data requirements

There are no additional data required.

8 Conclusion

The applicant has proven that Mida Foam 196 FI 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:

Based on Reg. (EC) 1272/2008:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Sodium hypochlorite; Sodium hydroxide (CAS 1310-73-2)			
Pictogram:	GHS05	Signal word:	Danger
	GHS09		
H-statements:	H290	May be corrosive to metals	
	H314	Causes severe skin burns and eye damage.	
	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.	
	P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].	
	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/...	
Supplemental Hazard information:	EUH031	Contact with acids liberates toxic gas	
Child-resistant fastening obligatory?			**Not applicable**
Tactile warning of danger obligatory?			**Not applicable**

Explanation:	
Pictogram:	-
H-statements:	The applicant has classified the product (H400) on the basis of the harmonized classification (CLP00) of the active substance. However, this classification was changed by the RAC (2016) with respect to the aquatic endpoints: for Aquatic Acute 1 (H400) an M-factor of 10 was assigned and the classification as Aquatic Chronic 1 with an M-factor of 1 was added. The classification of the product was adjusted to H410 (or H400+H411) based on these new insights.
P-statements:	P260 is highly recommended for products with H314.
Other:	-

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

10 References

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