HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 19 maart 2013 is van

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

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

Chriox 5

op basis van de werkzame stoffen perazijnzuur en waterstofperoxide.

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.

- 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 121, eerste lid, de juncto artikel 44, eerste lid Wet gewasbeschermingsmiddelen en biociden
Classificatie en etikettering	artikel 89, tweede lid, Verordening 528/2012, jo. artikel 130a, vierde lid, WBB, jo. artikel 50 WGB oud
Gebruikt toetsingskader	RGB (Hoofdstuk 10)

3 BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

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

3.2 Analysemethoden

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

3.3 Risico voor de mens

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

3.4 Risico voor het milieu

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

3.5 Werkzaamheid

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

Bezwaarmogelijkheid
Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 1 mei 2015

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

14818 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20130279 TB
Type aanvraag:	aanvraag tot toelating van de biocide op basis van niet geplaatste stof(fen) (overgangsrecht)
Middelnaam:	Chriox 5
Verzenddatum aanvraag:	19 maart 2013
Formele registratiedatum: *	27 maart 2013
Datum in behandeling name:	

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

2 Stofinformatie

Werkzame stof	Gehalte
perazijnzuur	4,9%
waterstofperoxide	23,0%

De werkzame stoffen perazijnzuur en waterstofperoxide zijn opgenomen in het reviewprogramma maar nog niet geplaatst op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

3 Toelatingsinformatie

Toelatingsnummer:	14818 N
Expiratiedatum:	1 mei 2025
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Met water mengbaar concentraat
Uiterste gebruiksdatum:
12 maanden na productiedatum

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BIJLAGE II Etikettering van het middel Chriox 5

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: azijnzuur, perazijnzuur, waterstofperoxide

Pictogram	GHS02 GHS05 GHS07 GHS09
Signaalwoord	GEVAAR
Gevarenaanduidingen	EUH071 Bijtend voor de luchtwegen. H242 Brandgevaar bij verwarming. H290 Kan bijtend zijn voor metalen. H302 Schadelijk bij inslikken. H314 Veroorzaakt ernstige brandwonden en oogletsel. H332 Schadelijk bij inademing. H335 Kan irritatie van de luchtwegen veroorzaken. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P210 Verwijderd houden van warmte, hete oppervlakken, vonken, open vuur en andere ontstekingsbronnen. Niet roken. P234 Uitsluitend in de oorspronkelijke verpakking bewaren. P260 Stof/rook/gas/nevel/damp/spuitnevel niet inademen. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P284 Adembescherming dragen. P303 + P361 + P353 + P310 BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken. Huid met water afspoelen/afdouchen. Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P305 + P351 + P338 + P310 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P403 + P235 Op een goed geventileerde plaats bewaren. Koel bewaren.
Aanvullende etiketelementen	
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

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BIJLAGE III WG/GA van het middel Chriox 5

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van:

1. bacteriën (excl. mycobacteria), bacteriesporen, en gisten op:
   a. oppervlakken in publieke sector en in ziekenhuizen en overige instellingen voor de gezondheidszorg.
   b. oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor, inclusief keukens in ziekenhuizen en overige instellingen voor de gezondheidszorg, exclusief melkwinningsapparatuur op de boerderij.
2. bacteriën (excl. mycobacteria), bacteriesporen, gisten, schimmels, en virussen op oppervlakken van medische instrumenten door middel van dompelen.
3. bacteriën (excl. mycobacteria en bacteriesporen) en gisten op oppervlakken in ruimten bestemd voor dieren en bijbehorende ruimten, exclusief transportvoertuigen.
4. bacteriën (excl. mycobacteria), bacteriesporen, en gisten op oppervlakken van installaties door middel van cleaning-in-place (CIP) in farmaceutische, cosmetische en voedselverwerkende industrie, inclusief ionenwisselaars. Het middel mag uitsluitend worden toegepast met daarvoor geschikte doseerapparatuur voor het desinfecteren van het inwendige van procesapparatuur.
5. bacteriën (excl. mycobacteria en bacteriesporen), gisten, en virussen voor thermochemische desinfectie van wasgoed in wasserijen. Het middel mag uitsluitend worden toegepast met daarvoor geschikte doseerapparatuur voor wasmachines.

Om bodem- en in het waterlevende organismen te beschermen dienen resten die het middel bevatten uitsluitend te worden afgevoerd naar het riool met aansluiting op de RWZI of de mestopslag. In geen geval mag dit middel worden geloosd op een Individuele Behandeling Afvalwater (IBA).

Indien middel wordt toegepast middels sprayen of schuimen moet geschikte adembescherming worden dragen.
Onbeschermde personen dienen niet aanwezig te zijn in de ruimten waar de behandeling door middel van sprayen en schuimen plaatsvindt.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Algemeen
Het middel is bestemd voor de desinfectie van oppervlakken, apparatuur en gebruiksvoorwerpen.

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

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Behandelde oppervlakken of materialen die met eet- en drinkwaren en de grondstoffen hiervoor in contact kunnen komen dienen na de inwerktijd grondig met schoon water te worden nagespoeld.

Toepassingsgebieden en doseringen

1: Oppervlakken, apparatuur en materialen
Oppervlakken en materialen vooraf eerst grondig reinigen. Het daarbij gebruikte reinigingsmiddel goed afspoelen met schoon water. Overtollig water verwijderen. Bij het desinfecteren zoveel vloeistof gebruiken dat de oppervlakken gedurende de inwerktijd nat blijven.
Toepassen door middel van sprayen, dompelen, schuimen of met behulp van een natte schoonmaakdoek of zwabber.

Dosering :
Bacteriën en gisten: 0,5% (5 ml/L) met een minimale inwerktijd van 5 minuten
Bacteriesporen: 8 % (80 ml/L) met een minimale inwerktijd van 5 minuten.

2: Medische instrumenten
De te desinfecteren instrumenten eerst grondig reinigen. Het daarbij gebruikte reinigingsmiddel goed afspoelen met schoon water. Overtollig water verwijderen.
Toepassen door de instrumenten te dompelen.

Dosering :
Bacterie, gist, sporen, schimmels en virussen: 6 % (60ml/L) met een minimale inwerktijd van 60 minuten

3: Boerderijtoepassingen
De te desinfecteren apparatuur/oppervlakken eerst grondig reinigen. Het daarbij gebruikte reinigingsmiddel goed afspoelen met schoon water. Overtollig water verwijderen.
Toepassen in stallen middels spuiten of schuimen.

Dosering :
Bacterie en gist: 0.5 % (5 ml/L) met een minimale inwerktijd van 30 minuten

4: Cleaning in place *(*CIP)
De te desinfecteren apparatuur eerst grondig reinigen. Het daarbij gebruikte reinigingsmiddel goed afspoelen met drinkwater. Overtollig water verwijderen. Bij het desinfecteren zoveel vloeistof gebruiken dat de oppervlakken gedurende de inwerktijd nat blijven.
Leidingsystemen en apparatuur behandelen met behulp van een rondpomp systeem zoals gebruikelijk in een CIP installatie. Na behandeling grondig naspoelen met drinkwater.
Temperatuur: 20 - 30 ºC.
Dosering :
Bacteriën en gisten : 0,5 % (5 ml/L) met een minimale inwerktijd van 5 minuten.
Bacteriesporen: 8 % (80 ml/L) met een minimale inwerktijd van 5 minuten of
0.8% (8 ml/L) met een minimale inwerktijd van 60 minuten.

5: Wasgoed in wasmachines
Desinfectie van laag tot gemiddeld bevuild textiel bv. hotel & ziekenhuislinnen. Geschikt voor katoen en polyester-katoen. Geschikt voor toepassing in zacht water (<8ºDH).
De verpakking aansluiten op het automatische doseersysteem van de professionele wasmachines.
Chemisch-thermische desinfectie tussen 60℃ (15 min uten) en 70℃ (10 minuten).
Desinfectie volgt na reiniging met een alkalisch wasmiddel. Chriox 5 dient te worden toegevoegd nadat de ontsmettingstemperatuur is bereikt.

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Dosering :
2 ml / L waswater in de hoofdwas (0,2%).
Minimale inwerktijd : 15 minuten bij 60℃
10 minuten bij 70℃.

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BIJLAGE IV

RISKMANAGEMENT

Contents

1 Introduction

1.1 Applicant
Christeyns B.V.
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1.2 Active substance
Hydrogen peroxide and peracetic acid.

1.3 Product
Chriox 5

1.4 Function
Desinfectans (PT02, PT03 and PT04)

1.5 Background to the application
This concerns an application for authorization of a new biocidal product.

1.6 Intended uses
The proposed field of use of Chriox 5 is the control of bacteria (excluding mycobacteria), bacterial spores and yeasts in/on:
- surfaces in industrial, public and health care areas (PT02)
- surfaces in places where people reside (PT02
- CIP in pharmaceutical and cosmetic industry (PT02
- medical instruments (PT02)
- during the washing process of laundry (PT02)
- surfaces on farms, in animal housing (PT03)
- CIP in equipment used in food processing, ion exchangers included (PT04)
- surfaces which may be in contact with food and beverage and products used for the production of food and beverages including milking equipment, kitchens in hospitals en other services in the health care area (PT04)
- animal drinking water (PT05)

1.7 Packaging details
HDPE (1L, 5L, 20L, 30L, 60L)

2 Identity

H.2.1 Identity of the active substance

H.2.1.1 Hydrogen peroxide
The active substance hydrogen peroxide is not yet included in the Union list of approved substances of EU Regulation 528/2012. For PT1-6 a first draft CAR is available (November 2013, RMS FI).

Data on the identity are based on information included in the IUCLID dossier and the Merck Index.

Common name	Hydrogen peroxide
Name in Dutch	Waterstofperoxide
Chemical name	Hydrogen peroxide
CAS no	7722-84-1
EC no	231-765-0

.

Chemical name	Hydrogen peroxide

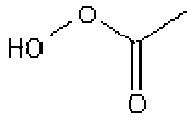
Other names	Hydrogen dioxide or hydroperoxide
CIPAC No	755
CAS No	7722-84-1
EEC No (EINECS or ELINCS)	231-765-0
Molecular formula	H_2O_2
Molecular mass	34.0
Structural formula	H-O-O-H

H.2.1.2 Peracetic acid

The active substance peracetic acid is not yet included in the Union list of approved substances of EU Regulation 528/2012. For PT1-6 a first draft CAR is available (2012, RMS FI).

Data on the identity are based on information included in the IUCLID dossier and the Merck Index.

Common name	Peracetic acid
Name in Dutch	Perazijnzuur
Chemical name	Peracetic acid
CAS no	79-21-0
EC no	210-186-8

Chemical name	Peracetic acid
Other names	Ethaneperoxoic acid or peroxyacetic acid or acetyl hydroperoxide
CIPAC No	-
CAS No	79-21-0
EEC No (EINECS or ELINCS)	210-186-8
Molecular formula	$C_2H_4O_3$
Molecular mass	76.05
Structural formula	

H.2.2 Identity of the biocidal product

Name	Chriox 5
Formulation type	SL
Content active substance	Hydrogen peroxide: 23.0% w/w Peracetic acid: 4.9% w/w

Packaging information:

	Material	Size / content	Other information
Professional use	HDPE	1L, 5L, 20L, 30L, 60L	-

H.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

H.3.1 Physical and chemical properties of the active substance

H.3.1.1 Hydrogen peroxide

Data on the physical and chemical properties are based on information included in the IUCLID dossier and the Merck Index.

	35 %	**70 %**
Melting point	-33 ℃	-40 ℃
Boiling point	108 ℃	125 ℃
Temperature of decomposition	> 100 ℃	> 100 ℃
Appearance	Clear colourless solution	Clear colourless solution
Density	1.132 g/cm^3 at 20 ℃	1.288 g/cm^3 at 20 ℃
Surface tension	74.0 mN/m	76.0 mN/m
Vapour pressure	30.7 hPa at 20 ℃	14.7 hPa at 20 ° C
Solubility in water	Miscible at any ratio	Miscible at any ratio
Oxidative properties	Classified as oxidizing agent	
Explosive properties	Vapour in equilibrium, with aqueous H_2O_2 solutions above 74 % by weight can explode. 'Voor waterstofperoxide 35 % (in water) is er kans op explosie door ontleding en vermenging met andere stoffen. Oplossing niet verwarmen en verontreiniging vermijden (Chemiekaarten 2000)'	

Hydrogen peroxide is considered a strong oxidiser en will react vigorously with combustible material and reducing agents resulting in the risk of fire and explosion. Usually, hydrogen peroxide is marketed as an aqueous solution (3-90%), possibly including stabilisers.

H.3.1.2 Peracetic acid

Data on the physical and chemical properties are based on information included in the IUCLID dossier and the Merck Index.

	5 %	**40 %**
Melting point	-28 ℃	-37 ℃
Boiling point Temperature of decomposition	Depending on the dilution, peracetic acid solutions have a boiling point around 100 ℃ or decompose before.	
Appearance	Clear, colourless solution with acrid odour	
Relative density	1.12 at 20 ℃	1.14 at 20 ℃
Vapour pressure	27 hPa (water)	14 hPa (water)
	0.4 hPa (H_2O_2)	0.2 hPa (H_2O_2) in a 35% solution!
	0.8 hPa (HAOc)	4.1 hPa (HOAc) in a 35% solution!
Solubility in water	miscible	
Solubility in organic solvents	Freely soluble in alcohol, ether and H_2SO_4	
Partition co-efficient (log P_{ow})	-1.25 (calculated)	
Hydrolytic stability	Dilute peracetic acid solutions break down by hydrolytic decomposition to acetic acid and hydrogen peroxide. The rate of hydrolysis is accelerated by temperature, pH, metal ions.	
Flashpoint	> 100 ℃;	40.5 ℃ (closed cup)

	74 – 83℃ (other source, closed cup)	62 ℃ flammable
Auto-flammability	430 ℃	225 ℃
Oxidative properties	Oxidizing according to EU A17 test; not oxidizing according to UN test	oxidizing
Explosive properties	No explosive properties	Explosible under specific conditions (temperature > 50 ℃, quick decomposition, contact with some materials)

Peracetic acid is in equilibrium with hydrogen peroxide and acetic acid. The equilibrium is shifted by adding hydrogen peroxide or acetic acid. Decomposition of peracetic acid is violent and may results in formation of oxygen gas. Decomposition can be induced by high temperatures, high pH, catalysts like certain metals, or presence of organic matter. To reduce decomposition during storage, often stabilisers are added.

H.3.2 Physical and chemical properties of the biocidal product

Appearance	Clear colourless liquid with pungent odour
Explosive properties	Not explosive
Oxidative properties	Oxidising, contains organic peroxides type D
Autoflammability	±435℃
Flashpoint	> 96 ℃
pH 1% solution	pH (1%)=2.46 pH (100%)=0.5±0.2 acidity calculated as H_2SO_4=7.5% w/w
Particle size distribution	Not applicable
Surface tension	Not applicable
Viscosity	Not applicable
Relative density	1.115
Storage stability/Shelf life/Packaging	Shelf life was tested during 12 months at 20℃ in HDPE. Checked parameters: appearance, packaging stability, weight change, content active ingredient, pH, free acidity and relative density. All data remained within acceptable limits. The loss of peracetic acid after 12 months of storage was 9.5%. This is acceptable for this type of product.
Technical properties	Not applicable
Physical and chemical compatibility	Not applicable

H.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: 12 months in HDPE

Data requirements

None.

4 Analytical methods for the technical active substance

Data on the analytical methods are based on information included in the IUCLID dossier and the Merck Index.

H.4.1 Analytical methods for the technical active substance

H.4.1.1 Hydrogen peroxide

Technical as (principle of method)	Hydrogen peroxide: CIPAC (RE 56) E 318
Impurities in technical as (principle of method)	None required.

H.4.1.2 Peracetic acid

Technical as (principle of method)	Peracetic acid: Iodometric titration with starch as indicator
Impurities in technical as (principle of method)	None required.

H.4.2 Analytical methods for analysis of the biocidal product

Preparation (principle of method)	Hydrogen peroxide: titration with ceric sulphate Peracetic acid: iodometric titration

H.4.3 Residue analytical methods

Considering both hydrogen peroxide and peracetic acid react violently with organic matter, it is not considered feasible or relevant to monitor these substances in the environment. For the breakdown product acetic acid, commonly available methods can be used. For determination of free hydroxyl radicals, various analytical methods are described in literature.

H.4.4 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements

None.

5 Efficacy

5.1 Function

Chriox 5 is a disinfectant based on hydrogen peroxide (23% w/w) and peracetic acid (4.9% w/w).

5.2 Field of use envisaged

The proposed field of use of Chriox 5 is the control of bacteria (excluding mycobacteria), bacterial spores and yeasts in/on:

- surfaces in industrial, public and health care areas (PT02)
- surfaces in places where people reside (PT02
- CIP in pharmaceutical and cosmetic industry (PT02
- medical instruments (PT02)
- during the washing process of laundry (PT02)

- surfaces on farms, in animal housing (PT03)

- CIP in equipment used in food processing, ion exchangers included (PT04)
- surfaces which may be in contact with food and beverage and products used for the production of food and beverages including milking equipment, kitchens in hospitals en other services in the health care area (PT04)

- animal drinking water (PT05)

These uses are included in PT02, PT03, PT04 and PT05.

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

The provided studies which were relevant for the assessment are summarized in table 1.

Table 1: Summary of studies provided to demonstrate the efficacy of Chriox 5

Test method	Concentration	Soiling Conditions	Contact time	Temperature	Species tested	Log reduction
EN 1276 (phase 2, step 1)	0.5%	3 g/l bovine albumin	5 min.	20℃	**Bacteria:** *Pseudomonos aeruginosa* *Enterococcus hirae* *Escherichia coli* *Staphylococcus aureus*	log R >5
EN 1650 (2008) (phase 2, step 1)	0.5%	3 g/l bovine albumin	5 min	20℃	**Yeast:** *Saccharomyces cerevisiae*	log R>4
EN 1650 (phase 2, step 1)	6.0% 0.05%	3 g/l bovine albumin	15 min. 15 min.	20℃	**Fungi:** *Aspergillus brasiliensis* **Yeast:** *Candida albicans*	log R >4 log R >4
EN 1650 (phase 2, step 1)	5.0% 0.5%	1% reconstituted milk (w/v)	15 min.	20℃	**Fungi:** *Aspergillus brasiliensis* **Yeast:** *Candida albicans*	log R >4 log R >4
EN 13697 (phase 2, step 2)	0.5% 0.5%	1% reconstituted milk (w/v)	5 min.	20-23℃	**Bacteria:** *Pseudomonos aeruginosa* *Enterococcus hirae* *Escherichia coli* *Staphylococcus aureus* **Yeast:** *Candida albicans*	log R >4 log R >3
EN 13704 (phase 2, step 1)	8%	3 g/l bovine albumin	5 min.	20℃	**Bacteria spore:** *Bacillus subtilis*	log R >3
EN 1656 (phase 2, step 1)	0.3% 0.3%	3 g/l bovine albumin	30 min. 1 min.	10℃ 20℃	**Bacteria:** *Enterococcus hirae* *Proteus vulgaris* *Pseudomonos aeruginosa* *Staphylococcus aureus*	log R >5 log R >5
EN 1657 (phase 2,	1.5%	3 g/l bovine albumin	30 min.	10℃	**Fungi:** *Aspergillus brasiliensis*	log R >4

Test method	Concentration	Soiling Conditions	Contact time	Temperature	Species tested	Log reduction
step 1)	0.5%				**Yeast:** *Candida albicans*	log R >4
EN 1650 (phase 2, step 1)	6.0% 0.05%	3 g/l bovine albumin	15 min.	20℃	**Fungi:** *Aspergillus brasiliensis* **Yeast:** *Candida albicans*	log R >4 log R >4
EN 14476 (phase 2, step 1)	0.8% 0.8%	3 g/l BSA + 3ml Erythrocytes/ l	60 min. 5 min.	20℃	**Virus:** PoliovirusType 1 **Virus:** AdenovirusType 5	log R >4 log R >4
EN 13704 (phase 2, step 1)	0.8% 8.0%	3 g/l bovine albumin	60 min. 10 min.	20℃	**Bacterial spores:** *Bacillus subtilis* **Bacterial spores:** *Bacillus subtilis*	log R >3 log R >3
EN 1276 (phase 2, step 1)	0.5%	1% reconstituted milk (w/v)	5 min.	20℃	**Bacteria:** *Pseudomonos aeruginosa* *Enterococcus hirae* *Escherichia coli* *Staphylococcus aureus* *Listeria monocytogenes* *Salmonella typhimurium* *Campylobacter jejuni*	log R >5
EN 13697 (phase 2, step 2)	0.5%	1% reconstituted milk (w/v)	5 min.	20-23℃	**Bacteria:** *Pseudomonos aeruginosa* *Enterococcus hirae* *Escherichia coli* *Staphylococcus aureus* *Listeria monocytogenes* *Salmonella typhimurium* **Yeast:** *Candida albicans*	log R >4 log R >3
EN 1650 (phase 2, step 1)	5.0% 0.5%	1% reconstituted milk (w/v)	15 min. 15 min.	20℃	**Fungi:** *Aspergillus brasiliensis* **Yeast:** *Candida albicans*	log R >4 log R >4

Test method	Concentration	Soiling Conditions	Contact time	Temperature	Species tested	Log reduction
EN 13704 (phase 2, step 1)	0.8% 4.8%	1% reconstituted milk (w/v)	60 min. 10 min.	20℃	**Bacterial spores:** *Bacillus subtilis* **Bacterial spores:** *Bacillus subtilis*	log R >3 log R >3
DGHM test Laundry	2ml/L + 1,2 ml/L detergent Only detergent No biocide, no detergent	12.5 ml defibrinated sheep blood/kg pre-washed hospital laundry	15 min	60℃	*Enterococcus faecium*	log R >7 log R 1,7-2,3 log R 2-2,6
DGHM test Laundry	2ml/L + 1,2 ml/L detergent Only detergent No biocide, no detergent	12.5 ml sheep blood/kg pre-washed hospital laundry	10 min	70℃	*Enterococcus faecium*	log R >8,08 log R 5,9-6,9 log R 4,0-5,6
BGA, DVV quantitative suspension test	2ml/L	20g/L BSA or 10% FKS	10 min	70℃	*Bovine parvovirus*	log R >4
BGA, DVV quantitative suspension test	2ml/L	20g/L BSA or 10% FKS	15 min	60℃	*Bovine parvovirus*	log R >4
EN1650	H_2O_2 0.007% PAA 0.003%		10 min	70℃	*Candida albicans*	The thermal process already accomplished sufficient reduction of the inoculum.

Disinfection of surfaces in the industrial, public, food, and health care areas
For surface disinfection in the industrial, public and health care areas and surfaces which may be in contact with food and beverage, suspension tests (phase 2, step1) have been done with the standard bacteria and bacterial spores at 5 min contact time, 20℃ and 3 g/l BSA. This is the correct contact time and temperature. The soiling corresponds with clean conditions for the medical area and dirty conditions for the other areas (industrial, food, public). For bacteria the required log reduction was demonstrated at a concentration of 0.5% and for bacterial spores at 8% at 5 minute contact time.
For surface disinfection against yeasts normally a suspension test at 5 min contact time, and 20℃, with BSA soiling, and the standard test organ isms *Candida albicans* should be performed. This test was not provided. However, several other suspension tests were provided demonstrating sufficient log reduction against *C. albicans* at 15 min contact time

with either milk or BSA soiling and demonstrating sufficient log reduction against *Saccharomyses cerevisiae* at 5 min contact time with BSA soiling. In addition a surface test was performed with 5 min contact time with milk soiling also demonstrating sufficient log reduction. All tests were performed with 0.5% Chriox 5 or lower.
The suspension tests with either milk or BSA soiling demonstrate that milk soiling is a worst case soiling for yeasts: 0.1% Chriox 5 with milk soiling does not give the required log reduction, while 0.05% Chriox 5 with BSA soiling does. Therefore the surface test with milk soiling is representative. The surface test and the suspension test with *S. cerevisiae* demonstrate that Chriox 5 is sufficiently active in 5 min at a concentration of 0.5%.

Disinfection of surfaces of medical instruments by dipping
For use against bacteria and yeasts the same tests as for general surface disinfection in the medical area are acceptable. For this use it is obligatory to show efficacy against fungi and viruses in addition to bacteria and yeasts. Suspension tests (phase 2, step1) have been provided with the standard fungi and viruses at 20°C and 3 g/l BSA. Efficacy has been demonstrated against fungi with 6% Chriox 5 at 15 min contact time, and against viruses with 0.8% Chriox 5 at 60 min contact time. For bacterial spores a suspension test showing efficacy at 0.8% at 60 min contact time is provided. The 3 g/l BSA soiling corresponds with clean conditions for the medical area.

Disinfection via CIP
For this use the same tests as for general surface disinfection are acceptable against bacteria and yeasts. For bacterial spores efficacy is demonstrated with 0.8% Chriox 5 at 60 min contact time or with 8% Chriox 5 at 5 min contact time. The proposed label recommends 2% Chriox 5 at 10 min contact time. The tests do not demonstrate that this concentration and contact time combination will be efficacious. Therefore, the label will be adapted according to the results.

Disinfection of surfaces on farms, in animal housing
For surface disinfection on farms, in animal housing, suspension tests (phase 2, step1) have been done with the standard bacteria and yeasts at 30 min contact time, 10℃ and 3 g/l BSA. The soiling corresponds with clean conditions for this area of use. For bacteria the required log reduction was demonstrated at a concentration of 0.3% and for yeasts at a concentration of 0.5%.
For bacterial spores no test were performed at 10℃ . Since this is the required test temperature for this area of use, efficacy against bacterial spores is not demonstrated.
These tests are acceptable for the application by spraying or foaming.

Disinfection of milking equipment on the farm
For disinfection of milking equipment suspension tests (phase 2, step1) have been done with the standard bacteria, yeasts and bacterial spores at 20℃ and with 10 g/l reconstituted milk. Efficacy was demonstrated for bacteria with 0.5% Chriox 5 in 5 min contact time, for yeasts with 0.5% Chriox 5 in 15 min contact time, and for bacterial spores with 4.8% Chriox 5 in 10 min contact time. In addition a surface test was done with the standard bacteria and yeasts, but not for bacterial spores. Efficacy was demonstrated with 0.5% Chriox 5 in 5 min contact time.
These results are not in accordance with the dosing recommended on the label.
No field test is performed, which is obligatory under NL transitional law. Therefore, efficacy of Chriox 5 as disinfectant of milking equipment has not been demonstrated. On request of the applicant this use will be deleted from the label.

Disinfection of laundry
Two simulated-use trials in a washing machine were performed with a product similar to Chriox 5 and heat resistant bacteria. Two suspension tests were performed with a product similar to Chriox 5 and heat resistant virus. In addition a test was provided which showed that yeasts will be killed at high temperatures without biocides, indicating that the currently

available test organisms are not suitable for demonstrating yeasticidal efficacy at high temperatures.
These tests demonstrated sufficient efficacy of Chriox 5 against heat resistant bacteria and heat resistant viruses at 60℃ with a contact time of 15 minutes and at 70℃ with a contact time of 10 minutes.

Animal drinking water
For this use the same suspension tests as for general surface disinfection in the medical area are acceptable against bacteria and yeasts. However, for this use efficacy should also be demonstrated in a (semi-) field trial should be performed. This test was not provided. Therefore, efficacy of Chriox 5 as disinfectant for animal drinking water was not sufficiently demonstrated. On request of the applicant this use will be deleted from the label.

5.3.2 Evaluation of the label (WG/GA)
Most tests are done under clean conditions for the medical and veterinary area. Therefore, the label should state that prior to disinfection the surfaces in these areas should be cleaned. The dosing for use as disinfectant via CIP will be adapted according to the results. On request of the applicant the use for disinfection of milking equipment and animal drinking water will be deleted from the WG/GA.

5.4 Mode of action
Chriox 5 is an equilibrium PAA solution containing the active substances hydrogen peroxide and peracetic acid. The destruction of the microbial cell by this PAA solution can be grouped into three mechanisms:
- Denaturation of cell proteins and interruption of cell transport
- Inactivation of enzymes essential to cell metabolism, and
- Disruption of cell membranes and their permeability.

5.5 Limitations on efficacy including resistance

5.5.1 Resistance
The mode of action of peracetic acid and hydrogen peroxide is very unspecific. Consequently, it seems to be unlikely that organisms will develop resistance to a product containing these actives. Nevertheless, it is recommended to use disinfectants that have different modes of action, for example an oxidizing agent such as Chriox 5 alternating with a surfactant.

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 Chriox 5, when used in accordance with the proposed label (WG/GA), is effective in controlling :
- bacteria (excluding mycobacteria), bacterial spores, and yeast in
  - surfaces in industrial, public and health care areas (PT02)
  - surfaces in places where people reside (PT02
  - CIP in pharmaceutical and cosmetic industry (PT02
  - CIP in equipment used in food processing, ion exchangers included (PT04)
  - surfaces which may be in contact with food and beverage and products used for the production of food and beverages, including kitchens in hospitals en other services in the health care area, excluding milk equipment (PT04)
- bacteria (excluding mycobacteria), bacterial spores, yeast, fungi and viruses in medical instruments (PT02)
- bacteria (excluding bacterial spores and mycobacteria), yeast and viruses during the washing process of laundry (PT02)
- bacteria (excluding bacterial spores and mycobacteria), and yeast in surfaces on farms, in animal housing (PT03)

6 Human toxicology

Human health effects assessment active substance
Hydrogen peroxide
A first draft CA-report for hydrogen peroxide is available for PT1-6 on which comments have been provided by the Netherlands. The risk assessment is based on the List of Endpoints from the first draft CAR; however, as the CAR is not finalized yet, it should be considered provisional. Where relevant, remarks are provided below in italics.

List of endpoints

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	No significant absorption; local effects
Rate and extent of dermal absorption:	Not determined
Rate and extent of inhalation absorption:	Not determined
Distribution:	None
Potential for accumulation:	None
Rate and extent of excretion:	None
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	805 m/kg bw (70%) 1232 mg/kg bw (35%) Acute Tox. 4, H302
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	>170 mg/m^3 Acute Tox. 4, H332
Skin irritation	≥50%: corrosive, H314 35% ≤ C < 50% H_2O_2; irritant, H315
Eye irritation	5% ≤ C < 8% H_2O_2: irritant; H319 ≥8% H_2O_2: severe irritant; H318
Skin sensitization (test method used and result)	Non-sensitising (modified Magnusson-Kligman and human data)

Repeated dose toxicity

Species/ target / critical effect	Rodent
Lowest relevant oral NOAEL / LOAEL	NOAEL = 26 mg/kg bw/day (100 ppm, 90-day mouse)
Lowest relevant dermal NOAEL / LOAEL	Not established
Lowest relevant inhalation NOAEL / LOAEL	7 ppm (5.44 mg/m^3); no adverse effects at the highest tested dose*

***** A new 90-day inhalation study with rats has been submitted by the applicant and it has been agreed at the EU level to use this study to derive the limit value for respiratory effects. The RMS Finland suggested the value of 2.5 ppm (3.6 mg/m^3) as a NOAEC in this study based on the effects on body weight at the highest dose level; however, it is the opinion of the Netherlands that observed effects are not adverse (observed changes are within the historical control range, the effects were observed in males only). Thus the Netherlands consider the highest dose level of 7 ppm a NOAEC in this study.

Genotoxicity	Mutagenic *in vitro* in a bacterial gene mutation test both in the presence and absence of metabolic activation, in a mammalian gene mutation test without metabolic activation and in a chromosomal aberration test in the presence and absence of metabolic activation. The positive results of the *in vitro* genotoxicity tests were not confirmed *in vivo* in a bone marrow micronucleus test and a UDS test in liver cells. However, there is no evidence that hydrogen peroxide has reached the target organ in the *in vivo* UDS test. Likewise, in micronucleus test with exposure via drinking water hydrogen peroxide has most probably not reached the bone marrow. Due to the uncertainty with regard to availability of the test substance in the target organ, the result of this study is equivocal. In a micronucleus test with i.p. application no increase in the frequency of micronucleated polychromatic erythrocytes was observed. Effects in the body marrow (decreased ratio of polychromatic erythrocytes to normochromatic erythrocytes) were noticed indicating the suitability of test conditions. The results of the genotoxicity studies do not meet the current classification criteria for mutagenicity.

Carcinogenicity	
Species/type of tumour	Not considered carcinogenic. Primary local irritation (corrosion) at the site of contact. Not considered genotoxic *in vivo*. Genotoxic mechanisms cannot be ruled out in the carcinogenicity of hydrogen peroxide. However, the endogenous defence mechanisms against reactive oxygen species may suggest a threshold for carcinogenicity of hydrogen peroxide.
lowest dose with tumours	Not applicable

Reproductive toxicity	
Species/ Reproduction target / critical effect	Not reprotoxic, no systemic availability
Lowest relevant reproductive NOAEL / LOAEL	Not applicable.
Species/Developmental target / critical effect	Not reprotoxic
Lowest relevant developmental NOAEL / LOAEL	Not applicable.

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Available studies give no indication of a neurotoxic potential
Lowest relevant developmental NOAEL / LOAEL.	n.a.

Other toxicological studies

-	-

Medical data

Medical surveillance data on manufacturing plant personnel	Information from EU Risk Assessment Report (2003) and publications: Reports of respiratory irritation symptoms when exposed to hydrogen peroxide vapour with progressive dyspnoea and bilateral diffuse nodular infiltration of lung. Improvement after withdrawal from exposure. STOT SE 2, H335 Reports of irritation in the eyes and airways, headaches, temporary loss of olfaction, symptoms and signs in the skin, and blanching of hair. Human poisoning by oral ingestion. Oxygen embolism has been observed.

Summary	Value	Study	Safety factor
ADI (acceptable daily intake, external long-term reference dose)	n.a.; not systemically available		
$AEL_{systemic}$	n.a.; not systemically available		
$AEC_{local\ dermal}$	35%**	Limit for irritation	
$AEC_{local\ respiratory}$	1.7 mg/m^3 (2.2 ppm)***	Rat 90-day study	3.2
ARfD	n.a.; not systemically available		
Drinking water limit			
Reference value for dermal absorption	100 % as default		

** The specific concentration limit of 35% for skin irritation for hydrogen peroxide is proposed by the RMS Finland as the limit value for dermal effects. If eye exposure could occur then the limit value for eye irritation of 5% needs to be taken into account.
*** Currently a discussion at the EU level is ongoing regarding the assessment factor for the $AEC_{inhalation}$ derivation. It is the opinion of the Netherlands that factor 3.2 is sufficient, as rats are known to be more sensitive in inhalation studies than humans due to the fact that they are obligatory nose breathers. Furthermore, the effects used for the NOAEC setting were observed at the port of entry, which seems to suggest that both toxicokinetic and toxicodynamic factors are not contributing to interspecies differences. Therefore factor 3.2

has been used by the Netherlands to derive the provisional $AEC_{inhalation}$ of 1.7 mg/m^3. It should however be noted that the discussion is not yet finalised and the derived value should be regarded as provisional.

Local effects
Hydrogen peroxide at high concentrations is a corrosive substance and produces local effects after acute and repeated exposure. Hydrogen peroxide quickly decomposes at the site of contact and does not become systemically available, therefore the risk assessment will be based on local effects.

Data requirements active substance
No additional data requirements are identified.

Peracetic acid
Peracetic acid is produced by reacting hydrogen peroxide with acetic acid in aqueous solution. In this process, peracetic acid is not obtained as a pure substance but in the form of aqueous equilibrium solutions containing peracetic acid, acetic acid, hydrogen peroxide and water. The peracetic acid content in equilibrium solutions ranges between 0.4% and 17% (w/w). The equilibrium solution is the biocidal product which is placed on the market.

List of Endpoints
The provided List of Endpoints is based on the first draft CAR of peracetic acid. As this draft CAR has not yet been discussed at the TM, the List of Endpoints should be regarded as provisional.

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Not determined
Rate and extent of dermal absorption:	Not determined; 100% as a default
Rate and extent of inhalation absorption:	Not determined; 100% as a default
Distribution:	20 % of radio-activity tissue-bound with highest levels found in liver, gastro-intestinal tract and exposed skin
Potential for accumulation:	No evidence for bioaccumulation
Rate and extent of excretion:	- approx. 30 – 60 % of the applied dose recovered as CO_2 after 72 hours with the majority formed after 24 hours; an initial lag phase of approx. 1 hour evident - about 17 % of given radioactivity excreted via the urine after 72 hours; majority of urinary excretion occurred after 24 hours - about 4 - 5 % of given radioactivity excreted via the faeces and 17 % via urine after 72 hours; majority of faecal excretion occurred after 24 hours
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	1020 mg/kg; (Acute Tox. 4 *, H302; Xn, R22)
Rat LD_{50} dermal	1147 mg/kg; (Acute Tox. 4 *, H312; Xn, R21)
Rat LC_{50} inhalation	1 mg/L ≤ LC50 ≤ 5 mg/L; (Acute Tox.4 *, H332; Xn, R20)

Skin irritation	Corrosive; (Skin Corr. 1A, H314; C, R35)
Eye irritation	Corrosive (severe damage to the eyes) ; (Skin Corr. 1A H314; Xi, R41)
Skin sensitization (test method used and result)	Non-sensitising (GPMT)

Repeated dose toxicity

Species/ target / critical effect	Rat (oral): local irritation in stomach/gastro-intestinal-tract, no systemic effects
Lowest relevant oral NOAEL / LOAEL	90-days gavage study in rats NOAEL 15 mg/kg bw/day corresponding to 0.055% peracetic acid
Lowest relevant dermal NOAEL / LOAEL	Not established
Lowest relevant inhalation NOAEL / LOAEL	No study required for this endpoint for animal welfare reasons and owing to the intrinsic properties of peracetic acid (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)

Genotoxicity

In vitro: Positive results in *in vitro* cytogenetic assay (chromosome aberrations) in human lymphocytes. Negative results in Ames test, gene mutation assay in mammalian cells, negative/equivocal *in vitro* chromosome aberration assay with Chinese hamster lung fibroblasts
In vivo: Equivocal in three micronucleus tests and *in vivo* UDS. The biological meaning of any result from the *in vivo* studies is questionable in view of uncertainty of the availability of the test substance in the target organ.

Weight of evidence indicates no concern of mutagenic / genotoxic potential

Carcinogenicity

Species/type of tumour	No study required for this endpoint for animal welfare reasons and owing to the intrinsic properties of peracetic acid (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability). No concern of mutagenic / genotoxic potential. Site of contact carcinogenicity not tested.
lowest dose with tumours	Not applicable

Reproductive toxicity

Species/ Reproduction target / critical effect	No indication of reproductive toxicity in 90-days oral and continuous breeding studies. In the absence of both teratogenic effect and findings on reproductive organs in repeated

	dose toxicity studies, no study is required for this particular endpoint for animal welfare reasons and owing to the intrinsic properties of peracetic acid (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)
Lowest relevant reproductive NOAEL / LOAEL	Not applicable.
Species/Developmental target / critical effect	Rat: maternal effects: reductions in body weight, body weight gain developmental effects: impairment of ossification (bones missing or poor/hypertrophic ossification)
Lowest relevant developmental NOAEL / LOAEL	Maternal: 12.5 mg peracetic acid/kg bw/d Developmental: 12.5 mg peracetic/kg bw/d

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	No indicative signs from acute and repeated dose studies; no structural alerts
Lowest relevant developmental NOAEL / LOAEL.	n.a.

Other toxicological studies

Neurotoxicity	No indicative signs from acute and repeated dose studies; no structural alerts
Toxic effects on livestock and pets	Not required since the mode of action of peracetic acid is known, i.e. the primary toxicological effect (local irritation/corrosion) which is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. Peracetic acid is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid The toxicity of peracetic acid has been investigated and it has been shown not to be mutagenic or teratogenic. In the summary report of the Committee for Veterinary Medicinal Products (CVMP) on Peracetic acid (EMEA/MRL/060/96-FINAL, Doc. No. 983-001), peracetic acid is admitted for use in livestock animals and that there is no need to establish an MRL for peracetic acid.
Studies related to the exposure of the a.s. to humans	Not required since the mode of action of peracetic acid is known, i.e. the primary toxicological effect (local irritation/corrosion) which is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. Peracetic acid is not systemically available in

	the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid. These degradation products will form in any species and no other pathways of degradation occur. No degradation pathways other than those known from animal studies are expected to occur. Thus, peracetic acid will not be transformed to further substances which were not observed and assessed in the available mammalian toxicity studies.
Food and feeding stuffs	Peracetic acid is not intended to be used in or on food or feeding stuff. In uses, however, where residues on food stuff packaging material cannot be excluded, no safety concern for does exist since peracetic acid is rapidly degraded to the physiological metabolites hydrogen peroxide, oxygen and acetic acid. Based on the evaluation of and the conclusions made by the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food, possible residues of peracetic acid on food and feeding stuff are not considered to be associated with a safety concern. Thus, there is no requirement for submission of information as laid down in the Technical Guidance Document on Data Requirements.
Other tests related to exposure of the a.s. to human considered to be necessary	No other tests related to the exposure of the active substance to humans for the purpose of performing reliable human health risk assessments studies necessary. The proposed biocidal products are sufficiently covered by the aforementioned tests. There are no endpoints of concern which would require further testing.
Tests to assess toxic effects from metabolites of treated plants	Peracetic acid is not used in products for action against plants. Therefore, no tests to assess toxic effects of metabolites from treated plants are required.
Mechanistic studies	Based upon the known mode of action of peracetic acid, no mechanistic studies are required. The toxicity of peracetic acid is due to its locally irritating properties, i.e. decomposition to hydrogen peroxide, oxygen and acetic acid. After contact with organs and tissues, hydrogen peroxide will undergo decomposition into water and oxygen. The primary toxicological effect (local irritation) is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. Peracetic acid is not systemically available in

	the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid. Acetic acid is introduced in the C2-pool or further metabolised via physiological pathways to carbon dioxide and water. All occurring metabolites are rapidly eliminated and do not bioaccumulate.
Further human health related studies	In view of the known mode of action and considering results of available mammalian toxicity studies, no further human health-related studies are required.

Medical data

Medical surveillance data on manufacturing plant personnel	No data available

Direct observations, e.g. clinical cases, poisoning incidents	1: The cytotoxic and irritating potential of peracetic acid in humans used as a disinfectant for hand washing procedures applied by surgeons was investigated. Three of 15 surgeons developed immediately erythema and 6 of 15 surgeons developed dermatosis of the hands after 7 days following daily soaping, brushing and disinfection of skin with Peracetic acid at a concentration of 0.5 %. Peracetic acid applied as Wofasteril caused dermal irritation reactions in a third of health care workers. 2: Several recommendations were made to allow a safe handling with concentrated Peracetic acid solutions: - wearing protective gloves and protective glasses for diluting concentrated peracetic acid - dilutions should be made in a ventilated room - for spray application of dilutions for disinfection purposes a respirator should be used. 3: Effects of diluted peracetic acid solutions used as an aerosol (0.8 % peracetic acid) as a disinfectant for human skin (0.08 or 0.2 % peracetic acid) and for the treatment of a recurrent, pruritic epidermitis (0.1 % peracetic acid): - irritation of the respiratory tract, lachrimation, salivation, increased nasal discharge and partly temporal loss of olfactory senses (0.8 % peracetic acid) - slight skin desquamation after 1 or 2 days without hypersensitivity (0.2 % peracetic acid) - daily skin disinfection for 3 years using solutions of 0.2 % peracetic acid mixed with alcohol did not cause any adverse effects - temporarily reduced skin roughness after 1 day. The hands appeared slippery when wet, smooth and well-manicured (0.2 % peracetic acid) - treatment of a recurrent, pruritic epidermitis using a 0.1 % peracetic acid successful - Concentrations of 0.2 % peracetic acid can be considered as non to only slightly irritating to skin. 4: After a Patch test with dilutions of 1:33 (1500 mg/L peracetic acid), 1:20 (2500 mg/L peracetic acid) and 1:15 (3500 mg/L according to publication, correct value should be 3300 mg/L) it was concluded that up to 2500 mg/L peracetic acid (corresponding to an about 0.25 % solution) is non-irritant. At 3300 mg/L peracetic acid (corresponding to an about 0.33 % solution) is a mild irritant.
Health records, both form industry and any other sources	The Persteril dilution containing 0.2 % peracetic acid was well tolerated by the 20 volunteers. The concentration of 0.2 % peracetic acid is sufficient for eradication of pyogenic staphylococci and 97 % reduction of residual flora on the hand within 3 minutes. Peracetic acid does not have a residual effect. Solutions of peracetic acid with concentrations

	of 0.2 % do not damage the skin.
Epidemiological studies on the general population	No data available
Diagnosis of poisoning including specific signs of poisoning and clinical tests	Not available.
Sensitization/allergenicity observations	The cases of two subjects who developed cough wheezing and shortness of breath after being exposed to peracetic acid-hydrogen peroxide (peracetic acid-HP) vapours are investigated. The main symptoms observed were rhinorrhoea, conjunctivitis, continuous cough, breathlessness and chest tightness appeared after several hours of exposure to peracetic acid-HP vapours and improved after removal from exposure. It was concluded that symptoms in these subjects were generated by an irritant mechanism and occupational prolonged exposure to vapours of peracetic acid-HP mixtures caused symptoms which were the consequence of a sustained irritation process rather than a real asthmatic reaction.
Specific treatment in case of an accident or poisoning: first aid measures and medial treatment	Basic aid: decontamination and symptomatic treatment is warranted. No specific antidote is known. Eyes: In case of contact with eyes rinse thoroughly with water. Contact a physician immediately. Skin: Remove contaminated clothes. Wash affected body areas carefully with plenty of water and soap. Ingestion: Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Inhalation: Ensure supply of fresh air. Contact a physician as necessary.
Prognosis following poisoning	Depending on severity of effects

Summary	Value	Study	Safety factor
ADI (acceptable daily intake, external long-term reference dose)	n.a.; peracetic acid is not systemically available		
$AEL_{acute/medium/long-term}$	n.a.; peracetic acid is not systemically available		
$AEC_{local\ dermal\ short/medium-term}$	0.2%	Human volunteer study	None
$AEC_{local\ dermal\ long-term}$	0.1%	Rabbit one year study	2
$AEC_{inhalation}$	0.23 mg/m^3 (0.075 ppm)	RD10 0.6 ppm in Sensory irritation study in mice	8

		(Gagnaire et al. 2002, Doc. No. 592-048; Doc IIIA, A6.1.3/04)	
ARfD	n.a.; peracetic acid is not systemically available		
Drinking water limit			
Reference value for dermal absorption	100 % as default		

Local effects
Peracetic acid is a corrosive substance and produces local effects after acute and repeated exposure. Peracetic acid quickly decomposes at the site of contact and does not become systemically available, therefore the risk assessment will be based on local effects.

Data requirements active substance
No additional data requirements are identified.

6.1 Human exposure assessment active substance

6.1.1 General aspects

The formulation Chriox 5 is a liquid concentrate containing hydrogen peroxide and peracetic acid as active substances, at concentrations 23.0% and 4.9%, respectively. The proposed fields of use of Chriox 5 are:
PT2: use against bacteria and yeasts on surfaces and equipment in public and private areas, hospitals and other health care facilities; CIP in pharmaceutical and cosmetic industries; laundering of low to medium polluted textile in e.g. hospitals and hotels. The formulation can only be applied using a special dosing equipment for laundering machines.
PT3: use against bacteria on surfaces on farms and in animal housing facilities
PT4: CIP in food and feed industry, including ion exchangers; on surfaces that can come into contact with food and drinks, including milking equipment on farms and including kitchens in hospitals and other health care facilities
PT5: use against bacteria drinking water for animals

The maximal dose levels of Chriox 5 are:
For the disinfection of surfaces and equipment, including surfaces in public and private areas, hospitals and other health care facilities, and surfaces which can come into contact with food and drinks: 8%, corresponding to 1.84% hydrogen peroxide and 0.39% peracetic acid
For the disinfection of medical instruments: 6%, corresponding to 1.38% hydrogen peroxide and 0.29% peracetic acid
For the use on surfaces on farms and in animal housing facilities: 2%, corresponding to 0.46% hydrogen peroxide and 0.10% peracetic acid
For the disinfection of milking equipment: 0.5%, corresponding to 0.12% hydrogen peroxide and 0.02% peracetic acid
For CIP in pharmaceutical and cosmetic industry and for surfaces that can into contact with food and feed: 8%, corresponding to 1.84% hydrogen peroxide and 0.39% peracetic acid
For animal drinking water disinfection: 2%, corresponding to 0.46% hydrogen peroxide and 0.10% peracetic acid
For the laundering machines: 0.2%, corresponding to 0.046% hydrogen peroxide and 0.002% peracetic acid

The formulation Chriox 5 is intended for professional use only. The formulation will be applied by coarse spraying, foaming or wiping (surface disinfection, including use on farms), automated spraying in closed systems (disinfection of the equipment used in food processing, no personnel involved), fogging (use in animal housing, fully automated process, no personnel involved), or by dipping (medical or milking equipment disinfection). In case of CIP, laundering machines and animal drinking water disinfection, exposure will occur only during the mixing and loading step, as the actual disinfection will take place in a closed system.

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

The professional user can be dermally and respiratory exposed to hydrogen peroxide and peracetic acid during mixing and loading and application of Chriox 5 via course spraying, foaming, wiping and dipping. As Chriox 5 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 Chriox 5 is intended for professional use only.

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

Secondary respiratory exposure of bystanders is possible during the hard surface disinfection by coarse spraying. However, this exposure is expected to be lower than the exposure of professional users during the application of the formulation by coarse spraying. Both hydrogen peroxide and peracetic acid are expected to react quickly with organic matter on the surface and decompose, therefore no secondary dermal exposure is envisaged. In the first draft CAR on peracetic acid the following justification is given:

“Secondary exposure of food and feed with peracetic acid, e.g. upon contact with treated surfaces or equipment, is considered to be not relevant, since peracetic acid is highly unstable and will rapidly degrade upon contact with organic matter.”

Furthermore, the applicant has indicated that surfaces which may come into contact with food and feed need to be rinsed thoroughly after the application. Therefore exposure via food and feed is excluded.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

No studies with Chriox 5 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

Professional users may be dermally and respiratory exposed to active substances hydrogen peroxide and peracetic acid during mixing and loading of Chriox 5 and during the disinfection by coarse spraying, foaming, wiping or dipping. The scenarios of the CIP, textile laundering and drinking water disinfection are expected to be covered by the scenario of mixing and loading, as no direct exposure of professional user will occur during the actual disinfection step. Also no exposure of professional users will occur during the automated spraying and fogging, as the disinfection will take place in closed systems with no people present. The scenario of foaming is considered to be covered by scenario of spraying, as the application is

more or less equal, except that the use of foam is expected to result in lower dermal and respiratory exposure of professional users.
During the mixing and loading professional users may be exposed to the undiluted formulation, corresponding to the maximal concentrations of 23.0% hydrogen peroxide and 4.9% peracetic acid. During the surface disinfection by coarse spraying, foaming or wiping, and equipment disinfection by dipping professional users may be exposed to the 8% formulation as the highest in-use dilution, corresponding to 1.84% hydrogen peroxide and 0.39% peracetic acid.

Both hydrogen peroxide and peracetic acid cause primarily local effects by exposure; therefore risk assessment will be based on local effects.

Mixing and loading
During mixing and loading, the concentrations of hydrogen peroxide and peracetic acid in undiluted formulation are below the $AEC_{local\ dermal}$ of 35% for hydrogen peroxide, but above the $AEC_{local\ dermal}$ 0.1% for peracetic acid. Therefore the use of personal protective equipment (gloves, coverall) is prescribed for professional users during mixing and loading operations.

To estimate potential respiratory exposure to hydrogen peroxide and peracetic acid during mixing and loading of undiluted Chriox 5 Mixing and Loading Model 7 (corrected) for manual pouring of liquids is used according to HEEG Opinion 2008 (endorsed at TM I 2008). This model gives an indicative respiratory exposure of 0.94 mg biocidal product/m^3, which corresponds to 0.216 mg/m^3 hydrogen peroxide and 0.046 mg/m^3 peracetic acid. These concentrations are below the $AEC_{inhalation}$ of 1.7 mg/m^3 for hydrogen peroxide and the $AEC_{local\ inhalation}$ of 0.23 mg/m^3 for peracetic acid. The resulting risk indices are (0.216/1.7 =) 0.13 and (0.046/0.23 =) 0.20 for hydrogen peroxide and peracetic acid, respectively. Based on this no adverse effects are expected for protected (gloves, coverall) professional users from exposure to hydrogen peroxide and peracetic acid during mixing and loading operations with undiluted Chriox 5.

Application by coarse spraying, foaming, wiping and dipping
During the application of the in-use dilution of Chriox 5 by coarse spraying, foaming, wiping or dipping the highest in-use concentrations of hydrogen peroxide (1.84%) and peracetic acid (0.39%) are below the $AEC_{local\ dermal}$ of 35% for hydrogen peroxide, but above the respective $AEC_{local\ dermal}$ of 0.1% for peracetic acid. Therefore the use of personal protective equipment (gloves, protective clothing) is prescribed for professional users during the application of Chriox 5 by coarse spraying, foaming, wiping or dipping.

To estimate potential respiratory exposure to hydrogen peroxide and peracetic acid during the application of the in-use dilutions of Chriox 5 by coarse spraying or by foaming, Spraying Model 1 (User Guidance v.1, 2002, p.31) is used. This model gives an indicative respiratory exposure of 104 mg biocidal product/m^3. The in-use concentrations of hydrogen peroxide and peracetic acid are 1.84% and 0.39%, respectively. Therefore the resulting concentrations of hydrogen peroxide and peracetic acid in air are 1.91 mg/m^3 and 0.41 mg/m^3, respectively. For both substances, the estimated concentration are above the $AEC_{inhalation}$ of 1.7 mg/m^3 and 0.23 mg/m^3, respectively; the resulting risk indices are (1.91/1.7 =)1.12 for hydrogen peroxide and (0.41/0.23 =)1.76 for peracetic acid. Therefore the use of respiratory protective equipment is prescribed for professional user. As hydrogen peroxide and peracetic acid cause only local effects by respiratory exposure, the use of respiratory protective equipment is considered to be sufficient to prevent these effects from occurring and to ensure a sufficient level of protection for professional users. The following sentence will be added to the WG/GA: “Wear suitable respiratory protective equipment during the application of the formulation by coarse spraying or by foaming”.

To estimate potential respiratory exposure to hydrogen peroxide and peracetic acid during the application of the 8% in-use dilution of Chriox 5 by wiping, Surface Disinfection Model 1 (User Guidance v.1, 2002, p. 28) is considered to be the most appropriate. This model gives

the indicative respiratory exposure of 22.9 mg biocidal product/m^3, corresponding to 0.42 mg/m^3 hydrogen peroxide and 0.09 mg/m^3 peracetic acid. These concentrations are below the $AECs_{local\ inhalation}$ of 1.7 mg/m^3 for hydrogen peroxide and 0.23 mg/m^3 for peracetic acid. The resulting risk indices are (0.42/1.7 =) 0.25 and (0.09/0.23 =) 0.39. Therefore no adverse local respiratory effects are expected for unprotected professional users during the application of 8% in-use dilution of Chriox 5 by wiping.

To estimate potential respiratory exposure to hydrogen peroxide and peracetic acid during the disinfection by dipping using the 8% in-use dilution of Chriox 5, Dipping Model 4 (User Guidance v.1, 2002, p.27) was used in the first draft CAR of peracetic acid. The indicative inhalation exposure given by this model is 0.2 mg biocidal product/m^3, which in case of the in-use dilution of Chriox 5 corresponds to 0.0037 mg/m^3 hydrogen peroxide and 0.00078 mg/m^3 peracetic acid. These concentrations are significantly below the $AECs_{local\ inhalation}$ of 1.7 mg/m^3 for hydrogen peroxide and 0.23 mg/m^3 for peracetic acid. The resulting risk indices are (0.0037/1.7=) < 0.01 and (0.00078/0.23 =) < 0.01. Therefore no adverse local respiratory effects are expected for unprotected professional users during the disinfection by dipping using the 8% in-use dilution of Chriox 5.

Overall conclusions for professional user

In summary, based on the risk assessment, no adverse effects from dermal and respiratory exposure to hydrogen peroxide and peracetic acid are expected to protected (gloves, coverall) professional users during the mixing and loading operations with undiluted Chriox 5.

Based on the risk assessment, no adverse effects from dermal and respiratory exposure to hydrogen peroxide and peracetic acid are expected for protected (gloves, protective clothing, respiratory protective equipment) professional users due to the application of the 8% in-use dilution of Chriox 5 by coarse spraying or by foaming.

Based on the risk assessment, no adverse effects from dermal and respiratory exposure to hydrogen peroxide and peracetic acid are expected for protected professional (gloves, protective clothing) users due to the application of the 8% in-use dilution of Chriox 5 by wiping or dipping.

6.3.2 Non-professional users, including the general public

The formulation Chriox 5 is intended for professional use only.

6.3.3 Indirect exposure as a result of use

Both hydrogen peroxide and peracetic acid are expected to react quickly with organic matter on the surface and decompose. Secondary respiratory exposure of bystanders during the application of Chriox 5 cannot be excluded due to high volatility of hydrogen peroxide and peracetic acid. However, this exposure is expected to be lower than the exposure of professional users during the application of the formulation. As no concern for the respiratory exposure of unprotected professional users exists during the application of Chriox 5 by wiping or dipping, also no concern for bystander exposure exists. However, for the application by coarse spraying or by foaming, the use of respiratory protective equipment is prescribed for professional users in order to prevent possible adverse local effects from respiratory exposure. As no respiratory protective equipment can be prescribed for bystanders, the following sentence needs to be included in the WG/GA: "Unprotected persons should be kept out of treatment areas, when product is applied by coarse spraying or by foaming".

6.3.4 Combined exposure

The formulation Chriox 5 is contains a mixture of two active substances, hydrogen peroxide and peracetic acid. The combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity.
Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profiles based on the individual substances. However, both

hydrogen peroxide and peracetic acid cause primarily local effects by exposure. Local effects are considered to be additive in nature. For dermal effects, the use of protective gloves and coverall is prescribed for professional users. For respiratory effects, the following sums of the risk indices per application are calculated:

Mixing and loading: 0.13 + 0.20 = 0.33
Application by wiping/foaming: 0.25 + 0.39 = 0.64
Application by dipping: < 0.01 + < 0.01 = < 0.01

As can be seen, the resulting risk indices are < 1 for all applications. Therefore no concern for adverse effects from combined exposure to hydrogen peroxide and peracetic acid exists.

6.3.5 Substances of concern
The formulation Chriox 5 does not contain substances of concern.

6.4 Overall conclusions for the aspect human health

Based on the risk assessment, no adverse effects from dermal and respiratory exposure to hydrogen peroxide and peracetic acid are expected to protected (gloves, coverall) professional users during the mixing and loading operations with undiluted Chriox 5. Furthermore, no adverse effects from dermal and respiratory exposure to hydrogen peroxide and peracetic acid are expected for protected (gloves, protective clothing, respiratory protective equipment) professional users due to the application of Chriox 5 by coarse spraying or by foaming. Moreover, no adverse effects from dermal and respiratory exposure to hydrogen peroxide and peracetic acid are expected for protected professional (gloves, protective clothing) users due to the application of Chriox 5 by wiping or dipping.
Based on the risk assessment, as a precaution the following sentence will be added to the WG/GA: "Unprotected persons should be kept out of treatment areas, when product is applied by coarse spraying or by foaming ".

Furthermore, when used according to the WG/GA, no adverse health effects are expected for the general public by indirect exposure to hydrogen peroxide and peracetic acid as a result of the application of Chriox 5.

7 Environment

7.1 Introduction
Authorisation is requested for the products Chriox 5, containing hydrogen peroxide (H_2O_2) and peracetic acid ($C_2H_4O_3$) as active substances. The biocidal product concerns:
- a general disinfectant (PT02) to control organisms on surfaces in industrial, public and health care areas, automatic cleaning systems, medical equipment and in laundry;
- a veterinary hygiene disinfectant to control organisms in animal houses and on equipment (PT03);
- a disinfectant for food and feed areas (PT04) to control infectious diseases and avoid contamination of food or feed articles, e.g. food processing equipment, ion exchangers, surfaces and equipment and milking parlours;
- a drinking water disinfectant in animal houses (PT05);

The products are for professional use only. The intended uses and corresponding maximum dose and use concentration for Chriox 5 are described in Table E.1.

Table E.1. Intended uses, dose, and use concentrations of the active substances in Chriox 5.

Area of use envisaged	Concentration active substance in product (g/kg)	Dose (g product/kg product to be preserved)	Concentration active substance in preserved product (mg/kg)
PT2:			
surfaces in industrial, public and health care areas	PA: 49.0 H2O2: 230.0	80.0	PA: 3920 H2O2: 18400
cleaning in place pharmaceutical and cosmetic industry			
medical equipment		60.0	PA : 2940 H2O2 : 13800
laundry		2	PA : 98 H2O2 : 460
PT3:			
animal houses	PA: 49.0 H2O2: 230.0	20.0	PA : 980 H2O2 : 4600
equipment			
PT4:			
equipment used in food processing	PA: 49.0 H2O2: 230.0	80.0	PA: 3920 H2O2: 18400
equipment used in food and beverage industry			
ion exchangers in food and beverage industry			
surfaces and equipment			
milking parlours		5.0	PA : 245 H2O2 : 1150
PT5:			
animal drinking water	PA: 49.0 H2O2: 230.0	20.0	PA : 980 H2O2 : 4600

PA = peracetic acid. H2O2 = hydrogen peroxide

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

7.3 Environmental exposure assessment

7.3.1 Chemistry and/or metabolism

In the products, and in the subsequent dilutions, peracetic acid is in chemical equilibrium with hydrogen peroxide and acetic acid. Both hydrogen peroxide and peracetic acid are strong oxidising agents that strongly react with organic substances, resulting in water, free oxygen and acetic acid.

Acetic acid is a natural occurring substance found in the environment, food, and organisms. The compound is readily biodegradable resulting in only carbon dioxide and water. Moreover, acetic acid disappears from soils within 2 days due to biodegradation and incorporation into humic or fulvic acids. Possible pH effects on the environment were not considered, because the receiving compartments are expected to have sufficient buffering.

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 products for the different applications. Compartments indicated with a 'Q' will be qualitatively assessed only. 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[4]	Freshwater[1]	Saltwater[1]	Soil[2,3]	Air
PT2:					
surfaces in industrial, public and health care areas	++ (Q)	+ (Q)	-	- (Q)	- (Q)
cleaning in place pharmaceutical and cosmetic industry					
medical equipment (e.g. endoscopes)					
laundry					
PT3:					
animal houses	++ (Q)	+ (Q)	-	+ (Q)	- (Q)
equipment					
PT4:					
equipment used in food processing	++ (Q)	+ (Q)	-	- (Q)	- (Q)
equipment used in food and beverage industry				- (Q)	
ion exchangers in food and beverage industry				- (Q)	
surfaces and equipment				- (Q)	
milking parlours				+ (Q)	
PT5:					
animal drinking water	++ (Q)	+ (Q)	-	- (Q)	- (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 disinfection, waste water holding residues of the product are predominantly discharged to the sewer and via the sewage treatment plant (STP) eventually end up in surface water. In some cases (i.e. in stables and in immersion baths), direct release to the soil compartment is possible due to spillage or leaching after application near a porous floor/surface.
Due to the active substances' chemical properties, the assessment will be performed qualitatively.

7.4 Risk characterisation for the environment

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

7.4.1 Aquatic compartment (incl. sediment) and STP

Water and sediment organisms and micro-organisms in the STP
Considering the active substances' mode of action, negligible amounts will reach the STP as the active substances are being consumed during disinfection. Once released to the sewer the remaining amounts of hydrogen peroxide and peracetic acid rapidly decrease due to oxidation with the excess organic matter present in the sewer pipeline system. Oxidation continues once the product arrived in the STP as half-lives reported for both compounds are less than 2 minutes. The concentrations in the STP's effluent are expected to be negligible.

In view of this, a low risk for aquatic organisms, sediment organisms, and micro-organisms in the STP, surface water, and sediments is expected.

Direct exposure of the product to the surface water should be avoided, due to the acute effects of the active substances on aquatic organisms in the direct proximity of the release. Additionally, release of the product or it's dilution to an private on-site waste water treatments (In Dutch: Individuele Behandeling Afvalwater (IBA) may result in malfunction of the waste water treatment system, as high loads of hydrogen peroxide and peracetic acid may kill the microbial population instantly because of the system's limited volume (3-6 m^3). Degradation in the IBA's sewer is not expected as it is short and not fully loaded with organic material. 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.

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 peracetic acid or hydrogen peroxide in Dutch surface water.

Surface water intended for the abstraction of drinking water
Biocidal products with the active substances peracetic acid or hydrogen peroxide 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 its presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb. In addition, the active substances are not included on 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 these products 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 for all products.

7.4.2 Terrestrial compartment

Soil organisms and non-target arthropods (including bees)
No half lifes are available for the degradation of peracetic acid and hydrogen peroxide in soil. Considering that the active substances quickly (minutes) react with the organic material in the soil, exposure to the soil compartment will not result in a risk to soil organisms.
The exposure of bees is considered negligible as bees are not considered to forage where the products are applied. Moreover, both compounds can not accumulate in plants and exposure of bees via pollen is considered negligible. Therefore, risk for soil organisms, non target arthropods and bees are considered negligible and the standards for the terrestrial environment are met when the products are applied in accordance to the WG/GA.

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. An exceeding of the drinking water criterion is not expected considering the biochemical profile (quick degradation once released to the environment) of the compounds. Leaching to shallow groundwater will be negligible and therefore the standards for groundwater are met.

Persistence in soil

Hydrogen peroxide and peracetic acid are chemically instable and highly reactive oxidants. Hence, the active substances are not persistent and the standards for persistence (DT_{50} <180 days) are met.

7.4.3 Non compartment specific effects relevant to the food chain

Bioconcentration
Logarithmic octanol-water partition coefficients (log K_{ow}) are -1.5 for hydrogen peroxide and -0.52 for peracetic acid. As the log K_{ow} for both substances are < 3, the risk for bioconcentration in aquatic organisms is considered low. Bioconcentration and secondary poisoning are not likely to occur with strongly oxidative compounds. The risk for bioconcentration in the proposed use is therefore considered not relevant. The standards for bioaccumulation are met.

Primary and secondary poisoning of birds and mammals
For the proposed use of the active substances direct or indirect exposure of birds and mammals to the active substance or contaminated aquatic and terrestrial organisms is considered negligible as the active substances have a low potential to bioaccumulate. The risk for the primary and secondary poisoning is considered acceptable and the proposed applications meets the standards for birds and mammals.

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 hydrogen peroxide and peracetic acid contribute to the depletion of the ozone layer, as the compounds are not listed as ‘controlled substance’ listed in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Moreover, AOPwin calculates a half life in air for hydrogen peroxide of 16 hours and for peractic acid of 32 hours (OH timeframe 24 hrs/day, 0.5×10^6 OH radicals/cm^3). These 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. Considering this, the environmental risk to air is deemed acceptable.

7.5 Measures to protect the environment (risk mitigation measures)

The aquatic risk assessment concludes that there is no risk when the remaining products are discharged to the sewer, or alternatively to a slurry pit. Risks for micro-organisms in on-site STPs (IBA’s in Dutch) and subsequent malfunction of the water treatment are expected when high amounts of the active substances enter the system. Therefore, a precautionary measure will be added to the WG/GA (see next section)

7.6 Overall conclusion for the aspect Environment

Based on the available data, it can be concluded that the product Chriox 5 complies with the environmental standards and will not cause unacceptable effects on the environment when used in accordance with the proposed label (WG/GA) on the condition that waste water is disposed to the sewer connected to the STP or the manure storage. Therefore, the following precautionary measure will be added to the WG/GA:

> EN: Possible residues containing the product must be discharged to the slurry pit or to a municipal STP. It is not allowed to discharge this product to an on-site wastewater treatment system.
>
> NL: Om bodem- en in het waterlevende organismen te beschermen dienen resten die het middel bevatten uitsluitend te worden afgevoerd naar het riool met

aansluiting op de RWZI of de mestopslag. In geen geval mag dit middel worden geloosd op een Individuele Behandeling Afvalwater (IBA).

7.7 Data requirements

There are no additional data required.

8 Conclusion

The applicant has proven that Chriox 5 under the proposed Legal Conditions for Use and the Directions for Use (WG/GA), is sufficiently effective and that no unacceptable risk is expected to human health, the person who uses the product and the environment (Art. 121 jo art. 49 first paragraph Dutch 2007 Plant Protection Products and Biocides Act).

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 *:			
Acetic acid, hydrogen peroxide, peracetic acid			
Pictogram:	GHS02 GHS05 GHS07 GHS09	Signal word:	Danger
H-statements:	H242	Heating may cause a fire	
	H290	May be corrosive to metals	
	H302	Harmful if swallowed	
	H314	Causes skin burns and serious eye damage	
	H332	Harmful if inhaled	
	H335	May cause respiratory irritation	
	H410	Very toxic to aquatic life with long lasting effects	
P-statements:	P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking.	
	P234	Keep only in original container.	
	P403+P235	Store in a well-ventilated place. Keep cool.	
	P260	Do not breathe dust/fume/gas/mist/vapours/spray.	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	P284	Wear respiratory protection.	
	P303+P361+P353+P310	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER/doctor/…	
	P305+P351+P338+P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.	
Supplemental Hazard information:	EUH071	Corrosive to respiratory tract	

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

Explanation:	
Pictogram:	-
H-statements:	H272 is considered redundant, because the concentration H_2O_2<50%. H242 is assigned, because the product contains a cat. D organic peroxide. H290 is assigned because the pH of the neat product is <2. H410 is assigned based on ecotoxicity data for the active substance (source: first draft CAR 2012) and its rapid biodegradability in combination with its concentration.
P-statements:	P210, P234 and P403+P235 are highly recommended in combination with H242. P220 was proposed in combination with H272. Because H272 is considered redundant, also P220 is considered redundant. P260 is assigned instead of P261 proposed by the applicant, as it is highly recommended with H314 according to Regulation 1272/2008/EC. P280 is assigned based on the H314 classification, based on the risk assessment gloves and coverall (and RPE) is prescribed. P284 is assigned based on the risk assessment. According to the Guidance on labelling and packaging P310 is highly recommended in combination with P303+P361+P353 and P305+P351+P338, and therefore added to the proposal.
Other:	EUH071 is assigned, as the formulation is corrosive and can be inhaled.

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

10 References

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