HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 21 mei 2013 is van

OXY'PHARM
917 rue Marcel Paul
94500 CHAMPIGNY-SUR-MARNE
FRANKRIJK

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

NOCOLYSE FOOD

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

3 BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

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

3.2 Analysemethoden

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

3.3 Risico voor de mens

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

3.4 Risico voor het milieu

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

3.5 Werkzaamheid

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

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

Ede, 23 december 2015

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

15012 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20130671 TB
Type aanvraag:	aanvraag tot toelating van de biocide op basis van niet geplaatste stof(fen) (overgangsrecht)
Middelnaam:	NOCOLYSE FOOD
Verzenddatum aanvraag:	15 mei 2013
Formele registratiedatum: *	5 juli 2013
Datum in behandeling name:	9 september 2015

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

2 Stofinformatie

Werkzame stof	Gehalte
waterstofperoxide	7,9%

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

3 Toelatingsinformatie

Toelatingsnummer:	15012 N
Expiratiedatum:	1 januari 2026
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel

4 Verpakkingsinformatie

Aard van het preparaat:
Andere vloeistoffen voor directe toepassing

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BIJLAGE II Etikettering van het middel NOCOLYSE FOOD

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

Pictogram	GHS07
Signaalwoord	WAARSCHUWING
Gevarenaanduidingen	H319 Veroorzaakt ernstige oogirritatie.
Voorzorgsmaatregelen	P264 Na het werken met dit product ... grondig wassen.
	P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen.
	P305 + P351 + P338 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen.
	P337 + P313 Bij aanhoudende oogirritatie: een arts raadplegen.
Aanvullende etiketelementen	
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

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BIJLAGE III WG/GA van het middel NOCOLYSE FOOD

A.

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van bacteriën (exclusief mycobacteriën), bacteriesporen, gisten, schimmels en virussen op oppervlakken die in contact kunnen komen met eet- en drinkwaren en grondstoffen hiervoor.

Toegestaan is uitsluitend het gebruik door middel van verneveling in afgesloten ruimten met behulp van Nocospray of Nocomax apparatuur.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.

GEBRUIKSAANWIJZING

Deze desinfectie mag uitsluitend worden uitgevoerd door professionals die een opleiding voor ruimtedesinfectie hebben gehad en zijn gecertificeerd.

Het product kan uitsluitend worden gebruikt in combinatie met Nocospray/Nocomax apparatuur die het product verspreidt.

NOCOLYSE FOOD is een kant-en-klare oplossing in water en hoeft niet te worden verdund.

Oppervlakken, apparatuur en materiaal in de te desinfecteren ruimte eerst grondig reinigen. Een daarbij gebruikt reinigingsmiddel afspoelen met schoon water. Overtollig water verwijderen. Voorafgaand aan de desinfectie moeten vochtige plekken worden gedroogd en kastdeuren en laden geopend. Putjes en andere natte plekken moeten apart gedesinfecteerd worden met een daarvoor geschikt middel.

Tijdens de desinfectie mogen geen mensen en dieren in de te behandelen ruimte aanwezig zijn. De ruimte mag niet worden betreden voor de beluchting is afgerond (d.w.z. gemeten peroxide concentratie < 1 ppm). Indien een ruimte met een concentratie > 1ppm toch betreden moet worden, moet adembescherming gedragen worden. Oppervlakken die met levensmiddelen in aanraking komen na de desinfectie grondig naspoelen met water. Tevens moeten alle geneesmiddelen en voedingsmiddelen worden verwijderd uit de te behandelen ruimte. Objecten die niet gedesinfecteerd moeten of kunnen worden dienen te worden verwijderd.

Toepassing:

- Noteer voorafgaand aan het eerste gebruik de datum van opening op de fles. Het product in een geopende fles is 2 maanden houdbaar.
- Schroef de 1-liter fles op het Nocospray verspreidingssysteem of de 20-liter fles op het Nocomax verspreidingssysteem.
- Stel het apparaat in al naar gelang de grootte van de ruimte en houdt hierbij de aanbrengtijd als beschreven in het protocol aan.

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Dosering:

- Ruimtes dienen tweemaal achter elkaar behandeld te worden met 7 ml product per m^3.
- Na iedere behandeling dient een contacttijd van minimaal 2 uur aangehouden te worden waarin de ruimte niet betreden mag worden.

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BIJLAGE IV

RISKMANAGEMENT

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1 Introduction

1.1 Applicant

OXY'PHARM
917 rue Marcel Paul
94500 CHAMPIGNY-SUR-MARNE
FRANCE

1.2 Active substance

The active substance is hydrogen peroxide.

1.3 Product

NOCOLYSE FOOD

1.4 Function

NOCOLYSE FOOD is a disinfectant of surfaces, including surfaces that can get in contact with foods (PT04).

1.5 Background to the application

This is an application for authorization of a new biocidal product.

1.6 Intended uses

Intended is the professional use to control bacteria, viruses, yeasts, mould and spores on surfaces in the food and feed area.

1.7 Packaging details

1L – 20L in HDPE.

2 Identity

2.1 Identity of the active substance

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

The active substance hydrogen peroxide will be included in the Union list of approved substances of EU Regulation 528/2012 at February 1, 2017. A final CAR for hydrogen peroxide is available for PT 1-6 (dated March 2015).
Data on the identity are based on information included in the IUCLID dossier and the Merck Index.

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

2.2 Identity of the biocidal product

Name	NOCOLYSE FOOD
Formulation type	AL
Content active substance	Hydrogen peroxide: 7.9% w/w

Packaging information:

	Material	Size / content	Other information
Professional use	HDPE	1L-20L	Equipped with degassing caps and transparent line of visibility.

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

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 °C	-40 °C
Boiling point	108 °C	125 °C
Temperature of decomposition	> 100 °C	> 100 °C
Appearance	Clear colourless solution	Clear colourless solution
Density	1.132 g/cm^3 at 20 °C	1.288 g/cm^3 at 20 °C
Surface tension	74.0 mN/m	76.0 mN/m
Vapour pressure	30.7 hPa at 20 °C	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 and 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.

3.2 Physical and chemical properties of the biocidal product

Appearance	Clear colourless liquid with no odour
Explosive properties	Not explosive
Oxidative properties	Not oxidising
Auto flammability	Not auto flammable
Flashpoint	No data, based on the composition the product is expected not to be flammable
pH 1% solution	pH neat = 3

Particle size distribution	Not applicable
Surface tension	Not applicable
Viscosity	Not applicable
Relative density	1.03
Storage stability/Shelf life/Packaging	Two years at room temperature in HDPE. Tested parameters: active substance content and packaging. All data remain within acceptable limits. The stability of the product in uncapped bottles was tested during 2 months at room temperature. Tested parameter was the active substance content. Data remained within acceptable limits. The product is stable during 2 months in uncapped bottles.
Technical properties	Not applicable
Physical and chemical compatibility	Not applicable

3.3 Overall conclusions physical and chemical properties

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

Supported shelf life of the formulation is 2 years in HDPE.

Data requirements

None.

4 Analytical methods for detection and identification

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

4.1 Analytical methods for the technical active substance

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

4.2 Analytical methods for analysis of the biocidal product

Preparation (principle of method)	Titration with potassium permanganate

4.3 Residue analytical methods

Hydrogen peroxide reacts violently with organic matter, it is not considered feasible or relevant to monitor this substance in the environment. For determination of free hydroxyl radicals, various analytical methods are described in literature.

4.4 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements

None.

5 Efficacy

5.1 Function

NOCOLYSE FOOD is a disinfectant based on hydrogen peroxide (7.9% w/w).

5.2 Field of use envisaged

The proposed field of use of NOCOLYSE FOOD is the control of bacteria, bacterial spores, yeasts, fungi and viruses on surfaces that can get in contact with foods.

These uses are included in PT04.

The product is intended for professional use only.

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

Six studies were provided and were used in this assessment. Other provided studies were disregarded due to irrelevant soiling conditions or non-standard test organisms. The relevant studies are summarised in Table 1.

Table 1. Summary of studies assessed

Test (version) Phase, step	**Test organism**	**Test parameters**	**Results**
Bacteria			
EN 1276 (2010) 2,1	*Staphylococcus aureus* *Pseudomonas aeruginosa* *Escherichia coli* *Enterococcus hirae*	**Concentration (%):** 40%, 80% middel **Interfering substances:** 0.3g/L BSA **Contact time:** 5 min **Test temperature:** 20°C	**log R>5:** 40 %; 5 min; Clean; 20°C
EN 13697 (2001) 2,2	*Staphylococcus aureus* *Pseudomonas aeruginosa* *Escherichia coli* *Enterococcus hirae*	**Concentration (%):** 1, 50, 100% middel **Interfering substances:** 0.3g/L BSA **Contact time:** 5 min / 15 min **Test temperature:** 18-25°C	**Bacteria** **log R>7:** 50 %; 5 min; Clean; 18-25°C
AFNOR NF T 72-281 2, 2	*Escherichia coli* *Enterococcus hirae*	**Concentration (%):** 3 ml/m³ **Interfering substances:** 1/20 reconstituted milk + 0.3 g/L BSA **Contact time:** 2 hrs **Test temperature:** start 19-22°C	**log R=6.11:** 3 ml/m³ dirty 2 hrs; 19-22°C

Test (version) Phase, step	Test organism	Test parameters	Results
	Staphylococcus aureus	**Concentration (%):** 5 ml/m³ **Interfering substances:** 1/20 reconstituted milk + 0.3 g/L BSA **Contact time:** 2 hrs **Test temperature:** start 19-22°C	**log R=5.23:** 5 ml/m³ dirty 2 hrs; 19-22°C
	Pseudomonas aeruginosa	**Concentration (%):** 7 ml/m³ **Interfering substances:** 1/20 reconstituted milk + 0.3 g/L BSA **Contact time:** 1 hr **Test temperature:** start 19-22°C	**log R=5.58:** 7 ml/m³ dirty 1 hr; 19-22°C
Yeasts			
EN 1650 (2008) 2, 1	*Candida albicans*	**Concentration (%):** 40, 80% **Interfering substances:** 0.3g/L BSA **Contact time:** 15 min **Test temperature:** 20°C	**log R>4:** 40 %; Clean 15 min; 20°C
EN 13697 (2001) 2,2	*Candida albicans*	**Concentration (%):** 1, 50, 100% middel **Interfering substances:** 0.3g/L BSA **Contact time:** 5 min / 15 min **Test temperature:** 18-25°C	**log R>6:** 50 %; 15 min; Clean; 18-25°C
AFNOR NF T 72-281 (step 2.2 test)	*Candida albicans*	**Concentration (%):** 3 ml/m³ **Interfering substances:** 1/20 reconstituted milk + 0.3 g/L BSA **Contact time:** 2 hr **Test temperature:** start 19-22°C	**log R=6.73:** 3 ml/m³ dirty 2 hr; 19-22°C
Bacterial spores			
EN 13704 (2002) 2,1	*Bacillus subtilis*	**Concentration (%):** 0.5, 1, 20% **Interfering**	**log R>3:** 20 %; Clean;

Test (version) Phase, step	**Test organism**	**Test parameters**	**Results**
		substances: 0.3g/L BSA **Contact time:** 60 min **Test temperature:** 20°C	60 min; 20°C
AFNOR NF T 72-281 2, 2	*Bacillus subtilis*	**Concentration (%):** 3 ml/m³ **Interfering substances:** 1/20 reconstituted milk + 0.3 g/L BSA **Contact time:** 2 hr **Test temperature:** start 19-22°C	**log R=4.04:** 3 ml/m³ dirty 2 hr; 19-22°C
Fungi			
EN 1650 (2008) 2, 1	*Aspergillus fumigatus*	**Concentration (%):** 40, 80% **Interfering substances:** 0.3g/L BSA **Contact time:** 15 min **Test temperature:** 20°C	**log R>4:** 40 %; Clean 15 min; 20°C
EN 13697 (2001) 2, 2	*Aspergillus niger*	**Concentration (%):** 1, 50, 100% middel **Interfering substances:** 0.3g/L BSA **Contact time:** 5 min / 15 min **Test temperature:** 18-25°C	**log R>5:** 50 %; 15 min; Clean; 18-25°C
AFNOR NF T 72-281 2, 2	*Aspergillus fumigatus* *Aspergillus.brasiliensis*	**Concentration (%):** 3 ml/m³ **Interfering substances:** 1/20 reconstituted milk + 0.3 g/L BSA **Contact time:** 2 hr **Test temperature:** start 19-22°C	**log R=5.53:** 3 ml/m³ dirty 2 hr; 19-22°C
Viruses			
EN 14476 (2005) 2, 1	*Poliovirus* *Adenovirus*	**Concentration (%):** 80% **Interfering substances:** 0.3 g/L BSA **Contact time:** 15, 30, 45, 60 min **Test temperature:**	**Log R>4:** 80 %; Clean 15 min; 20°C

Test (version) Phase, step	Test organism	Test parameters	Results
		20°C	
AFNOR NF T 72-281 2, 2	*Murine Norovirus S99/RAW264.7*	**Concentration (%):** 3 ml/m³ **Interfering substances:** 1/20 reconstituted milk + 0.3 g/L BSA **Contact time:** 2 hr **Test temperature:** start 19-22°C	**log R=4.4:** 3 ml/m³ dirty 2 hr; 19-22°C

The available information was sufficient to evaluate the efficacy of NOCOLYSE FOOD for control of bacteria (excluding mycobacteria), bacterial spores, yeasts, fungi and viruses, considering evaluation is done under article 121 of the WGB. The studies show that NOCOLYSE FOOD complies with the criteria for lg reduction for disinfectants for the key species of the target organisms, when used in accordance with the instructions described on the WG/GA. As no guideline is available for a phase 2 step 2 test for room disinfection with viruses, the adapted AFNOR test with murine norovirus was deemed acceptable considering the efficacy shown against poliovirus and adenovirus in the phase 2 step 1 tests.

One test in which a room was disinfected by vaporisation demonstrated that that the product, applied via a Nocospray apparatus, is efficacious against bacteria, bacterial spores, yeasts, fungi, and viruses. As the test was performed using different concentrations, contact times and number of treatments, the effective application rate of the product is a combination of the worst-case test conditions: two 2-hour treatments with 7ml/m^3 of the product.

5.3.2 Evaluation of the label (WG/GA)

The applicant has provided a WG/GA in Dutch. This has been adapted to our standards. Dosing instructions and contact times were adapted in line with the provided efficacy data. As efficacy was only demonstrated under clean conditions in the suspension tests, standard cleaning instructions for room disinfection were added to the WG/GA. Since no efficacy was demonstrated against mycobacteria, mycobacteria were excluded from the bacterial claim.

5.4 Mode of action

Hydrogen peroxide has a rapid biocidal effect against microorganisms. It owns its efficacy to its activity as a powerful oxidising agent that is known to damage cellular proteins, lipids etc. It breaks down into innocuous residues.

5.5 Limitations on efficacy including resistance

5.5.1 Resistance

Hydrogen peroxide is successfully used as a biocide on a worldwide scale for many years against a wide range of micro-organisms. Because of the unspecific mode of action, resistance development is not likely to occur.

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 NOCOLYSE FOOD, when used in accordance with the proposed label (WG/GA), is effective in controlling bacteria (excluding mycobacteria), bacterial spores, yeasts, fungi

and viruses on surfaces that can get in contact with foods.

6 Human toxicology

Human health effects assessment active substance

Hydrogen peroxide

Hydrogen peroxide is considered a bulk chemical. Therefore, limited data is required because the properties of hydrogen peroxide are well documented. The applicants are allowed to use the IUCLID database of this active substance.

A final CAR for hydrogen peroxide is available for PT 1-6 (dated March 2015). At the time of the evaluation, the assessment is based on the List of Endpoints (LoEP) from the final draft AR-report for which Finland is the Reporting Member State. Since the CAR was not finalized yet, the toxicological profile below should be regarded as provisional. Where relevant, additional remarks/information are given 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
Distribution:	None
Potential for accumulation:	None
Rate and extent of excretion:	None
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	805 mg/kg bw (70 %). (486 mg/kg bw; 100%, females) 1232 mg/kg bw (35 %) (492 mg/kg bw; 100%, combined)
Rat LD_{50} dermal	>2000 mg/kg bw
Rat LC_{50} inhalation	>170 mg/m^3 (vapour, highest attainable vapour concentration)
Skin corrosion/irritation	35%≤ c <50% H_2O_2: irritant ≥50% H_2O_2: corrosive
Eye irritation	5%≤ c <8% H_2O_2: irritant ≥8% H_2O_2: severe irritant
Respiratory tract irritation	Is an irritating substance to respiratory tract
Skin sensitisation (test method used and result)	Not sensitizing (modified Magnusson-Kligman and human data)
Respiratory sensitisation (test method used and result)	-

Repeated dose toxicity

Short term

Species / target / critical effect	Rodent
Relevant oral NOAEL / LOAEL	Not established, not systemically available
Relevant dermal NOAEL / LOAEL	Not established
Relevant inhalation NOAEL / LOAEL	2 ppm; 2.9 mg/m3 (28-day rat)

Subchronic

Species/ target / critical effect	Rodent
Relevant oral NOAEL / LOAEL	NOAEL: 26 mg/kg bw/day (100 ppm, 90-day mouse)
Relevant dermal NOAEL / LOAEL	Not established
Relevant inhalation NOAEL / LOAEL	NOAEC: 10 mg/m^3 (7 ppm, 90-day rat)

Long term

Species/ target / critical effect	
Relevant oral NOAEL / LOAEL	not assessed
Relevant dermal NOAEL / LOAEL	not assessed
Relevant inhalation NOAEL / LOAEL	not assessed

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 bone 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.Information on local genotoxicity in literature was added in the CAR. Due to the irritating properties of hydrogen peroxide, the risk mitigation measures include the use of personal protective equipment. The RMS considers the protections sufficient, and does not consider the local genotoxicity as a relevant

	endpoint for a risk assessment.

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
Relevant NOAEL/LOAEL	

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	Not reprotoxic, no systemic availability
Relevant maternal NOAEL	
Relevant developmental NOAEL	

Fertility

Species/critical effect	Not reprotoxic, no systemic availability
Relevant parental NOAEL	
Relevant offspring NOAEL	
Relevant fertility NOAEL	

Neurotoxicity

Species/ target/critical effect	Available studies give no indication of a neurotoxic potential

Developmental Neurotoxicity

Species/ target/critical effect	Available studies give no indication of a neurotoxic potential

Immunotoxicity

Species/ target/critical effect	

Developmental Immunotoxicity

Species/ target/critical effect	

Other toxicological studies

Medical data

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. 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
AEC inhalation$_{long\text{-}term}$	1.25 mg/m^3	NOAEC in 90-day inhalation study (rat)	8
AEC inhalation$_{medium\text{-}term}$	1.25 mg/m^3	NOAEC in 90-day inhalation study (rat)	8
AEC inhalation$_{short\text{-}term}$	1.25 mg/m^3	NOAEC in 90-day inhalation study (rat)	8
ADI[1]	not established, not systemically available. The agreed acceptable max concentration is 0.1 mg/L in human drinking water. In the main use in PT 5, drinking water of chicken, max concentration: 5 mg/L		
ARfD	not established		

Dermal absorption

Study (*in vitro/vivo*), species tested	not feasible, not assessed
Formulation (formulation type and including concentration(s) tested, vehicle)	-
Dermal absorption values used in risk assessment	100 % as default

Local effects

The AR describes that no dermal irritation occurs after application of 10% hydrogen peroxide. At a higher concentration of 35 % hydrogen peroxide causes slight to moderate reversible erythema and edema in a skin irritation study. In addition, irreversible desquamation of skin triggers classification of Skin irritation 2, H315: “Causes skin irritation". When the in-use concentration of hydrogen peroxide in a product is below the skin irritating threshold (concentration limit for classification for skin irritation is 35%), only the inhalation route of exposure will be relevant in the quantitative exposure and risk assessment.

In addition to skin irritation properties, hydrogen peroxide causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to the rabbit eye has been demonstrated. This result supports the current classification with Eye irritation 2, H319: “Causes serious eye irritation” for 5 % ≤ hydrogen peroxide < 8 % and for 8% ≤ hydrogen peroxide < 50% classification with Eye damage 1, H318.

As hydrogen peroxide quickly decomposes at the site of contact and does not become systemically available, 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

[1] If residues in food or feed.

NOCOLYSE FOOD is a ready-to-use liquid and contains 7.9% hydrogen peroxide as active substance. The proposed field of use of NOCOLYSE FOOD is disinfection of surfaces, including surfaces that can get in contact with foods (PT04).

The formulation NOCOLYSE FOOD is for professional use only.

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

The professional user can be dermally exposed to hydrogen peroxide during mixing and loading of NOCOLYSE FOOD. Hydrogen peroxide is considered to be a moderately volatile substance in an aqueous solution (vapour pressure of 214 Pa at 20°C (293 K) and a Henry's law constant of 7.5*10-4 Pa*m3/mol at 20°C (293K)), therefore inhalation exposure to hydrogen peroxide is possible during mixing and loading.

NOCOLYSE FOOD will be applied by fogging, using an automated fogging equipment (Nocospray). No people may be present in the treated areas during the treatment. Therefore dermal and respiratory exposure of professional users is considered to be negligible during the application of this product.

As NOCOLYSE FOOD is used by professionals, oral exposure to hydrogen peroxide 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 NOCOLYSE FOOD is to be used by professionals only.

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

Indirect exposure of professional users and general public is considered to be unlikely due to high reactivity of hydrogen peroxide, which would lead to its quick reaction with organic matter on the surfaces and subsequent decomposition. In addition, the potential secondary exposure is considered to be negligible, as the treated areas may not be entered until the concentration of hydrogen peroxide in the air is decreased below 1 ppm.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

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

6.2.2 Data requirements formulated product

No additional data requirements are identified.

6.3 Risk characterisation for human health

6.3.1 Professional users

The professional user can be dermally and respiratory exposed to hydrogen peroxide during mixing and loading of NOCOLYSE FOOD. As NOCOLYSE FOOD will be applied by fogging, using automated fogging equipment (Nocospray), where no people are present, dermal and respiratory exposure are considered to be negligible during the application of this product.

<u>Mixing and loading</u>

For dermal exposure, the professional user could be exposed to the ready-to-use product, which contains 7.9% hydrogen peroxide. This is below the skin irritation threshold of 35% for hydrogen

peroxide. Therefore, no adverse effects from dermal exposure to hydrogen peroxide are expected for the unprotected professional user during loading of the product.

The inhalation exposure to hydrogen peroxide during loading operations was calculated using the Mixing and Loading Model 7 (HEEG 2008, TNsG part 2 p.142 (corrected)) for liquids. It is a worst case approach, because NOCOLYSE FOOD is a ready-to-use product and mixing is not necessary. The indicative inhalation exposure is 0.94 mg biocidal product/m^3. Considering the hydrogen peroxide concentration of 7.9%, this corresponds to the concentration of hydrogen peroxide of 0.074 mg/m^3 in air. This concentration is below the $AECinhalation_{short/medium/long\text{-}term}$ of 1.25 mg/m^3 for hydrogen peroxide. Therefore no adverse effects from respiratory exposure to hydrogen peroxide are expected for unprotected professional users during loading of NOCOLYSE FOOD.

6.3.2 Non-professional users, including the general public
The formulation NOCOLYSE FOOD is to be used by professionals only.

6.3.3 Indirect exposure as a result of use
Indirect exposure of professional users and general public is considered to be unlikely due to high reactivity of hydrogen peroxide, which would lead to its quick reaction with organic matter on the surfaces and subsequent decomposition. In addition, the potential secondary exposure is considered to be negligible, as the treated areas may not be entered until the concentration of hydrogen peroxide in the air is decreased below 1 ppm. This is supported by residue measurements (non-GLP) as provided by the applicant, revealing residue levels below 1 ppm or detection limit.

6.3.4 Combined exposure
NOCOLYSE FOOD 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
The formulation NOCOLYSE FOOD does not contain potential substances of concern.

6.4 Overall conclusions for the aspect human health
Based on this risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional user after dermal and respiratory exposure to hydrogen peroxide as a result of the application of NOCOLYSE FOOD , when used in accordance to the WG/GA.

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

7 Environment

7.1 Introduction
Authorisation is requested for the product NOCOLYSE FOOD, a biocidal disinfectant containing hydrogen peroxide as active substance (7.9% w/w). The product is for professional use with an atomizing apparatus (the so called Nocospray) to control bacteria, viruses, yeasts and mould on surfaces in the food and feed area (PT4). The product is applied on a daily, occasional and curative basis, with an increasing concentration and duration of application.
The risk assessment is performed for products based on active substances which have not yet been included in the Union list of approved substances of EU Regulation 528/2012.

The intended use is described in table E.1.

Table E.1 Intended uses of NOCOLYSE FOOD

Area of use envisaged	Application product	Dosage product
professional use to control bacteria, viruses, yeasts, mould and spores on surfaces in the food and feed area (PT4)	Atomizing apparatus (''Nocospray" and "Nocomax")	Min 1 mL/m^3 (daily use) Max 5 mL/m^3 (occasional and curative use)

7.2 Product related studies

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. A final CAR for hydrogen peroxide is available for PT 1-6 (dated March 2015.

7.3 Environmental exposure assessment product

7.3.1 Chemistry and/or metabolism
The chemical reaction of hydrogen peroxide with substances in the aquatic and soil compartment will result in the formation of water and other harmless substances.
Because the diversity of reaction products is inexhaustible and it is considered impossible to make a proper identification, it is decided to exclude them from the risk assessment. Also 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

Emission routes
Various phases in the life cycle of a product may cause emissions and environmental exposure. Emissions from active substance production and product formulation are considered less relevant compared to emissions from the application phase, in service and waste phase of the product.

Emissions to air may occur after application of NOCOLYSE FOOD due to ventilation. However, the active substance hydrogen peroxide will react rapidly and no exposure of the environment is expected. The proposed indoor use will not result in an emission to soil.
It is expected that the room will not be wet cleaned after application as this will affect the efficacy of the product and therefore product residues will not reach the STP. The proposed use will not result in a direct emission to surface water. Indirect emission of hydrogen peroxide to surface waters via STP will not occur.
The foreseeable routes of entry into the environment during the application, in-service and waste phase are listed in Table E.2.

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

	Environmental compartments and groups of organisms exposed				
Use scenario	**STP**	**Saltwater***	**Soil****	**Air**	**Birds and mammals**
Professional use to control bacteria, viruses, yeasts and mould on surfaces in the food and feed area (PT4)	-	-	-	++	-

++ Compartment primarily exposed
+ Compartment secondarily exposed (surface water from STP discharge, vertebrates eating contaminated fish)

(+) Compartment potentially exposed
- Compartment not exposed
* Including sediment
** Including groundwater, bees and non-target arthropods

7.4 Risk characterisation for the environment
A qualitative risk assessment was performed for all emission routes.

7.4.1 Aquatic compartment (incl. Sediment) and STP

Aquatic and sediment organisms
The proposed use will not result in a direct emission to surface water. Indirect emission of hydrogen peroxide to surface waters via STP will not occur (see below). Risk for aquatic and sediment organisms is considered acceptable.

STP
As the proposed use will not result in exposure of the STP, risk for micro-organisms in the STP is considered acceptable.

Surface water intended for the abstraction of drinking water
As the proposed use will not result in exposure of the aquatic compartment, risk for surface water used for the production of drinking water is considered acceptable.

7.4.2 Atmosphere
The proposed use will result in a limited emission to air, due to ventilation from indoor areas in which application of the product has taken place.
Because hydrogen peroxide will react rapidly, significant exposure of the air is not expected. Risk for the air compartment is therefore considered acceptable.

7.4.3 Terrestrial compartment

Soil organisms and non target arthropods (including bees)
As the proposed use will not result in exposure of the soil compartment, risk for soil organisms and non target arthropods is considered acceptable.

Groundwater
As the proposed use will not result in exposure of the groundwater compartment, risk for the groundwater is considered acceptable.

Persistence in soil
Hydrogen peroxide reacts rapidly with organic and inorganic material in soil. Hydrogen peroxide is not persistent in soil. Hydrogen peroxide meets the standards for persistence.

7.4.4 Non compartment specific effects relevant to the food chain

Bioconcentration
Hydrogen peroxide has a log Kow value of 1.5 and calculated BCF-values in fish and earthworms of 1.4 and 3.3, respectively, indicating low potential to bioaccumulate.
Since the log Kow of hydrogen peroxide is < 3, hydrogen peroxide meets the standards for bioaccumulation.

Primary and secondary poisoning of birds and mammals
As the proposed use will result in a limited emission to air and hydrogen peroxide reacts rapidly, primary poisoning of birds and mammals is not expected.

The proposed use will not result in secondary exposure of birds and mammals, and thus the risk for the primary and secondary poisoning is considered acceptable.

Measures to protect the environment (risk mitigation measures)
No additional measures to protect the environment (risk mitigation measures) are required.

7.5 Overall conclusion

It can be concluded that:

1. The proposed applications of the active substance hydrogen peroxide meet the standards for aquatic and sediment organisms.
2. The proposed applications of the active substance hydrogen peroxide meet the standards for micro-organisms in the STP.
3. The proposed applications of the active substance hydrogen peroxide meet the standards for the production of drinking water from shallow groundwater and surface water.
4. The proposed applications of the active substance hydrogen peroxide meet the standards for the air compartment.
5. The active substance hydrogen peroxide meets the standards for persistence.
6. The proposed applications of the active substance hydrogen peroxide meet the standards for soil organisms.
7. The active substance hydrogen peroxide meets the standards for bioconcentration.
8. The proposed applications of the active substance hydrogen peroxide meet the standards for primary and secondary poisoning of birds and mammals.
9. The proposed applications of the active substance hydrogen peroxide meet the standards for non-target arthropods including bees.

Based on the available data, it can be concluded that NOCOLYSE FOOD, when used in accordance with the proposed label (WG/GA) complies with the environmental standards and will not cause unacceptable effects on the environment.

Data requirements
There are no additional data required.

8 Conclusion

The applicant has proven that NOCOLYSE FOOD 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

Proposal for the classification and labelling of the formulation
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 *:			
-			
Pictogram:	GHS07	Signal word:	Warning

H-statements:	H319	Causes serious eye irritation.
P-statements:	P264	Wash hands thoroughly after handling.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337 + P313	IF eye irritation persists: Get medical advice/attention.
Supplemental Hazard information:	-	

Child-resistant fastening obligatory?	-
Tactile warning of danger obligatory?	-

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

10 References

There are no references available.