File No: LTD/1967

May 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Glutens, hydrolyzates, reaction products with lauroyl chloride, sodium salts

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1967	iNova Pharmaceuticals (Australia) Pty Ltd	Glutens, hydrolyzates, reaction products with lauroyl chloride, sodium salts	Yes	1 tonne per annum	Component of rinse-off facial cleaners

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical) is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Serious eye damage/eye irritation (Category 2A)	H319 – Causes serious eye irritation

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 2	H401 – Toxic to aquatic life

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical) is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, use of rinse-off facial cleaners containing the notified chemical at ≤ 5.7% concentration is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Products containing ≤ 30% of the notified chemical should carry the following hazard classification:
  - Serious eye damage/eye irritation (Category 2A): H319 – Causes serious eye irritation

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Imperative gloves
  - Coveralls
  - Goggles

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical reclassified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling is not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, physical collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical;
  - the concentration of the notified chemical exceeds or is intended to exceed 5.7% in rinse-off facial cleaners.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from component of rinse-off facial cleaners , or is likely to change significantly;
  - the amount of chemical being introduced has increased, or is likely to increase, significantly;

- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet
The SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
iNova Pharmaceuticals (Australia) Pty Ltd (ABN: 88 000 222 408)
Level 10, 12 Help Street
CHATSWOOD NSW 2067

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: degree of purity and residual monomers/impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, dissociation constant, flash point, flammability, autoignition temperature, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
EU

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Proteol OAT
Proteol OAT PF

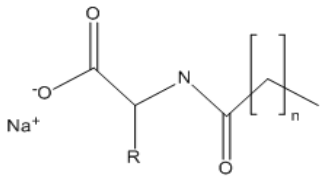
CAS NUMBER
161074-67-5

CHEMICAL NAME
Glutens, hydrolyzates, reaction products with lauroyl chloride, sodium salts

OTHER NAME
Sodium lauoryl oat amino acids (generic name listed on the SDS)

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



n = 10
R = oat aminoacid

MOLECULAR WEIGHT
Estimated to be 257-363 g/mol for lauroyl amino acids

ANALYTICAL DATA

METHOD	Nuclear Magnetic Resonance Spectroscopy
Remarks	The NMR spectrum is consistent with the structure of the notified chemical.
TEST FACILITY	SEPPIC

METHOD	UV-spectrum
Remarks	λ_{max} = 197 nm The UV-Vis spectrum is consistent with the structure of the notified chemical.
TEST FACILITY	SEPPIC

METHOD	Infrared Spectroscopy
Remarks	Peaks at 3288.8, 2955.5, 2922.6, 2852.6, 1585.2, 1456.5, 1406.6, 1311.5, 1162.5, 1111.5, 851.2, 772.5 and 721.1 cm^{-1}. The IR spectrum is consistent with the structure of the notified chemical.
TEST FACILITY	SEPPIC

3. COMPOSITION

DEGREE OF PURITY
> 40 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid (slightly turbid)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< 10 °C	Measured
Boiling Point	108.6 °C at 98.5 kPa	Measured
Density	1,085 kg/m^3 at 20 °C	Measured
Vapour Pressure	2.111 kPa at 20 °C 2.751 kPa at 25 °C	Measured
Water Solubility	278 g/L at 25 °C	Measured
Hydrolysis as a Function of pH	Not determined	The chemical is a salt and is not expected to significantly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	log Pow = 0.51 at 20 °C	Measured
Adsorption/Desorption	log Koc < 1.25 at 20 °C	Measured
Dissociation Constant	Not determined	The notified chemical is a salt and is expected to dissociate under environmental conditions (pH 4-9)
Flash Point	Not determined	-
Flammability	Non-flammable	SDS
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical) is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported as a component of facial cleaners at ≤ 5.7% concentration.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1	1	1	1	1

PORT OF ENTRY
Sydney

IDENTITY OF RECIPIENT
iNova Pharmaceuticals (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The product containing the notified chemical at ≤ 5.7% concentration will be imported in 200 mL and 1 L sealed plastic bottles packed in cardboard cartons. The products containing the notified chemical will be distributed to retail outlets within Australia by road or by rail or by air.

USE
The notified chemical is intended to be used as a component in rinse-off facial cleaners at 3 or 5.7% concentration.

OPERATION DESCRIPTION
The notified chemical will be imported as a component of finished rinse-off facial cleaners. There will be no reformulations in Australia.

The finished products containing the notified chemical will be used by consumers (≤ 5.7% concentration) and workers, such as workers in beauty salons (≤ 3% concentration). Depending on the nature of the product, application could be by hand or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	0	< 1
Beauty therapists	10 min	52

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified chemical as a component of rinse-off facial cleaners (at ≤ 5.7% concentration) only in the event of accidental rupture of containers.

Exposure to the notified chemical at ≤ 3% concentration in end-use products may occur in workers in beauty salons where the services provided involve the application of cosmetic and personal care products to clients. The principle route of exposure will be dermal, while accidental ocular and inhalation exposure also possible. Such workers may use appropriate personal protective equipment (PPE) to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure

There will be repeated exposure of the public to the notified chemical (at ≤ 5.7% concentration) through the use of it in facial cleansers. The principal route of exposure will be dermal, while accidental ocular exposure is also possible.

An internal dose of 1.463 mg/kg bw/day was estimated using data on a typical use pattern of a cosmetic product category in which the notified chemical may be used at up to 5.7% concentration (SCCS, 2010; Cadby *et al*, 2002; SDA, 2005). This estimation assumed a worst case scenario with a dermal absorption rate of 100% for the chemical and is for a person who is a simultaneous user of cosmetic products that may contain the notified chemical.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion**
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, combined repeated dose toxicity study with the reproduction/developmental toxicity screening test – 55 days	NOAEL = 1,000 mg/kg bw/day for males NOEL = 1,000 mg/kg bw/day for females NOEL = 100 mg/kg bw/day for males NOEL = 1,000 mg/kg bw/day for reproductive toxicity
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic
Genotoxicity – in vitro mammalian cell gene mutation test	non genotoxic

*Toxicity data are from studies conducted with 30% concentration of the notified chemical.

Toxicokinetics, metabolism and distribution

The notified chemical has a low molecular weight (< 500 Da) and a log Pow of 0.51. Therefore, absorption across biological membranes is expected. However the high water solubility of the notified chemical may limit dermal absorption.

Acute toxicity

Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) was found to have low acute oral and dermal toxicity in rats. No information is available on inhalation toxicity.

Irritation

Based on studies conducted in rabbits, Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) was considered to be slightly irritating to the skin and irritating (category 2A) to eyes. Based on this result, the notified chemical at a concentration of 100% could be irritating to the skin and severely irritating to eyes. As no data for the neat chemical was provided, no hazard classification for the chemical was recommended for skin and eye irritation. However, the notifier has classified the neat chemical as Category 1 eye irritant and Category 2 skin irritant.

Information on irritation to the respiratory tract is not available.

Sensitisation
A Magnusson and Kligman maximisation test performed in guinea pigs using Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) found no evidence of sensitisation.

Repeated dose toxicity
A 55-day combined repeated dose toxicity study including the reproduction/developmental toxicity screening test was conducted using Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) in the rats. No clinical signs of toxicity were noted in test animals. Treatment related effects were observed in the stomach of male animals only, and included moderate acanthosis, slight hyperkeratosis and slight subepithelial inflammatory cell infiltrates at 300 and 1,000 mg/kg bw/day. Moderate acanthosis, slight hyperkeratosis, moderate chronic inflammatory cell foci (statistically significant) in prostrate, minimal epithelial ulceration, erosion and moderate subepithelial inflammatory cell infiltrates were observed in one male treated with the high dose. The study authors asserted that although gastric changes observed in males treated with mid and high doses were considered to be adverse, a squamous-lined counterpart to the rodent forestomach is not present in human stomach. Therefore these observed effects in this study are not considered to be indicative of human health hazards and a NOAEL of 1,000 mg/kg bw/day and a NOEL of 100 mg/kg bw/day for males were established. A NOEL of 1,000 mg/kg bw/day was established for females and also for reproductive toxicity, as no treatment-related adverse effects were observed in females and in the reproductive parameters measured.

Mutagenicity/Genotoxicity
Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) was non-mutagenic in an *in vitro* mammalian chromosome aberration test and in *an in vitro* mammalian cell gene mutation test.

Health hazard classification
Based on the available information, Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) warrants hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Serious eye damage/eye irritation (Category 2A)	H319 – Causes serious eye irritation

As no data are available for the neat chemical, hazard classification for neat notified chemical is not possible.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the toxicological information provided, Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) is slightly irritating to skin and irritating (category 2A) to eyes.

Workers involved in professions where the services provided involve the application of cosmetic products containing the notified chemical to clients may be exposed to the notified chemical at ≤ 5.7% concentration. Such workers may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, the risk to such workers is expected to be of a similar or lesser extent than that experienced by consumers using the various products containing the notified chemical.

6.3.2. Public Health
Cosmetic products containing the notified chemicals at ≤ 5.7% concentration will be available to the public. The principal route of exposure will be dermal, while accidental ocular exposure is also possible.

Irritation
Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical) is slightly irritating to skin and irritating (category 2A) to eyes. The intended concentration in the finished product will be 3.0 to 5.7% of the notified chemical and in accordance with the GHS criteria, if a product contains ≥ 10% of a category 2A eye irritant, that product needs to be classified for Category 2A eye irritation with the hazard statement “Causes serious eye irritation”. The eye irritation risk associated with use of the notified chemical in cosmetic products may be further minimised by the inclusion of appropriate labelling and directions for use to warn against eye contact.

Repeated dose toxicity
The repeated dose toxicity potential was estimated by calculation of the margin of exposure (MoE) for the notified chemical using the worst case exposure scenario from use of a product of 1.463 mg/kg bw/day. Using a NOAEL of 1,000 mg/kg bw/day derived from a 55 day repeated dose oral toxicity study on Proteol OAT or Proteol OAT PF (containing approximately 30% of the notified chemical), the MoE was estimated to be 684. A MoE value ≥ 100 is generally considered to be acceptable for taking into account intra- and inter-species differences. Therefore, repeated exposure to the notified chemical at up to 5.7% is not considered to pose an unreasonable risk.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported as a component of a formulated cosmetic product. No reformulation will occur in Australia. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the product containing the notified chemical is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The notified chemical is expected to be released to the aquatic compartment through sewers during its use in rinse-off facial cleaners.

RELEASE OF CHEMICAL FROM DISPOSAL
It is estimated by the notifier that a maximum of 3% of the import volume of the notified chemical (or up to 30 kg), may remain in containers once the consumer products are used up. Wastes and residues of the notified chemical in empty containers are likely to either share the fate of the container and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate
Following its use in rinse-off facial cleaners in Australia, the majority of the notified chemical is expected to enter the sewer system, before potential release to surface waters nationwide. Based on the result of the biodegradability study, the notified chemical is considered readily biodegradable (95% in 28 days). For details of the environmental fate studies, refer to Appendix C. Based on its high water solubility and low adsorption coefficient (log K_{OC} < 1.25), release to surface waters may occur as limited partitioning to sludge and sediment is expected under environmental pH. The notified chemical is not expected to bioaccumulate due to its low partition coefficient (log P_{OW} = 0.51) and ready biodegradability. Therefore, in surface waters the notified chemical is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

The majority of the notified chemical will be released to sewer after use. A small proportion of the notified chemical may be applied to land when effluent is used for irrigation, or when sewage sludge is used for soil remediation. The notified chemical may also be applied to land when disposed of to landfill as collected spills and empty container residue. The notified chemical in landfill, soil and sludge are expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)
The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified chemical into sewer systems nationwide and with no removal within sewage treatment plants (STPs).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year

Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC - River:	0.61	µg/L
PEC - Ocean:	0.06	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.61 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20.19 µg/kg and 40.39 µg/kg, respectively.

7.2. Environmental Effects Assessment

The ecotoxicological investigations were conducted on PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical). The results based on the notified chemical at 100% are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h EC50 > 30 mg/L	Inconclusive
Daphnia Toxicity	48 h EC50 = 2.49 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	72 h E_rC50 > 30 mg/L	Inconclusive

Based on the above ecotoxicological endpoints for the PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical), it is expected to be toxic to aquatic invertebrates. As no specific endpoint was determined in the fish and algal study, the toxic effects of the notified chemical to fish and algae is inconclusive.

Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is formally classified as “Acute Category 2; Toxic to aquatic life”. Based on the acute toxicity, ready biodegradability and low bioaccumulation potential of the PROTEOL OAT or PROTEOL OAT PF (contains approximately 30% of the notified chemical, it is not formally classified under the GHS for chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for Daphnia. An assessment factor of 1000 was used given only the acute endpoint for Daphnia is used in the PNEC calculation. The endpoint for fish and algae was not taken into consideration as the toxicity was inconclusive.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Daphnia, 48 h)	2.49	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	2.49	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.61	2.49	0.243
Q - Ocean	0.06	2.49	0.024

The risk quotient for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical) is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified chemical is considered readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in rinse-off facial cleaners, PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical) is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -10 °C

Method	USP <651> method was used.
Remarks	Freezing point of PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical) was determined by placing it in a cool bath (-12ºC) until the notified substance was frozen or the temperature is reached approximately -10ºC.
Test Facility	Exempt Information (undated)

Boiling Point 108.6 ± 0.5 °C at 98.5 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Determined using the differential scanning calorimetry method.
Test Facility	Exempt Information (2009a)

Density 1,084 -1,086 kg/m^3 at 20 °C

Method	In-house method
Remarks	Determined using a density meter.
Test Facility	Exempt Information (2008a)

Vapour Pressure 2.111 kPa at 20 °C
2.751 kPa at 25 °C

Method	OECD TG 104 Vapour Pressure.
Remarks	Determined using the static method. PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical) showed abrupt disintegration and the liquid foamed out t=of the test vessel when the effusion method was used.
Test Facility	Exempt Information (2009b)

Water Solubility 278 g/L at 25 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method
Test Facility	Exempt Information (2011a)

Partition Coefficient (n-octanol/water) log P_{ow} = 0.51 at 20 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water).
Remarks	Flask Method
Test Facility	Exempt Information (2011b)

Adsorption/Desorption log K_{oc} < 1.25 at 20 °C

Method	OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge
Remarks	High Performance Liquid Chromatography (HPLC)
Test Facility	Exempt Information (2010a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical).
METHOD	OECD TG 401 Acute Oral Toxicity
Species/Strain	Rat/Sprague Dawley OFA
Vehicle	Distilled water
Remarks - Method	The test substance was administered at a constant volume of 5 mL/kg. GLP Certificate.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/5

LD50	> 2,000 mg/kg bw
Signs of Toxicity	One hour after the treatment slight piloerection was observed in all treated animals. No other clinical signs were observed during the course of the study.
Effects in Organs	No macroscopic findings were observed at necropsy.
Remarks - Results	The body weight of the animals was within the range commonly recorded for this strain and age.

CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Exempt Information (1998)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical).
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/Sprague Dawley (SPF Caw)
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No protocol deviations. GLP Certificate.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	0	0/10
2	5/sex	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	Well defined erythema was noted in all treated animals 24 h after treatment and this persisted up to day 4 in males and up to day 8 in females.
Signs of Toxicity - Systemic	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	The body weight of the animals was within the range commonly recorded for this strain and age.

CONCLUSION	The test substance is of low toxicity via the dermal route
TEST FACILITY	Exempt Information (2008b)

B.3. Irritation – skin

TEST SUBSTANCE	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical).
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 Males
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No protocol deviations. GLP Certificate.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2.0	1.0	2.0	2	72 h	0
Oedema	2.0	0.7	1.3	2	72 h	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	A day after the treatment 3 animals showed well defined erythema and persisted up to 72 h. This reaction was reversible on between day 3 and day 6. Well defined oedema was observed in all treated animals 24 hours after the treatment and persisted up to 72 hours. This reaction was reversible between day 2 and day 6. Two treated animals showed slight dryness on the treated cutaneous structure between at day 3 and between day 6 and day 8. The other treated animal showed dryness between at day 3, between day 6 and day 10 and day 13 and day 14. At 30% concentration, the notified chemical is slightly irritating to the skin and it is estimated that at a concentration of 100%, it is an irritant to the skin.
CONCLUSION	The test substance at 30% concentration is slightly irritating to the skin. At 100% concentration, the notified chemical is expected to be irritating to the skin.
TEST FACILITY	Exempt Information (2008c)

B.4. Irritation – eye

TEST SUBSTANCE	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical).
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3F
Observation Period	17 days
Remarks - Method	No significant protocol deviations GLP Certificate.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2.0	2.0	2.0	2.0	10 days	0
Conjunctiva: chemosis	2.0	2.0	2.0	2.0	8 days	0
Conjunctiva: discharge	1.3	2.0	1.3	3.0	3 days	0
Corneal opacity	2.0	2.0	2.0	2.0	16 days	0
Iridial inflammation	0.3	1.0	0.3	1.0	6 days	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results

Moderate chemosis of the conjunctiva was observed in all treated animals at the 1 hour observation and the symptoms persisted in two animals at the day 8 observation and in one animal at the day 7 observation.

Moderate redness of the conjunctiva was observed in all animals at the 1 hour observation and persisted in two animals at the day 8 observation and in one animal at the day 10 observation.

Slight cornea opacity was observed in all animals 24 hours after the treatment and the symptoms persisted up to 16 days for one animal, for 15 days for one animal and for 8 days for one animal.

Slight iridial inflammation was noted in all animals 1 hour after the treatment and the symptoms persisted for 6 days for one animal and for 24 hours for other two animals.

Moderate to severe ocular discharge was noted in all animals at the 1 hour observation and persisted in two animals at the day 3 observation and in one animal at the day 2 observation.

All signs of irritation were resolved at the day 17 observation.

There was no mortality or clinical signs of systemic toxicity.

At 30% concentration, the notified chemical is an irritant to the eye and it is expected that at 100% concentration, the notified chemical is estimated to be severely irritating to the eye.

CONCLUSION

The test substance at a concentration of 30% is irritating (category 2A) to the eye. At 100% concentration the notified chemical is expected to be severely irritating to the eye.

TEST FACILITY

Exempt Information (2008d)

B.5. Skin sensitisation

TEST SUBSTANCE

PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the test substance)

METHOD

OECD TG 406 Skin Sensitisation – Guinea Pig Magnusson and Kligman Maximisation Method

Species/Strain

Guinea pig/Dunkin-Hartley

PRELIMINARY STUDY	Maximum Non-irritating Concentration: 3.125 intradermal: 100%, diluted at 50%, 25%, 12.5%, 3.125%, 1.56% and 0.78%, 0.39%, 0.195% and 0.0975% in isotonic sodium chloride. topical: 100%, diluted at 50%, 25% and 12.5% in isotonic sodium chloride.
MAIN STUDY	
Number of Animals	Test Group: 5 F Control Group: 11 F
Vehicle	Distilled water
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde.
INDUCTION PHASE	Induction Concentration: intradermal: test substance diluted at 0.39% in isotonic sodium chloride. topical: test substance at 100% concentration.
Signs of Irritation	No cutaneous reaction was observed after the first induction phase. Dryness was observed in all animals (11/11), 24 hours after the removal of occlusive patch during the second induction.
CHALLENGE PHASE	
1st challenge	topical: 3.125% test substance in distilled water
2nd challenge	topical: 1.56% test substance in distilled water
Remarks - Method	No protocol deviations. GLP Certificate.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	3.125	0	0	0	0
	1.56	0	0	0	0
Control Group	3.125	0	0	0	0
	1.56	0	0	0	0

Remarks - Results	No mortality or abnormality for any body weight gain were noted.
CONCLUSION	There was no evidence of reactions to the test substance indicative of non-skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	Exempt Information (2008e)

B.6. Repeat dose toxicity

TEST SUBSTANCE	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the test substance)
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Wistar (Han™:HsdRccHan™:WIST)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 55 days (including a two week maturation phase, pairing, gestation and early lactation for females). Dose regimen: 7 days per week Post-exposure observation period: none
Vehicle	Arachis oil
Remarks - Method	No significant protocol deviations GLP Certificate.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*

Control	10/sex	0	0/20
low dose	10/sex	100	0/20
mid dose	10/sex	300	0/20
high dose	10/sex	1,000	0/20

Mortality and Time to Death
No unscheduled mortalities reported for adults.

Clinical Observations
Increased salivation immediately after dosing from day 11 was observed in males treated with the high dose. A male in the high dose group and two males from the mid dose group also showed noisy respiration on days 11 and 13 and days 6 and 35 respectively. The study author stated that these type observations were often reported following oral administration of an unpalatable or slightly irritant test substance.

Two females treated with the high dose and one female with the mid dose showed generalised fur loss. The study author asserted that these observations were consistent with low incidence findings for laboratory rats of the strain and age.

No abnormalities were noted for functional observations, body weight, food consumption and water consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment-related effects were noted in the haematological and blood chemical parameters measured.

Reproductive performance
There were no treatment-related effects on mating performance, fertility and gestation length.

Litter responses
In total nine females from the control groups and all ten females treated with 100, 300 and 1,000 mg/kg/day gave birth to a live litter and successfully reared young to day 5 of age.

There were no treatment-related effects on offspring litter size and viability and offspring growth and development based on all litters reared to termination on day 5 of lactation/age.

Effects in Organs
Necropsy findings: small right testis and hydronephrosis in right kidney were observed in mid dosed adult males. Mass in right epididymis was also observed in high dosed adult males. Neither the incidence, type of distribution of macroscopic findings observed at necropsy of decedent offspring nor offspring killed at scheduled termination (day 5 of age) indicated any adverse effect of maternal treatment.

Organ weight: treatment related but statistically not significant reduction in brain weight was noted in both sexes. Treatment related but statistically not significant reduction in kidneys, liver and spleen weight was observed in males and spleen weight in females. Higher adrenalin weights were noted in females treated with all dose levels and in males at mid and high doses.

One male treated with the mid dose showed moderate acanthosis, slight hyperkeratosis and slight subepithelial inflammatory cell infilterates. Moderate acanthosis, slight hyperkeratosis, moderate chronic inflammatory cell foci (statistically significant) in prostrate, minimal epithelial ulceration, erosion and moderate subepithelial inflammatory cell infiltrates were observed in one male treated with the high dose.

Marked periportal pigment deposits in liver, moderate extramedullary haemopoiesis in spleen in two females and moderate atrophy in thymus in one female were observed in a female treated with high dose.

Remarks – Results
Treatment related effects were observed in stomach only. The microscopic gastric changes would support the possibility of irritation but such irritation must have been slight since there were no visible signs of gastric irritancy in these animals at necropsy. The study authors asserted that although gastric changes observed in males treated with mid and high doses were considered to be adverse, a squamous-lined counterpart to the rodent forestomach is not present in human stomach. No such effects were noted in females in the high and mid

dose groups or in the animals of either sex in the low dose group.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1,000 mg/kg bw/day in this study, based on that adverse effects in the stomach at the high dose were not considered indicative of a hazard to human health. The No Observed Effect Level (NOEL) was established as 100 mg/kg bw/day for males due to effects noted in the mid and high dose groups. As no such effects were noted in females in any dose group, the NOEL was established as 1,000 mg/kg bw/day for females.

As no treatment-related effects were noted in the reproductive parameters measured, the NOEL for reproductive toxicity including fertility and mating in adults and for developmental toxicity in their subsequent progeny was established as 1,000 mg/kg bw/day.

TEST FACILITY Exempt Information (2009c)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the test substance)

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain	Human
Cell Type/Cell Line	Peripheral blood lymphocytes
Metabolic Activation System	S9 fraction prepared from Aroclor 1254-induced male Wistar rat
Vehicle	Sterile water
Remarks - Method	No protocol deviations. GLP Certificate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 0.079*, 0.157*, 0.313*, 0.625* and 1.25*	4 h	32 h
Test 2	0*, 0.079*, 0.157*,0.313* and 0.625*	continuous	36 h
Present			
Test 1	0*, 0.079*, 0.157*, 0.313*, 0.625* and 1.25*	4 h	32 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	≥ 1.6*			
Test 1		> 1.25	> 1.25	negative
Test 2		≥ 0.625	> 0.625	negative
Present	≥ 1.6*			
Test 2		> 1.25	> 1.25	negative

*Haemolysis was observed.

Remarks - Results

Hemolysis was observed in the preliminary studies with and without S9 at and above 1.6 µL/mL. In test 2 (without S9) of the main study, hemolysis was observed at 1.25 µL/mL.

In the main study with continuous exposure without S9, the percentage mitotic indices were found comparable with the solvent control, though a mild inhibition of MI was observed in concentrations 0.157 and 0.313 µg/mL and a (> 50%) mitotic inhibition in 0.625 µg/mL. This inhibition in MI was considered to be a dose response. The percentage frequency of structural aberrations in test concentrations exhibited a lack of significant induction in chromosomal aberrations without S9 and found to be comparable with the solvent control, though a mild insignificant induction

in aberration was observed in 0.625 µg/mL, which was towards the toxic concentration also indicated by a (> 50%) mitotic inhibition. Owing to the low mitotic index only 51 metaphases were analysed for aberrations in 0.625 µg/mL by blind scoring.

The test substance did not induce any statistically significant increases in the mutant frequency at any tested concentration in each exposure group with and without metabolic activation.

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION The test substance was not clastogenic to peripheral blood lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY Exempt Information (2009d)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical)

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.

Species/Strain	Mouse
Cell Type/Cell Line	Heterozygous mouse lymphoma cells
Metabolic Activation System	S9 fraction prepared from Aroclor 1254-induced male Wistar rat
Vehicle	Sterile water
Remarks - Method	No protocol deviations. GLP Certificate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 0.157*, 0.313*, 0.625*, 1.25* and 2.5*	3 h	48 h
Test 2	0*, 0.157*, 0.313*, 0.625*, 1.25* and 2.5*	3 h	48 h
Test 3	0*, 0.157*, 0.313*, 0.625*, 1.25* and 2.5*	24 h	48 h
Test 4	0*, 0.157*, 0.313*, 0.625*, 1.25* and 2.5*	24 h	48 h
Present			
Test 1	0*, 0.157*, 0.313*, 0.625*, 1.25* and 2.5*	3 h	48 h
Test 2	0*, 0.157*, 0.313*, 0.625*, 1.25* and 2.5*	3 h	48 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	≥ 0.313			
Test 1		> 2.5	> 2.5	negative
Test 2		> 2.5	> 2.5	negative
Test 3		> 2.5	> 2.5	negative
Test 4		> 2.5	> 2.5	negative
Present	≥ 0.0625			
Test 1		> 2.5	> 2.5	negative
Test 2		> 2.5	> 2.5	negative

Remarks - Results No precipitation was observed at any dose level either with or without metabolic activation.

The test substance did not induce any statistically significant increases in

	the mutant frequency at any tested concentration in each exposure group with and without metabolic activation. The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The test substance was not clastogenic to L5178 $TK^{+/-}$ cell line in mouse lymphoma assay treated in vitro under the conditions of the test.
TEST FACILITY	Exempt Information (2009e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

Test Substance	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical).
Method	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	None
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

Results

Test substance		*Toxicity control*		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
6	84-93	6	84	6	77-81
14	91-111	14	93	14	84-89
21	96-114	21	96	21	87-90
28	89-101	28	89	28	87-89

Remarks - Results	All validity criteria for the test were satisfied. Nitrification occurred in the test media containing the test material during the test period. Thus, the mean biodegradation of the test material was corrected for the oxygen consumption during nitrate and nitrite formation. The reference item (sodium benzoate) attained 87% biodegradation after 14 days and 88% biodegradation after 28 days thereby confirming the suitability of the inoculums and test conditions. The toxicity control attained 93% degradation after 14 days and 96% biodegradation after 28 days thereby confirming that the test material was not toxic to the sewage treatment micro-organisms used in the study. The test material attained 95% degradation after 28 days. Therefore, the test material is considered to be readily biodegradable according to the OECD (301 B) guideline.
Conclusion	The test substance is readily biodegradable.
Test Facility	Exempt Information (2009f)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

Test Substance	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical).
Method	OECD TG 203 Fish, Acute Toxicity Test – Semi static.
Species	*Oncorhynchus mykiss* (Rainbow trout)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon (TOC) analysis

Remarks – Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

Results

Concentration mg/L Nominal	*Number of Fish*	*Mortality*				
		3 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0	0
32	7	0	0	0	0	0
56	7	0	0	0	0	0
100	7	0	0	0	0	0

LC50	> 30 mg/L at 96 hours
NOEC	30 mg/L at 96 hours
Remarks – Results	The validity criteria for the test were not specified. The test solutions were renewed daily. As the toxicity cannot be attributed to a single component or a mixture of components but to the test material as a whole, the results were based on nominal concentrations. In the test report, the 96 h LC50 and NOEC for fish were determined to be > 100 mg/L and 100 mg/L, respectively, based on nominal concentrations. As the test substance contains 30% of the notified chemical, the 96 h LC50 and NOEC were recalculated to >30 mg/L and 30 mg/L respectively, to predict the toxic effects caused by the notified chemical.
Conclusion	As a specific toxicity endpoint was not determined in this study, the toxicity of this test substance to fish is inconclusive.
Test Facility	Exempt Information (2015a)

C.2.2. Acute toxicity to aquatic invertebrates

Test Substance	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical).
Method	OECD TG 202 Daphnia sp. Acute Immobilisation Test – Semi static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon (TOC) analysis
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

Results

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	20	0	0
1.8	20	0	0
3.2	20	0	15
5.6	20	35	70
18	20	40	65
56	20	45	85
100	20	25	90

LC50	2.49 mg/L (95% CI 4.1-16 mg/L) at 48 hours
NOEC	0.54 mg/L at 48 hours
Remarks - Results	The validity criteria for the test were not specified. The test media were freshly prepared at 0 and 24 hours prior to dosing. As the toxicity cannot

	be attributed to a single component or a mixture of components but to the test material as a whole, the results were based on nominal concentrations. In the test reports, the 48 h EC50 and NOEC for daphnids were determined to be 8.3 mg/L (95% CI 4.1-16 mg/L) and 1.8 mg/L, respectively, based on nominal concentrations. As the test substance contains 30% of the notified chemical, the 48 h EC50 and NOEC were recalculated to 2.49 mg/L and 0.54 mg/L respectively, to reflect the toxic effects caused by the notified chemical.
Conclusion	The test substance is considered to be toxic to aquatic invertebrates.
Test Facility	Exempt Information (2010b)

C.2.3. Algal growth inhibition test

Test Substance	PROTEOL OAT or PROTEOL OAT PF (containing approximately 30% of the notified chemical).
Method	OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test.
Species	*Desmodesmus subspicatus* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 0.1, 1.0, 10, and 100 mg/L Actual: Not reported
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Total organic carbon (TOC) analysis
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

Results

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 100	100	> 100	100

Remarks - Results	All validity criteria for the test were satisfied. Renewal of the test solutions was not specified. As the toxicity cannot be attributed to a single component or a mixture of components but to the test material as a whole, the results were based on nominal concentrations. In the test reports, the 72 h E_rC50 and NOEC for algae were determined to be > 100 mg/L and 100 mg/L, respectively, based on nominal concentrations. As the test substance contains 30% of the notified chemical, the 72 h E_rC50 and NOEC were recalculated to > 30 mg/L and 30 mg/L respectively, to predict the toxic effects caused by the notified chemical.
Conclusion	As a specific toxicity endpoint was not determined in this study, the toxicity of this test substance to algae is inconclusive.
Test Facility	Exempt Information (2010c)

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