File No: LTD/1806

July 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Protein hydrolyzates, wheat, [2-hydroxy-3-(trimethylammonio)propyl], chlorides (INCI Name: Hydroxypropyltrimonium Hydrolyzed Wheat Protein)

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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
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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/1806	BASF Australia Ltd	Protein hydrolyzates, wheat, [2-hydroxy-3-(trimethylammonio)propyl], chlorides (INCI Name: Hydroxypropyltrimonium Hydrolyzed Wheat Protein)	Yes	< 1 tonne per annum	A component of rinse-off cosmetic products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer 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*
Skin irritation (category 2)	H315 – Causes skin irritation
Serious eye damage/eye irritation (category 1)	H318 – Causes serious eye damage

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):
R38: Irritating to skin
R41: Risk of serious eye damage

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, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - H315 – Causes skin irritation

- H318 – Causes serious eye damage

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation processes:
  - Enclosed, automated processes, where possible

- 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 polymer during reformulation processes:
  - 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 polymer during reformulation processes:
  - Eye protection
  - Gloves
  - Coveralls

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

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

- If products and mixtures containing the notified polymer are classified 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 are not appropriate, dispose of the notified polymer 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 polymer 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 polymer 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 polymer;
- the notified polymer is intended to be used in products other than rinse-off cosmetic products;
- the concentration of the notified polymer exceeds or is intended to exceed 1% in rinse-off cosmetic products;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of rinse-off cosmetic products, or is likely to change significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer 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.

(Material) Safety Data Sheet
The (M)SDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1,000 Da (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume and identity of analogue

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China, New Zealand and Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Gluadin WQTM P (~ 30% notified polymer)
Hydroxypropyltrimonium Hydrolyzed Wheat Protein (INCI Name)

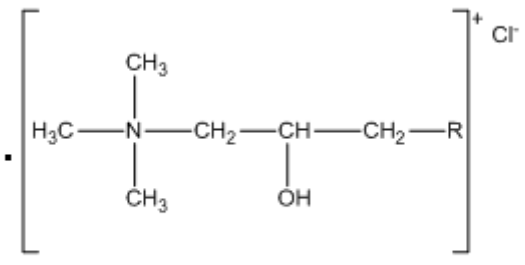
CHEMICAL NAME
Protein hydrolyzates, wheat, [2-hydroxy-3-(trimethylammonio)propyl], chlorides

OTHER NAME(S)
QAC (PROT-HYDROL wheat germ -2-hydroxypropylamin) triMe Cl
Wheat Germ Protein Hydrolyzates

CAS NUMBER
156798-11-7

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



Where R equals wheat protein hydrolysates ¶

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference GPC spectrum provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow liquid.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported in formulation
Boiling Point	156 °C at 101 kPa	Measured
Density	1,423 kg/m^3 at 20 °C	Measured
Vapour Pressure	≤ 9.4 × 10^{-3} kPa at 20 °C	Measured
Water Solubility	> 710 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Hydrolytically stable (< 10%)	Measured
Partition Coefficient (n-octanol/water)	log Pow = -2.202 at 23 °C	Measured
Adsorption/Desorption	Not Determined	The notified polymer is expected to have strong potential to adsorb to sediment soil due to the presence of cationic functional groups.
Dissociation Constant	Not Determined	Contains ionisable functionalities. Therefore, the notified polymer is expected to be ionised at the environmental pH range of 4 – 9.
Flash Point	Not determined	Not expected to have a flash point based on the lack of flammability.
Flammability	Non-flammable	Measured
Autoignition Temperature	> 400 °C	Measured
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties.

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

Reactivity
The notified polymer 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 notified polymer 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 polymer will not be manufactured in Australia. The notified polymer will be imported at ~ 30% 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
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in closed head 25 kg cans and will be transported by road from the wharf to the storage warehouse before dispatch. No repacking will occur in Australia.

USE
The notified polymer will be used as a conditioning agent in rinse-off cosmetic products (at concentrations < 1%) and will be available for both professional and public use.

OPERATION DESCRIPTION
The procedure for reformulation of the imported notified polymer (at ~ 30% concentration) will likely vary depending on the nature of the cosmetic products formulated and may involve both automated and manual transfer steps. However, in general, it is expected that the formulation process will involve blending operations that will be highly automated and occur in a fully enclosed environment, followed by automated filling of the formulated products into containers of various sizes.

The finished products containing the notified polymer (at < 1% concentration) may be used by consumers and professionals such as hairdressers and workers in beauty salons. Depending on the nature of the product, these could be applied in a number of ways, such as by hand or using 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)*
Manufacturing operators	1	20-50
Laboratory analyst	1	10
Hairdresser/ store persons	1-8	20-240

EXPOSURE DETAILS
Transport and Storage
Transport and storage workers are not expected to be exposed to the notified polymer (at ~ 30% concentration) except in the unlikely event of an accident.

Reformulation
During reformulation into cosmetic products, dermal and ocular exposure of workers (at ~ 30% concentration) may occur during the weighing and transfer stages, blending, quality control analysis and cleaning/maintenance operations. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment (PPE) such as overalls, safety glasses and impervious gloves, as anticipated by the notifier in the application dossier. Inhalation exposure is unlikely to occur as the notified polymer has a low vapour pressure ($\leq 9.4 \times 10^{-3}$ kPa at 20 °C) and will be in a liquid mixture.

End Use

Exposure to the notified polymer in end-use products (at < 1% concentration) may occur in professions where the services provided involve the application of rinse-off cosmetic products to clients (e.g. hair dressers). The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible. Such professionals may use some 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 polymer.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified polymer (< 1% concentration) through the use of rinse-off cosmetic products. The principal route of exposure would be dermal, while ocular and inhalation exposures are also possible.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. The results from toxicological investigations conducted on an analogue of the notified polymer (analogue 1) are summarised in the table below. Details of the studies of analogue 1 can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	irritating
Rabbit, eye irritation	severely irritating

Toxicokinetics, metabolism and distribution

No toxicokinetics, metabolism and distribution studies were submitted for the notified polymer. For dermal absorption, molecular weights below 100 Da are favourable for absorption and molecular weights above 500 Da do not favour absorption (ECHA, 2014). A substance is not likely to be sufficiently lipophilic to cross the stratum corneum if log P values are < -1; hence, dermal absorption is likely to be low (ECHA, 2014). Given the relatively high molecular weight of the notified polymer (NAMW > 500 Da) and the low partition coefficient (log Pow = -2.202 at 23 °C), dermal absorption is expected to be limited. However, the notified polymer contains a significant proportion of low molecular species < 500 Da which may be absorbed more readily.

Acute toxicity

Analogue 1 was found to have low acute oral toxicity in rats.

Irritation

Analogue 1 was found to be irritating to the skin of rabbits. Analogue 1 is considered to cause serious eye damage as effects persisted to the end of the 21 day study when tested on rabbits. Based on studies conducted on rabbits for analogue 1 the notified polymer is expected to be irritating to skin and cause serious eye damage.

Sensitisation

No skin sensitisation data were provided for the notified polymer. It was noted that the notified polymer contains a quaternary amine functional group which is a structural alert for sensitisation.

Health hazard classification

Based on the available information, the notified polymer 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***
Skin irritation (category 2)	H315 – Causes skin irritation
Serious eye damage/eye irritation (category 1)	H318 – Causes serious eye damage

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R38: Irritating to skin
R41: Risk of serious eye damage

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation
Exposure of workers to the notified polymer at ~ 30% concentration may occur during blending operations. The notified polymer is expected to be irritating to the skin and severely irritating to eyes and the repeated dose toxicity effects of the notified polymer and the potential to cause skin sensitisation have not been determined. Therefore, caution should be exercised when handling the notified polymer during reformulation processes.

Provided that control measures are in place to minimise worker exposure, including the use of automated processes and PPE, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

End-use
Beauty care professionals will handle cosmetic products containing the notified polymer at < 1% concentration. If PPE is used, the risk to these professionals who regularly use cosmetic products containing the notified polymer is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis. For details of the public health risk assessment see Section 6.3.2.

6.3.2. Public Health
The repeated dose toxicity of the notified polymer has not been determined. However, systemic exposure to the notified polymer is expected to be limited by its relatively high molecular weight (although it is noted that there is a large proportion of low molecular weight species < 500 Da), low partition coefficient and the rinse-off nature of the cosmetic products. In addition, skin and eye irritation and skin sensitisation effects from use of the notified polymer at the proposed concentrations < 1% in rinse-off cosmetic products are not expected.

Therefore, based on the information available, the risk to the public associated with the use of the notified polymer at < 1% concentration in rinse-off cosmetic products, is not considered to be unreasonable. In the absence of data on the repeated dose toxicity and skin sensitisation potential of the notified polymer, use of the notified polymer is supported only under limited exposure conditions, which are reflected in the low concentration of the notified chemical in end-use products and the rinse-off nature of the cosmetic products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer is not manufactured in Australia. Therefore, there will be no releases due to manufacturing activities. The notified polymer is expected to be imported into Australia as a component of a formulation for cosmetic products. The release of the notified polymer from local reformulation or repackaging is expected to be < 5% of the total annual import volume and is likely to be treated in an on-site treatment plant. The sludge and liquid effluent discharged from the on-site treatment plant is expected to be disposed of to landfill and trade waste, respectively.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be used as a component of cosmetic products, which will be directly applied to the consumer's hair and body. The cosmetic products will be rinsed off and enter the drainage/sewerage system, where it will be directed to various waste water treatment facilities.

RELEASE OF CHEMICAL FROM DISPOSAL
The containers holding the notified polymer are expected to be sent for recycling wherever possible once the container is no longer to be used. However, as end users are the general public, a proportion of containers are anticipated to be sent to landfill. It is expected that there may be residual notified polymer of up to 0.5% of the total annual volume remaining within the empty containers.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified polymer is expected to enter the sewer system through its use as a component of rinse-off cosmetic products, before potential release to surface waters nationwide. The acceptable analogues 1 and 2 for the notified polymer are not expected to be readily biodegradable, but show

inherent biodegradability (88-90% in 28 days). For details of the environmental fate studies, please refer to Appendix C. Leaching of the notified polymer in landfill is possible given it is soluble in water. However, this is expected to be slow considering the strong adsorption of the polymer to soil due to the presence of potential cationic groups. The notified polymer is not expected to bioaccumulate due to its low n-octanol/water partition coefficient (log P_{OW} = -2.202) and inherent biodegradability. Therefore, in surface waters the notified polymer is expected to disperse and degrade through abiotic and biotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

A worst case PEC for discharge of the notified polymer to surface waters has been calculated assuming that all of the imported quantity of the polymer is discharged to sewers nationwide and that no removal occurs in sewage treatment plants. The details of the calculation are as follows:

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	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:	0.061	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.606 µg/L may potentially result in a soil concentration of approximately 4.039 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer 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 results from ecotoxicological investigations conducted on an analogue 1 to the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96h LC50 = 5.6 mg/L	Toxic to fish
Inhibition of Bacterial Respiration	16h EC50 = 14 mg/L	Moderate chronic toxicity to bacteria

Based on the ecotoxicological endpoints for analogue 1, it is expected to be toxic to fish on an acute basis. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as “Acute Category 2; Toxic to aquatic life”. Based on the acute toxicity, inherent biodegradability and low bioaccumulation potential of the notified polymer, it is not expected to be harmful to aquatic life on a long term basis, and is therefore not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using the fish toxicity endpoint (96 hours, LC50 = 5.6 mg/L) of analogue 1 and a conservative assessment factor of 1000. The most conservative assessment factor of 1000 was used as the ecotoxicity endpoint for only one trophic level was available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish)	5.60	mg/L
Assessment Factor	1,000	
PNEC:	5.60	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated for a worst case discharge scenario based on the predicted PEC and PNEC.

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.61	5.6	0.108
Q - Ocean:	0.06	5.6	0.011

The risk quotient for discharge of treated effluents containing analogue 1 to the aquatic environment (Q < 1) indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters based on its maximum annual importation quantity. The notified polymer is not expected to be readily biodegradable or bioaccumulate in the environment. Therefore, the notified polymer is unlikely to result in ecotoxicologically significant concentrations in the aquatic environment on the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point 156 °C at 101 kPa

Method	EEC Council Regulation No 92/69 A.2 Boiling Temperature.
Remarks	Measured using differential scanning calorimetry and thermogravimetric analysis. The study authors note that there was a residue in the crucible following the measurements suggesting that the notified polymer was decomposing rather than boiling.
Test Facility	Henkel (2013a)

Density 1,423 ± 50 kg/m^3 at 20 °C

Method	EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	The pycnometer method was used.
Test Facility	Henkel (2013b)

Vapour Pressure ≤ 9.4 × 10^{-3} kPa at 20 °C

Method	EEC Council Regulation No 92/69 A.4 Vapour Pressure.
Remarks	It was determined by the differential scanning calorimetry.
Test Facility	Henkel (2013c)

Water Solubility > 710 g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method/Column Elution Method. More than 710 g/L of freeze dried notified polymer was dissolved in water under gel building. Due to the fact that the formation of the gel is a continuous process and no discrete point can be identified at which dissolution in water switches to gelling, the water solubility was approximated to > 710 g/L. The water solubility was determined at 20 °C and a pH = 5.0
Test Facility	Henkel (2013f)

Hydrolysis as a Function of pH

Method	OECD TG 111 Hydrolysis as a Function of pH.
Remarks	Following the preliminary test of OECD 111 (5 days incubation at 50 °C at pH values 4, 7 and 9), the notified polymer is considered to be hydrolytically stable (according to the criteria described in OECD 111 (less than 10% hydrolysis)).
Test Facility	Henkel (2014a)

Partition Coefficient (n-octanol/water) log Pow = -2.202 at 23 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water)
Remarks	Shake Flask Method. Preliminary tests showed that the test item is well soluble in water. Therefore, the shake-flask method was employed.
Test Facility	Henkel (2013g)

Flammability Non-flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks	There was no propagation of the flame along the test material.
Test Facility	Henkel (2013d)

Autoignition Temperature > 400 °C

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	The test material had no relative self-ignition temperature.
Test Facility	Henkel (2013e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue 1

METHOD: OECD TG 420 Acute Oral Toxicity - Fixed Dose Method.
EC Directive92/69/EEC B.1bis Acute Toxicity (Oral) Fixed Dose Method.

Species/Strain	Rat/SPF Wistar Shoe:WIST
Vehicle	Water
Remarks - Method	No significant protocol deviations. A sighting study was conducted with one female.

RESULTS

Sighting Study

Dose mg/kg bw	*Administered*	*Evident Toxicity*	*Mortality*
2,000	2,000 mg/kg bw	Slight	0/1

Signs of Toxicity	Piloerection and a pinched abdomen, with no changes in bodyweight gain.
Effects in Organs	There were no abnormalities.

Main Study

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

Discriminating Dose	> 2,000 mg/kg bw
Signs of Toxicity	Instances of piloerection, a pinched abdomen and decreased motor activity were observed up until day 3.
Effects in Organs	No abnormalities were noted at necropsy.

CONCLUSION: The test substance is of low toxicity via the oral route.

TEST FACILITY: Scantox (1997a)

B.2. Irritation – skin

TEST SUBSTANCE: Analogue 1

METHOD: OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/SPF Mol:Russian
Number of Animals	3 F
Vehicle	Test substance administered as supplied
Observation Period	21 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. The skin irritation scores were only presented for the observations at 1, 24, 48 and 72 hours after exposure.

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 (L)	2	1	2	2	< 7 days	0
Erythema/Eschar (R)	2	2	2	2	< 7 days	0
Oedema (L)	1	0.3	1.7	2	< 7 days	0
Oedema (R)	1	0.3	1.7	2	< 7 days	0

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

Remarks - Results

No skin irritation was present at the 1 hour observation. At the 24, 48 and 72 hour observations slight to well defined erythema was present in all animals. At the 24 hour observation very slight oedema was present in all animals. The oedema had resolved in one animal by the 48 hour observation and increased in another to slight with the last animal remaining unchanged, with no changes for observations at 72 hours after exposure. At the 7 day observation no erythema or oedema were reported by the study authors, although scaling was reported as being present in all animals. At the 14 day observation scaling completely covered the test areas of all rabbits but by the 21 day observation it had resolved in one animal and only residual amounts were present on the other two animals.

CONCLUSION

The test substance is irritating to the skin.

TEST FACILITY

Scantox (1997b)

B.3. Irritation – eye

TEST SUBSTANCE

Analogue 1

METHOD

OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain: Rabbit/SPF Mol:Russian

Number of Animals: 2 M, 1 F

Observation Period: 21 days

Remarks - Method: No significant protocol deviations. The eye irritation scores were only presented for the observations at 1, 24, 48 and 72 hours after exposure.

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	1	1	2	< 21 days	0
Conjunctiva: chemosis	3	1.7	2.3	3	> 21 days	1
Conjunctiva: discharge	3	2.7	2.7	3	< 21 days	0
Corneal opacity	2	2	1.3	2	< 21 days	0
Iridial inflammation	1	1	1	1	< 21 days	0

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

Remarks - Results

At the one hour observation scattered to diffuse corneal opacity was seen in two animals along with congestion in the iris. Conjunctival irritation was present in all three animals. At the 24 hour observation translucent areas of cornea were observed after treatment with Fluorescein in all three animals. The corneal opacity remained at the same level in two animals but declined in one animal to scattered or diffuse in one animal at the 48 hour observation and remained unchanged at the 72 hour observation. Corneal opacity was only observed in two animals at the 7 day observation decreasing to just one animal at the 14 day observation and was absent in all animals at the 21 day observation. Congestion of the iris was present all animals from the 24 to 72 hour observations but was not mentioned thereafter. Significant swelling and discharge with conjunctival redness were seen in all animals at the 24 hour observation through to the 72 hour observation, before decreasing in severity but still being present at the 7 day observation. At the 14 day observation swelling and redness was present in only one animal with slight swelling persisting at the 21 day observation.

CONCLUSION

The test substance is severely irritating to the eye.

TEST FACILITY Scantox (1995)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Analogue 2

METHOD
- Inoculum: Activated Sludge
- Exposure Period: 28 Days
- Auxiliary Solvent: None reported
- Analytical Monitoring: Dissolved organic carbon (DOC)
- Remarks - Method: The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	92
14	2	14	100
21	0	21	97
28	9	28	97

Remarks - Results: All validity criteria were met. The biodegradation of the notified polymer was determined as 9% after 28 days of incubation. The test item did not reach the pass level of 70% for ready biodegradability in the DOC Die-Away Test either within the 10-day window or after 28 days of incubation.

CONCLUSION: The test substance is not readily biodegradable.

TEST FACILITY: Henkel (1993)

C.1.2. Inherent biodegradability

TEST SUBSTANCE: Analogue 1

METHOD
- Inoculum: Activated Sludge
- Exposure Period: 28 Days
- Auxiliary Solvent: None reported
- Analytical Monitoring: Dissolved organic carbon (DOC)
- Remarks – Method: The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported. Diethylene glycol was tested in parallel to the test substance as a reference substance to control the proper test procedure.

RESULTS

Test substance		*Diethylene glycol*	
Day	*% Degradation*	*Day*	*% Degradation*
7	79	7	91
14	84	14	99
21	78	21	99
28	88	28	100

Remarks – Results: The degradation/elimination rates of 88–90% DOC decrease after 28 days indicate easy elimination of the test sample under wastewater treatment

plant conditions. The test is considered valid if the DOC decrease achieved by the reference substance after 28 days is greater than 70%.

CONCLUSION The test substance is inherently biodegradable.

TEST FACILITY Henkel (1994)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Analogue 1

METHOD Annex to Commission Directive 92/69/EEC of July 31, 1992- Semi static
Species Zebrafish *(Brachydanio rerio)*
Exposure Period 96 hours
Auxiliary Solvent None Reported
Water Hardness None Reported
Remarks – Method The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality (%)*				
Nominal		*4-6h*	*24 h*	*48 h*	*72 h*	*96 h*
0	10	0	0	0	0	0
1.25	10	0	0	0	0	0
2.50	10	0	0	0	0	0
5.00	10	0	30	40	40	40
10.00	10	60	100	100	100	100

LC50 5.6 mg/L at 96 hours.

Remarks – Results All validity criteria were within acceptable limits.

CONCLUSION The test substance is toxic to fish.

TEST FACILITY Henkel (1995a)

C.2.2. Inhibition of microbial activity

TEST SUBSTANCE Analogue 1

METHOD Cell multiplication inhibition lest according to DIN 38412, Part B
Species Pseudomonas putida MIGULA strain
Exposure Period 16±1 hours
Concentration Range Nominal: 3, 10, 30, and 100 mg/L
Remarks – Method The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed. Pseudomonas putida is used as a model organism that is representative of bacteria from activated sludge and surface waters. The test is used to determine the bacteriotoxic effects of a substance that might affect biodegradation in wastewater treatment plants. For this purpose, the test bacteria were cultivated in a defined nutrient solution at various test substance concentrations over several generations under aerobic conditions and a possible inhibitory effect on cell multiplication was established. The chronic effect of the test material on bacteria within 16 ± 1 h is determined.

RESULTS
EC50 14 mg/L

Remarks – Results	The results are specified as EC0 (highest lest concentration with cell multiplication inhibition of < 10%). EC10 and EC50 (test concentration with an inhibition of cell multiplication inhibition of 10% or 50%).
CONCLUSION	The test substance has moderate chronic toxicity to the test organism.
TEST FACILITY	Henkel (1995b)

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