File No: LTD/1824

November 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-(2-hydroxytetradecyl)-ω-hydroxy-, ω-C_{16-18}-alkyl ethers (INCI name: Ceteareth-60 Myristyl Glycol)

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
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/1824	Akzo Nobel Pty Ltd	Poly(oxy-1,2-ethanediyl), α-(2-hydroxytetradecyl)-ω-hydroxy-, ω-C_{16-18}-alkyl ethers (INCI name: Ceteareth-60 Myristyl Glycol)	Yes	≤ 10 tonne/s per annum	Cosmetic ingredient

*ND = not determined

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 table below.

Hazard classification	*Hazard statement*
Eye irritation (Category 2)	H319 – Causes serious eye irritation

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:

R36: Irritating to eyes

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
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 reported 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:
  - Eye Irritation (Category 2): H319 – Causes serious eye irritation

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:
  - Enclosed, automated processes, where possible
  - Exhaust ventilation

- 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:
  - Avoid contact with skin and eyes
  - Avoid generating dust

- 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:
  - Safety glasses, coveralls, impervious gloves
  - Respirator (where ventilation is inadequate)

  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 polymer has a number-average molecular weight of less than 1,000;
- the concentration of the notified polymer exceeds or is intended to exceed 5% concentration in cosmetic products;
- information becomes available on the repeated dose toxicity potential of the notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a cosmetic ingredient or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, 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 the notified polymer (and products containing the notified polymer) provided by the notifier was (were) 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)
Akzo Nobel Pty Ltd (ABN: 59 000 119 424)
8 Kellaway Place
WETHERILL PARK NSW 2164

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

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 and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physicochemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

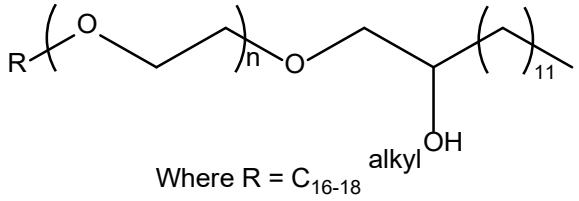
MARKETING NAME(S)
Elfacos GT 282
Ceteareth-60 Myristyl Glycol (INCI name)

CAS NUMBER
243133-67-7
(Alternate trade name CAS number: 96081-39-9; note, this CAS number will not be added to the AICS)

CHEMICAL NAME
Poly(oxy-1,2-ethanediyl), α-(2-hydroxytetradecyl)-ω-hydroxy-, ω-C16-18-alkyl ethers

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



Where R = C_{16-18}

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white to off-white solid pellets.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	48 °C	(M)SDS
Density	1,070 kg/m^3 at 25 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low, based on the molecular weight.
Water Solubility	Soluble in cold water	(M)SDS (up to 20%).
Hydrolysis as a Function of pH	Stable at pH 2–12	Technical specification sheet (Akzo Nobel, 2008).
Partition Coefficient (n-octanol/water)	Not determined.	The notified polymer is an emulsifier and will tend to accumulate at the phase interface of octanol and water and/or form emulsions.
Adsorption/Desorption	Not determined.	The notified polymer is expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined.	No dissociable functionality.
Particle Size	Not determined.	Supplied as pellets.
Flash Point	~ 168 °C (closed cup)	(M)SDS
Autoignition Temperature	Not determined.	Not expected to autoignite under normal conditions of use.
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.

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

Physical hazard classification
Based on the limited 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 chemical will not be manufactured within Australia. The notified polymer will be imported into Australia either in neat form or already blended in finished cosmetic products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 10	≤ 10	≤ 10	≤ 10	≤ 10

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER
Akzo Nobel Pty Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as pellets in 20 kg plastic bags in cardboard cartons and packed into pallets for distribution to the reformulation sites. In cases where finished products containing the notified polymer are introduced (container sizes up to 500 mL), the products will be packed in dozens inside a shipper with multiple shippers per pallet and multiple pallets per container.

USE

The notified polymer will be used as an ingredient in rinse-off and leave-on cosmetic products at concentrations of ≤ 5%.

OPERATION DESCRIPTION

Reformulation

The notified polymer may also be imported for reformulation in Australia. At the reformulation sites, the notified polymer will be blended into end-use cosmetic products. The procedures will vary depending on the nature of the cosmetic product being formulated and are expected to involve both manual and automated steps.

At the reformulation sites, production compounders will weigh an appropriate amount of the raw material into a separate container and then add the amount directly into a flame proof mixing tank with other ingredients. Mixing and dispensing will be carried out in a closed system with flame proof mixers and pumps designed not to create aerosols or a dust hazard and earthed for static discharges. Quantities of the cosmetic products containing the notified chemical will be sampled and tested by a chemist for quality control purposes. The formulated products will then be transferred to containers of various sizes. They will then be distributed for retail sale.

End-use

Finished cosmetic products containing the notified polymer (at proposed concentrations of ≤ 5%) may be used by consumers or by professionals, such as workers in beauty salons. Depending on the nature of the product, the application could be by hand, sprayed or using an applicator.

Where the notified polymer will be imported in finished cosmetic products, the products will be stored at the notifier's warehouse in Melbourne or Sydney, before being distributed to warehouses and shops for retail sale to consumers.

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	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing and capping)	8	12
Store persons	4	12
End users	8	365

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come in contact with the notified polymer either in neat form or in end-use cosmetic products, only in the event of accidental rupture of containers.

Reformulation

During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified polymer (at 100% or ≤ 5% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Inhalation exposure to the notified polymer in powder form may

occur if dust is generated. Mixing and dispensing is expected to carried out in a closed system with flame proof mixers and pumps designed not to create aerosols or a dust hazard and earthed with static discharges. Exposure is expected to be minimised through the use of adequate ventilation, exhausted hoods, and through the use of personal protective equipment (PPE) such as safety glasses with side shields, goggles, face shields, appropriate respirators (in case of inadequate ventilation), gloves, apron or coverall (also full face protection if potential exists for direct exposure to aerosols or splashes).

End use
Exposure to the notified polymer in end-use products (at ≤ 5% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons). Application of products could be by hand, sprayed or through the use of an applicator. 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

Public exposure to the notified polymer is expected to be widespread and frequent through daily use of cosmetic products containing the notified polymer at ≤ 5% concentration. The principal routes of exposure will be dermal, while ocular and inhalation exposures (e.g. through the use of spray products) are also possible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer 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 > 5,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Guinea pig, skin irritation (repeated application)	non-irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – non-adjuvant test (Buehler).	no evidence of sensitisation (100%)
Guinea pig, skin sensitisation – Magnusson and Kligman.	no evidence of sensitisation (50%)
Human, skin sensitisation – RIPT (50 and 100%)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Photosensitisation	photosensitisation (≥ 25% concentration)

The notified polymer is a dialkyl polyethylene glycol (PEG) ether consisting of hydrophobic cetyl/stearyl (ceteareth) and myristyl alcohols substituted at the ends of a hydrophilic PEG group. The notified polymer is structurally related to other polyethylene glycols substituted with long chain aliphatic alcohols. Therefore, in addition to studies conducted on the notified polymer, information on other polyethylene glycol compounds (for example, from the safety assessments of cetearyl alcohol PEG ethers (CIR, 1999), and alkyl PEG ethers (CIR, 2012)) is briefly discussed below and is considered to support the health hazard conclusions for the notified polymer. The available data are for PEG ethers substituted with one aliphatic alkyl chain.

Toxicokinetics, metabolism and distribution
No information on the toxicokinetics of the notified polymer was provided.

No percutaneous absorption data is available for the notified polymer. The notified polymer has a molecular weight > 1,000 Da, which suggests a limited dermal absorption potential. The absorption potential is dependent on the length of the alkyl chain and the number of ethoxylate units (of the PEG), where increasing chain length and/or number of units leads to a decrease in dermal absorption (CIR, 2012). Some PEG derivatives have the potential to enhance the dermal penetration of other chemicals after topical application (CIR, 2012). Dermal penetration of the notified polymer is expected to be enhanced where skin is severely damaged (similar to other PEG derivatives) (CIR, 2012).

Acute toxicity
The notified polymer was found to have low acute toxicity by the oral route in a study conducted in rats.

No acute dermal toxicity data was provided for the notified polymer. Acute dermal toxicity studies performed with alkyl PEG ethers were of low toxicity (no systemic effects or mortalities reported) via this route (CIR 1999, 2012).

No acute inhalation toxicity data was provided for the notified polymer. The CIR safety assessment report indicated that some alkyl PEG ethers (or their fatty alcohol precursors) used in products that may be inhaled (e.g. aerosols) may irritate the respiratory tract (CIR, 2012). However, the report also stated that in the absence of inhalation toxicity data, alkyl PEG ethers can be used safely in aerosol products, because the aerosol particle size consists of a low fraction of respirable particles (CIR, 2012).

Irritation
In an acute dermal irritation study, conducted similarly to OECD TG 404, the notified polymer was applied undiluted to two patches on the back of 6 New Zealand albino rabbits. One patch was unabraded and the second patch was abraded. One animal showed very slight (barely perceptible) erythema 24 and 48 hours after patch removal at the intact site, and at the 24 hour observation only at the abraded site. No oedema was noted. The effects noted in this study were insufficient to warrant classification of the notified chemical as a skin irritant. In a 28-day repeated application test the notified polymer was non-irritating to the skin of guinea pigs at concentrations up to 10%.

In a human cumulative (21 day) skin irritation study completed on 23 subjects, the notified polymer (at 50% and 100% concentration) was determined by the study authors to have the potential to cause mild dermal irritation during normal use.

In a rabbit eye irritation study with undiluted notified polymer, all animals (6/6) presented with more diffuse and easily discernible conjunctival redness at the 1 hour observations, with this severity of irritation being observed at the subsequent 24 (5/6) hour observation. Two animals continued to show abnormal conjunctival vessels at the 48 hour observation. Three animals showed chemosis effects; 2/3 with obvious swelling and partial lid eversion, and 1/3 with above normal swelling at the 1 hour observation only. Moistened discharge with the test article remaining in conjunctivae was noted in all animals' lids and hairs at the 1 hour observation. This effect had reduced in severity by the 24 hour observation and had alleviated prior to 48 hours. Two animals presented with above normal iris folding, evident at the 1 hour observation only. The cornea of one of these animals and another animal were noted to lack the normal lustre also at the 1 hour observation.

The range and severity of effects noted in this study warranted classification of the notified polymer as an eye irritant.

Sensitisation
A Buehler guinea pig maximisation test was conducted with the notified polymer to determine its skin sensitisation potential. Under the conditions of the study, the notified polymer (at 50% induction and challenge concentrations) was found to be a non-sensitiser, with no responses noted in any animals at both the 24 and 48 hour observations after challenge patch removal. In a test conducted similarly to OECD TG 406, the notified polymer was not a skin sensitiser. There was evidence of reactions indicative of photo-sensitisation to the notified polymer at concentrations ≥ 25%, under the conditions of the test.

Repeated dose toxicity
No data was provided on the repeated dose toxicity of the notified polymer.

Repeated dose toxicity studies performed with alkyl PEG ethers generally indicated the absence of toxicologically adverse effects at doses ≤ 100 mg/kg bw/day (CIR 2006, 2012). However, the notified polymer is likely to have some differences in physiological action due to the differences in structure (dialkyl PEG ether compared with alkyl PEG ethers, alkyl chain length, number of ethoxylate units) and dermal penetration potential. There were also a wide range of NOAELs reported for the chemicals in this category. Therefore, there is some uncertainty in the evidence supporting the low toxicity of the notified polymer from repeated exposure.

Mutagenicity/Genotoxicity
The notified polymer was non-mutagenic in an in vitro bacterial reverse mutation study. No further in vitro or in vivo genotoxicity data were provided for the notified polymer.

Reproductive and developmental toxicity

No data was provided on the reproductive and/or developmental toxicity of the notified polymer.

It is generally recognised that the PEG monomer, ethylene glycol, and certain of its monoalkyl ethers, are reproductive and developmental toxins (CIR, 2012). There is a possibility that PEG-derived cosmetic ingredients could present similar concerns (CIR, 1999). However, in general, the metabolites of concern are not expected to be formed in cosmetic formulations that contain polymers of ethylene glycol (CIR, 2012). From the data discussed, the safety assessment report also concluded that the toxicity of the monoalkyl ethers is inversely proportional to the length of the alkyl chain (CIR, 1996). Therefore, long alkyl chains, such as those in ceteareth compounds, similar to the notified polymer, were found by the CIR Expert Panel to not be a reproductive or developmental hazard (CIR, 1999).

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***
Eye irritation (Category 2)	H319 – Causes serious eye irritation

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):
R36: Irritating to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation
During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified polymer (≤ 100%) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Based on information available, the notified polymer is considered to be an eye irritant and slightly irritating to the skin. It is uncertain whether the notified polymer, like some alkyl PEG ethers, may irritate the respiratory tract following inhalation exposure. Therefore, caution should be exercised when handling the notified polymer during reformulation and quality control processes.

The use of enclosed, automated processes and PPE (e.g. impervious gloves, coveralls, eye protection and respiratory protection) should minimise the potential for exposure. Therefore, provided that adequate control measures are in place to minimise worker exposure, the risk to workers from use of the notified polymer is not considered to be unreasonable.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products containing the notified polymer to clients (e.g., hairdressers and beauty salon workers) may be exposed to the notified polymer (at ≤ 5% concentration). The risk to these workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer. Such professionals may use PPE (i.e., gloves and glasses) to minimise repeated exposure, and good general hygiene measures are expected to be in place to minimise the potential for exposure. Based on the information available, the risk to workers associated with use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Members of the public will experience widespread and frequent exposure to the notified polymer through daily use of cosmetic products at ≤ 5% concentration.

Eye and skin irritation effects are not expected from use of the notified polymer at the proposed concentration.

Inhalation exposure may occur from use of the notified polymer at ≤ 5% in spray products, including aerosols. However, due to the nature of the final products, airborne particle size distributions and concentrations in the breathing zone, incidental inhalation is not expected to lead to local respiratory effects or systemic effects.

The repeated dose toxicity effects of the notified polymer have not been determined. However, exposure is expected to be limited by the dermal absorption. In addition, limited data on alkyl PEG ethers generally indicate low repeated dose toxicity. Therefore, based on the information available, the risk to the public associated with the use of the notified polymer at ≤ 5% in cosmetic products, is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be manufactured overseas and imported, and will be reformulated in finished cosmetic hair and skin products at a concentration of ≤ 5%. Release of the notified polymer to the environment is unlikely except in the event of a transport accident or an accidental spill during handling. Accidental spills of formulated products containing the notified polymer are expected to be physically contained and then absorbed into inert material (e.g. sand or vermiculite). The absorbed polymer will be collected into sealed containers and finally disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

As the notified polymer is used in cosmetics and personal care products such as shampoos, facial and body cleansers, skin creams etc., it is expected that the entire annual import volume will be released to sewer through consumer use. A small proportion (estimated to be ≤ 2%) may remain as residues within the end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

Expired wastes and residue of the notified polymer in the empty containers (1%) is likely either to share the fate of the container and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate

No environmental fate data were supplied. The majority of the notified polymer is expected to be released to the sewerage system. In waste water treatment processes in sewage treatment plants (STPs), a high proportion (≥ 90%) of the notified chemical is expected to be removed from influent based on several fate studies of alcohol ethoxylates in STPs (Madsen et al., 2001). The high removal efficiency is due a combination of inherent biodegradation and partitioning of the notified polymer to sludge and suspended solids. The notified polymer that partitions to sludge will be removed for disposal to landfill or used on land for soil remediation. In soil, the notified polymer is expected to be degraded by abiotic and biotic processes to form water and oxides of carbon.

In surface waters, the notified polymer will partition to suspended solids and organic matter and is expected to biodegrade. Based on its surface activity, the notified polymer is not expected to bioaccumulate.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated assuming a worst case scenario of 100% release of the notified polymer into sewer systems nationwide and a 90% removal from STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	Mitigation
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

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 54.521 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1,500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.363 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 1.815 mg/kg and 3.63 mg/kg, respectively.

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 polymer 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 0.606µg/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 the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Acute		
Fish (Rainbow trout)	96 h LC_{50} = 2.2 mg/L	Toxic to fish
Fish (Zebra fish)	96 h LC_{50} = 1.77 mg/L	Harmful to aquatic invertebrates

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is toxic to fish and is formally classified as 'Acute Category 2: Toxic to aquatic life. The notified polymer is inherently biodegradable and based on its high molecular weight, it is not expected to bioaccumulate. Therefore, the notified polymer has not been formally classified for its long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the acute fish toxicity of the notified polymer and an assessment factor of 1,000 as measured acute endpoints are available for only one trophic level.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC_{50} (Fish).	1.77	mg/L
Assessment Factor	1,000	
PNEC:	1.77	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.61	1.77	0.34
Q - Ocean:	0.06	1.77	0.034

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity. The notified polymer is inherently biodegradable and is unlikely to persist in surface waters, soil or air. Therefore, on the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in cosmetic and domestic products, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility Completely soluble in cold water

Method	In-house method followed.
Remarks	-
Test Facility	Akzo Nobel (2015)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	Corn oil
Remarks - Method	GLP Compliance. No significant protocol deviations.

RESULTS

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

LD50	> 5,000 mg/kg bw
Signs of Toxicity	There were no treatment related signs of systemic toxicity noted in any of the animals over the study period.
Effects in Organs	No macroscopic abnormalities were observed at necropsy.
Remarks - Results	All animals survived until the scheduled termination and showed gains in bodyweight over the study period.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	MB RESEARCH LABS (1996a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer (at 50% w/v in vehicle)
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 F
Vehicle	Corn oil (mixed into an aqueous slurry)
Observation Period	7 days
Type of Dressing	Semi-occlusive (Coverlett® gauze patch)
Remarks - Method	GLP Compliance. The study was conducted using 2 separate back application sites (abraded and intact) for comparison. The dressing was held in place by wrapping the animals' trunk to a rubber sleeve. No indication was given if the applied aqueous slurry (containing the notified polymer) was washed from the animal after removal of the dressing.

RESULTS

Remarks - Results	One animal showed very slight (barely perceptible) erythema 24 and 48 hours after patch removal at the intact site, and at the 24 hour observation only at the abraded site. No oedema or other clinical signs were noted during the study.
CONCLUSION	The notified polymer is slightly irritating to the skin, under the conditions of the test.
TEST FACILITY	Unilever Research U.S (1996)

B.3. Irritation – skin

TEST SUBSTANCE	Notified polymer.
METHOD	28 day repeated topical application test.
Species/Strain	Guinea Pig/albino Pirbright (DHPK (SPF-LAC.)/Boe.)
Number of Animals	10 F
Vehicle	Deionised water.
Observation Period	28 days
Type of Dressing	None specified.
Remarks - Method	GLP Compliance. The test substance was tested at 0.4, 2 and 10% w/v as 0.03 mL applications. A negative control (water treated) site was used for each animal. The study was conducted using randomly-selected virgin 20 mm^2 application sites (shaved and intact) for comparison.
RESULTS	
Remarks – Results	No local skin irritation or signs of systemic toxicity were noted during the study.
CONCLUSION	The notified polymer was non-irritating to the skin of guinea pigs, under the conditions of the test.
TEST FACILITY	IBR (1986a)

B.4. Irritation - skin (human volunteers)

TEST SUBSTANCE	Notified polymer (50% w/v in vehicle and undiluted).
METHOD	21 day repeated topical application test
Study Design	Procedure: Patches containing 0.2 mL test substance mixed with the vehicle were applied on consecutive days for a total of 21 applications. Patches were removed by the applicants after 24 hours and graded after an additional 24 hours. Effects were scored using the BASE N-10 Irritation Scores (scores 0–630 with classes 1–5).
Study Group	21 F, 9 M; age 18+ years
Vehicle	Slurry (stated as made from generic baby oil (Drug Guild lot #539965))
Remarks - Method	Occluded. The test substance was spread on a 3.63 cm^2 patch, and allowed to evaporate for 30–90 minutes prior to patch application. Prior to the application of the patch, the test area was wiped with 70% isopropyl alcohol and allowed to dry. Parallel studies using the same cohort were run using the vehicle control (baby oil slurry), 0.1% SLS solution (positive control) and saline (negative control). While the gender breakdown of the participating subjects was specified, the individual sexes of the subject numbers were not disclosed. 23/30 subjects completed the 21 application days of the study, however 5/30 subjects received 5–18 applications. Two subjects never started the study. The 7/30 subjects who did not complete the study, were reported to have discontinued for reasons unrelated to the test material (reason given: unable to adhere to study schedule).

There were a few deviations from the study protocol. One deviation that may have impacted on results included on the first day of application, patches were only affixed for approximately 20–22 hours (instead of the prescribed 24 hours).
The scores for subjects 1-11 for the test substance at 100% were missing.

RESULTS

Participating Subject	*Mean Irritation Scores**		*Maximum value*		*Maximum Value at End of Observation Period*	
	Test substance (100%)	*Test substance with vehicle (50% w/v)*	*Test substance (100%)*	*Test substance with vehicle (50% w/v)*	*Test substance (100%)*	*Test substance with vehicle (50% w/v)*
1		0.3		1		1
2		0.2		1		0
3		0.1		1		0
4		0		0		0
5		0		0		0
6		0.1		1		0
7		0.3		2		1
8		0.1		1		-
9		0.1		1		0
10		0.1		1		0
11		0.3		1		0
12	0	0	0	0	-	-
13	0.6	0.2	1	1	-	-
14	0.5	0.1	1	1	0	0
15	0.6	0.4	1	1	-	-
16	1.4	0.9	2	1	2	1
17	1	0.7	2	1	0	0
18	0.2	0	1	0	1	0
19	1.4	0.6	2	1	1	0
20	1.1	0.4	2	1	2	1
21	0.8	0	2	0	1	0
22	0.7	0.5	1	1	1	0
23	1	0.5	1	1	1	0
24	0	0.5	0	1	0	0
25	1.2	0.1	2	1	2	0
26	0.2	0	1	0	0	0
27	1.3	0	2	0	2	0
28	0.2	0.1	1	1	-	-

- indicating the subjects that did not complete the study till the last reading.

Remarks - Results

Minimal to definite erythema was noted in subjects (/28) spanning the study period. Subjects presented with slight (/28) or marked glazing of the skin (/28), or glazed skin with peeling and cracking (/28). The base-10 cumulative score of 177.0 was reported based on the 23 subjects that completed the study, indicating mild cumulative irritation.The study authors concluded that the controls produced satisfactory responses, thus confirming the sensitivity of the study design.

CONCLUSION

The test substance was considered by the study authors to have slight potential for very mild cumulative skin irritation under the conditions of the test.

TEST FACILITY

HTR, INC. (1996)

B.5. Irritation – eye

TEST SUBSTANCE

Notified polymer

METHOD
Similar to OECD TG 405 Acute Ocular Irritation/Corrosion.
Used criteria EC Council Directive 1993 67/548 for results appraisal.

Species/Strain: Rabbit/New Zealand White
Number of Animals: 5 M & 1 F
Observation Period: 72 hours
Remarks - Method: No significant protocol deviations.
GLP Compliance.
Test substance (68 mg) administered in aqueous slurry with distilled water (as 0.1 mL dose).

RESULTS

Lesion	*Mean Score**						*Max. Value***	*Max. Duration of Any Effect** (hours)*	*Max. Value at End of Observation Period**
	1	2	3	4	5	6			
Conjunctiva: redness	1	0	0.7	1	0.7	0.7	2	< 72	0
Conjunctiva: chemosis	0	0	0	0	0	0	2	< 48	0
Conjunctiva: discharge	0.3	0	0.3	0.3	0.3	0.3	2	< 48	0
Corneal opacity	0	0	0	0	0	0	0***	< 24	0
Iridial inflammation	0	0	0	0	0	0	1	< 24	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animals.
** Max. = Maximum
*** 2 animals showing lack of normal corneal lustre at 1 hour observation only.

Remarks - Results
All animals (6/6) presented with more diffuse and easily discernible conjunctival redness at the 1 hour observations, with this severity of irritation being observed at the subsequent 24 (5/6) hour observation. Two animals continued to show abnormal conjunctival vessels at the 48 hour observation. Three animals showed chemosis effects (2/3 with obvious swelling with partial lid eversion and 1/3 with above normal swelling) at the 1 hour observation only. Moistened discharge with test article remaining in conjunctivae was noted in all animals' lids and hairs at the 1 hour observation. This effect had reduced in severity by the 24 hour observation and had alleviated prior to 48 hours.

Two animals presented with above normal iris folding, evident at the 1 hour observation only. The cornea of one of these animals and another animal were noted to lack the normal lustre also at the 1 hour observation.

All effects had resolved by the 72 hour observations.

Based on the effects seen, the study authors deemed the test substance to be an eye irritant.

CONCLUSION
The notified polymer is irritating to the eye.

TEST FACILITY
MB RESEARCH LABS (1996b)

B.6. Skin sensitisation

TEST SUBSTANCE
Notified polymer

METHOD
Similar to OECD TG 406 Skin Sensitisation – Buehler test.

Species/Strain: Guinea pig/Hartley albino

MAIN STUDY

Number of Animals: Test Group: 20 F Control Group: 10 F

INDUCTION PHASE	Induction Concentration: topical: 50%
Signs of Irritation	No responses were noted in any animal throughout the three weeks of administration.
CHALLENGE PHASE	topical: 50%
Remarks - Method	The test substance was prepared in distilled water (0.4 g) and applied to Webril padding of a Ready Band patch. No preliminary test was conducted. Induction and challenge phases were tested at the same concentration. No positive control test was run in parallel to the main test, and no historical data relating to a known skin sensitiser chemical was referred to in the study report. The induction phase consisted of 3, once a week 6 hour applications (averaging 5–7 days elapsing between each induction application). The challenge phase consisted of a once-off 6 hour application. 24 hours after challenge application, the animals were depilated with a cosmetic depilator (Nair® Hair Remover Lotion) and graded approximately 4 hours later.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group			
challenge	50%	0/20	0/20
Control Group			
previously unexposed	50%	0/10	0/10

Remarks - Results	No responses were noted in any animal during challenge.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	Unilever Research U.S (1996)

B.7. Skin sensitisation

TEST SUBSTANCE	Notified polymer
METHOD	Followed the Magnusson and Kligman Method (1969) Similar to OECD TG 406 Skin Sensitisation.
Species/Strain	Guinea pig/ Pirbright (DHPK (SPF-LAC.)/Boe.)
PRELIMINARY STUDY	
Number of Animals	Test Group: 5 F
Concentration	intradermal: 1, 2.5, 5 and 10%. topical: 25 and 50%.
Signs of Irritation	Observations were made at 24, 48 and 72 hours, post application. Animals treated at 5 and 10% showed slight to moderate erythema at the 24 (10/10), 48 (6/10) and 72 (2/10) hour observations. Slight erythema was seen in the 2.5% animals at the 24 (3/5) and 48 (1/5) hour observations. No irritation seen with 1% intradermal or the dermal applications.
MAIN STUDY	
Number of Animals	Test Group: 25 F Control Group: 25 F
INDUCTION PHASE	Induction Concentration: intradermal: 2.5% topical: 50%

CHALLENGE PHASE	topical: 50%
Remarks - Method	The test substance as supplied in waxy pellet form and was diluted with 80% ethanol. For the first dermal treatment, the application site was pre-treated with 10% SLS in white Vaseline. Dermal applications were cover under an occlusive patch. No bandage was applied to intradermal treatment sites. The induction phase consisted of 10 (five days per week), 30 minute applications. The challenge phase was performed 2 weeks after the 10th induction application. FCA (undiluted) as a positive control test was run in parallel to the main test, however the results were not presented in the final study report.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group			
challenge	50%	0/25	0/25
Control Group			
previously unexposed	50%	0/25	0/25

Remarks - Results	No responses were noted in any animal during the induction or challenge phases. All animals showed weight gains during the study period.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	IBR (1986b)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	Ames et. al Protocol (1975) Similar to OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA1538, TA98, TA100
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 1–10,000 µg/plate b) Without metabolic activation: 1–10,000 µg/plate
Vehicle	DMSO
Remarks - Method	GLP Compliance. A preliminary toxicity test was conducted at 39–10,000 µg/plate using the tester strain TA100. Vehicle and positive controls were used in parallel with the test material. Positive controls: i) without S9: Sodium-azide (used as the positive control for the tester strains: TA100, TA1535), 9-aminoacridine (TA1537) and 2-nitrofluorene (TA98, TA1538); ii) with S9: 2-aminoanthracene (TA100, TA1535, TA1538, TA98) and 9-aminoanthracene (TA1537).

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 10,000	> 10,000	> 10,000	negative
Test 2	> 10,000	> 10,000	> 10,000	negative
Present				
Test 1	> 10,000	> 10,000	> 10,000	negative
Test 2	> 10,000	> 10,000	> 10,000	negative

Remarks - Results

The test material did not cause a visible reduction in the growth of the bacterial background lawn and/or a substantial reduction in the frequency of revertant colonies at ≤10,000 μg/plate both in the presence and absence of metabolic activation

No significant increases in the frequency of revertant colonies were recorded for any of the strains of bacteria, at any dose level either with or without metabolic activation.

The controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

IBR (1982)

B.9. Skin photosensitisation

TEST SUBSTANCE

Notified polymer

METHOD

Similar to OECD TG 406 Skin Sensitisation – Buehler test.

Species/Strain

Guinea pig/ Pirbright (DHPK (SPF-LAC.)/Boe.)

PRELIMINARY STUDY

Number of Animals

Test Group: 8 F (2 per concentration)

Concentration

topical: 25, 50, 75 and 100%.

Signs of Irritation

The two animals treated at 100% showed slight patchy erythema and slight, but confluent to moderate patchy erythema at 48 hours after patch removal. No irritation seen with 25, 50 and 75%.

MAIN STUDY

Number of Animals

Test Group: 10 F Control Groups: each 5 F

INDUCTION PHASE

Induction Concentration:

topical: 75%

Signs of Irritation

No responses were noted in any animal throughout the three weeks of administration.

CHALLENGE PHASE

topical: 1, 5, 25 and 75%

Remarks - Method

The test substance as supplied in waxy pellet form and was diluted with 80% ethanol. Control samples were diluted with acetone. A 2 hour irradiation (12 J/cm^2) was used in the Induction (UVA and UVB) and Challenge (UVA only) phases, respectively.

The induction phase consisted of 10 (five days per week), 30 minute applications. The challenge phase was performed 2 weeks after the 10th induction application.

Positive control tests were run in parallel to the main test using TBS (tribromosalicylanilide) and TCC (trichlorobanilide). Occlusive patch

conditions were only used for the preliminary study in order to exclude primary irritation.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after Challenge Phase:*					
		- UV			*+ UV*		
		24 hours	*48 hours*	*72 hours*	*24 hours*	*48 hours*	*72 hours*
Test Group	1%	0/10	0/10	0/10	0/10	0/10	0/10
	5%	0/10	0/10	0/10	0/10	0/10	0/10
	25%	2/10	3/10	3/10	4/10	4/10	5/10
	75%	5/10	5/10	4/10	10/10	10/10	10/10
Control Groups							
TBS	1%	0/5	0/5	0/5	3/5	2/5	2/5
TCC	1%	2/5	2/5	0/5	5/5	5/5	5/5

Remarks - Results

No responses were noted in any animal during the induction phase.

Slight, but confluent or moderate, but patchy erythema was noted in both irradiated and non-irradiated groups of animals treated with 25 and 75% test substance. No effects were noted in any animals treated at 1 and 5% test substance. All animals showed weight gains during the study period.

The positive controls produced satisfactory responses (moderate erythema seen in various animals at all 3 observations), thus confirming the sensitivity of the test system.

CONCLUSION

There was evidence of reactions indicative of photo-sensitisation to the notified polymer at ≥ 25% concentration, under the conditions of the test.

TEST FACILITY

IBR (1986c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 302 B Inherent Biodegradability: Zahn-Wallens Test.
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved Organic Carbon (DOC)
Remarks - Method	No significant protocol deviations. GLP Compliance. Two blank controls with inoculums (without test substance) were run in parallel to determine the amount of CO_2 derived from the inoculums.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
14	72		
21	85		
24	87		
28	94		> 70

Remarks - Results	The results of the degradation test are valid, because the required conditions were met: more than 70% of the reference substance were degraded within the 28 day test period. The degree of degradation of the notified polymer after the cultivation period was 94%, warranting classification in reference to the guidelines.
CONCLUSION	The notified polymer is inherently biodegradable.
TEST FACILITY	Akzo Nobel (1989)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static Test.
Species	Rainbow trout *(Oncorhynchus mykiss)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Not conducted.
Remarks – Method	No significant protocol deviations. GLP Compliance.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*			
Nominal		*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

1.0	7	0	0	0	0
1.8	7	0	1	1	1
3.2	7	0	5	5	7

LC_{50}	2.2 mg/L at 96 hours.
NOEC (or LOEC)	1.0 mg/L at 96 hours.
Remarks – Results	The results are based on nominal concentrations.

CONCLUSION The notified polymer is toxic to fish

TEST FACILITY Safepharm (2001)

C.2.2. Acute toxicity to fish

TEST SUBSTANCE Notified polymer.

METHOD OECD TG 203 Fish, Acute Toxicity Test – Semi static Test.

Species	Zebra fish *(Brachydanio rerio)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported.
Analytical Monitoring	Not conducted.
Remarks – Method	No significant protocol deviations. GLP Compliance.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*		
Nominal		*48 hours*	*72 hours*	*96 hours*
control	7	0	0	0
0.63	7	0	0	0
1.25	7	0	0	0
2.5	7	7	7	7
5	7	7	7	7
10	7	7	7	7

LC_{50}	1.77 mg/L at 96 hours.
NOEC (or LOEC)	1.25 mg/L at 96 hours.
Remarks – Results	The results are based on nominal concentrations.

CONCLUSION The notified polymer is toxic to fish.

TEST FACILITY Akzo Nobel (1992)

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