File No: LTD/1909

September 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

1,2,3-Propanetriol, homopolymer, decanoate (INCI Name: Polyglyceryl-6 Dicaprate)

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

TABLE OF CONTENTS

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/1909	L'Oreal Australia Pty Ltd	1,2,3-Propanetriol, homopolymer, decanoate (INCI Name: Polygyceryl-6 Dicaprate)	ND*	≤ 1 tonne per annum	Cosmetic ingredient

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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 polymer during reformulation:
  - Avoid contact with 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:
  - Goggles or face shield

  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 chemical;
- ecotoxicity data for the notified polymer becomes available
- further information becomes available on repeated dose toxicity of the notified polymer

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from 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 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
L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road
MELBOURNE VIC 3004

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: other names, structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, site of manufacture and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polyglyceryl-6 Dicaprate (INCI name)

CAS NUMBER
74504-65-7

CHEMICAL NAME
1,2,3-Propanetriol, homopolymer, decanoate

MOLECULAR FORMULA
$C_{10}H_{20}O_2$. $x(C_3H_8O_3)_x$

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference GC and IR spectra were provided. The notified polymer contains species with different degrees of esterification.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White to pale yellow paste/oil/solid with characteristic odour

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer is liquid at ambient temperature
Boiling Point	Not determined	-

Density	Not determined	-
Vapour Pressure	Not determined	Based on the molecular weight of the notified polymer (> 500), the vapour pressure is expected to be low.
Water Solubility	Not determined	Expected to be poorly dispersible based on the molecular structure
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surface activity
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on surface activity
Dissociation Constant	Not determined	Not expected to dissociate under normal environmental conditions
Flash Point	270 °C	(M)SDS
Flammability	Not determined	-
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 oxidising properties

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. It will be imported into Australia as a raw material or as a component of a blend or as a component of end-use cosmetic products.

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

TRANSPORTATION AND PACKAGING
The notified polymer will be imported into Australia by sea as raw material in 16 kg tin canisters or as a component of end-use cosmetic products in containers of various make and sizes. It will be transported by road from the dock to distribution and retail sites.

USE
The notified polymer will be used in leave-on and rinse-off cosmetic products at concentrations ≤ 10%. The notified polymer will not be used in aerosols.

OPERATION DESCRIPTION
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. Repackaging of the products will not occur.

The notified polymer may also be imported as raw material for reformulation into end-use products in Australia. At the reformulation sites, production compounders will weigh an appropriate amount of the raw material into a

separate container, and then add it directly into a flame proof mixing tank with other ingredients. Mixing and dispensing is expected to be carried out in a closed system. Quantities of the cosmetic products containing the notified polymer will be sampled and tested by a chemist for quality control purposes. They will then be distributed for retail sale.

Products containing the notified polymer (up to 10%) may also be used in professions where the services involve the application of cosmetic products to clients (e.g. hairdressing or beauty salons).

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 and retail workers may come into contact with the notified polymer at ≤ 100% concentration when handling the imported material or end-use cosmetic products, in the event of a spill or rupture of container. The primary work activity undertaken by the workers will be loading and off-loading of containers. Incidental exposure to the notified polymer may occur via skin or eye during the clean-up of accidental spills.

Reformulation
If imported as a raw material, the notified polymer will be blended into end-use cosmetic products. During reformulation, dermal and ocular exposure of workers may occur during weighing and transfer stages, blending, quality control analysis, packaging and cleaning and maintenance of equipment. The notifier has stated that blending is expected to be carried out in closed systems with flame proof mixers and pumps, designed not to create aerosols or a dust hazard and earthed for static discharge. Dermal and accidental ocular exposure may also occur during the manual transfer steps. Inhalation exposure is not expected due to the high molecular weight and low vapour pressure of the notified polymer and the use of enclosed systems and control measures such as local exhaust ventilation.

End-use by professionals
Beauty care professionals may come into contact with the notified polymer while applying cosmetic products containing the notified polymer. The principal route of exposure will be dermal.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified polymer at up to 10% concentration through the use of cosmetic products. The principal route of exposure would be dermal, while incidental oral, ocular and inhalation exposures are also possible from facial use of the cosmetic products.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on a structural analogue with a C8 carbon chain rather than C10 are summarised in the following table. For full details of the studies, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rabbit, skin irritation	non-irritating

Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution
No study data on toxicokinetics, metabolism and distribution of the notified polymer was provided. The notified polymer is a homopolymer of glycerol esterified with the fatty acid decanoic acid and is expected to be metabolised in a manner similar to other polyglyceryl fatty acid esters. Various studies show that 95-98% of polyglyceryl fatty acid esters containing fatty acids of various chain lengths and homopolymer of glycerol containing 2-20 glycerol units are digested and utilized in the body when ingested via the oral route (CIR 2016). The ester bond in the notified polymer is expected to be acted upon by lipases, releasing the free fatty acid(s) and polyglycerol. Free fatty acids generated are expected to undergo normal degradation whereas polyglycerol has been found not be acted upon by enzymes (CIR 2016). Polyglycerols consisting of up to 3 glycerol monomers are readily absorbed and excreted via the kidneys whereas polyglycerols with more than 4 glycerol monomers (such as the notified polymer) are not absorbed and are excreted via faeces (EFSA 2013). The notified polymer is of relatively low molecular weight (most species 500 - 1000 Da) and is surface active, hence dermal absorption may occur. If the notified polymer penetrates the skin, it is expected to be hydrolysed into polyglycerol and decanoic acid in a manner similar to glyceryl arachidonate which also belong to the class polyglyceryl fatty acid esters (Eppler *et al.*, 2007).

Acute toxicity
No data on acute toxicity potential of the notified polymer was provided. Based on various acute oral toxicity studies conducted on this class of polymers (polyglyceryl fatty acid esters, CIR 2016) the notified polymer is expected to be of low toxicity via the oral and dermal routes.

Irritation and sensitisation
No studies on the notified polymer were provided. Based on a dermal study in rabbits conducted on the analogue, the notified polymer is expected to be non-irritating via the dermal route. The analogue was tested at 20% in an ocular irritation study in one rabbit only, where it was slightly irritating to the eyes. Based on this limited information, the notified polymer is expected to have some eye irritation potential.

Based on a Maximisation skin sensitisation study conducted on the analogue, the notified polymer is expected to be non-sensitising. This is further supported by reported studies conducted on other polyglyceryl fatty acid esters which found the polymers to be non-sensitising (CIR 2016).

Repeated dose toxicity
No information on repeated dose toxicity of the notified polymer or a close analogue was available. Dietary studies conducted on various polyglyceryl fatty acid esters did not produce any adverse effects (CIR 2016). Information on repeated dose dermal toxicity is not available.

Mutagenicity/Genotoxicity
No mutagenicity/genotoxicity studies on the notified polymer were provided. The notified polymer is not expected to be mutagenic based on limited evidence on the analogue (bacterial reverse mutation study in two strains).

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Limited toxicity information is available on the notified polymer. It is likely to have some eye irritation potential.

Reformulation workers including transport and storage, compounders and chemists may have dermal contact with the notified polymer at up to 100% concentration, and perhaps accidental ocular exposure. At these concentrations there is the potential for irritation effects. Therefore, caution should be exercised when handling the notified polymer during reformulation processes.

Based on the available information, the risk to the health of workers during the handling of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The public is likely to have repeated exposure to the notified polymer through use of cosmetic products containing it at ≤ 10% concentration. At the proposed use concentration, any irritation effects will be greatly reduced. As no information on repeated dose toxicity on the notified polymer or a close analogue was available, a margin of exposure has not been determined. Further information on the repeated dose toxicity of the notified polymer would allow a detailed assessment supporting the proposed end-use concentration.

Based on available information, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a raw material for reformulation into finished cosmetic products, or as a component of finished cosmetic products. 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 polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer from this process to the environment is not expected. The process will be followed by automated filling of the formulated products into containers of various sizes suitable for retail sale. Wastes containing the notified polymer generated during reformulation include equipment wash water, empty import containers, and spilt materials. It is estimated by the notifier that a maximum of 1% (or up to 10 kg) of the notified polymer may be released from reformulation processes. Wastes may be collected and released to sewers in a worst case scenario, or disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The notified polymer is expected to be released to the aquatic compartment through sewers during its use in various cosmetic products.

RELEASE OF CHEMICAL FROM DISPOSAL

It is estimated by the notifier that a maximum of 3% (or up to 30 kg) of the notified polymer may remain in end-use containers once the consumer products are used up. Wastes and residue of the notified polymer in empty containers are likely to share the fate of the container and be disposed of to landfill. Wastes and residue containing the notified polymer may also be released to sewer when containers are rinsed before recycling through an approved waste management facility.

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 in cosmetic products, before potential release to surface waters nationwide. Based on the results of a ready biodegradability study, the notified polymer is considered readily biodegradable (84% in 28 days). For details of the environmental fate study, please refer to Appendix B. Based on its surfactant properties, significant release to surface waters is unlikely to occur, as partitioning to sludge and sediment is expected under environmental pH. The notified polymer is not expected to bioaccumulate due to its surfactant properties and ready biodegradability. Therefore, the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

The majority of the notified polymer will be released to sewer after use. A small proportion of the notified polymer may be applied to land when effluent is used for irrigation, or when sewage sludge is used for soil remediation. A minor amount of the notified polymer may also be disposed of to landfill as collected spills and

empty container residue. The notified polymer in landfill, soil and sludge are expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

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 polymer into sewer systems nationwide, and no removal within sewage treatment plants (STPs).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import 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:	0.606	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 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 the 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 results from an ecotoxicological investigation conducted on the inhibition to microbial respiration of the notified polymer are summarised in the table below. Details of this study can be found in Appendix B. As no other ecotoxicity data were submitted for the notified polymer, ecotoxicity endpoints for related non-ionic surfactants of the alcohol ethoxylate (AE) group and alcohol alkoxylate (AA) group are also summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity		
AE C_{13} EO7[1]	96 h LC50 = 4.5 mg/L	Toxic to fish
Daphnia Toxicity		
AE C_{13} EO7-8 (46% branching) [2]	48 h EC50 = 5 mg/L	Toxic to aquatic invertebrates
Algal Toxicity		
AE C_{13} EO7-8 (46% branching) [2]	72 h EC50 = 5 mg/L	Toxic to algae
AA $C_{10\text{-}13}$ EO6, PO3[3]	72 h EC50 = 1-10 mg/L	
Inhibition of Bacterial Respiration	3 h IC50 > 1,000 mg/L	Not inhibitory to microbial respiration

[1] Dorn *et al*., 1993
[2] Kaluza and Taeger, 1996
[3] Bertleff *et al*., 1997

Based on the above ecotoxicological endpoints for the analogue substances, the notified polymer is expected to be toxic to aquatic life. However, there is insufficient data on the physico-chemical properties of the notified polymer to determine the extent of the analogy between the notified polymer and the related substances. Therefore, the applicability of these results to the notified polymer needs to be treated with caution, and should be considered to be a conservative worst-case estimation for the notified polymer. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009), the notified polymer is not formally classified for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive endpoint for fish. A conservative safety factor of 500 was used, given acute endpoints for three trophic levels are available for related substances.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae, 72 h)	1	mg/L
Assessment Factor	500	
Mitigation Factor	1.00	
PNEC:	2	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	0.606	2	**0.303**
Q – Ocean	0.061	2	**0.030**

The risk quotient for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified polymer is considered to be readily biodegradable, and is not expected to be bioaccumulative based on its surfactant properties. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in cosmetic products, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Irritation – skin

TEST SUBSTANCE	Analogue
METHOD	Method similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	1
Vehicle	1,3-butylene glycol
Observation Period	72 h
Type of Dressing	Occlusive
Remarks - Method	The test was conducted using one test animal. The analogue was tested at 100% and 10% concentration in vehicle. 0.5mL of test substance was applied and was held in place for 24 hr. The test substance was applied on intact skin and abraded skin.
RESULTS	
Remarks - Results	No skin response such as erythema and oedema were observed both in the intact and abraded sites at 24, 48 and 72 h reading after application at sites exposed to 105 and 100% test substance.
CONCLUSION	The test substance is non-irritating to the skin.
TEST FACILITY	Confidential

A.2. Irritation – eye

TEST SUBSTANCE	Analogue 20% solution
METHOD	Method similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White (Yac:NZW(KBL))
Number of Animals	1
Observation Period	96 h
Remarks - Method	The test was conducted using 1 test animal. The analogue chemical was tested at 20% concentration in 1,3-butylene glycol (vehicle). 0.1 mL of test substance was administered to the conjunctival sac.
RESULTS	
Remarks - Results	Mild conjunctival redness, chemosis and discharge on a scale of 1 was noted 1 hour after treatment. No
CONCLUSION	The test substance is slightly irritating to the eye.
TEST FACILITY	Confidential

A.3. Skin sensitisation

TEST SUBSTANCE	Analogue
METHOD	Method similar to OECD TG 406 Skin Sensitisation – Magnusson and Kligman method.
Species/Strain	Guinea pig/Std:Hartley
PRELIMINARY STUDY	Not conducted
MAIN STUDY	
Number of Animals	Test Group: 3 Control Group: 0
Vehicle	Propylene glycol
Positive control	Not conducted in parallel with the test substance. Details of when the

	positive control test was conducted not provided in the study report.
INDUCTION PHASE	Induction Concentration: intradermal: 20% topical: 20%
Signs of Irritation	None
CHALLENGE PHASE	
Challenge	topical: 20%
Remarks - Method	Only 3 animals were used for the test. Freund's Complete Adjuvant was used. A 10% solution of sodium dodecyl sulfate was applied to the skin during the induction phase.

RESULTS

Remarks - Results	No skin reaction was observed in any test animals during the induction phase and 24 h and 48 h after challenge.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	Confidential

A.4. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue
METHOD	Method similar to OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA98 and TA100
Metabolic Activation System	S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 5-5,000 µg/plate b) Without metabolic activation: 5-5,000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	Only one test was conducted.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity	*Precipitation*	*Genotoxic Effect*
Absent	≥ 2,000	> 5,000	Negative
Present	≥ 2,000	> 5,000	Negative

Remarks - Results	Cytotoxicity was observed in bacterial strain TA100 only. The positive controls gave satisfactory results confirming the validity of the strain and S9 mix.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Confidential

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
- Inoculum: Activated sludge
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring: Theoretical Carbon Dioxide ($ThCO_2$)
- Remarks - Method: The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Test substance		*<Reference Substance>*	
Day	*% Degradation*	*Day*	*% Degradation*
7	47	7	73
14	68	14	84
21	78	21	88
28	84	28	89

Remarks - Results: All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 5 days (65%) and reached 89% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. An independent study of the inhibition to bacterial respiration showed the 3 h IC50 > 1,000 mg/L, indicating that toxicity was not a factor inhibiting the biodegradability of the test substance.
The test substance attained 84% degradation by 28 days. As the test substance is surface active, the 10-day window is not applicable. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 B) guideline.

CONCLUSION: The notified polymer is readily biodegradable.

TEST FACILITY: Confidential

B.2. Ecotoxicological Investigations

B.2.1. Inhibition of microbial activity

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
- Inoculum: Activated sludge
- Exposure Period: 3 hours
- Concentration Range: Nominal: 10-1,000 mg/L; Actual: Not determined
- Remarks – Method: The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. 3,5-Dichlorophenol was used as the reference control. The respiration rate was determined by measurement of Biological Oxygen Demand during the test after 3 hours of exposure.

RESULTS

IC50	> 1,000 mg/L at 3 hours
NOEC	1,000 mg/L at 3 hours
Remarks – Results	All validity criteria for the test were satisfied. The 3 h IC50 was determined to be > 1,000 mg/L, based on nominal concentrations.

CONCLUSION The notified polymer is not inhibitory to microbial activity.

TEST FACILITY Confidential

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