File No: LTD/1989

February 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Decanedioic acid, polymer with 1,2,3-propanetriol, octanoate (INCI name: Capryloyl Glycerin/Sebacic Acid Copolymer)

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

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1989	A.S. Harrison & Co Pty Ltd	Decanedioic acid, polymer with 1,2,3-propanetriol, octanoate (INCI name: Capryloyl Glycerin/Sebacic Acid Copolymer)	ND*	≤ 90 tonnes per annum	Emollient in cosmetic and personal care products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited available information, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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 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 unfinished blended bulk raw material containing the notified polymer at ≤ 56% concentration:
  - 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 unfinished blended bulk raw material containing the notified polymer at ≤ 56% concentration:
  - Coveralls, goggles, impervious gloves

  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 g/mol;
  - the polymer is intended to exceed 10% concentration in cosmetic and personal care products; or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from an emollient in cosmetic and personal care products, 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.

Safety Data Sheet
The 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

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

APPLICANT(S)
A.S. Harrison & Co Pty Ltd (ABN: 89 000 030 437)
75 Old Pittwater Road
Brookvale NSW 2100

NOTIFICATION CATEGORY
Limited (Reduced fee notification): Synthetic polymer with Mn ≥ 1,000 Da – Polymer has been assessed by a competent authority under a comparable category.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: structural formula, molecular weight and polymer constituents

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Adsorption/desorption.

NOTIFICATION IN OTHER COUNTRIES
Canada (2012)

2. IDENTITY OF CHEMICAL

2.1. Identity of the Notified Polymer

MARKETING NAME(S)
LexFeel N5, N20, N50, N100, N200, N350 (products containing the notified polymer), Lex Film GSC (100% notified polymer)

CAS NUMBER
1190099-88-7

CHEMICAL NAME
Decanedioic acid, polymer with 1,2,3-propanetriol, octanoate

OTHER NAME(S)
Capryloyl Glycerin/Sebacic Acid Copolymer (INCI name)

MOLECULAR FORMULA
$(C_{10}H_{18}O_4.C_3H_8O_3)_x.xC_8H_{16}O_2$

ANALYTICAL DATA
Reference GPC spectra were provided.

2.2. Identity of Analogues

One analogue was provided for the notified polymer.

CAS NUMBER
68130-55-2

CHEMICAL NAME
Hexanedioic acid, mixed esters with decanoic acid, heptanoic acid, octanoic acid and pentaerythritol

OTHER NAME(S)
Pentaerythrityl adipate/caprate/caprylate/heptanoate (INCI name)

MOLECULAR WEIGHT
> 500 Da

3. COMPOSITION

DEGREE OF PURITY
100%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Viscous liquid

Property	Value	Data Source/Justification*
Melting Point/Freezing Point	< 25 °C	Measured
Boiling Point	323 °C at 101.3 kPa	Measured
Density	1,040 kg/m^3 at 20 °C	Measured
Reid Vapour Pressure	0.002 kPa at 30 °C	Measured
Water Solubility	< 0.001 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	t½ > 1 year at 25 °C (pH 4.0, 7.0, and 9.0)	Measured
Partition Coefficient (n-octanol/water)	log Pow = 5.1	Measured
Adsorption/Desorption	log Koc = 4.24	Measured
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	231 °C	Measured
Flammability	Non flammable	Measured
Autoignition Temperature	-	Measured
Explosive Properties	Non explosive	Measured
Oxidising Properties	Non oxidising	Measured

* Shriram (2012)

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. It will be imported as a blended bulk raw material containing the notified polymer at ≤ 56% concentration or as a component of finished cosmetic and personal care products containing the notified polymer at ≤ 10% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	40-50	50-60	60-70	70-80	80-90

PORT OF ENTRY
Various ports

IDENTITY OF MANUFACTURER/RECIPIENTS
A.S. Harrison & Co Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported by ship as a blended bulk raw material containing the notified polymer at ≤ 56% concentration, contained in 7 gallon HDPE closed head pails and/or 55 gallon stainless steel drums with tamper-evident closures. The notified polymer will be transported by road from port to the notifier's warehousing facilities in Melbourne and/or Sydney for storage and later distributed to manufacturers/reformulators. Once formulated into cosmetic and personal care products containing the notified polymer at ≤ 10% concentration and packaged into consumer packaging (e.g. plastic tubes, jars, bottles, and sticks), these products will be packed into shippers and transported by road to various warehousing facilities or directly to retail outlets around Australia.

The notified polymer will also be imported by ship as a component of finished cosmetic and personal care products containing the notified polymer at ≤ 10% concentration, contained in consumer packaging packed in bulk cartons. The notified polymer will be transported by road from port to the distributor's site for storage and later distributed by road to various warehousing facilities or directly to retail outlets around Australia.

USE
The notified polymer will be used as an emollient in cosmetic and personal care leave-on and rinse-off products - shampoo, conditioner, hair styling products, body wash, face cream, general purpose cream, body cream/lotion and secondary/cosmetic sunscreens, at ≤ 10% concentration.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. Blended bulk raw material containing the notified polymer at ≤ 56% concentration will be formulated into finished cosmetic and personal care products containing the notified polymer at ≤ 10% concentration and packaged into consumer packaging (e.g. plastic tubes, jars, bottles, and sticks).

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 from dock to warehouse	1-2	30
Warehouse	1-2	30
Transport from warehouse to formulators	1-2	20
Reformulation worker	1-3	30
Retail workers	> 8	240
Professionals	> 8	240

EXPOSURE DETAILS

Transport and Storage
The notified polymer will be imported by ship as an unfinished blended bulk raw material containing the notified polymer at ≤ 56% concentration in sealed 7 gallon HDPE closed head pails and or 55 gallon stainless

steel drums with tamper-evident closures. The raw material will be transported by road from the wharf to the notifier's site for storage prior to being distributed to manufacturers and reformulators.

The notified polymer will also be imported by ship as a component of finished cosmetic and personal care products containing the notified polymer at ≤ 10% concentration packaged in consumer packaging packed in bulk cartons. The finished products will be transported by road to distributors and thereon by road to retailers.

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident. In such a case dermal, ocular, and inhalation exposure may be occur. Dockside and warehouse workers are expected to wear personal protective Equipment (PPE) including overalls and gloves.

Local reformulation into finished formulations
The imported unfinished blended bulk raw material containing the notified polymer at ≤ 56% concentration will undergo various reformulation processes depending on the intended product and reformulation site. Typically, the raw material will be weighed, transferred to a mixing vessel, and undergo a blending process using automated and closed vessels. Quality control testing will be implemented during the process. The final finished product will be transferred to a storage tank, from which an automated system will be used to fill consumer packaging containers of various types and sizes including plastic tubes, jars, bottles, and sticks with the finished product. The containers will then be sealed and packaged into cardboard transport cartons, themselves packed into shippers before being transported by road to warehouses or directly to retail outlets.

Reformulation equipment will typically be cleaned with hot water and rinsed after every batch.

Workers may be exposed to the unfinished blended bulk raw material containing the notified polymer at ≤ 56% concentration during its transfer from the imported container into the mixing vessel and also during quality control testing conducted during the reformulation process. Dermal, ocular, and inhalation exposure may occur. It is anticipated that workers involved in reformulation will wear appropriate PPE including safety glasses, safety shoes, impervious gloves and overalls. It is also anticipated that adequate local ventilation will be provided as well as enclosed mixing vessels and filling areas and that the reformulation process will involve automated processes.

Retail workers
Retail workers will shelve finished cosmetic and personal care products containing the notified polymer at ≤ 10% concentration packaged in consumer packaging containers of various types and sizes including plastic tubes, jars, bottles, and sticks. Retail workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident. In such a case dermal, ocular, and inhalation exposure may occur. Retail workers are not expected to wear PPE protection

End-use by hairdresser and beauty salon professionals
Hairdresser and beauty salon professionals will apply finished cosmetic and personal care products containing the notified polymer at ≤ 10% concentration to clients by hand, applicator, spray, and aerosol. These workers are not expected to wear PPE protection.

6.1.2. Public Exposure

Consumer cosmetic and personal care products will contain the notified polymer at ≤ 10% concentration packaged in consumer packaging containers of various types and sizes including plastic tubes, jars, bottles, and sticks. These products will be applied by hand, applicator, spray, and aerosol. Consumers are not expected to wear PPE.

Public exposure to the notified polymer is expected to be widespread and frequent through daily use of cosmetic and personal care products containing the notified polymer. Exposure to the notified polymer will vary depending on individual use patterns. The principal route of exposure will be dermal, and accidental ocular exposure may also occur.

Public exposure to the notified polymer in Australia has been calculated using estimates for preservative exposure in the Scientific Committee on Consumer Safety' (SCCS's) Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation (SCCS, 2012) and applying the following assumptions:

- Bodyweight (BW) of 64 kg for females (enHealth, 2012);
- The maximum concentration of the notified polymer in cosmetic and personal care products as stated in the table below;

- 10% dermal absorption;
- An individual uses daily all product types containing the notified polymer;

Product type	Use level (mg/day)	Concentration of notified polymer (%)	Retention factor	Daily systemic exposure (mg/kg bw/day)
Body lotion	7820	10	1	1.22
Face cream	1540	10	1	0.24
Hand cream	2160	10	1	0.34
Secondary Sunscreens	6000	10	1	0.94
Hair styling products	4000	10	0.1	0.06
Shower gel	18670	10	0.01	0.03
Shampoo	10460	10	0.01	0.02
Hair conditioner	3920	10	0.01	0.01
		Total daily systemic exposure:		**2.85**

This exposure estimate was calculated using conservative use assumptions and is expected to reflect a worst case scenario. In reality, the level of exposure is expected to be lower than 2.85 mg/kg bw/day as it is assumed that consumers would not use all these products daily to the extent shown above.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and the analogue Hexanedioic acid, mixed esters with decanoic acid, heptanoic acid, octanoic acid and pentaerythritol submitted by the notifier are summarised in the following table. For full details of the studies on the notified polymer (other than those previously assessed in Canada), refer to Appendix B.

Endpoint	*Test substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity*	Analogue	LD_{50} > 2,000 mg/kg bw; low toxicity
Human RIPT	Notified polymer (100%)	Non-irritating or sensitising
Eye irritation (in vitro- HET-CAM)	Notified polymer (10%)	non-irritating
Rat, repeat dose dermal toxicity – 28 days.*	Analogue	NOAEL = 500 mg/kg/day
Mutagenicity – bacterial reverse mutation	Notified polymer	non mutagenic
Genotoxicity – in vitro mammalian cell micronucleus test	Notified polymer	non genotoxic

* Robust study summary submitted

Toxicokinetics, metabolism and distribution.
Based on the moderately high molecular weight (> 1,000 g/mol) and the lipophilicity of the notified polymer (water solubility < 1×10^{-3} g/L at 20 °C; log Pow = 5.1) dermal absorption is expected to be limited. However the polymer contains a significant proportion of low molecular weight species < 1,000 g/mol that may be dermally absorbed.

Acute toxicity.
There is no available acute toxicity data on the notified polymer. In an acute oral toxicity study, the analogue had a LD_{50} greater than 2,000 mg/kg/bw, indicating low acute toxicity.

Irritation and sensitisation.
The notified polymer has structural alerts for irritation, but was not irritating to eyes in a HET-CAM study at 10%. The HET-CAM assay has not yet been validated as a replacement test for the *in vivo* Draize test, and is not to be used for regulatory hazard classification purposes, based on a lack of adequate data (ICCVAM, 2010). Given the ICCVAM conclusions, it is uncertain whether the response in the HET-CAM assay for the notified polymer indicated non-irritancy potential for the notified polymer. No skin irritation or sensitisation was seen in a human repeat insult patch test (RIPT) conducted on the notified polymer at 100%.

The potential for eye irritation at high concentrations cannot be ruled out.

Repeated Dose Dermal Toxicity.
There is no available repeated dose toxicity data on the notified polymer. In a 28 day dermal toxicity study in rats with the analogue polymer, animals treated with a dose of 500 mg/kg bw/day or greater exhibited the following local effects seen microscopically: reversible dose-related increase and severity of hyperplasia and hyperkeratosis of the epidermis and sebaceous gland hyperplasia. High dose females (2,000 mg/kg/day) exhibited a significant increase in relative adrenal and brain weights, attributed to the lower final body weights of the treated animals. Based on these effects a NOAEL of 500 mg/kg/day was established for the analogue.

Mutagenicity/Genotoxicity.
The notified polymer was not mutagenic to bacteria in an *in vitro* reverse mutation study. It did not induce micronuclei in cultured human peripheral blood lymphocytes in an *in vitro* micronucleus test.

Health hazard classification
Based on the limited available information, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Hairdressers will handle the notified polymer at ≤ 10% concentration in cosmetic and personal care products, similar to public use. Therefore, the risk for beauty care professionals who regularly use 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.

Staff involved in the formulation and quality control testing of cosmetic and personal care products may come in contact with the imported unfinished blended bulk raw material containing the notified polymer at ≤ 56% concentration. Exposure is expected to be limited during product formulation by the engineering controls and PPE used, and the enclosed and automated processes involved. Under the proposed occupational settings and provided that formulation control measures are being adhered to, the notified polymer is not considered to pose an unreasonable risk to workers.

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
The general public will be repeatedly exposed to the notified polymer during the use of cosmetic and personal care products containing the notified polymer at ≤ 10% concentration.

Local effects
Based on the information available, the notified polymer is not expected to cause adverse local effects at the proposed concentration of use.

Systemic effects
The repeated dose toxicity potential was estimated by calculation of the margin of exposure (MoE) to the notified polymer using the worst case exposure scenario from use of multiple products containing the polymer. Using 10% dermal absorption, a total systemic dose of 2.85 mg/kg bw/day (see Section 6.1.2) and the NOAEL of 500 mg/kg bw/day, which was established in the 28-day repeat dose toxicity study performed on the analogue chemical, the margin of exposure (MOE) was estimated to be 175 for a female using daily all types of products containing the notified polymer. A MOE greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. Therefore, in light of the conservative exposure scenario considered and based on the information available, the risk to the public associated with the use of the notified polymer at up to 10% concentration in cosmetic and personal care products, and non-spray deodorants, 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 not be manufactured in Australia; therefore, there will be no release from this activity. The notified polymer will be imported as a blended bulk raw material or as a component of finished formulations/cosmetic/personal care products (≤ 10% w/w). Blending will be carried out in closed automated systems and the release from blending is expected to be very low. Accidental spills during reformulation are expected to be recovered where practicable or absorbed with inert material and disposed of to landfill. Empty containers are expected to be rinsed and the aqueous rinsates are expected to be disposed of in accordance with local regulations and industry standard operating practices. Usually, the rinsates are expected to go into a trade water system where they are anticipated to be treated prior to release into the sewer.

RELEASE OF CHEMICAL FROM USE

The notified polymer is a component in cosmetic and personal care products. Therefore, it is expected that the majority of the imported quantity will be released to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Where recovery is not practicable, wastes from spills are expected to be collected, contained and disposed of to landfill. Residue of the notified polymer in the empty containers is likely either to be disposed of to landfill, or to be washed to the sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate

The notified polymer is expected to be readily biodegradable based on the environmental fate study. For the details of the environmental fate studies refer to Appendix C. The majority of the notified polymer will be disposed of to the sewer and, as it is a high molecular weight non-ionic polymer, it is estimated to be removed up to 90% in sewage treatment plant by partitioning to sediment and sludge (Boethling & Nabholz, 1996). The notified polymer that partitions to sludge will be removed with the sludge for disposal to landfill or used in soil remediation. Hence, it is not anticipated to be significantly bioavailable to aquatic organisms. In the aquatic environment it is unlikely to bioaccumulate based on its high molecular weight. It is expected to degrade biotically and abiotically 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/Manufactured Volume	90,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	90,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	246.58	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	50.56	µg/L
PEC - Ocean:	5.06	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified 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 50.56 µg/L may potentially result in a soil concentration of approximately 0.34 mg/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 1.68 mg/kg and 3.37 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations on Daphnia and algae conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C. The analogue substance (Hexanedioic acid, mixed esters with decanoic acid, heptanoic acid, octanoic acid and pentaerythritol; CAS no. 68130-55-2), was used as read across to the notified polymer (ecotoxicity data for fish). The analogue substance has a highly similar chemical structure and functional properties as the notified polymer.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 5017 mg/L *	Not toxic to fish
Daphnia Toxicity	48 h EL50 > 100 mg/L **	Not toxic to aquatic invertebrates
Algal Toxicity	72 h EL50 > 100 mg/L**	Not toxic to algae

*Acceptable analogue data US EPA (2010). **Water accommodated fraction (WAF)

The notified polymer is not expected to be acutely harmful to aquatic organisms in the aquatic environment. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009), the notified polymer is not expected to be harmful to fish, invertebrates and algae on an acute or long term basis and is not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the endpoint for Daphnia and algae. A safety factor of 100 was used, given that acute endpoints for three trophic levels are available including a fish study for the analogue.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
EC50 (Daphnia, algae)	>100 mg/L
Assessment Factor	100
Mitigation Factor	1.00
PNEC:	1,000 µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	50.56	1,000	< 0.056
Q - Ocean	5.056		< 0.005

The Risk Quotients (RQ = PEC/PNEC) for a conservative discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified polymer is expected to be rapidly biodegradable in the environment. It is unlikely to bioaccumulate based on its high molecular weight. The majority of notified polymer disposed of to the sewer is expected to be removed by partitioning to sludge and sediment during sewage treatment plant processes. As a result, it is not likely to be present in ecotoxicologically significant concentrations in the aquatic environment. Therefore, the notified polymer is not expected to pose an unreasonable risk to the environment on the basis of the assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility < 0.001 g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Column Elution Method. The reported value was based on the test certificate, however, the test study report was not provided.
Test Facility	Shriram (2012)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH

pH	*T (°C)*	$t_{½}$
4	25 °C	$t_{½}$ > 1 year
7	25 °C	$t_{½}$ > 1 year
9	25 °C	$t_{½}$ > 1 year

Remarks	Since preliminary studies for hydrolysis at 50 °C (as per due OECD guidelines TG - 111) carried out for a period of 5 days of the given sample indicated hydrolysis of the given sample to about < 10%, further experimentation was not carried out on the basis of this. It can be concluded that the sample does not hydrolyse under any of the pH conditions i.e., at pH 4.0, 7.0 and 9.0. The reported values were based on the test certificate, however, the test study report was not provided.
Test Facility	Shriram (2012)

Partition Coefficient (n-octanol/water) log Pow = 5.1

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	The reported value was based on the test certificate, however, the test study report was not provided.
Test Facility	Shriram (2012)

Absorption Coefficient log K_{oc} = 4.24

Method	OECD TG 121 Adsorption - Desorption
Remarks	The reported value was based on the test certificate, however, the test study report was not provided.
Test Facility	Shriram (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure and Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	S9 from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 50 – 5,000 µg/plate b) Without metabolic activation: 50 – 5,000 µg/plate
Vehicle	Dimethyl sulphoxide
Remarks - Method	Concentrations were chosen on the basis of a preliminary test with TA100, with and without metabolic activation, at concentrations of 5000, 1600, 500, 160 and 50 µg/plate. As none of these concentrations showed cytotoxicity the results of the preliminary test were used in Test 1. Test 1 employed the plate incorporation procedure Test 2 employed the pre incubation procedure

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	> 5,000	> 5,000
Test 2	> 5,000	> 5,000	> 5,000	> 5,000
Present				
Test 1	> 5,000	> 5,000	> 5,000	> 5,000
Test 2	> 5,000	> 5000	> 5,000	> 5,000

Remarks - Results	Doses were chosen on the basis of a preliminary study using TA100. No cytotoxic effect was observed at any concentration. Precipitation was observed at concentrations of 5,000 and 1,600 µg/plate, however the precipitation resolved upon incubation.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	IDEA (2013)

B.2. Genotoxicity – in vitro

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 487 *In vitro* Mammalian Cell Micronucleus Test
Species/Strain	Human
Cell Type/Cell Line	Human peripheral lymphocytes
Metabolic Activation System	S9 from sodium phenobarbitone / β-naphthoflavone induced rat liver
Vehicle	Dimethyl sulphoxide
Remarks - Method	Blood from a single in-house donor was used in the study. Human lymphocytes division was stimulated using phytohemagglutinin The negative control was the solvent dimethyl sulphoxide. The positive controls used were mitomycin C, cyclophosphamide monohydrate and colchicine.

Metabolic Activation	Test Substance Concentration (µg/mL)	Exposure Period	Harvest Time

Absent			
Test 1	0.05*, 0.025*, 0.0125*	3	24
Test 2	0.05*, 0.025*, 0.0125*	24	24
Present			
Test 1	0.05*, 0.025*, 0.0125*	3	24

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test (>60%)	*Cytotoxicity in Main Test (>60%)*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 0.05	> 0.05	≥ 0.05	Negative
Test 2	> 0.05	> 0.05	≥ 0.05	Negative
Present				
Test 1	> 0.05	> 0.05	≥ 0.05	Negative

Remarks - Results

Cytoxicity at the dose levels tested ranged from 40.3% to 56.6%.
The test item did not result in a dose dependent increase in the number of micronucleus compared to the vehicle control group.
The positive controls resulted in dose dependent increases in the incidence of micronucleus with statistical significance at 5% level under identical conditions.

CONCLUSION

The notified polymer did not induce micronuclei in cultured human peripheral blood lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY

Bioneeds (2013a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.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 reported
Analytical Monitoring	TOC-V-CPH Carbon Analyzer
Remarks - Method	The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	19.1	3	67.8
7	61.4	7	81.3
14	83.7	14	83.9
28	81.5	28	79.5

Remarks - Results	All validity criteria for the test were satisfied. The reference compound, sodium benzoate, reached the 60% pass level by day 3 indicating the suitability of the inoculum. The toxicity control exceeded 25% biodegradation within 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the notified polymer after the cultivation period was 81.5% and it reached the pass level within the 10-day window. Therefore, the test substance is classified as readily biodegradable according to the OECD (301 B) guideline.
CONCLUSION	The notified polymer is readily biodegradable.
TEST FACILITY	Smithers (2012)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	200 mg $CaCO_3$/L
Analytical Monitoring	None reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. A Water Accommodated Fraction (WAF) of the notified polymer at the loading rates of 100 mg/L was prepared. A glass beaker containing the test item was placed on a stove at 45 ± 2 ºC for a few minutes followed by addition of reconstituted water. Then, the mixture was diluted with

reconstituted water to 500 mL and put on a sonicator for minimum of 12 hours. The mixture was further filtered through a membrane filter of 0.2 µm. The filtrate was used as treatment solutions with appropriate dilutions. There were no flocculants observed in the treatment solutions on day 0.

RESULTS

Nominal Concentration (mg/L)	*Number of D. magna*	*Cumulative % Immobilised 48 h*
Control	20	0
100	20	0

EC 50	> 100 mg/L at 48 hours
NOEL	100 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The 48 hour EC50 was greater than 100 mg/L.

CONCLUSION The notified polymer is not harmful to aquatic invertebrates

TEST FACILITY BIONEEDS (2013b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. A Water Accommodated Fraction (WAF) of the notified polymer at the loading rates of 100 mg/L was prepared. A glass beaker containing the test item was placed on a stove at 45 ± 2 ºC for a few minutes followed by addition of reconstituted water. Then, the mixture was diluted with reconstituted water to 500 mL and put on a sonicator for minimum of 12 hours. The mixture was further filtered through a membrane filter of 0.2 µm. The filtrate was used as treatment solutions with appropriate dilutions. There were no flocculants observed in the treatment solutions on day 0.

RESULTS

Biomass (72 h)		*Growth (72 h)*	
E_yL50 (mg/L)	*NOE_yL (mg/L)*	*E_rL50 (mg/L)*	*NOE_rL (mg/L)*
>100	100	>100	100

Remarks - Results	All validity criteria for the test were satisfied. The 72 hour E_rC50 was greater than 100 mg/L.

CONCLUSION The notified polymer is not harmful to algae.

TEST FACILITY BIONEEDS (2013c)

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