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April 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

1,2,3-Propanetriol, homopolymer, dodecanoate

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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
STD/1453	Johnson & Johnson Pte Ltd	1,2,3-Propanetriol, homopolymer, dodecanoate	ND*	≤ 1.5 tonne per annum	Component of cosmetic product

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

The environmental hazard classification according to the *Globally Harmonised System for the 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 Toxicity (Category 3)	H402 – Harmful to aquatic life
Chronic Toxicity (Category 3)	H412 – Harmful to aquatic life with long lasting effects

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 assessed use pattern, the notified polymerl 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 as introduced:
  - Avoid contact with skin and eyes

  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 for the 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

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, 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 polymer, 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 concentration of the notified chemical in the skin lotion exceeds 3%;
- additional information becomes available on the genotoxic 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 ingredient in skin lotion, or is likely to change significantly;
- the amount of polymer being introduced has increased from 1.5 tonnes per annum, 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)
Johnson & Johnson Pte Limited (ABN: 24 922 851 374)
45 Jones Street
ULTIMO NSW 2007

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1000 Da (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints, all human health endpoints (except chromosome damage *in vitro*) and fish toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2007)
Canada (2007)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polylado 10-1-L KFG

CAS NUMBER
74504-64-6

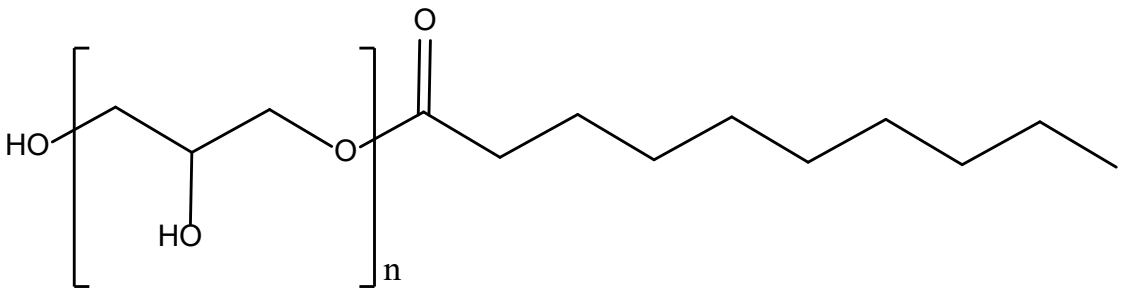
CHEMICAL NAME

1,2,3-Propanetriol, homopolymer, dodecanoate

OTHER NAME(S)
Decaglyceryl laurate

MOLECULAR FORMULA
$C_{12}H_{24}O_2.x.(C_3H_8O_3)_x$

STRUCTURAL FORMULA



MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	383 Da
Weight Average Molecular Weight (Mw)	838 Da
Polydispersity Index (Mw/Mn)	1.6
% of Low MW Species < 1000 Da	87.02%
% of Low MW Species < 500 Da	49.70%

ANALYTICAL DATA
Reference NMR,and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY ~60 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

Chemical Name	Decaglycerol		
CAS No.	9041-07-0	*Weight %*	40
Chemical Name	Dodecanoic acid, sodium salt (1:1)		
CAS No.	629-25-4	*Weight %*	< 2

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Amber liquid. Calculated data shown in the following table was conducted on the notified polymer with n =3 (MW 394.51 Da).

Property	Value	Data Source/Justification
Melting Point	212.65 °C	Calculated (MPBVP v1.43; US EPA

		2009)
Boiling Point	514.67 °C at 101.3 kPa	Calculated (MPBVP v1.43; US EPA 2009)
Density	1100 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	8.53 x 10^{-15} kPa at 25 °C	Calculated (MPBVP v1.43; US EPA 2009)
Water Solubility	1 g/L at 20 °C	Calculated (WSKOW v1.42; US EPA 2011). Based on its surface active properties, the notified polymer is expected to be water dispersible.
Hydrolysis as a Function of pH	$t_{½}$ = 7.7 years (pH 7) $t_{½}$ = 281 days (pH 8)	Calculated (HYDROWIN v2.00; US EPA 2011)
Partition Coefficient (n-octanol/water)	Not determined	Based on its surface active properties, the notified polymer is expected to partition to phase boundaries.
Surface Tension	29.8 mN/m	Measured
Adsorption/Desorption	Not determined	Based on its surface active properties, the notified polymer is expected to partition to phase boundaries.
Dissociation Constant	Not determined	Not expected to dissociate under environmental conditions.
Flash Point	> 93.3 °C at 101.1 kPa	(M)SDS
Flammability	Not determined	Not expected to be highly flammable based on flash point.
Autoignition Temperature	Not determined	Contains no functional groups that imply autoignition.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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

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

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the 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 be imported as a component of finished cosmetic skin lotions at ≤ 3% concentration.

The notified polymer may also be imported in the neat form (purity 60%) and reformulated into cosmetic skin lotions at ≤ 3 % concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1.2	1.2	1.5	1.5	1.5

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The finished skin lotion products containing the notified polymer (at ≤ 3% concentration) will be packaged in 266 mL and 295 mL containers suitable for retail sale.

USE
The notified polymer will be used at ≤ 3% concentration in skin lotion.

OPERATION DESCRIPTION
The notified polymer will be imported as a component of a skin lotion at ≤ 3% concentration. The notified polymer may at some point in the future be imported in neat form for formulation of cosmetic skin lotions at ≤ 3% concentration within Australia.

Formulation of cosmetic products
No information for reformulation processes have been provided.

End-use
The finished skin lotion containing the notified polymer at ≤ 3% concentration will be used by consumers. Application of products is expected to be by hand.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified polymer in the neat form (60% purity) or as a component of a skin lotion (≤ 3% concentration) only in the event of accidental rupture of containers.

Formulation of cosmetic products
During formulation of cosmetic products from the neat notified polymer, dermal, ocular and inhalation exposure of workers to the notified polymer (at 60% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment.

End-use
Exposure to the notified polymer (at ≤ 3% concentration) in end-use products may occur in professions where the services provided involve the application of lotion products (e.g. childcare workers). Exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using skin lotion products containing the notified polymer.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified polymer (at ≤ 3% concentration) through the use of skin lotions. The principal routes of exposure will be dermal, while ocular exposure is also possible. Inhalation exposure is expected to be negligible given the low vapor pressure of the notified polymer.

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*
Genotoxicity – *in vitro* chromosome aberration in Chinese hamster cells	genotoxic
Genotoxicity – *in vitro* chromosome aberration test in human peripheral blood lymphocytes	non genotoxic

Additional information on the expected health effects of the notified polymer is based on analogues of the notified polymer, namely: polyglycerol fatty acid esters (PGFAs; Analogue 1) and dodecanoic acid, monoester with 1,2,3-propanetriol (Analogue 2).

Analogue 1 represents a generic class of compounds which, like the notified polymer, are made up of polymerised glycerols reacted with fatty acids. Analogue 2 is equivalent to the notified polymer containing one glycerol unit (i.e. n=1) and therefore would be considered the closest analogue to the notified polymer. As analogue 2 is equivalent to the lowest possible molecular weight for the notified polymer, it represents the worst case scenario for absorption. Analogues 1 and 2 are therefore considered acceptable analogues for the notified polymer.

	Notified polymer	*Analogue 1*	*Analogue 2*
CAS name	1,2,3-Propanetriol, homopolymer, dodecanoate	Polyglycerol fatty acid esters (PGFAs)	Dodecanoic acid, monoester with 1,2,3-propanetriol
CAS number	74504-64-6	-	27215-38-9
Molecular weight (Da)	383 (NAMW)	-	274.2
Formula	$C_{12}H_{24}O_2.x(C_3H_8O_3)_x$	Consist of polymerised glycerols reacted with fatty acids. Composed of ≥ 70% di-, tri-, and tetraglycerols and ≤ 10% polyglycerols.	$C_{15}H_{42}O_4$
Water solubility	1 g/L at 20 °C		$1.3x10^{-3}$ g/L (calculated)
Partition co-efficient (log K_{ow})	Not determined		3.67 (calculated)
Vapour□pressure	8.53×10^{-15} kPa at 25 °C	-	3.83×10^{-8} at 25 °C (calculated)

The results from toxicological investigations of analogues 1 and 2 are summarised in the following table. In addition, data for the metabolic breakdown product of the notified polymer, dodecanoic acid (143-07-7), is also included.

Endpoint	*Dodecanoic acid*	*Analogue 1*	*Analogue 2*
Acute oral toxicity	LD50 12,000 mg/kg bw (rat) (Clayton and Clayton, 1982)	LD50 > 29,000 mg/kg bw (rat) (JEFCA, 1974)	LD50 > 20,000 mg/kg bw (rat) (CIR, 2004)
Acute inhalation toxicity	-	-	Low grade irritant response noted following aerosol exposure at 10% (CIR, 2004)
Eye irritation	-	-	Moderately irritating at 20% (CIR, 2004)
Skin irritation	-	-	Moderately irritating at 20% (CIR, 2004) Slightly irritating undiluted (CIR, 2004)
Skin sensitisation	-	-	No evidence of sensitisation at 25% (GPMT) (CIR, 2004) No evidence of sensitisation at 25% (HRIPT) (CIR, 2004)
Repeat dose oral toxicity	NOEL > 6000 mg/kg bw/day (18 weeks, rats) (Burdock and Carabin, 2007)	Adverse effects observed at 5% concentration in diet (80 weeks, mice) (JEFCA, 1974) NOAEL = 15% concentration in diet (5 weeks, rats) (JEFCA, 1974)	NOAEL = 25% concentration in diet (10 weeks, rats) (CIR, 2004)

Endpoint	*Dodecanoic acid*	*Analogue 1*	*Analogue 2*
		NOAEL = 10% concentration in diet (90 days, rats) (JEFCA, 1974) No adverse effects in humans fed up to 20 g/day over 3 weeks (JEFCA, 1974)	
Repeat dose inhalation toxicity			NOEC = 280 mg/m^3 (14x1 hour exposure for 3 weeks) (CIR, 2004)
Developmental and reproductive effects		NOAEL = 1.5% concentration in feed, three generations, rats (JEFCA, 1974)	
Carcinogenicity		NOAEL = 5% (2 years, rats) (JEFCA, 1974)	

Toxicokinetics, metabolism and distribution.
The notified polymer is expected to be metabolised in a similar manner to polyglycerol and other polyglycerol esters. The metabolism of tri-(G_3) and polyglycerol (G_{10}) and G_3 and G_{10} esters have been studied *in vivo* in rats (Michael and Coots, 1971). It was found that ester bonds were hydrolyzed to a large extent prior to absorption. The free fatty acids were readily absorbed via the thoracic duct pathway while the free or partially esterified polyglycerols were not as readily absorbed. Carbon dioxide was found to be the major product of fatty acid catabolism and polyglycerols were excreted unchanged in the urine.

The notified polymer is of low molecular weight (NAMW 383) and surface active, hence dermal absorption may occur. If the notified polymer penetrates the skin it is expected to be hydrolysed into polyglycerol and dodecanoic acid (Eppler et al., 2007).

Acute toxicity.
No acute toxicity studies are available for the notified polymer.

In an acute oral toxicity study conducted on analogue 1, no toxic effects were observed when administered in single doses by oral gavage at 7,000, 14,000 and 29,000 mg/kg bw in rats (JEFCA, 1974). Furthermore, analogue 2 and dodecanoic acid have been reported to have LD50s of > 20,000 mg/kg bw and 12,000 mg/kg bw, respectively (CIR, 2004; Clayton and Clayton, 1982). The notified polymer is therefore expected to be of low acute oral toxicity.

The notified polymer may be dermally absorbed and is expected to be hydrolysed into polyglycerol and dodecanoic acid resulting in a similar toxicity response to that of the oral route. The notified polymer is therefore expected to be of low acute dermal toxicity.

Exposure by inhalation of the notified polymer is not expected due to the low estimated vapour pressure (8.53 x 10^{-15} kPa). However, a low grade irritant response was noted following inhalation of an aerosol containing 10% analogue 2, although study details were not reported (CIR, 2004). The notified polymer is expected to be of low acute inhalation toxicity.

Irritation and sensitisation.
No irritation and sensitisation studies are available for the notified polymer.

A 20% emulsion of analogue 2 was evaluated for skin irritation potential in six albino rabbits and was found to be moderately irritating with a primary irritation score of 3.9 (CIR, 2004). However, in another skin irritation study using six rabbits, undiluted analogue 2 only induced minor erythema and oedema (CIR, 2004). In the human repeat insult patch tests (HIRPT) described below, mild to moderate erythema was observed in the induction phase at up to 50% concentration with analogue 2. Analogue 2 has been stated to have one fifth of the irritancy of sodium lauryl sulphate (CIR, 2004) which is commonly used in cosmetics (Wenninger and McEwan, 2006) and deemed safe for prolonged use at ≤ 1% by the OECD (1997). Based on the available information for

analogue 2, the notified polymer is expected to be moderately irritating to the skin. This is consistent with the notified polymer being surface active.

Analogue 2 was evaluated in a Draize test in rabbits and reported mild corneal (mean score of 0.17 out of a maximum score of 80 for corneal lesions) and conjunctival irritation (mean score 1.33 out of a maximum score of 20 for conjunctival lesions). Reactions were not observed in the iris (CIR, 2004). In another study, a 20% solution of analogue 2 reported an average score of 3.7 for conjunctival irritation (CIR, 2004). Given irritation was only observed in one animal (out of six), the study authors concluded that a 20% solution of analogue 2 was non-irritating to the eye. Based on the available information for analogue 2, the notified polymer is only expected to be at most slightly irritating to the eye.

In a guinea pig maximisation test analogue 2 was found to be non-sensitising when challenged at 25% concentration (CIR, 2004). In a modified Draize repeat insult patch test where 74 subjects completed the study, a 50% solution of analogue 2 in liquid paraffin oil induced mild to moderate erythema during induction in most of the subjects and questionable reactions during the challenge phase in 7 subjects (CIR, 2004). In a second insult patch test, a 25% solution of analogue 2 in liquid paraffin oil induced moderate erythema in 8 subjects during induction and in one subject during the challenge phase (CIR, 2004). No details were provided on the number of volunteers receiving analogue 2 as the test substance, though 93 volunteers were involved in the study which also investigated two other glyceryl monoesters. The investigators concluded that analogue 2 was non-sensitising. Based on the studies conducted on analogue 2 and absence of structural alerts for skin sensitisation, the notified polymer is not expected to be a skin sensitiser.

Repeated Dose Toxicity.
No repeated dose toxicity studies are available for the notified polymer.

Mice fed with analogue 1 for 80 weeks at 5% concentration in the diet showed no adverse effects on body weight, food consumption, peripheral blood picture and survival rates (JEFCA, 1974). Microscopic examination of all major organs showed nothing remarkable. However, liver and kidney weights of females were significantly higher. In other studies conducted on analogue 1, no adverse effects were observed in rats fed at 10% and 15% concentration in the diets in 5-week and 90-day repeat dose toxicity studies, respectively (JEFCA, 1974). Analogue 2 has also been reported to cause no test substance related gross or microscopic lesions when fed to rats at 25% concentration in the diet for 10-weeks (CIR, 2004). In addition, the expected metabolite, dodecanoic acid, was found to have a NOEL > 6000 mg/kg bw/day in an 18 week study in rats (Burdock and Carabin, 2007).

In human studies, thirty seven volunteers (aged 19 to 24) were fed analogue 1 at a dose of 2-20 g/day for three weeks in their diet (JEFCA, 1974). No abnormalities were observed in plasma proteins, serum amino acids, thymol and various other biochemical parameters as well as split faecal fat or total faecal nitrogen.

In a short term (14 1-hour exposures for a three week period) inhalation study in rats, analogue 2 was reported to have a NOEL of 280 mg/m^3 (CIR, 2004).

Overall, based on the weight of evidence, the notified polymer is not expected to cause repeated dose toxicity.

Reproductive and developmental toxicity
Rats kept on a diet containing 1.5% analogue 1 for three generations showed no significant variations in fertility or reproductive performance (JEFCA, 1974). In addition, no test substance related gross or histological abnormalities were noted.

Mutagenicity/Genotoxicity.
The notified polymer was positive in an *in vitro* chromosome aberration study in Chinese hamster cells with metabolic activation. Without metabolic activation there was a slight increase in aberrant cells but a dose response relationship was not observed. Given that *in vitro* chromosomal aberration studies can give a high frequency of false positives, the notifier has re-tested the notified polymer in human peripheral blood lymphocytes. In the second *in vitro* chromosome aberration study, the notified polymer was found to be non-mutagenic in human lymphocytes.

An Ames test has not been conducted on the notified polymer and there is no data available for analogues 1 and 2. However, other similar chemicals, glyceryl linoleate and glyceryl oleate have both been reported to be not mutagenic in an Ames test using *Salmonella typhimurium* (at 5000 mg/plate) (CIR, 2004). Furthermore, medium and long chain triacylglycerol oil (MLCT) was negative in an Ames test using *Salmonella typhimurium* and

Escherichia coli (at 5000 mg/plate) (Matulka, 2006). The approximate fatty acid composition of this MLCT consisted of caprylic acid (9.7%), capric acid (3.3%, palmitic acid (3.8%), stearic acid (1.7%), oleic acid (51.2%), linoleic acid (18.4%), linolenic acid (9.0%) and other fatty acids (2.9%).

Overall, considering the results from both studies, the notified polymer is not expected to be genotoxic.

Carcinogenicity.
Analogue 1 fed to 28 male and 28 female rats at 5% in their diet for two years showed no observed adverse effects, with tumour incidence and distribution reported as being similar in the control and test groups (JEFCA, 1974). Analogue 2 has shown marked antitumor activity in two leukaemia cell lines, L-5178Y and L-1210 (CIR, 2004). More recently, monoglyceride has been shown to induce apoptosis in several other human leukemic cell lines (Philippoussis et al., 2002). Therefore, based on the evidence, the notified polymer is not expected to be carcinogenic.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the 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
The notified polymer is moderately irritating to the skin and possibly slightly irritating to the eyes.

Compounders and laboratory staff involved in the formulation of cosmetic products may come in contact with the notified polymer at 60% concentration. At these concentrations there is the potential for irritation effects, particularly to the skin. No information on the reformulation process was provided. However, given the low hazardous nature of the notified polymer and provided control measures are in place to avoid skin and eye contact during reformulation, the notified polymer is not considered to pose an unreasonable risk to workers.

6.3.2. Public Health
The notified polymer will be used at ≤ 3% concentration in skin lotions. At the proposed use concentration irritation effects are not expected. Furthermore, the notified polymer is of low hazard and is not expected to cause systemic toxicity from repeated exposure; hence a margin of exposure has not been determined.

Based on the proposed use, 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 component of finished cosmetic products and will also be imported neat for blending. Accidental spills during transport are expected to be collected with inert material and disposed of to landfill. Residues of the notified polymer in empty import containers are expected to be disposed of to landfill. Some of the notified polymer may be released to sewer during equipment cleaning where reformulation activities take place.

RELEASE OF CHEMICAL FROM USE

The notified polymer is a component in body lotions. Therefore, it is expected that the majority of the imported quantity of notified polymer will eventually be washed off the skin and be released to sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Residue of the notified polymer in the empty end-use containers 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

The majority of the notified polymer is expected to be released to sewer during use in body lotions. During waste water treatment processes in sewage treatment plants (STPs), a proportion of the notified polymer is expected to be removed from waste waters due to its likelihood to partition to phase boundaries. The notified polymer that partitions to sludge will be removed with the sludge for disposal to landfill or used on land for soil remediation. The notified polymer that is released to surface waters is expected to partition to suspended solids and organic matter and disperse. Based on its surface activity and water dispersibility, the notified polymer is not expected to bioaccumulate. The notified polymer is not readily biodegradable but has the potential to biodegrade. It is estimated that the notified polymer is not rapidly hydrolysable with calculated half-lives of 7.7 years and 281.6 days at pH 7 and 8, respectively (HYDROWIN v2.00; US EPA 2011). Ultimately, the notified polymer is expected to degrade via biotic and abiotic processes in soil and surface waters to form water and oxides of carbon. For the details of the environmental fate studies please refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the reported use in body lotions, it is assumed that 100% of the notified polymer will be released to sewer on a nationwide basis over 365 days per year. It is also assumed under a worst-case scenario that there is no removal of the notified polymer during STP processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,500	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	4.11	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.91	µg/L
PEC - Ocean	0.091	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.909 µg/L may potentially result in a soil concentration of approximately 6.06 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 30.3 µg/kg and 60.6 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 toxicity		
Daphnia Toxicity (48 h)	EC50 = 36.63 mg/L	Harmful to aquatic invertebrates
Algal Toxicity (72 h)	EC50 = 18.96 mg/L	Harmful to algae

No data was available for toxicity of the notified polymer to vertebrates. Therefore, the notified polymer cannot be classified for toxicity to fish under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009). For the other available ecotoxicological endpoints, under the GHS, the notified polymer is considered, harmful to aquatic invertebrates and harmful to algae on an acute basis. Based on the acute toxicity endpoint for the most sensitive species, algae, the notified polymer is formally classified under the GHS as 'Acute Category 3; Harmful to aquatic life'. Based on the acute toxicity to aquatic organisms and lack of rapid biodegradability in the environment, the notified polymer is formally classified under the GHS as 'Chronic Category 3; Harmful to aquatic life with long lasting effects'.

7.2.1. Predicted No-Effect Concentration

The endpoint for the most sensitive species from the reported results (EC50, algae, 72 h) was used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 1000 was used as full study reports were available for two acute ecotoxicological endpoints.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae, 72 h)	18.96	mg/L
Assessment Factor	1000	
PNEC:	18.96	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.91	18.96	0.05
Q - Ocean	0.091	18.96	0.005

The Risk Quotients (Q = PEC/PNEC) for a conservative discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified polymer is not rapidly biodegradable in the environment however it is not expected to bioaccumulate based on its potential to partition to phase boundaries. Therefore, the notified polymer is not expected to pose an unreasonable risk to the environment based on its assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Surface Tension 29.8 mN/m

Method	In-house standard operating procedure for the Sigma 701 Tensiometer (USAD-36449)
Remarks	Concentration: 0.1 – 10% test substance. It was necessary to warm the test substance due to its viscosity and flow ability.
Test Facility	Lonza (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	V79
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Vehicle	Culture medium (MEM)
Remarks - Method	The positive controls used in the study were ethyl methanesulfonate (without metabolic activation) and cyclophosphamide (with metabolic activation). No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 8, 20, 50*, 65*, 70*, 95, 110, 125	4 h	20 h
Present			
Test 1	0, 30, 90, 250, 750, 1000*, 1250*, 1500*, 1750, 2000, 2250	4 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 125	≥ 65	> 70	Equivocal
Present				
Test 1	≥ 2500	≥ 1250	≥ 1000	Positive

Remarks - Results	Without metabolic activation a slight increase of aberrant cells was observed at concentrations of 50 and 70 µg/mL but not at 65 µg/mL. With metabolic activation, the aberration rates of the higher concentrations (1250 and 1500 µg/mL) were significantly increased and a dose relationship was observed. The positive controls caused statistically significant increases in the proportion of aberrant cells, demonstrating the sensitivity of the test system and the efficacy of the S9 mix.
CONCLUSION	The notified polymer was clastogenic to chinese hamster V79 cells treated in vitro under the conditions of the test.
TEST FACILITY	BSL Bioservice (2012)

B.2. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver

Vehicle	water
Remarks - Method	The positive controls used in the study were mitocycin C (without metabolic activation) and cyclophosphamide (with metabolic activation).

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10, 25, 50*, 125*, 250*, 500, 750, 1000	4 h	20 h
Test 2	10, 25, 50*, 125*, 200, 300*, 400, 500	20 h	20 h
Present			
Test 1	10, 25, 50, 125*, 250*, 500*, 750, 1000	4 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 1500	≥ 250	> 1000	Negative
Test 2	≥ 500	≥ 300	> 500	Negative
Present				
Test 1	≥ 1500	≥ 500	> 1000	Negative

Remarks - Results	No significant increases in chromosomal aberrant aberrations were observed in any treatment group at any dose level. The positive controls caused statistically significant increases in the proportion of aberrant cells, demonstrating the sensitivity of the test system and the efficacy of the S9 mix.
CONCLUSION	The notified polymer was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	BioReliance (2012)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Domestic sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Carbon analysis, total inorganic carbon (TIC) analysis
Remarks - Method	The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. The test was conducted on the product containing the notified polymer at ~60% concentration.

RESULTS

Test substance		*Dextrose*	
Day	*% Degradation*	*Day*	*% Degradation*
7	34.85	7	73.51
14	40.55	14	84.82
28	54.27	28	87.72

Remarks - Results	All relevant test validity criteria were met.
CONCLUSION	The test substance is not readily biodegradable.
TEST FACILITY	RespirTek (2011)

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	205 - 260 mg $CaCO_3$/L
Analytical Monitoring	Dissolved oxygen
Remarks - Method	The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. The test was conducted on the product containing the notified polymer at ~60% concentration.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
Nominal		*24 h*	*48 h*
0	4 × 5	0	0
10	4 × 5	0	0
20	4 × 5	0	0
40	4 × 5	0	0
80	4 × 5	15	19
160	4 × 5	15	20

EC50	36.63 mg/L at 48 hours
NOEC	24 mg/L at 48 hours

Remarks - Results	All relevant test validity criteria were met. The geometric mean was used to interpolate the values for the EC50 and NOEC. The EC50 and NOEC were also corrected to represent the percent active ingredient (~60%).
CONCLUSION	The notified polymer is harmful to aquatic invertebrates.
TEST FACILITY	Stillmeadow (2012a)

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: 0, 6.25, 12.5, 25, 50 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Cell density
Remarks - Method	The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations.

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
18.96	12.5	Not determined	Not determined

Remarks - Results	All relevant test validity criteria were met. The geometric mean was used to interpolate the values for the EC50 and NOEC. The EC50 and NOEC were also corrected to represent the percentage of active ingredient (~60%).
CONCLUSION	The notified polymer is harmful to algae.
TEST FACILITY	Stillmeadow (2012b)

BIBLIOGRAPHY

BioReliance (2012) *In vitro* mammalian chromosome aberration assay in human peripheral blood lymphocytes (HPBL) (Study No. AD51ZW.341.BTL, August, 2012). Maryland, United States, BioReliance. (Unpublished report submitted by the notifier).

BSL (2012) *In vitro* mammalian chromosome aberration test in Chinese Hamster V79 cells with 1,2,3-propanetriol homopolymer dodecanoate (Study No. 114867, February, 2012). Planegg, Germany, BSL Bioservice (Unpublished report submitted by the notifier).

Burdock, G.A. and Carabin, I.G. (2007). Safety assessment of myristic acid as a food ingredient. Food chem Toxicol. 45(4): 517-529.

CIR (2004). Final Report of the Amended Safety Assessment of Glyceryl Laurate, Glyceryl Laurate SE, Glyceryl Laurate/Oleate, Glyceryl Adipate, Glyceryl Alginate, Glyceryl Arachidate, Glyceryl Arachidonate, Glyceryl Behenate, Glyceryl Caprate, Glyceryl Caprylate, Glyceryl Caprylate/Caprate, Glyceryl Citrate/Lactate/Linoleate/Oleate, Glyceryl Cocoate, Glyceryl Collagenate, Glyceryl Erucate, Glyceryl Hydrogenated Rosinate, Glyceryl Hydrogenated Soyate, Glyceryl Hydroxystearate, Glyceryl Isopalmitate, Glyceryl Isostearate, Glyceryl Isostearate/Myristate, Glyceryl Isostearates,Glyceryl Lanolate, Glyceryl Linoleate, Glyceryl Linolenate, Glyceryl Montanate, Glyceryl Myristate, Glyceryl Isotridecanoate/Stearate/Adipate, Glyceryl Oleate SE, Glyceryl Oleate/Elaidate, Glyceryl Palmitate, Glyceryl Palmitate/Stearate, Glyceryl Palmitoleate, Glyceryl Pentadecanoate, Glyceryl Polyacrylate, Glyceryl Rosinate, Glyceryl Sesquioleate, Glyceryl/Sorbitol Oleate/Hydroxystearate, Glyceryl Stearate/Acetate, Glyceryl Stearate/Maleate, Glyceryl Tallowate, Glyceryl Thiopropionate, and Glyceryl Undecylenate. IJT 23(52) pp. 55-94. Cosmetic Ingredient Review, Washington DC, USA.

Clayton, G.D. and Clayton, F.E. (1982) Patty's Industrial Hygiene and Toxicology. Volume 2C: Toxicology. 3rd Revised Edition. John Wiley & Sons: New York.

Eppler, A.R., Kraeling M.E., Wickett R.R. and Bronaugh, R. (2007). Assessment of skin absorption and irritation potential of arachidonic acid and glyceryl arachidonate using in vitro diffusion cell techniques. Food. Chem. Toxicol. 45: 2109-2117.

JECFA (1974) Toxicological valuation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents. WHO Food Additives Series No. 5, Polyglycerol esters of fatty acids. Joint JEFCA Expert Committee on Food Additives.

King, W.R., Michael, W.R. and Coots, R.H. (1971a). Subacute oral toxicity of polyglycerol ester. Toxicol. Appl. Pharmacol. 20: 327-333.

Lonza (2013) Surface tension of Polyaldo 10-1-L (Study No. USAD-36330, February, 2013). Allendale, New Jersey, United States, Lonza Inc. (Unpublished report submitted by the notifier).

Matulka, R.A., Noguchi, O. and Nosaka, N. (2006). Safety evaluation of a medium- and long-chain triacylglycerol oil produced from medium-chain triacylglycerols and edible vegetable oil. Food Chem. Toxicol. 44(9):1530-1538.

Michael W.R. and Coots R.H. (1971b). Metabolism of polyglycerol and polyglycerol esters. Toxicol. Appl. Pharmacol. 20: 334-345.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

OECD (1997) Screening Information Data Set (SIDS) Initial Assessment, Vol. 4 Part 2: Sodium Dodecyl Sulfate. Paris, Organisation for Economic Co-operation and Development.

Philippoussis, F., Arguin C., Mateo, V., Steff, A and Hugo, P. (2003) Monoglycerides induce apoptosis in human leukemic cells while sparing normal peripheral blood mononuclear cells. Blood, 101: 292-294.

RespirTek (2011) OECD 301B Ready/Ultimate Biodegradability Assessment (Study No. LON-2285, April, 2011). Biloxi, Mississippi, United States, RespirTek Consulting Laboratory (Unpublished report submitted by the notifier).

Stillmeadow (2012a) *Daphnia magna* 48-hour Acute Toxicity Test (Study No. 15696-11, January, 2012). Sugar Land, Texas, United States, Stillmeadow Incorporated (Unpublished report submitted by the notifier).

Stillmeadow (2012b) *Pseudokirchneriella subcapitata* (formally *Selenastrum capricornutum*) 72-hour Algal Inhibition Test (Study No. 15697-11, January, 2012). Sugar Land, Texas, United States, Stillmeadow Incorporated (Unpublished report submitted by the notifier).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.

US EPA (2011) Estimation Programs Interface (EPI) Suite™ for Microsoft® Windows, v 4.10. United States Environment Protection Agency, Washington, D.C., USA. Website: http://www.epa.gov/oppt/exposure/pubs/episuite.htm. Accessed on 25 February 2013

Wenninger, J.A. and McEwan, G.N. (2006). The Cosmetic, Toiletry, and Fragrance Association International Cosmetic Ingredient Dictionary and Handbook, Washington DC.