File No: LTD/1779

November 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Castor oil, ethoxylated, dioleate (INCI Name: PEG-18 Castor oil dioleate)

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

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

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

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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/1779	L'Oreal Australia Pty Ltd	Castor Oil, ethoxylated, dioleate (INCI: PEG-18 Castor oil dioleate)	Yes	≤ 1 tonne per annum	Ingredient in cosmetics

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 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 Category 3	H 402 – Harmful to aquatic life

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical 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 neat notified chemical as introduced:
  - Avoid skin and eye contact

  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

- 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 1000;
- the concentration of the notified polymer is intended to exceed 10% as an ingredient in cosmetic products.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from an ingredient in cosmetics, 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 provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St. Kilda Road
MELBOURNE VIC 3004

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: molecular weight, analytical data, degree of purity, use details, import volume and site of reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: boiling point, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, flammability, reactivity, explosive and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2010)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PEG-18 Castor oil dioleate

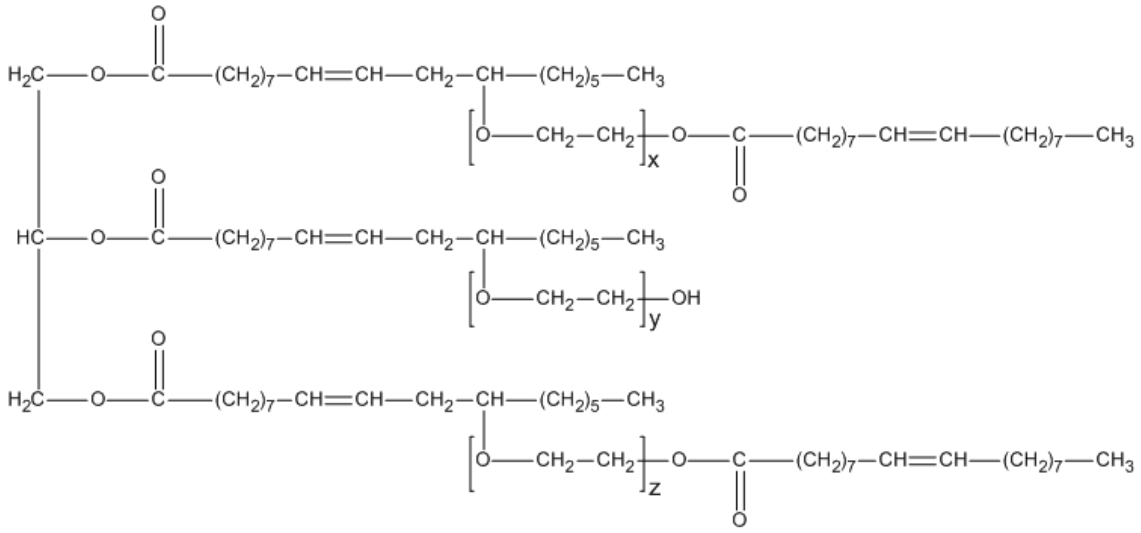
CAS NUMBER
110531-96-9

CHEMICAL NAME
Castor oil, ethoxylated, dioleate

OTHER NAME(S)
PEG-18 Castor oil dioleate (INCI)

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



Where x + y + z = an average of 18 ethylene oxide units.

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) > 1,000 Da

ANALYTICAL DATA
Reference IR spectra was provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow liquid with mild odour

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20 °C	(M)SDS
Boiling Point	Not determined	The notified polymer is expected to decompose before reaching the boiling point
Density	930 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	< 0.01 kPa at 20 °C	(M)SDS
Water Solubility	5.476 x 10^{-39} g/L at 20 °C	Estimated using QSAR (2014)
Hydrolysis as a Function of pH	$t_{½}$ = 30 days at pH 8 and 298 days at pH 7.	Estimated using QSAR (2014)
Partition Coefficient (n-octanol/water)	log Pow > 4	Estimated using QSAR (2014)
Adsorption/Desorption	log K_{oc} = 16.9	Estimated using QSAR (2014)
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	278 °C	(M)SDS
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF 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 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 not be manufactured in Australia. The notified polymer will be imported into Australia in pure form (> 90% concentration) or as a component of formulated end-use products (≤ 10% concentration).

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

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

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 100 kg iron drums or 950 kg containers on pallets. In Australia, the packages will be transported by road. The end-use products will be packaged in containers suitable for retail sale, with volumes generally < 500 mL.

USE
The notified polymer will be used as an emulsifier and viscosity increasing agent in a wide range of leave-on and rinse-off cosmetic products at a concentration of up to 10%.

OPERATION DESCRIPTION
The pure form of the polymer will be transported to the blending facility for reformulation and repackaging. The reformulated end-use consumer products will then be transported to retail outlets for sale to the public. The polymer that will be imported as a component of end-use product will be transported to a central warehouse for distribution to customer's warehouses and then to retailers at a later stage.

The procedure for incorporating the notified polymer into end-use cosmetic products (at ≤ 10% final concentration) will likely involve both automated and manual transfer steps. In general it is expected that the notified polymer will be weighed and added into a flame proof mixing tank where it will be blended with additional additives to form the finished cosmetic products. This will be followed by automated filling of the reformulated products into retail packaging of various sizes. Samples of the notified polymer and the finished cosmetic products will be taken at various stages of reformulation for quality control testing.

The finished cosmetic products containing the notified polymer at ≤ 10% concentration will be used by consumers and professionals such as hairdressers and workers in beauty salons. Depending on the nature of the products, application of the products could be by hand, spray or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4	12
Plant operator	8	12

Quality control worker	3	12
Packager	8	12
Store persons	4	12

EXPOSURE DETAILS

Transport and storage

At the notifier's facility, the primary work activity undertaken by transport and warehouse workers will include the handling, loading and off-loading of containers containing the notified polymer at up to > 90% concentration. Exposure of these workers will be limited to situations involving product sampling for quality control, or in the event of a discharge, clean up from a spill or leaking container. If such an event occurs, a worker may be exposed through dermal or ocular contact.

Reformulation

During reformulation dermal, ocular and inhalation exposure of workers to the notified polymer (at up to > 90% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. The notifier anticipates that typical practices by cosmetic and consumer product manufacturers will include enclosed mixing vessels and filling areas, local ventilation, PPE such as overalls, safety glasses and impervious gloves, and a high degree of process automation.

Beauty care professionals

Exposure to the notified polymer in cosmetic products (at ≤ 10% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons). The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible. Such professionals may use some PPE to minimise repeated exposure, but use is not expected. However, good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified polymer (at up to 10% concentration) through the use of a wide range of cosmetic and personal care products. The main routes of exposure will be dermal, while ocular, oral (during facial use), and inhalation exposures (through the use of spray products) are also possible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 3,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.*	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation*	non mutagenic

* These study reports were not written up in appendix B as an English translation was not provided.

Toxicokinetics, metabolism and distribution

No toxicokinetics, metabolism and distribution studies were submitted for the notified polymer. However, based on the high molecular weight (> 1,000 Da), the estimated low water solubility (< 1 mg/L) and high partition coefficient (log Kow > 4) dermal absorption of the notified polymer is expected to be very low (ECHA 2012).

Acute toxicity

The notified polymer was of low toxicity via the oral and dermal routes.

Irritation and sensitisation

The notified polymer was slightly irritating the skin and eyes of rabbits.

The notified polymer was tested for its dermal sensitisation potential in a Buehler Test conducted following OECD TG 406) (test facility confidential, 1997b). 30 Test animals (20 test and 10 control) were used for the

study. There was no evidence of reactions to the notified polymer indicative of skin sensitisation under the conditions of the test.

Repeated dose Toxicity
Repeated dose toxicity information on the notified polymer was not provided. The notified polymer is of high molecular weight and is unlikely to readily cross biological membranes. This is supported by the lack of systemic toxicity effects in the acute oral and dermal studies. Reports on analogues of the notified polymer also support the expected low systemic toxicity (CIR 1988, 1997 and 2005).

Mutagenicity/Genotoxicity
The notified polymer was non-mutagenic when tested using a Bacterial Reverse Mutation Assay (test facility confidential, 1994). The test was carried out both in the absence and presence of metabolic activation with *Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537 and TA 1538 strains.

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

Transport and Storage
Workers may experience dermal and accidental ocular exposure to the notified polymer up to > 90% concentration in the event of a discharge via spills or drum leakage. The exposure may occur during the handling of raw material for reformulation and/or finished cosmetic products for end-use by general public. The use of proper PPE (impervious gloves, overalls and goggles) should minimize the potential for exposure.

Therefore, provided adequate control measures are in place to minimize worker exposure, including PPE, the risk to workers from use of the notified polymer is not considered unreasonable.

Reformulation
Workers may experience dermal and accidental ocular and perhaps inhalation exposure to the notified polymer (at up to > 90% concentration) during formulation processes. This exposure may occur during handling of the drums, cleaning and/or maintenance of the equipment. At these facilities, exposure may also extend to compounders and laboratory staff involved in the formulation of the end products containing the notified polymer and the sampling and quality control testing of these products. The use of enclosed, automated processes and PPE (impervious gloves, goggles, coveralls and respiratory protection, if significant inhalation exposure is expected) should minimise the potential for exposure.

Therefore, based on the use of measures used to mitigate exposure and the overall low toxicity of the notified chemical, the risk to workers from use of the notified chemical is not considered to be unreasonable.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products to clients (e.g. beauty salon workers) may be exposed to the notified polymer. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, the exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the various cosmetic products containing the notified polymer (for details of the public health risk assessment, see section 6.3.2.).

Based on the information available, the risk to workers associated with use of the notified polymer at ≤ 10% concentration in cosmetic products is not considered to be unreasonable.

6.3.2. Public Health

Members of the public may be repeatedly exposed to the notified polymer at concentrations up to 10% during the use of cosmetic products containing it. The notified polymer is a slight skin and eye irritant, however at the proposed usage concentrations (≤ 10%) skin and eye irritation effects are not expected.

Based on the provided toxicological data and the concentration of the notified polymer to be used in end use cosmetic products, the risk to general public associated with use of the notified polymer at ≤ 10% concentration in cosmetic products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured or reformulated in Australia. It will be imported as a component of finished cosmetics and personal care products. It will be packaged in Australia in containers suitable for retail sale. There is unlikely to be any significant release to the environment from storage and transport, except in the case of accidental spills. Accidental spills are unlikely, given the imported product will be containerised. If spills do occur, the product containing the notified polymer is expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer is a component in rinse-off and leave-on cosmetic products (e.g. lipstick). The formulated product will be applied to body parts and will either be removed with tissues and disposed of to domestic garbage, or washed off the body with ultimate release to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Expired waste and residue of the notified polymer in empty containers (3%) 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 notified polymer is readily biodegradable based on the provided study report (71% in 28 days). The notified polymer is an emulsifier therefore, the experimental Kow and Koc values were not provided. Most of the notified polymer is expected to be released into sewer systems after use. A small amount of the notified polymer may be released to landfill as container residues or spills or thermally decomposed during containers' recycling. In landfill, the notified polymer is not expected to leach given the calculated high adsorption/desorption constant. In sewage treatment plants (STPs), the majority of the notified polymer is expected to be removed by adsorption to sludge sediment and be disposed of to landfill or fields, with a small proportion being released into public waters. In water or soil/landfill, the notified polymer is expected to undergo biotic or abiotic degradation processes, forming water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated assuming a worst case scenario of 100% release of the notified polymer into sewer systems nationwide and no removal from STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100.000%	
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:	0.61	µg/L
PEC - Ocean:	0.06	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 0.61 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 20.2 µg/kg and 40.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Acute		
Fish	96 h LC50 ≥ 100 mg/L	Not toxic to fish
Daphnia Toxicity	48 h EC50 = 64 mg/L	Harmful to aquatic invertebrates
Algal Toxicity	72 h E_rC50 ≥ 100 mg/L	Not toxic to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is not toxic to fish but harmful to aquatic invertebrates and is formally classified as 'Acute Category 3: Harmful to aquatic life. The notified polymer is readily biodegradable and based on its high molecular weight, it is not expected to bioaccumulate. Therefore, the notified polymer has not been formally classified for its long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the acute Daphnia toxicity of the notified polymer and an assessment factor of 100 as measured acute endpoints are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Daphnia).	64	mg/L
Assessment Factor	100	
PNEC:	640	µg/L

7.3. Environmental Risk Assessment

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

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.61	640	0.0009
Q - Ocean:	0.06	640	0.00009

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity. The notified polymer is readily biodegradable and is unlikely to persist in surface waters, soil or air. The calculated log Koc of 16.9 indicates bioaccumulation potential for the notified polymer in aquatic organisms. However, due to low water solubility and higher molecular weight of the notified polymer it is not expected to be bioaccumulative. Therefore, on the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in cosmetic and domestic products, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified Chemical

METHOD: OECD TG 401 Acute Oral Toxicity.
- Species/Strain: Rat/Bor:WISW (SPF TNO)
- Vehicle: Test substance administered as supplied
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	3,000	0/10

- LD50: > 3,000 mg/kg bw
- Signs of Toxicity: None
- Effects in Organs: None
- Remarks - Results: All animals showed expected bodyweight gains. Dissection at the end the study revealed no evidence of macroscopically detectable organ changes.

CONCLUSION: The notified polymer is of low toxicity via the oral route.

TEST FACILITY: Confidential (1987a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified Chemical

METHOD: OECD TG 402 Acute Dermal Toxicity – Limit Test.
- Species/Strain: Rat/Wistar (Hsd/Win:WU/SPF)
- Vehicle: Test substance administered as supplied
- Type of dressing: Semi-occlusive.
- Remarks - Method: No significant protocol deviations.

RESULTS

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

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity - Local: Scab formation was noted in 2 female rats on day 3 and 4, there were no other signs of irritation.
- Signs of Toxicity - Systemic: There were no deaths or test-substance related clinical signs. On the day 7 observation, 2 female rats showed a minimal loss of weight, two female rats showed minimal body weight gain, and the remaining female rat showed the expected body weight gain. The study authors stated that variation of body weight gain in that age of rat is a physiological finding and not substance related.
- Effects in Organs: No abnormalities were noted at necropsy.
- Remarks - Results: All male animals showed expected bodyweight gains, and no signs of local and systemic toxicity.

CONCLUSION: The notified polymer is of low toxicity via the dermal route.

TEST FACILITY: Confidential (1997a)

B.3. Irritation – skin

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/Small White Russian, Chbb-SPF
Number of Animals 3
Vehicle Test substance administered as supplied
Observation Period 8 days
Type of Dressing Occlusive.
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.00	0.67	1.33	2	< 6 days	0
Oedema	0	0	0	0	–	0

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

Remarks - Results Very slight erythema was noted in all treated sites one hour after patch removal and was evident till the 72 hour observation period. All erythema had resolved by the 6 days observation.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Confidential (1987b)

B.4. Irritation – eye

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/Small White Russian, Chbb-SPF
Number of Animals 3
Observation Period 6 days
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.33	0	0	1	< 48 h	0
Conjunctiva: chemosis	0	0	0	0	–	0
Conjunctiva: discharge	0	0	0	2	< 24 h	0
Corneal opacity	0	0	0	0	–	0
Iridial inflammation	0	0	0	0	–	0

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

Remarks - Results Conjunctival redness was observed in all treated eyes 1 hour after application of the test substance which lasted for 24 hours in one eye.
No iridal inflammation or corneal opacity was noted.

CONCLUSION The notified polymer is slightly-irritating to the eye.

TEST FACILITY Confidential (1987c)

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
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles. Two blank controls with inoculums but without any test substance were run in parallel to determine the amount of CO_2 derived from the inoculums.

RESULTS

Test substance		*Sodiumbenzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	7	3	3
7	40	7	24
14	68	14	37
23	73	23	61
28	75	28	65
29	78	29	65

Remarks - Results	The degree of degradation of the notified polymer after the cultivation period was 71% and it reached the pass level within the "10-day window". Therefore, the notified polymer is classified as readily biodegradable according to the OECD (301) guideline.
CONCLUSION	The notified polymer is readily biodegradable.
TEST FACILITY	Confidential (2001)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	Acute Toxicity 96 h, according to 92/96 EEC Semi-static.
Species	Brachydanio rerio
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	12.9 ºdH
Analytical Monitoring	Dissolved Oxygen Concentration (DOC) measurement
Remarks – Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		10	0	0	0	0	0
100	108	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC (or LOEC)	100 mg/L at 96 hours.
Remarks – Results	The concentration of the test substance at the beginning of reach removal period was in good agreement with the nominal value. Additionally, the test substance proved to be stable over 24 hours. Therefore, the nominal value was used for the calculation.
CONCLUSION	The notified polymer is not harmful to fish.
TEST FACILITY	Confidential (1993)

BIBLIOGRAPHY

CIR (1988) Final Report on the Safety Assessment of Glyceryl Riconoleate. J.Amer. Coll. of Toxicol. 7(6) 721-739 1988. Cosmetic Ingredient Review Expert Panel Meeting, 1100 17th Street NW Suite 412, Washington D.C. 20036-4702 USA. 1988.

CIR (1997) Final Report on the Safety Assessment of PEG-30, -33, -35, -36 and -40 Castor Oil and PEG-30 and -40 Hydrogenated Castor Oil. Int. J. Toxicol. 16(S3) 269-306 1997. Cosmetic Ingredient Review Expert Panel Meeting, 1100 17th Street NW Suite 412, Washington D.C. 20036-4702 USA. 1997.

CIR (2005) Final Report on the Safety Assessment of Ricinus Communis (Castor) Seed Oil, Hydrogenated Castor Oil, Glyceryl Ricnoleate, Glyceryl Ricinoleate SE, Ricinoleic Acid, Potassium Ricinoleate, Sodium Ricinoleate, Zinc Ricinoleate, Cetyl Ricinoleate, Ethyl Ricinoleate, Glycol Ricinoleate, Isopropyl Ricinoleate, Methyl Ricinoleate and Octyldodecyl Ricinoleate. Int. J. Toxicol. 26(S3) 31-77 2005. Cosmetic Ingredient Review Expert Panel Meeting, 1100 17th Street NW Suite 412, Washington D.C. 20036-4702 USA. 2007.

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

QSAR (2014) QSAR Programme: EPI Suite EPIwin Version 4.10. QSAR Data: PEG-18 Castor Oil Dioleate. Office of Pollution Prevention and Toxic Substances of the United States Environmental Protection Agency, and Syracus Research Corporation, USA, 6 April 2014.

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 >.