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September 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

1,2,4-Benzenetricarboxylic acid, 1,2,4-tritridecyl ester (INCI name: Tridecyl Trimellitate)

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
LTD/1654	L'Oreal Australia Pty Ltd	1,2,4-Benzenetricarboxylic acid, 1,2,4-tritridecyl ester (INCI name: Tridecyl Trimellitate)	ND*	≤ 1 tonne per annum	Component of cosmetic products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical 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).

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 at ≤ 40% (in foundation, lipstick, eye shadow and eyeliner) and ≤ 9% (in hand and face cream), the notified chemical 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 chemical 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 chemical:
  - Closed systems for blending, when available

- 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 chemical:
  - 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 the notified chemical
  - goggles
  - coveralls
  - 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.

Disposal

- The notified chemical should be disposed of to landfill.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the notified chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical;
- the concentration of the chemical exceeds or is intended to exceed:
  - 40% in foundation, lipstick, eye shadow and eyeliner, or
  - 9% in hand and face cream;
- additional information becomes available on the repeated dose toxicity of the notified chemical;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component in cosmetic products or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical 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 chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less 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 as follows: all physical-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Liponate TDTM

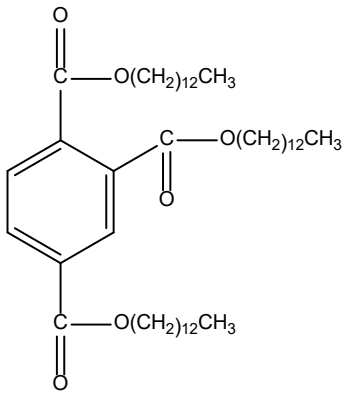
CAS NUMBER
94109-09-8

CHEMICAL NAME
1,2,4-Benzenetricarboxylic acid, 1,2,4 tritridecyl ester

OTHER NAME(S)
1,2,4-Benzenetricarboxylic acid, tritridecyl ester
Tridecyl Trimellitate (INCI name)
Liponate MOS-70 (containing up to 20% notified chemical)

MOLECULAR FORMULA
$C_{48}H_{84}O_6$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
757 Da

ANALYTICAL DATA
Reference IR and GLC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 99.97%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Isodecanol	< 0.03%
Tridecanol	< 0.03%

ADDITIVES/ADJUVANTS
None

4. IDENTITY OF ANALOGUE

CAS NUMBER
3319-31-1

CHEMICAL NAME
Tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate

OTHER NAMES
Triethylhexyl trimellitate (INCI name)

JUSTIFICATION
The analogue, tris (2-ethylhexyl)benzene-1,2,4-tricarboxylate (CAS: 3319-31-1) is considered an acceptable analogue based on structure and properties. The analogue is structurally similar to the notified chemical, with the exception of the alkyl chains. For the analogue, these chains are relatively short and branched, whereas those of the notified chemical are longer and linear. In addition, the analogue contains an ethyl hexyl group, which is absent in the notified chemical. Based on structure, the analogue data are expected to generally represent the physicochemical and health concerns of the notified chemical with worst case scenario for reproductive effects due to the ethyl hexyl moiety.

5. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless to slightly yellow viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Notified chemical is a liquid at room temperature
Boiling Point	> 400 °C at 101.3 kPa	(M)SDS*
Density	963 kg/m^3 at 15.6 °C	(M)SDS*
Vapour Pressure	1.08 x 10^{-18} kPa at 25 °C	Measured (modified Grain method) (QSAR)
Water Solubility	< 0.13 mg/L at 25 °C	Analogue data (OECD 2002)
Hydrolysis as a Function of pH	$t_{1/2}$ = 17.5 days (pH 7) $t_{1/2}$ = 11.9 days (pH 9)	Analogue data (OECD 2002)
Partition Coefficient (n-octanol/water)	log Pow > 5.94 at 25 °C	Analogue data (OECD 2002)
Adsorption/Desorption	log K_{oc} = 11.40 at 25 °C	Calculated (KOCWIN v2.00; US EPA 2011)
Dissociation Constant	Not determined	Not expected to dissociate under environmental conditions (pH 4-9) due to absence of dissociable functional groups.
Flash Point	277 °C (closed cup)	(M)SDS*
Flammability	Not determined	Not expected to be highly flammable based on flash point
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

*(M)SDS for neat notified chemical.

DISCUSSION OF PROPERTIES

Reactivity

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

Based on the submitted physico-chemical data depicted in the above table, the notified chemical 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.

6. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported into Australia as a component of finished cosmetic products (up to 40% concentration). In the future, the notified chemical may be imported neat for subsequent reformulation processes into cosmetic products.

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

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

PORT OF ENTRY

Melbourne and Sydney.

TRANSPORTATION AND PACKAGING

The notified chemical as a component (up to 40%) of finished cosmetic products will be imported in containers suitable for retail sale (up to 500 mL capacity) in either bottles or tubes. When imported at up to 100%, the notified chemical will be imported in 200 kg steel drums for distribution to reformulation sites. The containers will be circulated to distribution centres/reformulation sites and retail outlets within Australia by road.

USE

The notified chemical will be used as a component of leave-on cosmetic products ≤ 40% (in foundation, lipstick/lip gloss, eye shadow and eyeliner) and ≤ 9% (in hand and face cream).

OPERATION DESCRIPTION

The notified chemical is primarily intended to be imported as a component of finished cosmetic products. If reformulation processes are to occur in the future, the procedures for incorporating the notified chemical into end-use products will likely vary depending on the nature of the cosmetic product and may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be automated and occur in a fully enclosed environment, followed by automated filling into containers.

The finished cosmetic products containing the notified chemical may be used by consumers and professionals, such as workers in beauty salons. Application of products could be by hand or through the use of an applicator.

7. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

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

Chemist	3	12
Packers (Dispensing and Capping)	8	12
Salon Professionals	Unspecified	Unspecified
Cleaners	Unspecified	Unspecified

EXPOSURE DETAILS
Transportation and storage workers will only be exposed to the notified chemical (at 100% concentration) or to end use products (≤ 40% concentration) in the unlikely event of an accident.

During cosmetic formulation processes, including quality control, transfer, and cleaning and maintenance tasks, dermal and accidental ocular exposure may occur. Exposure is expected to be minimised by the use of local ventilation systems and personal protective equipment (PPE), including coveralls, goggles and impervious gloves. Due to the estimated low vapour pressure of the notified chemical, inhalation exposure is not expected.

Exposure of workers to the notified chemical in end-use products may occur in professions where the services provided involve the application of cosmetic products to clients (e.g., workers in beauty salons). Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical (≤ 40% concentration) through the use of cosmetic products. The main routes of exposure will be dermal and oral (through the use of lip products), with accidental ocular exposure also possible. Inhalation exposure is not expected based on the use pattern and estimated low vapour pressure of the notified chemical.

Data on typical use patterns of cosmetic product categories in which the notified chemical may be used are shown in the following table (SCCS, 2012). For these product categories, exposure is through the dermal route. Based on the molecular weight >500 and the expected high log Kow of the notified chemical, a dermal absorption of 10% was assumed for calculation purposes (ECHA, 2008).

Cosmetic products (Dermal exposure):

Product type	**Amount** (mg/day)	**C** (%)	**RF** (unitless)	**Daily systemic exposure** (mg/kg bw/day)
Foundation	510	40	1	0.340
Eye shadow	20	40	1	0.013
Eye liner	5	40	1	0.003
Face cream	1540	9	1	0.231
Hand cream	2160	9	1	0.324
Total				0.912

C = concentration (%); RF = retention factor.
Daily systemic exposure = (Amount × C × RF × dermal absorption)/body weight

The notified chemical is also proposed to be used in lipstick/gloss products. For these, exposure is through the oral route. The data is shown below (SCCS, 2012). A conservative 100% ingestion rate was assumed for calculation purposes.

Cosmetic products (Oral exposure):

Product type	**Amount** (mg/day)	**C** (%)	**Daily systemic exposure** (mg/kg bw/day)
Lipstick/gloss	57	40	0.380

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the notified chemical. This would result in a combined internal dose of 1.292 mg/kg bw/day.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD_{50} 5000 mg/kg bw; low toxicity
Rabbit, skin irritation (10%)	slightly irritating
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Rabbit, eye irritation (10%, mixture with other chemicals)	slightly irritating
Mouse, skin sensitisation – Local lymph node assay (100%)	no evidence of sensitisation
Human, skin sensitisation – HRIPT (100%)	no evidence of irritation or sensitisation
Repeat dose toxicity*	NOAEL = 100 mg/kg bw

*Data on analogue chemical

As no data were supplied on the notified chemical for several endpoints, information on the potential adverse health effects of the notified chemical have been supplemented with information on the analogue chemical published in an OECD SIDS Assessment report (SIDS 2002).

Toxicokinetics, metabolism and distribution.

The relatively high molecular weight of the notified chemical (757 Da), low water solubility (< 0.13 mg/L) and high logP value (> 5.94) indicate that the notified chemical will have limited absorption capacity through skin and the GI tract.

Acute toxicity.

The acute oral toxicity of the notified chemical was found to be low in a gavage rat study, where an LD_{50} of 5000 mg/kg bw/day was found in a limit test. The analogue chemical was also found to be of similar low toxicity: it showed no signs of toxicity in rats at 2000 mg/kg bw, via the oral route, or in rabbits at 2 mL/kg, via the dermal route (SIDS 2002).

Irritation and sensitisation.

The notified chemical was found to be slightly irritating or non-irritating to the skin of rabbits in two studies, one of which was carried out at 10% concentration in corn oil. However, at least one of the studies was not conducted according to an appropriate OECD guideline, with the notified chemical in contact with the skin for 24 hrs (rather than 4 h in OECD method). Skin irritation was not seen in the human repeated insult patch test (HRIPT).

The notified chemical was found to be slightly irritating to the eyes of rabbits in one study on the chemical itself, and in a mixture containing <20% of the notified chemical, diluted to 10% concentration in corn oil.

The notified chemical was not a skin sensitiser in a LLNA study or in a human repeated insult patch test.

Repeated Dose Toxicity.

In a reproductive/developmental screening study to OECD guidelines, rats were administered the analogue tris (2-ethylhexyl)benzene-1,2,4-tricarboxylate (CAS: 3319-31-1, SIDS 2002) at doses of 100, 300 and 1,000 mg/kg bw/day. Decreases in spermatocytes and spermatids in males were observed in the 300 and 1,000 mg/kg bw/day as a result of histopathological examination.

No effects on the general appearance, body weight, food consumption, autopsy findings or weights of reproductive organs of either sex, or on the histopathological features of the ovary of females, were detected.

Based on testicular toxicity, the NOAEL for repeated dose toxicity is considered to be 100 mg/kg bw/day.

Mutagenicity/Genotoxicity.

The genotoxicity of tris (2-ethylhexyl)benzene-1,2,4-tricarboxylate (CAS: 3319-31-1, SIDS 2002) was evaluated in many *in vitro* assay systems. The analogue chemical was non mutagenic in bacteria and non clastogenic in mammalian cells.

Health hazard classification
Based on the limited toxicity data provided, the notified chemical 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).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Blending
Dermal and ocular exposure of workers to the notified chemical (at 100% concentration) will occur during reformulation processes. Given that the exposure of workers is expected to be minimised through the use of automated processes, ventilated environments and wearing of PPE, 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 containing the notified chemical (at ≤ 40% concentration) to clients (e.g. beauty salon workers) may be exposed to the notified chemical. The risk to these workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical (for details of the public health risk assessment, see Section 6.3.2.).

6.3.2. Public Health

At the proposed usage concentration of ≤ 40% (in foundation, lipstick, eye shadow and eyeliner) and ≤ 9% (in hand and face cream) of the notified chemical in leave-on cosmetic products, acute toxicity effects are not expected. Based on available information, the risk of the notified chemical related to skin and eye irritation cannot be ruled out.

The repeat dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the notified chemical using the worst case exposure scenario from use of multiple products of 1.292 mg/kg bw/day (see Section 6.1.2) and the NOAEL of 100 mg/kg bw/day, which was established for repeated dose toxicity in a reproductive/developmental screening study on the analogue chemical. Using the abovementioned NOAEL, a MoE of 77 was estimated. In general, a MoE value ≥ 100 is considered acceptable to account for intra- and inter-species differences. However, it is noted that the cumulative exposure calculations are conservative relative to the NOAEL, which is based on testicular toxicity. In addition, both oral and dermal absorption of the notified chemical are expected to be lower than that of the analogue, on which the NOAEL is based. Overall, based on the available information, the risk to the public from use of the notified chemical at ≤ 40% in foundation, lipstick, eye shadow and eyeliner, and ≤ 9% in hand and face cream, 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 chemical will be imported as a component of finished cosmetic products and may 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 chemical in empty import containers are expected to be disposed of to landfill. Some of the notified chemical may be released to sewer during equipment cleaning where reformulation activities take place.

RELEASE OF CHEMICAL FROM USE

The notified chemical is a component of cosmetic products typically in foundation, lipstick, lip gloss formulations, eye shadow, eye liner, hand and face cream. It is expected that the majority of the imported quantity of notified chemical will eventually be washed off the skin and released to sewer. Alternatively, some of the notified chemical may be physically removed and disposed of to landfill, or ingested by the user.

RELEASE OF CHEMICAL FROM DISPOSAL

Residue of the notified chemical 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 chemical is expected to be released to sewer during use in cosmetic products. The notified chemical is hydrophobic, and therefore during waste water treatment processes in sewage treatment plants (STPs) a proportion of the notified chemical is expected to partition to sludge. The notified chemical that partitions to sludge will be removed with the sludge for disposal to landfill or used on land for soil remediation. The remaining quantity of the notified chemical is likely to remain in waste water and be released to surface waters. The analogue is less hydrophobic than the notified chemical, and therefore analogue data may underestimate the potential for the notified chemical to bioaccumulate. However, based on analogue data and calculated QSAR data (US EPA, 2011), the notified chemical is not expected to bioaccumulate. Although analogue data suggest that the notified chemical should not be expected to be readily biodegradable, calculated QSAR data predicts that the notified chemical will be readily biodegradable. The branched structure of the analogue may limit the bioavailability of the compound for biodegradation, and therefore may not be representative of the biodegradability of the notified chemical. Based on analogue data, the notified chemical is expected to undergo hydrolysis between pH 7-9, but not at pH 4. As both the analogue and notified chemical share identical functional groups for the purposes of hydrolysis, these data are considered highly representative. Ultimately, the notified chemical is expected to degrade via biotic and abiotic processes in soil and surface waters to form water and oxides of carbon.

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 uses in cosmetic products, it is assumed that 100% of the notified chemical will be released to sewer on a nationwide basis over 365 days per year. It is also assumed that under a worst-case scenario that there is no removal of the notified chemical during STP processes.

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%	
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:	0.061	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 chemical 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 0.606 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical 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

No ecotoxicity data were submitted for the notified chemical. The results from ecotoxicological investigations conducted on an analogue of the notified chemical were available in an internationally peer reviewed document (OECD, 2002) and are summarised in the table below. The analogue and notified chemical are expected to differ in hydrophobicity, and therefore analogue data may not give a highly accurate representation of the hazard posed by the notified chemical. However, any toxicity of the notified chemical is not expected to differ so significantly from that of the analogue as to alter the outcome of the assessment conclusion.

Endpoint	*Result*	*Assessment Conclusion*
Acute Toxicity		
Fish Toxicity (96 h)	LC50 > 100 mg/L	Not harmful to fish
Fish Toxicity (14 d)	LC50 > 75 mg/L	Not expected to be harmful to fish
Daphnia Toxicity (48 h)	EC50 > 180 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity (72 h)	EC50 > 100 mg/L	Not harmful to algae
Chronic Toxicity		
Daphnia Toxicity (21 d)	NOEC = 55.6 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity (72 h)	NOEC > 100 mg/L	Not harmful to algae

All studies were conducted using solubilisers, and therefore test concentrations do not represent realistic environmental concentrations. Although the analogue was found to have some long term effects to aquatic invertebrates, it is not expected to be harmful at the limit of solubility. Further, calculated QSAR data predicts that the notified chemical has no toxicological effects at the limit of solubility (US EPA, 2011). Therefore, the notified chemical is not expected to be harmful at the limit of solubility, and is not be formally classified under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

No toxicity effects are to be expected at the limit of solubility for the notified chemical, and therefore the predicted no-effect concentration (PNEC) cannot be calculated.

7.3. Environmental Risk Assessment

As no toxicity effects are to be expected at the limit of solubility for the notified chemical, the predicted no-effect concentration (PNEC) cannot be calculated. The notified chemical is not expected to pose an unreasonable risk to the environment based on its assessed use pattern.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	Equivalent to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Wistar derived albino rats
Vehicle	N/A
Remarks - Method	18-24 hours prior to dosing the rats were fasted. The test material was delivered by gavage at a dose level of 5.0 g/kg body weight. The rats were observed for mortality or other signs of gross toxicity for 14 days.

RESULTS

Group #	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M, 5F	5000	None

LD50	> 5000 mg/kg bw
Signs of Toxicity	No signs of toxicity.
Effects in Organs	No effect.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Consumer Product Testing (1984)

B.2. Irritation – skin (in vivo) (1)

TEST SUBSTANCE	Notified chemical (10%))
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 (sex not specified)
Vehicle	Corn oil
Observation Period	72 h
Type of Dressing	Occlusive
Remarks - Method	The test period was 24h, rather than 4h as in the OECD protocol. Readings were not taken at 1h or 48 h. Each rabbit received a single dermal application of 0.5 mL of the notified polymer on two test sites, one abraded and one intact. The test sites were occluded. After 24 h, the remaining test material was wiped from the skin, and the test sites observed individually for erythema, edema and any other effects at 24 and 72 hours.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	Intact: 0.25	1	<72 hrs	0
	Abraded: 0.5	1		
Oedema	Intact: 0	0	-	0
	Abraded: 0	0		

*Calculated on the basis of the scores at 24 and 72 hours only for ALL animals.

Remarks - Results	For intact skin, slight erythema was seen in one animal at 24 h but had resolved by 72 h.
CONCLUSION	The notified chemical is slightly irritating to the skin.

TEST FACILITY Consumer Product Testing Inc (1986)

B.3. Irritation – skin (in vivo) (2)

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Vehicle	-
Observation Period	7 days
Type of Dressing	Not stated
Remarks - Method	Tabular summary only provided, and the test period was not specified.
Remarks - Results	No erythema or oedema was observed at the 24, 48 or 72 h observations.

CONCLUSION The notified chemical was non-irritating to the skin under the conditions of the study.

TEST FACILITY Cosmeer (1995)

B.4. Irritation – eye (1)

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	
Observation Period	
Remarks - Method	Tabular summary only provided. Observation period was 7 days.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctival effects	0.3	0.3	0.7	4	< 72 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 effects were not distinguished as redness, chemosis or discharge. Severe conjunctival effects were seen at 1 h, which had reduced to slight effects at 24 h, and resolved by 72 h in all animals.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Cosmeer (1995)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain	CBA/J mouse
Vehicle	Mixture acetone/olive oil
Remarks - Method	The test substance was tested in two independent experiments, both on 28 female mice allocated to 7 groups of 4 animals. Test concentrations were 5, 10, 25, 50 and 100%. A positive control group (4 animals) receiving α-hexylcinnamaldehyde (HCA), a moderate sensitiser, at the concentration of 25% in MEK was run in parallel.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*	
Test Substance		1st experiment	2nd experiment
5	No	1.98	0.80
10	Yes (exp 1 only)	3.42	0.94
25	No	1.65	1.19
50	No	2.68	1.50
100	Yes (exp 1 only)	3.62	1.22
Positive Control (25%)		10.01	5.42

Remarks - Results	No mortality and no clinical signs were observed during the study. No cutaneous reactions and no increase in ear thickness were observed in the animals of the treated groups. A stimulation index slightly exceeding the threshold of 3 was noted at the concentration of 10% and 100% in experiment 1, In the repeat experiment, the stimulation index was <3 at all dose levels. Overall the test substance is not considered sensitising. The positive control tested performed as expected in both experiments, confirming the validity of the test system.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	CiTox Lab France (2012)

B.6. Human repeated insult patch test (HRIPT)

TEST SUBSTANCE	Notified chemical
METHOD	Repeated insult patch test with challenge
Study Design	Induction Procedure: 0.2 mL of the notified chemical was applied to the back of each subject between the scapulae and waist adjacent to the spinal mid-line. This procedure was performed Monday, Wednesday and Friday until 9 applications of the test article had been made. Subjects removed the patches 24 hours after each application. Rest Period: 14 days Challenge Procedure: challenge patch applied to a previously unpatched (virgin) test site. The site was scored 24 and 72 h after application.
Study Group	48F, 9M; age range 18-76 years
Vehicle	N/A
Remarks - Method	Occluded. The test substance was spread on a Parke-Davis Readi-Bandage® patch.
RESULTS	
Remarks - Results	51/57 subjects satisfactorily completed the test procedure. 5/57 subjects discontinued for personal reasons unrelated to the conduct of the study. 1/57 test panellist was discontinued due to violation of the protocol; the subject was taking concomitant medication.

	There was no skin reactivity observed at any time during the course of the study.
CONCLUSION	The notified chemical was non-sensitising and non-irritating under the conditions of the test.
TEST FACILITY	Essex Testing Clinic, Inc (2006)

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