File No: LTD/1749

January 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Sal, ext.
(INCI name: Shorea Robusta Seed Butter)

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:

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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/1749	L'Oreal Australia Pty Ltd	Sal, ext. (INCI name: Shorea Robusta Seed Butter)	ND*	≤1 tonne per annum	Cosmetic ingredient

*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 in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
Based on its assessed 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 safe work practices to minimise occupational exposure during formulation and handling of the notified chemical as introduced:
  - Avoid skin and eye contact

- 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 as introduced:
  - safety glasses
  - gloves
  - coverall

  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 chemical 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 chemical 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 chemical 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 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 in cosmetic products is intended to exceed 10%;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of cosmetics, or is likely to change 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 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(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)
Data items and details claimed exempt from publication: use details, site of manufacture/reformulation and identity of manufacturer/recipients.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Shorea Robusta Seed Butter (INCI name)

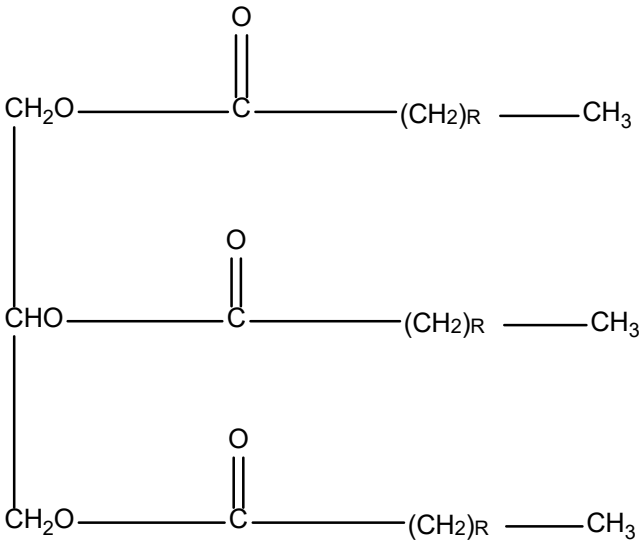
CAS NUMBER
91770-61-5

CHEMICAL NAME
Sal, ext.

OTHER NAME(S)
Shorea Robusta Seed Extract
Sal Butter
Beurre de Sale

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



R = 14 to 20 (some chain variants contain unsaturation. See fatty acid distribution below.)

SHOREA ROBUSTA SEED BUTTER- FATTY ACID DISTRIBUTION

FATTY ACID	CAS NO.	TRADE/ COMMON NAME	SPECIFICATION %
Hexadecanioc acid	57-10-3	Palmitic Acid	4.5-7.0
Octadecanoic acid	57-11-4	Stearic Acid	41.0-50.0
9-Octadecenoic acid (9Z)-	112-80-1	Oleic Acid	38.0-43.0
9,12-Octadecadienoic acid (9Z,12Z)-	60-33-3	Linoleic Acid	0.5-2.5
Eicosanoic acid	506-30-9	Arachidic Acid	5.0-10.0
Docosanoic acid	112-85-6	Behenic Acid	<0.8

MOLECULAR WEIGHT
Range 807 - 1060 Da

ANALYTICAL DATA
Reference IR spectra was provided.

Identity of Analogues:

Analogues	Analogue Name	CAS NO.	TRADE/ COMMON NAME
1	Octadecanoic acid	57-11-4	Stearic Acid
2	9-Octadecenoic acid (9Z)-	112-80-1	Oleic Acid

3. COMPOSITION

DEGREE OF PURITY
>99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Heavy metals < 20 ppm

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

Chemical Name	Hexane		
CAS No.	110-54-3	*Weight %*	Not detectable

ADDITIVES/ADJUVANTS

Chemical Name	Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, 1,1'-[2,2-bis[[3-[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-1-oxopropoxy]methyl]-1,3-propanediyl] ester		
CAS No.	6683-19-8	*Weight %*	0.04%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brownish solid paste

Property	Value	Data Source/Justification
Melting Point/Freezing Point	31 °C	(M)SDS
Boiling Point	>300 °C at 101.3 kPa	(M)SDS (at approximately 300 °C the chemical decomposes)
Density	890 kg/m3 at 20°C	(M)SDS
Vapour Pressure	<1 kPa at 20°C	(M)SDS
Water Solubility	5.6 x 10^{-4} g/L at 25 °C	Analogue 1&2 (IUCLID, 2003& 2006).
Hydrolysis as a Function of pH	Not determined	The notified chemical contains functional group that are expected to hydrolyse slowly in the environmental pH range (4-9) at ambient temperature.
Partition Coefficient (n-octanol/water)	log Pow = 8.42 at 25 °C	Analogue 1&2 (IUCLID, 2003& 2006).
Adsorption/Desorption	log K_{oc} = 4.7	Calculated (using KOCWIN v2.00; US EPA, 2009)
Dissociation Constant	Not Determined	Expected to have a pKa of ~ 4.5.
Particle Size	Not determined	Product is a solid paste.
Flash Point	>250 °C (closed cup)	(M)SDS
Solid Flammability	Not determined	Not expected to be flammable based on flash point.
Autoignition Temperature	Not determined	Expected to be high, based on flash point.
Explosive Properties	Not determined	Contains no structural alerts for explosive properties.
Oxidising Properties	Not determined	Contains no structural alerts for oxidising properties

Reactivity
The notified chemical 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 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.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured within Australia. The notified chemical will be imported into Australia either in neat form or already blended in finished 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

IDENTITY OF MANUFACTURER/RECIPIENTS
L'Oreal Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical or products containing the notified chemical at up to 10% will be imported into Australia by sea in containers. The containers will be transported from the wharf to distribution centres then to retailer warehouses.

USE
The notified chemical will be used as an ingredient in cosmetic products at up to 10% concentrations. The product types which the chemical will be used include lip products, eye area products, leave on and rinse off skin products and hair spray products.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. It will be imported into Australia neat or already blended in finished cosmetic products.

Dockside and warehouse workers will transport the raw and finished products from the wharf to the central distribution centres and place the pallets of products into the warehouse. Warehouse workers will be involved in transferring pallets in the central warehouse and operating a picking operation for stock to Distributors at the retailer's central distribution depots.

During the formulation process, quantities of the raw material and finished products will be sampled and tested by a chemist for QA purposes.

Production compounders will weigh an appropriate amount of the raw material into a separate container then add the amount directly into a flame proof mixing tank. Mixing and dispensing will be carried out in a closed system with flame proof mixers and pumps designed not to create aerosols or a dust hazard and earthed for static discharges.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing & Capping)	8	12
Store Persons	4	12
End Users	8	365

EXPOSURE DETAILS
Transport and storage
Dockside and warehouse workers are not expected to have any contact with the notified chemical, which is contained in sealed packages, except in the case of spills.

Reformulation
During the formulation process, the chemists may come into an accidental skin or eye contact with the notified chemical during sampling and testing for QA purposes. Workers involved in mixing and dispensing (compounders) may experience dermal, ocular and inhalation exposure from drips, spills, splashes and vapour when weighing the material and adding to mixing tanks. Workers are expected to use safety glasses with shields, gloves, apron or coverall during formulation process. Adequate ventilation and appropriately located exhaust hoods will be also used in the workplace.

End-use
Exposure to the notified chemical in end-use 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 this is not expected to occur in all workplaces. 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 chemical.

6.1.2. Public Exposure
Public exposure to the notified chemical is expected to be widespread and frequent through daily use of personal care products containing the notified chemical at concentrations up to 10%. Exposure to the notified chemical will vary depending on individual use patterns. The principal route of exposure will be dermal. Ocular and inhalation exposure may also occur. Accidental ingestion from the facial use of cosmetic products containing the notified chemical is also possible.

Exposure can be calculated using data on typical use patterns of cosmetic product categories in which the notified chemical may be used (SCCS, 2012; Cadby et al., 2002). For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. An adult bodyweight of 60 kg was used for calculation purposes.

Based on the relatively high molecular weight (>807 Da) and the estimated high partition coefficient log Pow value (8.42 for the analogue), a dermal absorption of 10% was assumed for the notified chemical (ECHA, 2012; Kroes, 2007).

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products that contain the notified chemical. This would result in a combined internal dose of 6.5 mg/kg bw/day.

6.2. Human Health Effects Assessment

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

Endpoint	*Chemical*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Analogue 1	LD50 > 4600 mg/kg bw; low toxicity
Rat, acute dermal toxicity	Analogue 2	LD50 > 3000 mg/kg bw; low toxicity
Rabbit, Skin irritation	Notified chemical	slightly irritating
Rabbit, Repeated dose (6 weeks) skin irritation	Notified chemical	slightly irritating
Rabbit, eye irritation	Notified chemical	slightly irritating
Guinea pig, skin sensitisation (adjuvant test)	Notified chemical	no evidence of sensitisation
Skin phototoxicity and photoallergy	Notified chemical	Not phototoxic or photoallergic
Rat, repeat dose oral toxicity – 24 weeks.	Analogue 2	LOAEL 7500 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	Analogue 1	non mutagenic
Mutagenicity – bacterial reverse mutation	Analogue 2	non mutagenic

Toxicokinetics, metabolism and distribution.

The notified chemical has a relatively high molecular weight (>807 Da). However its estimated high partition coefficient log Pow value (8.42 for the analogue) is expected to limit the potential for the chemical to be absorbed via the dermal route (ECHA, 2012; Kroes, 2007).

Acute toxicity.
No acute oral, dermal or inhalation toxicity data for the notified chemical were provided. However, information on expected metabolites analogues 1 & 2 indicated high oral and dermal LD50s (>4600 and >3000 mg/kg bw, respectively). Information is not available on acute inhalation toxicity.

Irritation and sensitisation.
The notified chemical was found to be slightly irritating to the skin (single and repeat application) and eye of rabbits and not a skin sensitiser in the guinea pig.

In a study in guinea pigs the notified chemical did not have phototoxic or photo-allergic effects on the skin.

Repeated dose toxicity.
No data on repeated dose toxicity for the notified chemical were provided. Information is available on the repeated dose toxicity of Analogues 1 and 2, which are expected metabolites of the notified chemical.

Several fatty acids including stearic acid (analogue 1), oleic acid (analogue 2) and sodium palmitate are listed as Generally Recognised as Safe (GRAS) by the U.S. Food and Drug Administration (FDA, 2013). Stearic acid is also included by the Council of Europe (1974), at a level of 4000 ppm, in the list of artificial flavouring substances that may be added to foodstuffs without hazard to public health.

In a sub-chronic fertility study, Sprague-Dawley rats (4-7/sex/dose group) were orally fed with 15% oleic acid (equivalent to 7500 mg/kg bw/day) (analogue 2) in the diet for 10-16 weeks. No adverse effects on growth or general health were observed. All animals showed a normal rate of gain in body weight and appeared normal except for the reproductive capacity of females. Post mortem examination showed no lesions in other organs than those of reproduction. No impairment of male rats' fertility was also observed. Mammary development was markedly reduced. The study authors set the LOAEL for sub-chronic toxicity for male and female rats at 7500 mg/kg bw/day (IUCLID, 2006). In the absence of information, a NOAEL of 750 mg/kg bw/day is calculated from the LOAEL by applying an uncertainty factor of 10 (HERA,2002).

Mutagenicity/Genotoxicity.
No data on genotoxicity for the notified chemical were provided. However, analogues 1 and 2 were negative in Ames tests and analogue 2 was also negative in Saccharomyces cerevisiae and in DNA and damage repair assays using Bacillus subtilis (HSDB (2014); CIR (1987) and BIBRA, 1986; IUCLID, 2000).

Health 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).

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 chemical (at up to 100% concentration) during transport or storage.

Reformulation
Workers may experience dermal, ocular and inhalation exposure to the neat notified chemical during formulation processes. This exposure may occur during handling of the chemical, cleaning and/or maintenance of the equipment. Exposure may also extend to compounders and laboratory staff involved in the formulation of the end products containing the notified chemical and the sampling and quality control testing of these products.

The use of enclosed process and PPE (safety glasses with shields, gloves, apron or coverall), and adequate ventilation and appropriately located exhaust hoods if significant inhalation exposure is expected) is expected to be used during formulation processes.

Based on the use of measures used to mitigate exposure and the overall low toxicity of the notified chemical, the risk to workers from transport/storage and 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 to clients (*e.g.*, hairdressers and 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.

Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. For hairdressing salons, good ventilation would be recommended if hair spray is routinely used in a confined space. 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 chemical. Based on the information available, the risk to workers associated with use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
Members of the public will experience widespread and frequent exposure to the notified chemical through daily use of cosmetic products (at up to 10%).

The potential systemic exposure to the public from the use of the notified chemical in cosmetic products was estimated to be 6.59 mg/kg bw/day. Using a NO(A)EL of 750 mg/kg bw/day, which was derived from a repeated dose toxicity study on the analogue (2) chemical, the margin of exposure (MOE) was estimated to be 114. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences, therefore, the MOE is considered to be acceptable.

Based on the available toxicity data, the notified chemical is not considered to pose an unreasonable risk to public health at concentrations up to 10% in cosmetic products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure
RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. It will be imported neat or as a component of finished cosmetics and personal care products. 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 chemical is expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The notified chemical is a component in rinse-off and leave-on cosmetic products. 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
Expected levels of residue of the notified chemical in the 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 majority of the notified chemical is expected to be released to sewer during use in cosmetic products. During waste water treatment processes in sewage treatment plants (STPs), most of the notified chemical is expected to be removed from waste waters by sorption to sludge due to its hydrophobic structure. The notified chemical that partitions and/or adsorbs to sludge will be removed with the sludge for disposal to landfill or used in soil remediation. The quantity of the notified chemical that is released to surface waters is expected to be very low due to its very low water solubility. However, if it reaches receiving waters, it is expected to partition and/or adsorb to suspended solids and organic matter, and disperse and degrade.

Analogue chemical 2 is considered applicable as read across to the notified chemical with regards to biodegradability. The analogue chemical is considered readily biodegradable (77% over 28 days) and it passed the 10-day window for it to be classified as readily biodegradable. The notified chemical is expected to biodegrade in a similar manner as its analogue. Since the notified chemical has low water solubility and rapid degradability, it is not expected to be significantly bioavailable in receiving waters. Therefore, the bioavailable fraction of the notified chemical in the receiving waters is expected to be low. Although the notified chemical is likely to bioaccumulate due to its hydrophobic structure, it may be negligible due to its low bioavailability and rapid degradability.

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 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:	0.06	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 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 0.61 µg/L may potentially result in a soil concentration of approximately 0.004 mg/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 0.02 mg/kg and 0.04 mg/kg, respectively.

7.2. Environmental Effects Assessment

Ecotoxicity results were provided for an acceptable analogue of the notified chemical in a reliable, internationally peer reviewed data set (Madsen 2001). The endpoints are summarised in the table below.

Endpoint; Guideline	*Species*	*Result*	*Assessment Conclusion*
Acute			
Fish Toxicity (96 h)	*Pimephales promelas*	LC50 = 205 mg/L	Not harmful
Fish toxicity (96 h)	*Lepomis macrochirus*	LC50 = 63.3 mg/L	Harmful
Fish toxicity (96 h)	*Oncorhynchus kisuth*	LC50 = 12 mg/L	Harmful

The reported analogue endpoint for fish toxicity exceeds the water solubility limit of the notified chemical, suggesting that aquatic toxicology would not be expected at water saturated levels. The notified chemical is not anticipated to be bioavailable as it is expected to have a high log K_{ow} value. Therefore, no effects on aquatic biota are predicted for the notified chemical at its water saturation concentration. The toxicity endpoint for fish was not related to a specific concentration of the test substance but only to the water solubility limit in the test medium. Classification should only be based on toxic responses observed in the soluble range and, therefore, the notified chemical cannot be formally classified under the Globally Harmonised System of Classification and Labelling 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

A risk quotient (PEC/PNEC) for the notified chemical was not calculated as a PNEC was not derived. Based on the analogue data, the notified chemical is expected to be rapidly biodegradable in the environment. Additionally, it has low potential to be bioavailable due to its low water solubility. The notified chemical is not expected to be harmful to aquatic organisms up to the limit of its solubility. Therefore, the notified chemical is not expected to pose an unreasonable risk to the environment based on the assessed use pattern.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD: Determination of the index of primary cutaneous irritation in the rabbit (following the recommendations of the Journal Official de la République Française of 21/4/71 and 5/6/73).

Species/Strain	Albino rabbit/New Zealand White
Number of Animals	6M
Vehicle	None
Observation Period	72 hours
Type of Dressing	Occlusive.
Remarks - Method	Determination of the primary cutaneous irritant reaction caused by a single application of 0.5 mL of the test substance for 23 hours (occlusive patch) on clipped skin of the animals. After 23 hours of contact with the skin, the patch is removed. One hour later the primary irritation index is evaluated then after 48 and 72 hours readings were performed. Readings were made for both scarified and non-scarified animals. Scores after 24 and 72 hours were added together for scoring. Irritation was evaluated by the erythema and oedema scores at 24 and 72 hours: Non-irritant: scores <0.5 Slightly irritant: scores 0.5-2 Moderately irritant: scores 2-5 Severely irritant: scores 5-8

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.625	2	72	1
Oedema	0.083	1	24	0

* Calculated on the basis of the scores at 24, and 72 hours for ALL animals. Six of the 12 animals had scarified skin.

Remarks - Results: The method varies from the current OECD guideline, particularly in having an exposure period of 23 h rather than 4 h.

CONCLUSION: The notified chemical is slightly irritating to the skin.

TEST FACILITY: IFREB (1981a)

B.2. Repeated dose skin Irritation –

TEST SUBSTANCE: Notified chemical

METHOD: Repeated application (daily, 5 days out of 7) of the test substance for 6 weeks.

Species/Strain	Albino rabbit/New Zealand White
Number of Animals	2x6 M
Vehicle	None
Observation Period	7 weeks
Type of Dressing	Occlusive
Remarks – Method	The right flank of rabbits was daily treated with 2 g of the test substance (5 days/week) for 6 weeks and the left flank was left without treatment, serving as the control. The skin was examined daily before each application compared to the

control area.
Body weights were measured and recorded weekly and at the end of the experiment.

Daily indexes are calculated by adding the scores obtained each day for erythema and oedema are expressed and dividing the total by the number of the treated animals. The weekly mean irritation index (WI) is calculated by the total daily indexes obtained for the 6 treated animals.
Weekly mean irritation index is used to arbitrarily classify the test substance as:

WI	**Classification of the substance**
Less than 0.5	Non-irritant
0.5-2 (included)	Slightly irritant
2-4 (included)	Moderately irritant
4-6 (included)	Very irritant
6-8	Severely irritant

Reversibility (recovery of the skin) was studied after 6 weeks repeated application of the test substance by stopping application for seven days and examining the skin.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Weekly Mean Irritation Index(WI)	1.08, 1,77, 2.00, 1.80, 1.80, 1.93	2	7 weeks	1.33

Remarks - Results

The main observed effect was erythema. Oedema was not seen. The Weekly Mean Irritation Indices (WI) was between 0.5 and 2 for each of treated animals, which is regarded as slightly irritant under the scoring system. At the end of the one week recovery period, the erythema effects were reduced in all animals.

Biopsy results after six week application of the test substance showed orthokeratosis of the corneal layer, epidermal thickening and non-inflammatory dermal congestive in all animals. These effects were partly reversed after the one week recovery period.

CONCLUSION

The notified chemical was slightly irritating to the skin under the conditions of the test.

TEST FACILITY

IFREB (1981b)

B.3. Irritation – eye

TEST SUBSTANCE

Notified chemical

METHOD

Determination of the index of ocular irritation in the rabbit (following the recommendations of the Journal Official de la République Française of 21/4/71 and 5/6/73) (similar to OECD TG 405).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 6 M
Observation Period: 7 days
Remarks - Method: The test method allowed the calculation of individual and mean index of ocular irritation at each observation time, and from these the index of acute ocular irritation was calculated.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.17	1	< 72 h	0
Conjunctiva: chemosis	0.67	2	< 72 h	0
Conjunctiva: discharge	0	1	< 24 h	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	1	1 h	0

* Calculated on the basis of the scores at 24h, 48h and 72h days for ALL animals.

Remarks - Results: No corneal effects were seen, and effects on the iris were seen at the 1h observation only. Conjunctival reactions had cleared by the 72 h observation.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: IFREB (1981c)

B.4. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: Similar to OECD TG 406 Skin Sensitisation - maximisation test (Magnusson / Kligman).

Species/Strain: Guinea pig/Albino Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 100% (0.25 mL and 0.5 mL applied)

MAIN STUDY

Number of Animals: Test Group: 10M, 10F

INDUCTION PHASE: Induction Concentration:
intradermal: 2 injections of 0.1 mL of 50% Freund's adjuvant (in sterile isotonic saline) only
topical: 10 applications of 0.5 g notified chemical (occlusive patch for 48 hrs).

Signs of Irritation: Slight erythema was seen in some animals, but was resolved by the 48 h observation.

CHALLENGE PHASE

challenge: topical: 0.5 g (occlusive patch on the abdomen for 48 hrs).

Remarks - Method: 0.5 g of the test substance if pasty (or 0.5 mL if liquid or viscous) was applied to the skin of each animal behind the left shoulder blade. Readings were made at 1, 6, 24 and 48 hours after removing the patch.
The test substance was not applied intradermally in the induction stage. A separate control group was not included. Only one challenge was carried out.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*		
Test Group	100% (0.5 g)	0	0	-	-

Remarks - Results: No irritation was observed in the preliminary test using 0.25 or 0.5 mL on 2M and 2F up to 48 hours.
In the main study 3M and 4F died during the test and were replaced and received the same treatment. Slight erythema was seen in some animals at

induction and challenge, mainly at the 1 h and 6 h observations. However no reactions were seen at challenge at 24 h or 48 h.
No positive sensitisation reactions to any of the treated animals were observed at challenge.

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

TEST FACILITY IFREB (1981d)

B.5. Skin phototoxicity and photoallergy

TEST SUBSTANCE Notified chemical

METHOD In-house method based on modification of a method by Harber, Targovnik and Baer.

Species/Strain Guinea pig/Albino Hartley

PRELIMINARY STUDY topical: 100% (0.5 and 1 mL)
Observations were made 1 h, 6 h, 24 h and 48 h after a single application of the test substance, in order to determine the skin irritancy.

MAIN STUDY

Number of Animals Test Group (II): 10M, 10F Control Group (I): 3M, 2F

INDUCTION PHASE Phototoxicity was determined in the early stages of the study, which was continued in order to evaluate the potential for photoallergy.
Induction Concentration: 100%
topical: application of 1 mL daily for three days of the test substance (groups I and II) + irradiation session after every application for group II only. The group II animals were irradiated with fluorescent lamps emitting wave lengths of 4000-3100 angstroms and 3500-2850 angstroms, covering UVA and UVB regions.

Signs of Irritation Erythema, oedema, thickening and drying of the skin were evaluated 1 h, 6 h, 24 h and 48 h after application. Skin samples were taken where responses were seen.

CHALLENGE PHASE Photoallergy was determined after a rest period of two weeks.
The test substance was applied to a section of skin which had not previously been irradiated or treated with the test substance. The skin was then evaluated after 1 h, 6 h, 24 h and 48 h.

Remarks - Method Group I and II two animals received an application of 1 mL of the test substance uniformly applied to the skin of each animal scapular region of the back. Only group two animals were covered with aluminium foil except the anterior region of their back which was exposed to UV radiation.

RESULTS

Remarks - Results In both the preliminary and main tests, slight scattered erythema was observed at some observation times after application of the test substance. In the main test there was no difference in incidence or severity of erythema between test and control animals. No oedema, thickening, drying or other anomalies were seen at any time.

No significant differences between group one (treated but not irradiated) and group two (treated and irradiated) or to any of the treated animals were observed.

CONCLUSION The notified chemical was not a skin phototoxic or photoallergic under the conditions of the test.

TEST FACILITY IFREB (1981e)

BIBLIOGRAPHY

BIBRA (1986) Toxicity Profile. Oleic acid. The British Industrial Biological Research Association. Surrey, UK.

Cadby, PA, Troy, WR and Vey, MGH (2002) Consumer Exposure to Fragrance Ingredients: Providing Estimates for Safety Evaluation. Regulatory Toxicology and Pharmacology, 36: 246-252.

CIR (1987). Final Report on the Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid and Stearic Acid. Elder RL et al. J.Amer. Coll. of Toxicol. 6 (3) 321-401 1987. Cosmetic Ingredient Review Expert Panel Meeting, 1100 17th Street NW Suite 412, Washington D.C. 20036-4702 USA. 1987. http://www.cir-safety.org/sites/default/files/115_draft_steary_suppl3.pdf

Council of Europe (1974) Natural Flavouring Substances, their sources and added artificial falvouring substances. Partial agreement in the Social and Public Health Field. List 1, No. 15, p127. Strasbourg.

ECHA, 2012. Guidance on information requirements and chemical safety assessment, Chapter R.7c: Endpoint specific guidance, p160, 2012.

FDA (2013). Substances Generally Recognised as Safe. Substances migrating from cotton and cotton fabrics used in dry food packaging. Code of Federal Regulations. 21CFR182.70. 15 March 1977 revised 1 April 2013. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.70

HERA (2002). Fatty Acid Salts. Human Health Risk Assessment. Draft for Public Comments. Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products. HERA Secretariat, Avenue Herrmann Debroux 15A. B-1160 Brussels Belgium. June 2002. http://www.heraproject.com/files/5-HH-04-HERA%20Fatty%20acid%20salts%20HH%20web%20wd.pdf

HSDB (2014a). Data taken from Hazardous Substances Data Bank. Stearic Acid. A database of the National Library of Medicine's TOXNET system (http://toxnet.nlm.nih.gov). U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894 USA. 9 February, 2014. http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+@rel+57-11-4

IFREB (Institut Francaise de Recherches et Essais Biologiques) (1981a). Determination of the Index of Primary Cutaneous Irritation in the Rabbit. Study No 109345. Institut Français de Recherches et Essais Biologiques, Centre de Lyon France. 28 September 1981.

IFREB (Institut Francaise de Recherches et Essais Biologiques) (1981b). Evaluation of the Superficial Cutaneous Irritation of a Test Substance by Repeated Application for 6 weeks in the Rabbit. Study No 109345. Institut Français de Recherches et Essais Biologiques Centre de Lyon France. 28 September 1981.

IFREB (Institut Francaise de Recherches et Essais Biologiques) (1981c). Determination of the Index of Ocular Irritation in the Rabbit. No 109345. Institut Français de Recherches et Essais Biologiques Centre de Lyon France. 28 September 1981.

IFREB (Institut Francaise de Recherches et Essais Biologiques) (1981d). Evaluation of the Sensitizing Potential of a Test Substance by Topical Applications in the Guinea Pig. No 109345. Institut Français de Recherches et Essais Biologiques Centre de Lyon France. 28 September 1981.

IFREB (Institut Francaise de Recherches et Essais Biologiques) (1981e). Method for the Evaluation of the Phototoxic and Photoallergic Potential of Topically Applied Test Substance in Albino Guinea Pig. No 109345. Institut Français de Recherches et Essais Biologiques Centre de Lyon France. 28 September 1981.

IUCLID (2000). Fatty Acids C18-22. Substance ID 90990-11-7. IUCID Dataset. European Chemical Bureau, Ispra, Italy. 19 February 2000. http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/90990117.pdf

IUCLID (2003). Stearic Acid. Substance ID 57-11-4. IUCID Dataset. European Chemical Bureau, Ispra, Italy. 5 December 2007. http://www.epa.gov/hpv/pubs/summaries/metalcarb/c14172rr.pdf

IUCLID (2006). Oleic Acid, Cobalt Salt. Substance ID 14666-94-5. IUCID Dataset. European Chemical Bureau, Ispra, Italy. 19 February 2000. http://www.epa.gov/hpv/pubs/summaries/9octadec/c16473rs.pdf

Kroes R. (2007). Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients. R. Kroes. Food and chemical toxicology 45 (2007) 2533-2562. 2007.

Madsen (2001) MiljØproject, Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, Environmental project No 615, Danish EPA, Denmark.

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

SCCS (2012) Notes of Guidance for testing of Cosmetic Ingredients and Their Safety Evaluation (8th revision). European Commission - Scientific Committee on Consumer Safety.

SWA (2012) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating.

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

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 (2009) Estimations Programs Interface Suite™ for Microsoft® Windows, v 4.00. United States Environmental Protection Agency. Washington, DC, USA. Accessed on 10 September 2014.