File No.: STD/1710

February 2021

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Decanoic acid, mixed diesters with octanoic acid and 1,3-propanediol

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS 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
Email:	assessments@industrialchemicals.gov.au
Website:	www.industrialchemicals.gov.au

Executive Director
AICIS

TABLE OF CONTENTS

SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1710	Symrise Pty Ltd	Decanoic acid, mixed diesters with octanoic acid and 1,3-propanediol	ND*	≤ 2 tonnes per annum	Cosmetic ingredient

*ND = Not determined. However, the data provided for this assessment indicated that the chemical is non-hazardous.

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the assessed chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human Health Risk Assessment
Under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

When used as an ingredient at a maximum concentration of 13% in cosmetic products, the assessed chemical is not considered to pose an unreasonable risk to public health.

Environmental Risk Assessment
On the basis of expected low hazard and reported use pattern, the assessed chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the assessed chemical during reformulation of products:
  - 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 assessed chemical during reformulation:
  - Gloves
  - Overalls

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the assessed chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Emergency procedures

- Spills or accidental release of the assessed chemical should be handled by physical containment, collection and subsequent safe disposal.

Disposal

- Where reuse or recycling are not appropriate, dispose of the assessed chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Regulatory Obligations

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under section 101 of the IC Act the introducer of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the final use concentration of the assessed chemical exceeds 13% in cosmetic products;
- the function or use of the chemical has changed from a cosmetic ingredient, 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 human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet
The SDS of the assessed chemical provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)
Symrise Pty Ltd (ABN: 67 000 880 946)
168 South Creek Road
DEE WHY NSW 2099

APPLICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year)

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
No details are taken to be protected information.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for all human health and environmental endpoints.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
EU REACH (2019)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SymMollient® PDCC

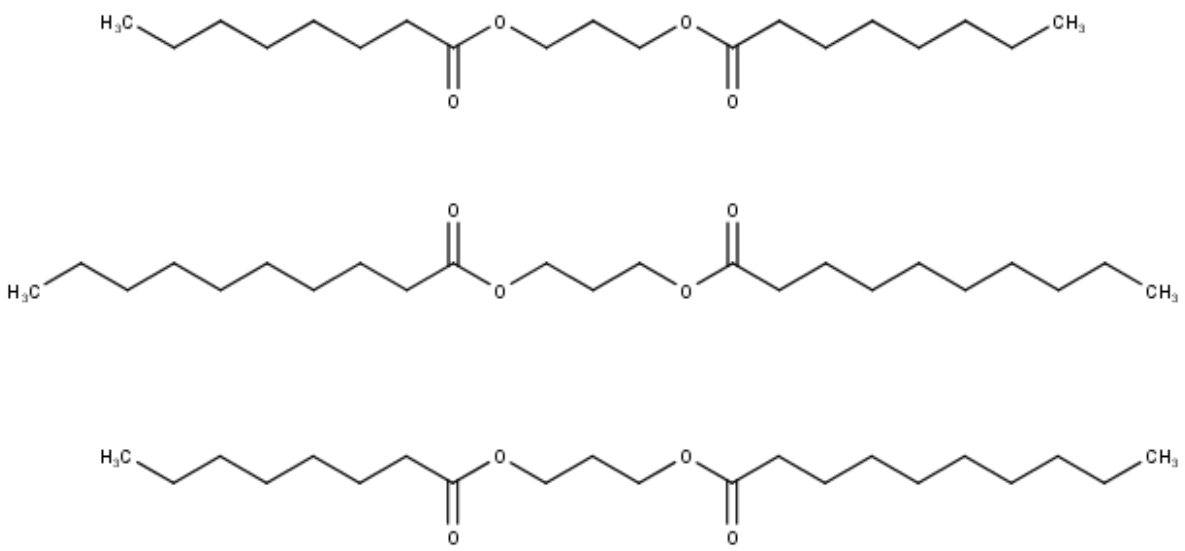
CAS NUMBER
1072005-10-7

CHEMICAL NAME
Decanoic acid, mixed diesters with octanoic acid and 1,3-propanediol

OTHER NAME(S)
Reaction mass of 3-(octanoyloxy)propyl decanoate and propane-1,3-diyl didecanoate and propane-1,3-diyl dioctanoate

MOLECULAR FORMULA
Unspecified
(Expected to be $C_{19}H_{36}O_4$, $C_{21}H_{40}O_4$ or $C_{23}H_{44}O_4$, based on structure of components)

STRUCTURAL FORMULA



The applicant indicated that the ratio of each component of the chemical was measured to be:
3-Octanoyloxypropyl octanoate: 31.9%
3-Octanoyloxypropyl decanoate: 51.9%
3-Decanoyloxypropyl decanoate: 15.6%

MOLECULAR WEIGHT
Unspecified (UVCB)
(Expected to be 328.4, 356.5 or 384.5 g/mol based on structure of components)

ANALYTICAL DATA
Reference NMR, MS, IR, UV-VIS, and GC spectra were provided.

ANALOGUES PROVIDED FOR TOXICOLOGICAL AND ENVIRONMENTAL DATA

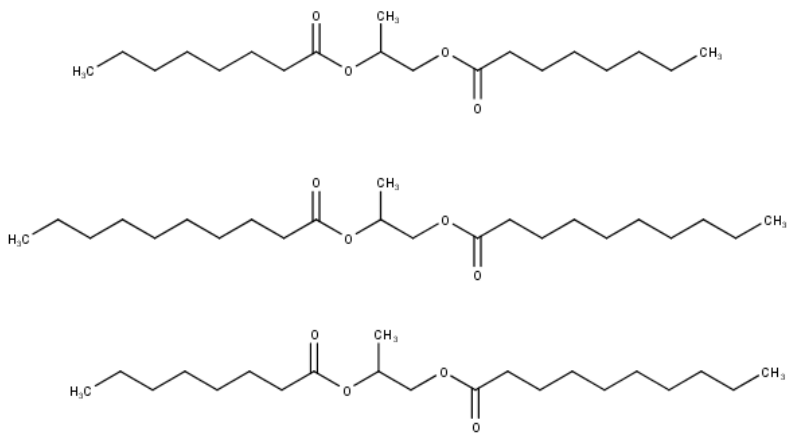
ANALOGUE 1

CHEMICAL NAME
Decanoic acid, mixed diesters with octanoic acid and propylene glycol

CAS NUMBER
68583-51-7

MOLECULAR FORMULA
$C_{10}H_{20}O_2.C_8H_{16}O_2.C_3H_8O_2$

STRUCTURAL FORMULA



JUSTIFICATION OF USE
Decanoic acid, mixed diesters with octanoic acid and propylene glycol is used as Analogue 1 in this assessment. It is the reaction product of propylene glycol and a mixture of octanoic acid and decanoic acid (C_8 and C_{10} fatty acids). The analogue is a diester with the same alkyl chain length as the assessed chemical. This analogue is used for the following endpoints: acute oral toxicity, acute inhalation toxicity, skin irritation, eye irritation, mutagenicity, developmental toxicity, and daphnia toxicity.

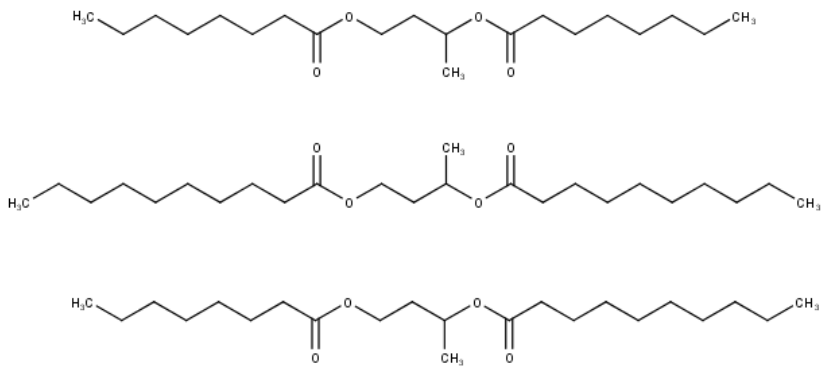
ANALOGUE 2

CHEMICAL NAME
Decanoic acid, reaction products with 1,3-butanediol and octanoic acid

CAS NUMBER
853947-59-8

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



JUSTIFICATION OF USE
Decanoic acid, reaction products with 1,3-butanediol and octanoic acid is used as Analogue 2 in this assessment. It is the reaction product of 1,3-butanediol and a mixture of octanoic acid and decanoic acid (C_8 and C_{10} fatty acids). Like Analogue 1, it is a diester with the same alkyl chain length as the assessed chemical. This analogue is used for the following endpoints: acute dermal toxicity, skin sensitisation, *in vitro* genotoxicity, fish toxicity, algal toxicity, biodegradation and inhibition of bacterial respiration.

3. COMPOSITION

DEGREE OF PURITY
~99% (UVCB)

HAZARDOUS IMPURITIES
None identified

NON HAZARDOUS IMPURITIES (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless to light yellow liquid

Property	*Value*	*Data Source/Justification*
Melting Point	-15 to 11 °C	Measured
Boiling Point	396 °C – 426 °C; expected to decompose before boiling	Calculated (SPARC v 4.5)
Density	910 – 930 kg/m^3 at 20 °C	Calculated (SPARC v 4.5)
Viscosity	11.8 mPa·s at 20 °C	Measured
Vapour Pressure	5.47×10^{-10} to 6.87×10^{-8} kPa at 20 °C	Calculated (SPARC v 4.5)
Water Solubility	0.15 mg/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups, however significant hydrolysis is not expected in the environmental pH range (4 – 9)
Partition Coefficient (n-octanol/water)	log Pow = 6.79 - 8.75 at 25°C	Calculated (KOWWIN v 1.67, EPISuite v 4.1)
Adsorption/Desorption	Not determined	Expected to sorb to sludge and sediment based calculated partition coefficients and low water solubility
Dissociation Constant	Not determined	No dissociable groups present
Flash Point	221 °C at 101.3 kPa	Measured
Autoignition Temperature	360 °C	Measured
Explosive Properties	Not determined	Not expected to be explosive
Oxidising Properties	Not determined	Not expected to be oxidising

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

Reactivity
The assessed 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 assessed chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed chemical will not be manufactured in Australia. It will be imported in neat form or as a component of finished cosmetic products at ≤ 13% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.1	0.1	1	1.5	2

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Symrise Pty Ltd

TRANSPORTATION AND PACKAGING
The assessed chemical, in neat form, will be imported into Australia by sea in 30 L (25 kg) plastic canisters. These canisters will then by transported by road to the facilities for storage or formulation of cosmetics. End-use products will be packaged and transported in different containers most suitable for retail sale.

USE
The assessed chemical will be used as an emollient in a variety of cosmetic products at a maximum concentration of up to 13%. Typical concentration in end-use cosmetics products would be 0.5 – 5%.

OPERATION DESCRIPTION

Reformulation
When reformulated in Australia, the processes for incorporating the assessed chemical into end-use products will likely vary depending on the specific type of cosmetic products formulated. This will typically involve adding the assessed chemical to a blending tank, where it will be mixed with additional additives to form finished cosmetic products. The blending operation will be mostly automated and occur in a closed/contained system, with ventilation as required. After reformulation, the finished products containing the assessed chemical (at ≤ 13% concentration) will be transferred into retail containers at sizes of up to 500 mL.

End-use
Finished cosmetic products containing the assessed chemical will be used by consumers and professionals (such as hairdressers and workers in beauty salons). Depending on the type of product, application of products may be done by hand, sprayed 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 workers	Unspecified	Unspecified
Mixers	4	2
Drum handling	4	2
Drum cleaning	4	2
Maintenance workers	4	2
Quality control	0.5	1
Packaging	4	2
Salon workers	Unspecified	Unspecified
Cleaners	Unspecified	Unspecified

EXPOSURE DETAILS

Transport and storage workers
Transport and storage workers may come into contact with the assessed chemical in neat form, or as a component of the imported product, only in the unlikely event of accidental rupture of containers.

Reformulation workers
During reformulation, dermal, ocular and possible inhalation exposure of workers to the assessed chemical in neat form may occur during weighing, transfer, blending, quality control analysis and cleaning/maintenance of equipment. According to the applicant, exposure is expected to be minimised through the use of local exhaust ventilation and automated systems, and through the use of personal protective equipment (PPE) such as impervious gloves, safety glasses, protective clothing and respiratory protection.

Professional end users
Exposure to the assessed chemical in end-use products (at ≤ 13 % concentration) may occur in professions where the services provided involve the application of cosmetic products to clients, such as hairdressers and beauty salon workers. The principal route of exposure is expected to be dermal, while ocular and inhalation exposures are also possible. Such professional workers may use PPE to minimise repeated or prolonged exposure and ensure that good hygiene practices are 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 assessed chemical.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the assessed chemical through the use of a variety of cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible, particularly if products are applied by spray.

Data on typical use patterns of cosmetic products (SCCS, 2012; Cadby *et al.*, 2002; ACI, 2010; Loretz *et al.,* 2006) in which the assessed chemical may be used are shown in the following tables. For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. A dermal absorption (DA) of 100% was assumed for the assessed chemical for calculation purposes. For the inhalation exposure assessment, a 2-zone approach was applied (Steiling *et al*., 2014; Rothe *et al*., 2011; Earnest, Jr, 2009). An adult inhalation rate of 20 m^3/day (enHealth, 2012) was used and it was conservatively assumed that the fraction of the assessed chemical inhaled is 50%. For calculation purposes, a lifetime average female body weight (BW) of 70 kg (enHealth, 2012) was used.

Cosmetic products (Dermal exposure)

Product type	**Amount** (mg/day)	**C** (%)	**RF**	**Daily systemic exposure** (mg/kg bw/day)
Body lotion	7,820	13	1	14.5229
Face cream	1,540	13	1	2.8600
Hand cream	2,160	13	1	4.0114
Deodorant (non-spray)	1,500	13	1	2.7857
Shampoo	10,460	13	0.01	0.1943
Hair conditioner	3,920	13	0.01	0.0728
Shower gel	18,670	13	0.01	0.3467
Hand wash soap	20,000	13	0.01	0.3714
Hair styling products	4,000	13	0.1	0.7429
Foundation	510	13	1	0.9471
Lipstick	57	13	1	0.1059
Total				**26.9611**

C = concentration (%); RF = Retention Factor Daily Systemic Exposure = (Amount × C × RF × DA) / BW

Hair spray (inhalation exposure)

Product type	**Amount** (g/day)	**C** (%)	**Inhalation Rate** (m^3/day)	**Exposure Duration (Zone 1)** (min)	**Exposure Duration (Zone 2)** (min)	**Fraction Inhaled** (%)	**Volume (Zone 1)** (m^3)	**Volume (Zone 2)** (m^3)	**Daily systemic exposure** (mg/kg bw/day)
Hairspray	9.89	13	20	1	20	50	1	10	**0.3826**

Total daily systemic exposure = Daily systemic exposure in Zone 1 [(amount × C × inhalation rate × exposure duration (zone 1) × fraction inhaled)/(volume (zone 1) × body weight)] + Daily systemic exposure in Zone 1 [(amount × C × inhalation rate × exposure duration (zone 2) × fraction inhaled)/(volume (zone 2) × body weight)]

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 assessed chemical. This would result in a combined internal dose of 27.3437 mg/kg bw/day. It is acknowledged that inhalation exposure to the assessed chemical from use of other cosmetic products (in addition to hair spray) may occur. However, it is considered that the combination of the conservative (screening level) hair spray inhalation exposure assessment parameters, and the aggregate exposure from use of the dermally applied products, which assumes a conservative 100% absorption rate, is sufficiently protective to cover additional inhalation exposure to the assessed chemical from use of other spray cosmetic and household products with lower exposure factors (e.g. air fresheners).

6.2. Human Health Effects Assessment

No toxicological study data were provided for the assessed chemical.

The results from toxicological investigations conducted on the analogue chemicals are summarised in the following table. For details of the studies (except for repeated dose toxicity, but including non-guideline studies conducted prior to OECD TGs for specific health end points), refer to Appendix B.

Endpoint	***Result and Assessment Conclusion***
Acute oral toxicity – mouse	LD50 > 4,600 mg/kg bw; low toxicity*
Acute dermal toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity^
Acute inhalation toxicity – rat	LC50 > 200 ppm/6 hour*
Skin irritation – rabbit	Non-irritating*
Eye irritation – rabbit	Slightly irritating*
Skin sensitisation – guinea pig, maximisation test	No evidence of sensitisation^

Endpoint	*Result and Assessment Conclusion*
Repeat dose oral toxicity – rat, 90 days	NOAEL = 1,000 mg/kg bw/day**
Mutagenicity – bacterial reverse mutation	Non mutagenic*
Genotoxicity – *in vitro* chromosome aberration test	Non genotoxic^
Developmental toxicity (Gestation days 6-15) – rat	NOAEL > 1,000 mg/kg bw/day*

*Conducted on Analogue 1
^Conducted on Analogue 2
**Conducted on the main metabolite of the chemical (Gingell *et al*, 2000)

Toxicokinetics, Metabolism and Distribution
No studies on toxicokinetics of the assessed chemical were provided. Based on the molecular weight (< 500 g/mol) of the assessed chemical, there is potential for the chemical to cross biological membranes. However, absorption is expected to be limited, based on the low water solubility (0.15 mg/L at 20 °C) and high partition coefficient (log Pow = 6.79 – 8.75) of the assessed chemical.

Based on information provided by the applicant, any assessed chemical that is absorbed is expected to be hydrolysed by lipases, breaking it down to fatty acids and 1,3-propanediol. The fatty acids will then be esterified with glycerol in the duodenum and then transported to the liver. The esterified fatty acids will be stored, metabolized or distributed together with lipoproteins in blood to the target tissues. The fatty acids will be metabolized by beta oxidation to CO_2 and water. 1,3-propanediol will be taken up from the gut, oxidized by alcohol dehydrogenase in the liver to form 3-hydoxy propionic acid, and eventually excreted in urine.

Based on studies conducted on humans and animals, it was found that several propylene glycol esters (which are similar in structure to the assessed chemical) could enhance dermal penetration of other compounds through the skin (CIR 2015). However, the extent of penetration would depend on the type of formulation.

Acute Toxicity
No acute toxicity studies were provided for the assessed chemical.

An acute oral toxicity study was conducted in mice using Analogue 1 at 5 mL/kg bw (calculated as 4,600 mg/kg bw based on density). No deaths or adverse effects were observed. An acute dermal toxicity study was conducted in rats using Analogue 2 at 2,000 mg/kg bw. No deaths or adverse effects were observed. An acute inhalation toxicity study was conducted in rats using Analogue 1 at 200 ppm with exposure for 6 hours. No deaths or adverse effects were observed. The exposure concentration was estimated as equivalent to 300 ppm (4.38 mg/L) for 4 hours. Overall, the analogue chemicals were considered to be of low acute toxicity.

Irritation and Sensitisation
No data on the assessed chemical were provided on eye, skin or respiratory irritation and skin sensitisation.

Based on the studies conducted in rabbits, Analogue 1 was considered to be non-irritating to the skin and slightly irritating to the eyes.

In a guinea pig maximisation test (GPMT) conducted using Analogue 2 at 100% topical induction concentration, no evidence of skin sensitisation was observed during the challenge phase.

Repeated Dose Toxicity
No data were provided for the assessed chemical or its close analogues on repeated dose toxicity.

The assessed chemical is expected to be metabolised into 1,3-propanediol as one of its primary metabolites, which has been assessed under IMAP (NICNAS) as a Tier I chemical. A repeated dose dietary study with 1,3-propanediol at 500 ppm (not converted to equivalent mg/kg bw/day) in rats for 15 weeks caused increased cross-linking of hepatic and testicular DNA. This was expected to be due to metabolic conversion of 1,3-propanediol to malondialdehyde (Summerfield and Tappel, 1984).

In a subsequent study, with oral exposure to 1,3-propanediol at 100, 300, and 1,000 mg/kg bw/day in rats for 90 days (Gingell *et al*, 2000), the NOAEL was reported to be 1,000 mg/kg bw/day, the highest dose tested. Spermatogenic endpoints such as testicular weight, mean sperm count, sperm production rate and morphology were investigated in the study and were not statistically significantly affected by the treatment at all doses. A 6.5% reduction of sperm motility was reported at the highest dose compared to the control, but this was not statistically significant and was not considered to be adverse by the study authors.

Based on the available information on metabolites of the assessed chemical, systemic toxicity from repeated dose exposure to the assessed chemical at very high doses (greater than 1,000 mg/kg bw/day) cannot be ruled out.

Mutagenicity/Genotoxicity
No data were provided for the assessed chemical on genotoxicity.

A bacterial reverse mutation study was conducted on the Analogue 1 using both the plate incorporation and pre-incubation method. A maximum concentration of 5,000 µg /plate was used in the main study. No increase in revertant colonies was observed, in the presence or absence of metabolic activation. In a chromosome aberration test on Analogue 2 using Chinese hamster lung cells, there were no chromosome aberrations observed, in the presence or absence of metabolic activation, after short-term and long-term treatment up to a maximum concentration of 100 µg/mL.

Toxicity for Reproduction/Developmental
A developmental toxicity screening test was conducted on Analogue 1 in female rats with oral exposure on gestation days 6 – 15 at dose levels of 100, 300 and 1,000 mg/kg bw/day (OECD TG 414). No adverse effects were observed in dams and pups at any of the dose levels tested. Therefore, a developmental NOAEL was established for the analogue chemical in the study as > 1,000 mg/kg bw/day.

Health Hazard Classification
Based on the available information on the two analogue chemicals and metabolites, the assessed chemical is not classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation
Based on the data available on analogues, no health hazards were identified with exposure to the assessed chemical, except for slight eye irritation. Only limited data are available on repeated dose toxicity. However, no systemic effects are expected from repeated dose exposure, unless at very high doses (> 1,000 mg/kg bw/day).

6.3.1. Occupational Health and Safety
Exposure to the assessed chemical at up to 100% concentration by workers involved in product formulation may occur during blending operations, quality testing and equipment cleaning and maintenance.

Control measures are in place to minimise worker exposure, including the use of automated processes and PPE such as impervious gloves, coveralls and respiratory protection if aerosols are generated.

Exposure to the assessed chemical (at up to 13% concentration in formulated products) of professional end-users such as beauticians, salon workers and masseurs may occur during application of the cosmetic products to customers, at similar levels to that experienced by consumers (see section 6.3.2).

Under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health
Members of the public will experience widespread and frequent exposure to the assessed chemical at ≤ 13% concentration through daily use of cosmetic products. The main route of exposure is expected to be dermal and inhalation, with some potential for accidental ocular or oral exposure.

The repeat dose toxicity potential was estimated by calculation of the margin of exposure (MoE) to the assessed chemical using the worst case exposure scenario from use of multiple cosmetic products containing the chemical at 13%, which was calculated as 27.3437 mg/kg bw/day (see Section 6.1.2). This is equivalent to 5.8242 mg/kg bw/day of the metabolite 1,3-propanediol, based on its equivalent molecular weight in the assessed chemical. Using the NOAEL of 1,000 mg/kg bw/day for 1,3-propanediol (Gingell *et al*, 2000), the margin of exposure (MOE) was estimated to be 172. A MOE value ≥ 100 is generally considered to be acceptable for taking into account intra- and inter-species differences.

Although the systemic NOAEL of 1,3-propanediol could be lower than 1,000 mg/kg bw/day, the internal dose estimated for the assessed chemical is conservative and likely to overestimate exposure (i.e.13% concentration of the assessed chemical in all product types with 100% dermal absorption). Due to its lipophilicity, dermal

absorption of the assessed chemical is likely to be lower than 100% used in the calculation, however, dermal absorption could vary based on other ingredients in cosmetic product formulations.

When used as an ingredient at a maximum concentration of 13% in cosmetic products, the assessed chemical is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The assessed chemical will not be manufactured within Australia. They will be imported into Australia as a neat product in plastic canisters for reformulation into cosmetic products or as a component of finished cosmetic products. Reformulation facilities of personal care product manufacturers are expected to employ highly automated processes within closed systems and subsequent automated filling of the finished product into end-use containers. Waste, residues and rinsates generated during the reformulation process are expected to be disposed of to landfill or sewer in accordance with local government regulations. Release of the assessed chemical to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the assessed chemical is expected to be released to sewers within Australia as a consequence of its use in wash-off cosmetic preparations.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues within end-use containers are expected to share the fate of the container and be disposed of to landfill or be released to sewer as rinsates from containers prior to recycling through an approved waste management facility.

7.1.2. Environmental Fate

The majority of the assessed chemical is expected to enter sewers within Australia as a consequence of its use in wash-off cosmetic preparations. A biodegradation study conducted on Analogue 2 indicates it to be readily biodegradable within sewage treatment plants (STPs) (Modified Sturm Test 92/69/EEC; 82% degradation in 28 days and passing the 10 day window). The English language full study report for the biodegradation study is unavailable however an English language summary of the biodegradation study was provided and used for this assessment (Hüls AG, 1997c).

The assessed chemical is expected to sorb to sludge in STPs based on their low water solubility (0.15 mg/L) and high partition coefficients (log Pow = 6.79 – 8.75). As a result, the assessed chemical is expected to be effectively removed and degraded through adsorption to sludge and biodegradation prior to potential release to surface waters nationwide. In instances of sewage sludge use in soil remediation or disposal to landfill the chemical residues within sludge, landfill or soil will have low soil mobility due to low water solubility and high partition coefficient. In the soil and aquatic compartments, the assessed chemical is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume the worst-case scenario with 100% release of the assessed chemical into sewer systems nationwide over 365 days per annum. It is also assumed under the worst-case scenario that there is no removal of the assessed chemical during sewage treatment processes. The resultant PEC for the assessed chemical in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	2,000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	2,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	5.48	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million

Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River:	1.12	µg/L
PEC – Ocean:	0.11	µg/L

The extent to which the assessed chemical is removed from the effluent in STP processes is based on the physico-chemical properties and its ready biodegradability, modelled by SimpleTreat 3.0 (Struijs, 1996) and is estimated as 93%, with 72% removal due to partitioning to biosolids. Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 8.089 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the assessed chemical may approximate 0.054 mg/kg in applied soil. Due to the assessed chemical's ready biodegradability, annual accumulation is not expected.

7.2. Environmental Effects Assessment

The results from ecotoxicological studies conducted on acceptable analogues of the assessed chemical are summarised in the table below. The English language full study reports for the ecotoxicity studies are unavailable, however, English language summaries of the studies were provided and used for this assessment (Hüls AG, 1997a, b, d; Hüls AG, 1995a).

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 14 mg/L	Not harmful to fish up to its water solubility limit^
Daphnia Toxicity	48 h EC50 > 2 mg/L	Not harmful to aquatic invertebrates up to its water solubility limit*
Algal Toxicity	72 h ErC50 > 3 mg/L	Not harmful to algae up to its water solubility limit^
Inhibition of Bacterial Respiration	3 h EC50 > 1100 mg/L	Not inhibitory to microbial respiration in sewage treatment plants^

*Conducted on Analogue 1
^Conducted on Analogue 2

Based on the above ecotoxicological endpoints for acceptable analogues, the assessed chemical is not expected to be harmful to aquatic life up to the limit of its water solubility. Therefore, the assessed chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute and chronic toxicities (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated as the assessed chemical is not expected to be harmful to aquatic organisms up to its water solubility limit.

7.3. Environmental Risk Assessment

A PNEC was not calculated for the assessed chemical and hence a risk quotient (Q=PEC/PNEC) could not be calculated. Based on its expected low hazard and the assessed use pattern, the assessed chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point -15 to 11 °C

Method	OECD TG 102 Melting Point/Melting Range
Remarks	Differential scanning calorimetry (DSC) was used. The test substance showed a melting area of crystalline components at a range of -15 to 11 °C during heating, with crystallisation at -8 °C during cooling.
Test Facility	Henkel (2012a)

Viscosity 11.8 mPa·s at 20 °C

Method	OECD TG 114 Viscosity of Liquids
Remarks	A rotational viscometer was used.
Test Facility	Henkel (2012b)

Water Solubility < 0.15 mg/L at 20 °C

Method	EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Column Elution Method
Test Facility	Henkel (2012c)

Flash Point 221.0 °C at 101.3 kPa

Method	EC Directive 92/69/EEC A.9 Flash Point
Remarks	A Pensky-Martens apparatus was used. A result of 204.0 °C was obtained in a preliminary test using a Rapid tester.
Test Facility	Henkel (2012d)

Autoignition Temperature 360 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)
Remarks	A Vertical-axis Ignition Temperature oven was used.
Test Facility	Henkel (2012e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Mice

TEST SUBSTANCE	Analogue 1
METHOD	Similar to OECD TG 401 Acute Oral Toxicity
Species/Strain	Mice/Tyler's original strain
Vehicle	None
Remarks – Method	No GLP Compliance Statement. Non-standard method that is similar to but pre-dates the OECD TG. A range-finding study was conducted at dose levels of 1, 2, 3, 4, and 5 mL/kg bw of the test substance.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mL/kg bw)*	*Mortality*
1	5 F, 5 M	5	0/10

LD50	> 5 mL/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were observed.
Remarks – Results	The LD50 is equivalent to > 4,600 mg/kg bw, calculated based on the density of the test substance.

CONCLUSION	The analogue chemical is of low acute toxicity via the oral route.
TEST FACILITY	Consultox (1972)

B.2. Acute Dermal Toxicity – Rat

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 402 Acute Dermal Toxicity (1987)
Species/Strain	Rat/Wistar
Vehicle	None. The test substance was applied undiluted.
Type of dressing	Semi-occlusive.
Remarks – Method	GLP Compliance Statement. Limit test. No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 F, 5 M	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity – Local	No abnormalities were observed.
Signs of Toxicity – Systemic	No signs of systemic toxicity were noted.
Effects in Organs	No macroscopic changes to the organs were observed.
Remarks – Results	All animals showed expected body weight gain over the observation period.

CONCLUSION	The analogue chemical is of low acute toxicity via the dermal route.
TEST FACILITY	Hüls AG (1992a)

B.3. Acute Inhalation Toxicity – Rat

TEST SUBSTANCE	Analogue 1
METHOD	Similar to OECD TG 403 Acute Inhalation Toxicity
Species/Strain	Rat/Sprague-Dawley
Vehicle	None
Method of Exposure	Whole-body exposure
Exposure Period	6 hours
Physical Form	Liquid aerosol (particulate)
Remarks – Method	No GLP Compliance Statement. Non-standard method that is similar to but pre-dates the OECD Test Guideline. The tables and appendices of the study report were not provided.

RESULTS

Group	*Number and Sex of Animals*	*Concentration (ppm)*	*Mortality*
1	10 M	200	0/10
2	3 M	Control (air)	0/3

LC50	> 200 ppm/6 hours
Signs of Toxicity	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were observed.
Remarks – Results	The study report stated that respirable size particles were obtained.
CONCLUSION	No adverse effects were observed via inhalation up to 200 ppm under the conditions of the study.
TEST FACILITY	FDLR (1978)

B.4. Skin Irritation – Rabbit

TEST SUBSTANCE	Analogue 1
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None.
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks – Method	No GLP Compliance Statement. Non-standard method that is similar to but pre-dates the OECD Test Guideline. The exposure time was 24 h, and observations were made immediately after exposure ceased, and 48 h after exposure ceased. Both intact and abraded skin were tested.

RESULTS

Remarks – Results	No signs of irritations were observed on any treated animals for the full duration of the study.
CONCLUSION	The analogue chemical is non-irritating to the skin.
TEST FACILITY	Consultox (1971)

B.5. Eye Irritation – Rabbit

TEST SUBSTANCE	Analogue 1
METHOD	Similar to OECD TG 405 Acute Eye Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	7 days
Remarks – Method	No GLP Compliance Statement. Non-standard method that is similar to but pre-dates the OECD Test Guideline. 3 of the treated animals had their treated eye washed with lukewarm water immediately after administering the test substance. Conducted simultaneously with a 10-day intramuscular irritation study. The study was not dated. Observations were made 1,2,3,4 and 7 days after administration

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4^	5^	6^			
Conjunctiva – Redness	0.3	0.7	0	0	0	0	2	<48 h	0
Conjunctiva – Chemosis	0	0	0	0	0	0	0	None	0
Conjunctiva – Discharge	0	0	0	0	0	0	0	None	0
Corneal Opacity	0	0	0	0	0	0	0	None	0
Iridial Inflammation	0	0	0	0	0	0	0	None	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animals
^ Animals that had their treated eye washed

Remarks – Results	Only slight erythema in the conjunctivae was observed in 2 animals after treatment. No signs of irritation were observed on any treated animals beyond 24 hours after treatment.
CONCLUSION	The analogue chemical is slightly irritating to the eye.
TEST FACILITY	Consultox (undated)

B.6. Skin Sensitisation – Guinea Pig Maximisation Test

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 406 Skin Sensitisation – Magnusson and Kligman maximisation test (1987)
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum non-irritating concentration: Intradermal: Very slight erythema and well defined oedema were seen at all concentrations tested, up to 10% Topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 20 F Control Group: 10 F
Vehicle	Maize germ oil
Positive Control	Not conducted in parallel with the test substance. It was stated that the sensitivity of guinea pigs to standard allergens such as 1-chloro-2,4-dinitrobenzene is checked at regular intervals.

INDUCTION PHASE	Induction concentration: Intradermal: 10% Topical: 100%
Signs of Irritation	As no irritation was observed in the preliminary dermal test, the animals in the main study were pre-treated with sodium dodecyl sulfate (10%) to induce irritation. Erythema and oedema of different severity was observed in the treated animals at the injection sites.
CHALLENGE PHASE	
1st Challenge	Topical: 100%
2nd Challenge	Not conducted
Remarks – Method	GLP Compliance Statement. No protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after 1st Challenge*
Test Group	100%	0/20
Vehicle Control Group	0%	0/10

Remarks – Results	There were no skin reactions observed on any of the treated or control animals after 48 h and 72 h in the 1st Challenge. Based on these results, the 2nd Challenge was not conducted. The treated animals showed comparable body weight gain over the observation period compared to the controls.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.
TEST FACILITY	Hüls AG (1992b)

B.7. Genotoxicity – Bacteria

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 471 Bacterial Reverse Mutation Test (1983) Both plate incorporation procedure (Test 1) and pre incubation procedure (Test 2) were used.
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Liver preparation from Arochlor 1254-induced rats
Concentration Range in Main Test	a) With metabolic activation: 50, 160, 500, 1,600, 5,000 µg/plate b) Without metabolic activation: 50, 160, 500, 1,600, 5,000 µg/plate
Vehicle	Acetone
Remarks – Method	GLP Compliance Statement. No protocol deviations. No preliminary test was carried out. Positive controls used: *In the absence of S9-Mix:* Sodium azide for strains TA 1535 and TA 100 9-aminoacridine for strain TA 1537 2-nitrofluorene for strains TA 98 *In the presence of S9-Mix:* 2-aminoanthracene for all tested strains

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 5,000	> 1,600	Negative
Test 2	-	> 5,000	> 1,600	Negative
Present				
Test 1	-	> 5,000	> 1,600	Negative
Test 2	-	> 5,000	> 1,600	Negative

Remarks – Results: There was no evidence of mutagenic activity at any concentration level of the test substance, in the presence or absence of metabolic activation.

The positive and vehicle controls gave satisfactory responses, confirming the validity and sensitivity of the test system.

CONCLUSION: The analogue chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Hüls AG (1995b)

B.8. Genotoxicity – *In Vitro* Chromosomal Aberration

TEST SUBSTANCE: Analogue 2

METHOD: OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test

Species/Strain	Chinese Hamster
Cell Type/Cell Line	Lung Cells, V79
Metabolic Activation System	Liver preparation from Arochlor 1254-induced rats
Vehicle	Ethanol
Remarks – Method	GLP Compliance Statement. No protocol deviations. A negative control and two positive controls (mitomycin C in the absence of S9, cyclophosphamide in the presence of S9) were run concurrently with the assessed chemical.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1, 2, 4, 6, 10*, 20, 40*, 60, 80*, 100	18 h	18 h
Test 2	10*, 40*, 80*	18 h	18 h
Test 3	80*	28 h	28 h
Present			
Test 1	1, 2, 4, 6, 10*, 20, 40, 60*, 80, 100*	3 h	18 h
Test 2	10*, 60*, 100*	3 h	18 h
Test 3	100*	3 h	28 h

*Cultures selected for metaphase analysis

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test**	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 100	> 100	Negative
Test 2	-	> 100	> 100	Negative
Test 3	-	> 100	> 100	Negative
Present				
Test 1	-	> 100	> 100	Negative
Test 2	-	> 100	> 100	Negative

Test 3	-	> 100	> 100	Negative

*Concentration at which mitotic index of test group was < 50% of mitotic index of the negative controls.

Remarks – Results	The test substance did not cause any dose related or statistically significant increase in the number of cells with structural chromosome aberrations in either the absence or presence of metabolic activation when tested up to the highest concentration. The positive and negative controls gave satisfactory responses confirming the validity of the test system.
CONCLUSION	The analogue chemical was not clastogenic to Chinese Hamster lung cells treated *in vitro* under the conditions of the test.
TEST FACILITY	Hüls AG (1997e)

B.9. Developmental Toxicity – Rat

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 414 Prenatal Developmental Toxicity Study (1981)
Species/Strain	Rat /Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Exposure days: 10 days (gestation days 6 – 15) Post-exposure observation period: 5 days (until gestation day 20)
Vehicle	Arachidis oil
Remarks – Method	GLP Compliance Statement. No protocol deviations.

RESULTS

Group	*Number of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
1	24 F	0	0/24
2	24 F	100	0/24
3	24 F	300	0/24
4	24 F	1,000	0/24

Mortality and Time to Death

There were no unscheduled deaths during this study.

Effects on Dams

No treatment-related effects were noticed in any of the treated dams, and body weight gain was comparable to the controls. No macroscopic changes were noted during necropsy. No other variations in reproductive parameters, including embryonic losses, total number of foetuses and placental/uterine weight, were observed.

Effects on Foetus

There were 6 dead foetuses from one dam in the control group, all with malformations. Hydrocephalus was also observed on one foetus out of 316 in the low dose group. These numbers were considered by the study authors to be within normal range for the animals used. A statistically significant decrease in the number of skull bones incompletely or non-ossified was observed in the low and high dose groups. However, this was due to the control group having a higher number of incompletely or non-ossified skull bones.

No statistically significant variations were observed in other developmental parameters, such as foetal weight, sex ratios, visceral effects or external malformations.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) for developmental toxicity was established as > 1,000 mg/kg bw/day in this study, based on the highest dose tested.

TEST FACILITY Henkel (1994)

BIBLIOGRAPHY

ACI (2010) Consumer Product Ingredient Safety, Exposure and Risk Screening Methods for Consumer Product Ingredients, 2nd Edition, American Cleaning Institute, Washington DC

Cadby et al. (2002) Consumer Exposure to fragrance Ingredients: Providing Estimates for Safety Evaluation. Regulatory Toxicology and Pharmacology 36: 246- 252.

CIR (2015) Safety Assessment of Propylene Glycol Esters as used in Cosmetics (Final Amended Report), Cosmetic Ingredient Review Expert Panel

Consultox (1971) A Report Prepared for Dynamit Nobel AG: Spezialol VP 840 Draize Skin Test (Study No. CL:71:62:504, April, 1971) London, UK, Consultox Laboratories Ltd. (Unpublished report submitted by the applicant).

Consultox (1972) A Report Prepared for Dynamit Nobel AG: Miglyol 840 Acute Oral Toxicity (Study No. CL:72:85:690, May, 1972). London, UK, Consultox Laboratories Ltd. (Unpublished report submitted by the applicant).

Consultox (undated) A Report Prepared for Dynamit Nobel AG: Miglyol 840 Irritation Studies (Study No. CL:76:129:1347, undated) London, UK, Consultox Laboratories Ltd. (Unpublished report submitted by the applicant).

Earnest, C.W., Jr. (2009) A Two-Zone Model to Predict Inhalation Exposure to Toxic Chemicals in Cleaning Products, MScEng thesis, The University of Texas at Austin.

enHealth (2012) Australian Exposure Factor Guidance. Guideline for Determining Human Health Risks from Environmental Hazards, Commonwealth of Australia.

FDRL (1978) Inhalation Toxicity of Miglyol 840 When Exposed to Sprague-Dawley Rats As a Mist at 200 ppm for Six Hours (Study No. 5718-2, April, 1978) Waverly, NY, USA, Food and Drug Research Laboratories Inc. (Unpublished report submitted by the applicant).

Gingell *et al*., (2000) Subchronic Toxicity Study of 1,3-Propanediol Administered Orally to Rats. International Journal of Toxicology, 19: 27–32.

Henkel (1994) Rilanit PC Embryotoxicity Study (including Teratogenicity) in the Rat (Segment 1I) Final report (Study No. RT 920404, January, 1994). Dusseldorf, Germany, Henkel AG & Co. KGaA (Unpublished report submitted by the applicant).

Henkel (2012a) Determination of the Melting Point/Melting Point Range of the test item Decanoic acid, mixed diesters with octanoic acid and 1,3-propanediol, CAS 1072005-10-7 (Study No. 11-17654/1-1/12-00685/1-1, January, 2012). Dusseldorf, Germany, Henkel AG & Co. KGaA (Unpublished report submitted by the applicant)

Henkel (2012b) Decanoic acid, mixed diesters with octanoic acid and 1,3-propanediol, Determination of Viscosity (Study No. 11-17654/1-5/12-00685/1-5, February, 2012). Dusseldorf, Germany, Henkel AG & Co. KGaA (Unpublished report submitted by the applicant)

Henkel (2012c) Determination of the Water Solubility of the test item Decanoic acid, mixed diesters with octanoic acid and 1,3-propanediol, CAS 1072005-10-7 (Study No. 11-17654/1-2/ 12-00685/1-2, March, 2012). Dusseldorf, Germany, Henkel AG & Co. KGaA (Unpublished report submitted by the applicant).

Henkel (2012d) Determination of the Flash Point of the test item Decanoic acid, mixed diesters with octanoic acid and 1,3-propanediol, CAS 1072005-10-7 (Study No. 11-17654/1-3/12-00685/1-3, January, 2012). Dusseldorf, Germany, Henkel AG & Co. KGaA (Unpublished report submitted by the applicant)

Henkel (2012e) Determination of the Auto Ignition Temperature of the test item Decanoic acid, mixed diesters with octanoic acid and 1,3-propanediol, CAS 1072005-10-7 (Study No. 11-17654/1-4/12-00685/1-4, March, 2012). Dusseldorf, Germany, Henkel AG & Co. KGaA (Unpublished report submitted by the applicant)

Hüls AG (1992a) Test of the Acute Dermal Toxicity of Miglyol 8810 for Rats (Study No. AD-91/0041, March, 1992). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

Hüls AG (1992b) Test of the Skin Sensitising Effect of Miglyol 8810 for Guinea Pigs (Magnusson and Kligman maximisation test) (Study No. HS-91/0041, March, 1992). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

Hüls AG (1995a) Acute Toxicity of the test item Miglyol 840 to *Daphnia magna*, CAS 68583-51-7 (Study No. DK-635, May, 1995). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

Hüls AG (1995b) *S. typhimurium* Reverse Mutation Assay (Ames-Test) with Miglyol 840 (Study No. AM-95/11, August, 1995). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

Hüls AG (1997a) Acute Toxicity of the test item Miglyol 8810 to *Scenedesmus subspicatus*, CAS 853947-59-8 (Study No. AW-460, August, 1997). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

Hüls AG (1997b) Acute Toxicity of the test item Miglyol 8810 to *Brachydanio rerio*, CAS 853947-59-8 (Study No. FK-1393, September, 1997). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

Hüls AG (1997c) Ready Biodegradability of the test item Miglyol 8810, CAS 853947-59-8 (Study No. ST-130/97, September, 1997). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

Hüls AG (1997d) Activated sludge respiration inhibition test of the test item Miglyol 8810, CAS 853947-59-8 (Study No. BH-97/08, July, 1997). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

Hüls AG (1997e) *in vitro* Chromosomal Aberration Assay with Miglyol 8810 (Study No. CA-97/0221, December, 1997). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the applicant).

NICNAS. NICNAS IMAP Human health Tier I Assessment for 1,3-Propanediol. Accessed at see https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=504-63-2 on 23 December 2020.

Loretz *et al*., (2006) Exposure Data for Personal Care Products: Hairspray, Spray Perfume, Liquid Foundation, Shampoo, Body Wash and Solid Antiperspirant. Food and Chemical Toxicology 44: 2008-2018.

Rothe *et al*., (2011) Special Aspects of Cosmetic Spray Safety Evaluations: Principles on Inhalation Risk Assessment. Toxicology Letters 205: 97-104.

SCCS (2012) The SCCS's notes of guidance for the testing of cosmetic substances and their safety evaluation (8th revision), European Commission - Scientific Committee on Consumer Safety

Steiling *et al*., (2014) Principle Considerations for the Risk Assessment of Sprayed Consumer Products. Toxicology Letters 227: 41-49.

Struijs J (1996). SimpleTreat 3.0: a model to predict the distribution and elimination of chemicals by sewage treatment plants. National Institute of Public Health and the Environment, Bilthoven, The Netherlands.

Summerfield and Tappel (1984) Cross-linking of DNA in Liver and Testes of Rats Fed 1,3-Propanediol. Chemico-Biological Interactions 50: 87–96.

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 >