File No: LTD/1645

March 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

1,2,3-Propanetriol, homopolymer, ether with methyl D-glucopyranoside dioctadecanoate (INCI name: Polyglyceryl-3 Methylglucose Distearate)

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

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

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

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1645	Unilever Asia Private Limited	1,2,3-Propanetriol, homopolymer, ether with methyl D-glucopyranoside dioctadecanoate (INCI name: Polyglyceryl-3 Methylglucose Distearate)	No	≤1 tonne per annum	Component of rinse-off and leave-on cosmetic products

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).

As no ecotoxicity data were submitted, the notified chemical is not recommended for environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS). Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

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
On the basis of the PEC/PNEC ratio and the 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 isolation and engineering controls to minimise occupational exposure to the notified chemical during reformulation processes:
  - Enclosed, automated processes, where possible
  - Ventilation system including local exhaust ventilation

- 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 during reformulation processes:
  - Goggles

- 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

- The notified chemical should be disposed of to landfill.

Storage

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

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical;
- the notified chemical is proposed to be used in aerosol spray cosmetics;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of rinse-off and leave-on cosmetic products, or is likely to change significantly;
- the concentration of the notified chemical exceeds or is intended to exceed 10% in leave-on or rinse-off cosmetic products;
- 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)

Unilever Asia Private Limited (ABN: 29 142 738 538)
C/- Unilever Australia Supply Services
20-22 Cambridge Street
Epping, NSW 2121

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: analytical data, degree of purity, impurities and additives/adjuvants.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Tego Care 450

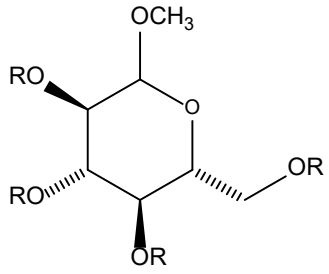
CAS NUMBER
187339-62-4

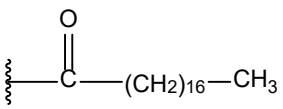
CHEMICAL NAME
1,2,3-Propanetriol, homopolymer, ether with methyl D-glucopyranoside dioctadecanoate

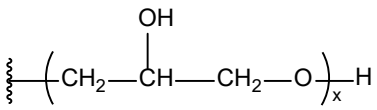
OTHER NAME(S)
Polyglyceryl-3 Methylglucose Distearate (INCI name)
Polyglycerol methylglucose distearate

MOLECULAR FORMULA
$C_{43}H_{82}O_8.x(C_3H_8O_3)_x$

STRUCTURAL FORMULA



Wherein 2 x R groups = 

and the remaining R groups = H or 

(for Polyglyceryl-3 Methylglucose Distearate, x = 3)

MOLECULAR WEIGHT
>897 Da (corresponds to $C_{46}H_{88}O_{10}$)

ANALYTICAL DATA
None

3. COMPOSITION

DEGREE OF PURITY >95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: ivory pellets

Property	Value	Data Source/Justification
Melting Point/Freezing Point	52-58 °C	(M)SDS
Density	900 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight of the chemical
Water Solubility	Not determined	Expected to be low based on its predominantly hydrophobic nature, however, the notified chemical may be dispersible in water based on its potential surface activity
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality, however, it is expected to hydrolyse slowly in the environmental pH range (4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to the interface between n-octanol and water based on its potential surface activity
Adsorption/Desorption	Not determined	Expected to partition to phase boundaries based on its potential surface activity
Dissociation Constant	Not determined	Does not contain dissociable functionality
Acid Value	0-12 mg KOH/g	Measured
Iodine Value	<5 g I/100g	Measured
Saponification Value	120-140 mg KOH/g	Measured
Particle Size	Not determined	Manufactured in pellet form
Flash Point	>100 °C	(M)SDS
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use
Explosive Properties	Predicted negative	Contains no functional groups that would imply explosive properties
Oxidising Properties	Predicted negative	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES
Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the limited 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 be imported into Australia as a component of finished cosmetic products. In the future, the notified chemical may be imported neat for subsequent reformulation processes into cosmetic products.

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

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

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Unilever Asia Private Limited (Unilever Australia Supply Services)

TRANSPORTATION AND PACKAGING
The notified chemical as a component (up to 10%) of finished cosmetic products will be imported in containers suitable for retail sale (up to 500 mL capacity). When imported at up to 100%, the notified chemical will be in containers suitable for distribution to reformulation sites. The containers will be distributed to distribution centres/reformulation sites and retail outlets within Australia by road.

USE
The notified chemical will be used as a component of leave-on (up to 10%) and rinse-off (up to 6%) cosmetic products.

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

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

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4	12
Chemist/quality assurance	3	12
Compounder	8	12
Packaging	8	12
Salon workers	Unspecified	Unspecified

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified chemical (up to 100%) only in the event of an accidental rupture of containers.

During reformulation processes, dermal, ocular and perhaps inhalation exposure of workers to the notified chemical (up to 100%) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of mechanical

ventilation and/or enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, goggles and impervious gloves.

Dermal, inhalation and ocular exposure to the notified chemical in end-use products (up to 10%) may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. hair dressers, workers in beauty salons). Such professionals may use some PPE to minimise exposure, and 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

There will be widespread and repeated exposure of the public to the notified chemical (up to 10% in cosmetics) through use of the products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >5000 mg/kg bw; low toxicity
Rabbit, acute dermal toxicity	LD50 >5000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – GPMT	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution.

No toxicokinetic data on the notified chemical were submitted. The molecular weight of the notified chemical (> 897 Da) does not favour absorption across the gastrointestinal tract or through the skin. The expected low gastrointestinal and dermal absorption are further supported by the lack of systemic toxicity observed in the acute oral and acute dermal toxicity studies. Inhalation absorption from inhaled aerosols cannot be ruled out.

Acute toxicity.

The notified chemical was of low acute oral toxicity (LD50 >5000 mg/kg bw) in rats and of low acute dermal toxicity (LD50 >5000 mg/kg bw) in rabbits. No acute inhalation toxicity studies were submitted for the notified chemical. Based on the high molecular weight, the vapour pressure of the notified chemical is expected to be low; therefore inhalation exposure is not expected unless aerosols are formed.

Irritation and sensitisation.

The notified chemical was not a skin irritant but was a slight eye irritant in rabbit studies. The notified chemical was not a skin sensitiser in a guinea pig maximisation test.

Repeated Dose Toxicity.

No repeat dose toxicity data on the notified chemical were submitted. The potential for systemic toxicity is considered to be low based on the expected low absorption of the notified chemical.

Mutagenicity/Genotoxicity.

The notified chemical was not mutagenic in a bacterial reverse mutation assay.

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

Dermal, inhalation and ocular exposure of workers to the notified chemical (up to 100%) may occur during

reformulation and packaging processes. Given that the exposure of workers is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, goggles and impervious gloves, the risk to workers from reformulation and packaging of the notified chemical is not considered to be unreasonable.

Workers involved in professions where the services provided involve the application of cosmetic products containing the notified chemical (up to 10%) 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 (for details of the public health risk assessment, see Section 6.3.2.).

6.3.2. Public Health

At the proposed usage concentration of up to 10% notified chemical in rinse-off and leave-on cosmetic products, eye irritation is not expected. Dermal absorption of the notified chemical is expected to be limited. The notified chemical may be ingested, however, systemic exposure via the oral route is expected to be limited by the low amount of notified chemical available for oral exposure, (demonstrated by the low application amount of lip care products - SCCS, 2010), and the expected low absorption from the gastrointestinal tract. In the event of systemic exposure, exposure levels are likely to be negligible. Therefore, the risk associated with use of the notified chemical at up to 10% concentration in rinse-off and leave-on cosmetic products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. Therefore, no release to the environment is expected from this activity. Releases to the environment may occur following accidental spills during import, transport or storage. Notified chemical that is spilled is expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations.

The notified chemical may be reformulated in Australia into a variety of cosmetic products. Typical wastes that will be generated during reformulation and that may contain the notified chemical include reformulation equipment washings, empty import containers and spilt materials. Due to its potential water dispersibility, some of the notified chemical may be released to sewers in dilute aqueous rinsate. Up to 1% of the notified chemical is expected to be disposed of to landfill as residues in empty import containers.

RELEASE OF CHEMICAL FROM USE

Formulated products containing the notified chemical are expected to be applied to skin and hair. It is expected that the majority of the annual import volume will be washed off the skin and hair and released to the sewer following consumer use.

RELEASE OF CHEMICAL FROM DISPOSAL

Expired product and residues of the notified chemical in the empty consumer containers (3%) are likely either to share the fate of the container and be disposed of to landfill, or be washed to sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate

No environmental fate data were submitted.

The majority of the notified chemical is expected to be disposed of to sewer following its use in cosmetic products. Based on the surface activity of the notified chemical, it has the potential to be water dispersible and remain in the water compartment after sewage treatment processes. The notified chemical released to surface waters is expected to disperse and degrade. The notified chemical disposed of to landfill is expected to partition to phase boundaries based on its potential surface activity. Based on its structure and water dispersibility, the notified chemical is expected to hydrolyse slowly in the environmental pH range. The notified chemical is likely to be readily biodegradable with ultimate degradation potentially occurring within weeks (BIOWIN v4.10, US EPA, 2011; Madsen, 2001) and is expected to eventually degrade to form water and oxides of

carbon. The notified chemical may be bioavailable based on its potential to be water dispersible. However, the notified chemical is not expected to readily bioaccumulate based on its potential to rapidly degrade.

7.1.3. Predicted Environmental Concentration (PEC)

A worst-case predicted environmental concentration (PEC) was calculated assuming 100% of the total import volume of the notified polymer is released to sewer over 365 days per year with no removal from sewage treatment plant (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	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.61	µg/L
PEC - Ocean:	0.061	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.606 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20.2 µg/kg and 40.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified chemical has potential surface activity and may be water dispersible. Based on the structure of the notified chemical and considering the toxicity of alkyl glycosides to aquatic life, the potential worst-case toxicities are outlined in the table below (Madsen *et al.,* 2001).

Endpoint	*Result*	*Assessment Conclusion*
Acute Toxicity		
Fish Toxicity (96 hour)	LC50 = 1 – 100 mg/L	Potentially toxic to fish
Daphnia Toxicity (48 hour)	EC50 = 10 – 100 mg/L	Potentially harmful to aquatic invertebrates
Algal Toxicity (96 hour)	EC50 = 10 – 100 mg/L	Potentially harmful to algae

Based on the data for alkyl glycosides, the notified chemical is potentially toxic to fish and potentially harmful to daphnia and algae. However, the ecotoxicological endpoints are based on potential worst-case toxicities and are expected to be conservative estimates, which are presented here only for the purposes of risk assessment. Therefore, the notified chemical is not formally classified for acute aquatic hazard under the GHS (United Nations, 2009). As the notified chemical is likely to rapidly biodegrade, it is not classified for chronic aquatic hazard under the GHS.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) was calculated using the worst-case toxicity estimate for the most sensitive species, fish. As this is a worst-case estimate for PNEC, the lowest value for toxicity (LC50 = 1 mg/L) was used. An assessment factor of 1000 was used as measured toxicity data was not available for the notified chemical and the values used are based on estimates for the toxicity of the notified chemical.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish)	> 1	mg/L
Assessment Factor	1000	

PNEC:	> 1 µg/L

7.3. Environmental Risk Assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River	0.61	> 1	< 0.61
Q - Ocean	0.061	> 1	< 0.061

Based on a worst-case scenario where the notified chemical is, at worst, toxic to fish, the risk quotients (PEC ÷ PNEC = Q) for river and marine waters have been calculated to be less than one. As this is a worst-case scenario, the actual value for Q is likely to be much less than the calculated value. The notified chemical is also not expected to bioaccumulate based on its surface activity and potential to rapidly biodegrade. Therefore, the notified chemical is not expected to pose an unreasonable risk to the environment based on the assessed use pattern.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 401 Acute Oral Toxicity
Species/Strain	Rat/Sprague-Dawley
Vehicle	Water
Remarks - Method	Minimal details of the study conduct were provided. The study report did not specify whether necropsy was conducted following sacrifice on day 14.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	5000	0/5
2	5 F	5000	0/5

LD50	>5000 mg/kg bw
Signs of Toxicity	None
Remarks - Results	All animals appeared active and healthy during the study.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	PSL (1993a)

A.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 402 Acute Dermal Toxicity
Species/Strain	Rabbit/New Zealand White
Vehicle	Moistened with distilled water
Type of dressing	Semi-occlusive
Remarks - Method	Minimal details of the study conduct were provided. The test substance was applied to a shave 4×6 inch area.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	5000	0/5
2	5 F	5000	0/5

LD50	>5000 mg/kg bw
Signs of Toxicity - Local	None reported
Signs of Toxicity - Systemic	None
Effects in Organs	None
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	PSL (1994a)

A.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion

Species/Strain	Rabbit/New Zealand White
Number of Animals	3M + 3F
Vehicle	Moistened with distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	Minimal details of the study conduct were provided.

RESULTS

Remarks - Results	Very slight erythema (grade 1) was observed in a single male at 1 hour. Scores of zero were observed for all animals at all other observations points.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY PSL (1994b)

A.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion

Species/Strain	Rabbit/New Zealand White
Number of Animals	3M + 3F
Observation Period	72 hours
Remarks - Method	Minimal details of the study conduct were provided.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.6	3	<72 hours	0
Conjunctiva: chemosis	0.3	2	<72 hours	0
Conjunctiva: discharge	0.1	1	<48 hours	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY PSL (1993b)

A.5. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 406 Skin Sensitisation – GPMT

Species/Strain	Guinea pig/Hartley albino
Vehicle	Water
PRELIMINARY STUDY	Maximum Non-irritating Concentration: 25% (topical)
MAIN STUDY	
Number of Animals	Test Group: 10 Positive Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 50%
Signs of Irritation	Very faint to faint erythema was observed following topical induction.
CHALLENGE PHASE	
1st challenge	topical: 25%
Remarks - Method	The preliminary study was conducted with occlusive dermal doses

applied for 24 hours at up to 95% concentration (to account for water used to moisten the test substance) to 5 animals. Very faint erythema was observed in one animal treated at 25% concentration but this concentration was still considered to be the maximum non-irritant concentration. Irritation increased with concentration in the preliminary study. The positive control 1-chloro-2,4-dinitrobenzene (DNCB) was assessed in a similar way with 6 animals up to a 0.10% concentration.

The intradermal induction conducted on day 0 consisted of three pairs of 0.05 mL injections (one on each side of the upper back): 1) 50% FCA solution in water, 2) 5% solution of test substance in water and 3) 1:1 mixture of 50% FCA and 5% solution of test substance. A positive control group was treated similarly except that a 0.08% solution of DNCB in 80% ethanol, was used in place of the test substance.

The topical induction conducted on day 6 consisted of a single 0.4 mL dermal dose of a 50% solution of test substance in water, occluded for 48 hours. The positive control group were treated similarly with the 0.08% solution of DNCB. Test sites were cleansed with water following the exposure period.

Thirteen days after topical induction, the animals were challenged with 25% solution of test substance or 0.03% solution of DNCB in acetone, occluded for 24 hours. Dermal reactions were observed at 24 and 48 hours. Additional naïve controls were treated with either the test substance (5 animals) or the positive control (5 animals).

Based on a marginal positive result in the positive control group, these animals were rechallenged 5 days after the initial challenge, with an additional five naïve control animals.

A negative control group was not included.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group					
main	25% notified chemical	7/10	5/10	-	-
naïve	25% notified chemical	4/5	1/5	-	-
Positive Control Group					
main	0.03% DNCB	8/10	3/10	10/10	9/10
naïve	0.03% DNCB	0/5	0/5	2/5	0/5

DNCB, 1-chloro-2,4-dinitrobenzene.

Remarks - Results

All positive skin reactions at challenge in the test groups were very faint erythema, as were the reactions in the positive control group. The positive control group were rechallenged to demonstrate a more clearly positive result. The main and naïve animals in the test group showed similar dermal reactions, thus the test substance is not considered to have sensitising potential.

The 0.4 mL volume applied at topical induction and challenge was below the 0.5 mL volume recommended in the current OECD test guideline. This deviation may decrease the sensitivity of the test.

CONCLUSION

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

TEST FACILITY PSL (1994c)

A.6. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 471 Bacterial Reverse Mutation Test
Pre-incubation and plate incorporation method

Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test`	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Corn oil
Remarks - Method	A range-finding study was conducted with strains TA100 and WP2uvrA in the presence and absence of metabolic activation between 5-5000 µg/plate. The main study was conducted using the plate incorporation (Test 1) and the pre-incubation (Test 2) procedures. The TA1538 strain was repeated using the plate incorportation method in a third test due to an equivocal finding.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	>5000	negative
Test 2	-	>5000	≥500	negative
Present				
Test 1	>5000	>5000	>5000	negative
Test 2	-	>5000	≥500	negative

Remarks - Results An equivocal finding was observed in Test 1 in the absence of metabolic activation in tester strain TA1538 at 1000 µg/plate in the mean revertants per plate that was 2.1 times the concurrent solvent control. A negative result was obtained when this strain was repeated.

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

TEST FACILITY SITEK (1994)

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