File No: SN/25

June 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Rape Oil, Polymer with Tung Oil (INCI name: Brassica Campestris/Aleurites Fordi Oil Copolymer)

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
SN/25	Ingredients Plus Pty Ltd	Rape Oil, Polymer with Tung Oil (INCI name: Brassica Campestris/Aleurites Fordi Oil Copolymer)	ND	≤ 2 tonnes per annum	Component in rinse-off and leave-on cosmetic products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004)

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

When used 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 reported use pattern, the notified chemical is not expected to pose a 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 to the notified chemical during formulation 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 notified during formulation of products:
  - Coveralls, impervious gloves, and goggles

  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

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

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(2) of the Act; if
- the function or use of the chemical has changed from a component in rinse-off and leave-on cosmetic products, or is likely to change significantly;
- the amount of chemical being introduced has increased from 2 tonnes per annum, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet
The (M)SDS of the notified chemical 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)
Ingredients Plus Pty Ltd (ABN: 25 112 469 619)
Unit 8, 9-11 South Street
Rydalmere, NSW, 2116

Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* [the IC(NA) Act], as LTD/1461, with the Summary Report of the assessment published in the *Chemical Gazette* of 6th July, 2010.

The Director of NICNAS was informed of an increase in the introduction volume of the notified chemical in excess of the permitted volume under the limited category (1 tonne/annum). Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical known as Rape Oil, Polymer with Tung Oil (INCI name: Brassica Campestris/Aleurites Fordi Oil Copolymer).

In accordance with Section 65 of the IC(NA) Act, a notice requiring the secondary notification of Rape Oil, Polymer with Tung Oil (INCI name: Brassica Campestris/Aleurites Fordi Oil Copolymer) was published in the *Chemical Gazette*. The notice of 1st May, 2012 stipulated that the following data were required to undertake further assessment of Rape Oil, Polymer with Tung Oil (INCI name: Brassica Campestris/Aleurites Fordi Oil Copolymer):

1. Any changes in the following data items from that submitted in the original notification:
   a) proposed uses of the chemical;
   b) concentration of the chemical in end-use products;
   c) import quantity (and changes to occupational exposure for workers);
   d) physico-chemical properties.

2. Comment on the potential for hydrolysis/expected metabolism of the chemical (and, if relevant, the expected hydrolysis products) following ingestion;

3. Additional data regarding:
   a) the toxic effects of the chemical following repeated exposure (especially via the oral route);
   b) the genotoxic effects of the chemical, if available;
   c) the environmental effects of the chemical (such as toxicity to fish and invertebrates, effects on algae and biodegradability), if available.

The requested data was to be provided through the submission of studies [tests conducted on the notified chemical, constituent monomers (tung oil and rape oil) or suitable analogue] or other sources of information.

This report, SN/25, represents the revised assessment for Rape Oil, Polymer with Tung Oil (INCI name: Brassica Campestris/Aleurites Fordi Oil Copolymer). Where additional data has been provided, it has been incorporated into the report (if necessary) and the implications of the data for the health and environmental risks of the notified chemical considered.

NOTIFICATION CATEGORY
Secondary notification

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a Function of pH, Partition Coefficient, Absorption/Desorption, Dissociation Constant, Flammability Limits and Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LTD/1461

NOTIFICATION IN OTHER COUNTRIES
EU, USA and Japan prior to 2002

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Glossamer L6600

CAS NUMBER
185323-46-0

CHEMICAL NAME
Rape oil, polymer with tung oil

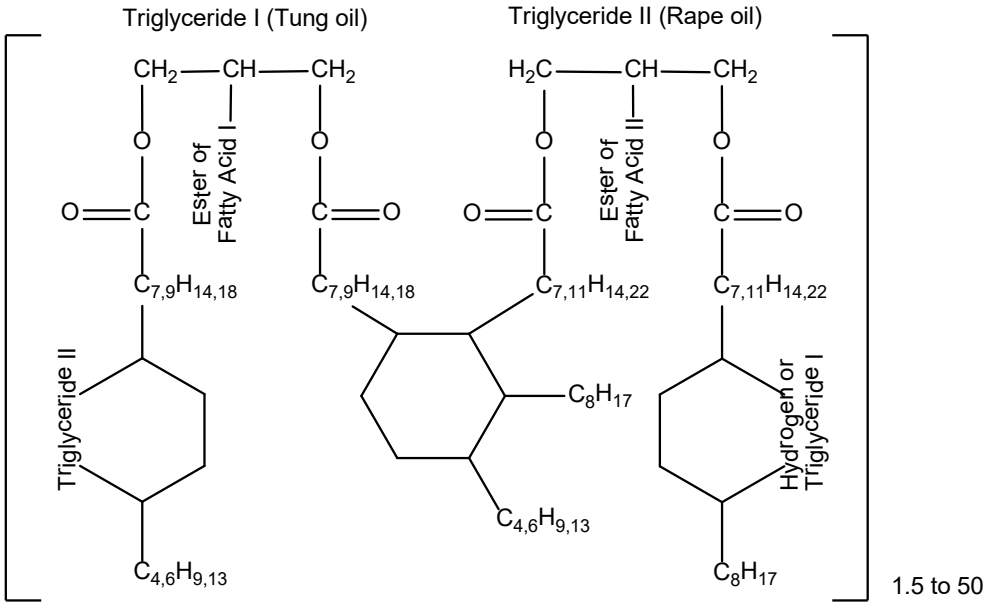
OTHER NAME(S)
Brassica Campestris/Aleurites Fordi Oil Copolymer (INCI name)

MOLECULAR FORMULA
unspecified (UVCB substance)

STRUCTURAL FORMULA

Note: UVCB Representative Structure.

- Rape oil consists primarily of the glycerides of the fatty acids erucic (18:1), linoleic (18:2) and oleic (18:1).
- Tung oil consists primarily of the glycerides of the fatty acid eleostearic (18:3)
- The notified chemical has a reported iodine value (indicating the degree of unsaturation) of 103.5.



Where Fatty Acid I (from Tung oil) is Stearic (18:0), Oleic (18:1)
Where Fatty Acid II (from Rape oil) is Stearic (18:0), Oleic (18:1), Erucic (22:1), Behenic (22:0)

MOLECULAR WEIGHT

Mn 2,200 [Note: The notified chemical consists of *ca*. 40 wt% of high molecular weight polymerised product (and low molecular weight oligomers) and *ca*. 60 wt% of a mixture of tung oil (Mn: 1,230) and rapeseed oil (Mn: 1,430)]. The percentages of low molecular weight species are 9.8% < 1000 and 1.2% < 500.

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY UVCB Substance. The notified chemical consists of *ca*. 40 wt% of high molecular weight polymerised product (and low molecular weight oligomers) and *ca*. 60 wt% of a mixture of tung oil (Mn: 1,230) and rapeseed oil (Mn: 1,430).

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None identified

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight) None identified

ADDITIVES/ADJUVANTS Tocopherol (natural): 0.1 wt%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: yellow liquid

Property	Value	Data Source/Justification
Pour point	-21 ºC	Measured
Boiling Point	291.7 ºC	Measured
Relative Density	0.9393 at 60/60 ºF	Measured
Vapour Pressure	0.013 kPa at 25 ºC	Measured
Water Solubility	~0.04 g/L	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable functionality. However,

		hydrolysis is expected to be slow in the environmental pH range (4-9).
Partition Coefficient (n-octanol/water)	Not determined	The notified chemical is expected to partition from water to oil based on its hydrophobic structure.
Adsorption/Desorption	Not determined	The notified chemical is expected to partition to soil, sediment and sludge based on its hydrophobic structure.
Dissociation Constant	Not determined	The notified chemical does not contain dissociable functionality.
Flash Point	268 °C	Measured
Autoignition Temperature	424 °C	Measured
Explosive Properties	Not determined	The notified chemical contains no functional groups that would imply explosive properties.

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

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 be introduced into Australia (at 100% concentration) in HDPE buckets (net weight 18.14 kg).

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

Year	*1 tonnes*	*2 tonnes*	*3 tonnes*	*4 tonnes*	*5 tonnes*
Original notification	≤ 1	≤ 1	≤ 1	≤ 1	≤ 1
Maximum total (based on secondary notification)	≤ 1	≤ 1	≤ 2	≤ 2	≤ 2

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Following its introduction into Australia, the notified chemical will initially be delivered to Ingredients Plus Pty Ltd, Rydalmere, NSW, and then delivered to reformulation sites within Australia.

TRANSPORTATION AND PACKAGING
The notified chemical will be contained in HDPE buckets (Nett weight 18.14 kg). Shrink-wrapped pallets of the buckets will be transported by road to reformulation sites. Following reformulation, end-use products containing the notified chemical will be distributed within Australia *via* road or freight-train. End-use products may also be transported overseas *via* sea-freight or air-freight.

USE
The notified chemical is proposed to be used as a waterproofing and/or conditioning agent in cosmetic and personal care products at concentrations ≤ 10%. The notified chemical may be used in rinse-off and leave-on

products, including secondary sunscreens, lip products and hair-care products (for example, in hair conditioner at 0.3%).

OPERATION DESCRIPTION

The operation description details will likely vary depending on the nature of the cosmetic and personal care products formulated, and may involve both automated and manual transfer steps. In general, it is expected that following distribution to reformulation sites and quality-assurance analysis, the notified chemical will be added to mixing vessels at the specified concentration and then transferred to appropriate containers for distribution to retail stores and sale to the general public. The following, more-detailed operation description refers to the formulation of a hair conditioner product containing the notified chemical at 0.3%.

Following quality-assurance analysis, the notified chemical will be manually added to mixing vessels (final concentration 0.3%). The product containing the notified chemical will be transferred *via* automated processes to pallecon boxes, which will in-turn be transferred to product filling lines (*via* forklift). Automated processes will then be used to transfer the product to 750 mL HDPE bottles for end-use (open system). During this process, the end-use product will be exposed to the atmosphere until the containers are sealed for distribution to retail stores.

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	1-2	50
Mixing/weighing	≤ 8	240
Quality control samplers	0.5	240
Cleaners/maintenance	≤ 8	240

EXPOSURE DETAILS

Transport and storage workers may come into contact with the notified chemical (at 100% or as a component of end-use products) only in the event of accidental rupture of containers.

During formulation, exposure to the notified chemical (100% and/or as a component of end-use products) may occur during weighing and transfer stages, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of mechanical ventilation and personal protective equipment [PPE; (M)SDS of the notified chemical recommends the use of eye/face protection and chemical resistant gloves)].

Exposure to the notified chemical in end-use products may occur in professions where the services provided involve the application of personal care products to clients (e.g. hair dressers, workers in beauty salons). Such professionals may use some PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of either a similar or lesser level than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure

There will be widespread and repeated dermal exposure of the public to the notified chemical through the use of the rinse-off and leave-on cosmetic and personal care products.

6.2. Human Health Effects Assessment

Original notification:

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 B.

Endpoint	*Result and Assessment Conclusion*

Rat, acute oral toxicity (50%)	LD50 > 5,000 mg/kg bw; low toxicity
Rabbit, skin irritation (≤ 20%)	slightly irritating
Rabbit, eye irritation (10%)	minimally irritating
Guinea pig, skin sensitisation – non-adjuvant test (10%)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation (10%)	non mutagenic
Comedogenicity (10%)	non-comedogenic.

Toxicokinetics, metabolism and distribution.
Based on the high molecular weight (> 1000 Da) and low water solubility (~0.04 g/L) of the notified chemical, the potential to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited. However, the chemical contains a significant proportion of low molecular weight species (*ca*. 10% < 1000 Da) that may be absorbed.

Acute toxicity.
The notified chemical (tested at 50% concentration) was found to be of low acute oral toxicity (LD50 > 5,000 mg/kg bw).

Irritation and Sensitisation.
The notified chemical (tested at 3 concentrations: 5%, 10%, 20% notified chemical) was a slight skin irritant in rabbits. However, only 5% concentration showed slight dermal irritation whereas 10% and 20% concentrations showed no irritation effects.

The notified chemical (tested at 10% concentration) was found to be minimally irritating to the eyes of rabbits. These results suggest that the notified chemical (100%) may be a slight eye irritant.

The notified chemical (tested at 10% concentration) was not a skin sensitiser in guinea pigs (Buehler method).

The notified chemical (tested at 10% concentration) was found to be non-comedogenic in a rabbit comedogenicity assay.

Mutagenicity.
The notified chemical (tested at 10% concentration) was not mutagenic in a bacterial reverse mutation study.

Additional information
No repeat dose toxicity studies were conducted on the notified chemical.

Information regarding the potential toxicity of tung oil is, in general, sparce. The available information on this chemical is also conflicting in terms of the health effects of the chemical, and in terms of the component of the tung nut that is responsible for any observed toxicity (*i.e.* it may be components of the nut and the meal and/or the oil).

Secondary notification:
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 B.

Endpoint	*Result and Assessment Conclusion*
Repeat dose toxicity (in vitro)	low potential for toxicity

An *in vitro* test for repeat dose toxicity potential was conducted on the notified chemical, which the study authors note is equivalent to the toxicity expected in a 14 day repeat dose screening in vivo test in rats. The test represents a multi-endpoint biochemical assessment of general systemic toxicity and uses a proprietary algorithm to predict probability of effect. The study author's note that the chemical exhibited a low probability for toxicity under the conditions of this test. However, this study has not been validated for regulatory purposes and its reliability in predicting the in vivo effects of repeated exposure to the notified chemical is unknown.

It is noted that the expected low order of toxicity following oral administration is consistent with the limited potential for absorption of the notified chemical. However, it is also acknowledged that while the potential for absorption following oral administration is likely to be limited, hydrolysis of the notified chemical is expected to occur. It is noted that extensive information has been published on the general toxicity that is associated with alkyl esters and/or fatty acids and glycerol (e.g. CIR, 2013; CIR, 2012; OECD, 2002; and Erikson 1941)).

Overall, the available information indicates that the notified chemical is not expected to present a significant concern for toxicity following repeated administration.

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
The notified chemical is expected to be of low systemic toxicity but may be slightly irritating to the skin and eyes. It was not considered to be a skin sensitiser.

Workers may experience dermal and accidental ocular exposure to the notified chemical (at up to 100% concentration) during formulation of cosmetics. At such concentrations, there is potential for skin and eye irritation effects. However, the use of enclosed, automated processes and PPE (impervious gloves, goggles, and coveralls) should minimise the potential for exposure.

End-use
Beauty care professionals will handle the notified chemical at up to 10% concentration, similar to public use. The risk to workers who regularly use products containing the notified chemical is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis. For details of the public health risk assessment, see Section 6.3.2.

6.3.2. Public Health
The general public will have widespread and frequent exposure to the notified chemical during the use of cosmetic products containing the notified polymer at up to 10% concentration.

Local effects
Based on the information available, the notified chemical is considered to be a slight skin and eye irritant. However, at the proposed use concentration of up to 10% notified chemical in rinse-off and leave-on cosmetic products, skin and eye irritation are not expected.

Systemic effects
Dermal (and gastrointestinal) absorption of the notified chemical is expected to be limited. The notified chemical was found to be of low acute oral toxicity and was predicted to have a low probability of in vivo effects in an in vitro repeat dose toxicity study. Overall, based on the information available, adverse systemic effects from repeated exposure to the notified chemical at up to 10% concentration in cosmetic products are not expected.

Therefore, based on the available information, the risk to the health of members of the public using 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 be imported as a raw material for blending. It is expected to be released to landfill as residue in import containers (estimated to be < 1% of the annual import volume). Blending will be executed in closed automated systems and notified chemical residue remaining in blending equipment is estimated to be < 1%. Washings from blending equipment are anticipated to be included in the next formulation batch or treated by means of on-site waste treatment plants.

Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The notified chemical is a component in cosmetic products. Therefore, it is expected that the majority of the imported quantity will be released to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL
Residue of the notified chemical in the empty containers (< 1%) is likely either to share the fate of the container and be disposed of to landfill, or to be washed to the sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate
No environmental fate data were submitted. The majority of the notified chemical will be disposed of to the sewer and, as it is a high molecular weight non-ionic chemical, it is estimated to be removed by up to 90% in sewage treatment plant from adsoprtion to sediment and sludge (Boethling & Nabholz, 1996). Notified chemical in the aquatic compartment is unlikely to bioaccumulate based on its high molecular weight. In landfill, the notified chemical is likely to adsorb to soil and be immobile. It is expected to degrade biotically and abiotically to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)
Original notification:
Assuming that most of the notified chemical will be washed to the sewer, the following Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis was calculated.

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)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.65	µg/L
PEC - Ocean:	0.06	µg/L

The notified chemical is expected to adsorb to sludge and sediment, hence the removal of the notified chemical from influent by sewage treatment plant (STP) processes is expected. However, in this worst case model, the majority of the notified chemical is assumed to be released in effluent. 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 0.647 µg/L may potentially result in a soil concentration of approximately 4.316 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 21.58 µg/kg and 43.16 µg/kg, respectively. However, given the adsorptive nature of the notified chemical, these values should be considered as theoretical maximum concentrations only.

Secondary notification:
The proposed import volume of the notified chemical has been doubled to ≤ 2 tonnes per annum. However, as no Risk Quotient was calculated in the original assessment for use of the notified chemical (see below for details), revised PEC values were not determined.

7.2. Environmental Effects Assessment
No ecotoxicity data were submitted. Nonionic chemicals of high molecular weight and limited water solubility are generally of low concern for the environment (Boethling & Nabholz, 1996).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was not calculated as no ecotoxicity data were submitted and nonionic chemicals of high molecular weight and limited water solubility are generally of low concern for the environment.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not calculated as the PNEC was not determined. However, the majority of notified chemical disposed of to the sewer is expected to be removed by adsorption to sludge and sediment in sewage treatment plant processes, and is unlikely to bioaccumulate based on its high molecular weight. Therefore, the notified chemical is not expected to pose a risk to the environment on the basis of the reported use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour point -21 ºC

Method	ASTM D 97a
Remarks	Full report not provided
Test Facility	SGS (2004)

Boiling Point 291.7 ºC

Method	ASTM D 1120
Remarks	Full report not provided
Test Facility	SGS (2004)

Relative Density 0.9393 @ 60/60 ºF

Method	ASTM D 1298
Remarks	Full report not provided
Test Facility	PLTL (2004)

Vapour Pressure 0.013 kPa at 25ºC

Method	ASTM D 2879
Remarks	Full report not provided
Test Facility	PLTL (2004)

Water Solubility ~0.04 g/L

Method	In house method.
Remarks	The notified chemical (1.0 g) was added to distilled water (50 mL), in triplicate. The sample preparations were agitated vigorously, and excess test substance was visually observed on the surface of the water. A blank was run in parallel. All samples were centrifuged to separate the oily phase to the surface. The water phases were filtered through Whatman filter paper (#541, 150 mm diameter), and 10 mL aliquots were added to tared aluminium weighing dishes. The samples were evaporated to dryness at 70 °C, cooled in a dessicator and reweighed. Pure test substance was dried concurrently, to confirm that it was not volatile at 70 °C.
Test Facility	IAL (2004)

Flash Point 268 ºC

Method	ASTM D 93
Remarks	Full report not provided
Test Facility	PLTL (2004)

Autoignition Temperature 424 ºC

Method	ASTM E-659
Remarks	Full report not provided
Test Facility	PLTL (2004)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (50% in corn oil)
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	None
Remarks - Method	No significant protocol deviations
RESULTS	
Remarks - Results	There were no mortalities observed.
LD50	> 5,000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	PSL (1996a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified chemical (5%, 10% and 20% in corn oil)
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand albino
Number of Animals	3 male, 3 female
Vehicle	None.
Observation Period	*ca.* 1, 24, 48 and 72 hours after patch removal
Type of Dressing	Semi-occlusive.
Remarks - Method	0.5 mL of the test substances (and 100% corn oil control) were applied to 1 of 4 sites on each animal (3 male, 3 female). After 4 hours of exposure, the pads were removed and the sites wiped to remove residual test article. Individual dose sites were scored according to the Draize scoring system at *ca.* 1, 24, 48 and 72 hours after patch removal.
RESULTS	
Remarks - Results	For the 10% and 20% test substances, no dermal irritation was observed. For the 5% test substance, very slight edema and/or erythema was recorded at 3/6 sites. The irritation cleared from the affected sites within 24 hours.
CONCLUSION	The test substances are slightly irritating to the skin.
TEST FACILITY	PSL (1996b)

B.3. Irritation – eye

TEST SUBSTANCE	Notified chemical (10% in corn oil)
METHOD	Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	4 male, 5 female
Observation Period	*ca.* 1, 24, 48 and 72 hours post-instillation
Remarks - Method	0.1 mL of the test substance was instilled into the right eye of each animal. The treated eyes of three rabbits were rinsed with saline, the eyes of the remaining six were not rinsed. The left eye served as a control. Ocular irritation was evaluated based on scores determined at *ca.* 1, 24, 48 and 72 hours post-instillation.

RESULTS

Remarks - Results	No corneal opacity or iritis was noted during the study. At 1 and 24 hours post-instillation, all treated eyes exhibited conjunctivitis. All rabbits were free of ocular irritation by 72 hours.
CONCLUSION	The test substance is minimally irritating to the eye.
TEST FACILITY	PSL (1996c)

B.4. Skin sensitisation

TEST SUBSTANCE	Notified chemical (10% in corn oil)
METHOD	Similar to OECD TG 406 Skin Sensitisation – Buehler test method.
Species/Strain	Guinea pig/Hartley albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Positive control Group: 10
INDUCTION PHASE	Induction Concentration: 100% (topical)
Signs of Irritation	Very faint erythema was observed in two treated animals following the first and second inductions.
CHALLENGE PHASE	
1st challenge	topical: 100%
Remarks - Method	- 1-Chloro-2,4-dinitrobenzene [DNCB, 0.08% in 80% aqueous ethanol (induction phase) and 0.04% *w/w* in acetone (challenge phase)] was used as the positive control. - In addition to the 10 animals each in the Test and Positive Control Groups, there were 5 animals each in the Test Naïve and Positive Naïve Control Groups (treated at challenge only).

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100%	2/10	0/10
Positive Control Group	0.04%	7/10	5/10

Remarks - Results	Very faint erythema was noted at two test sites 24 hours after challenge. The irritation cleared from both affected sites by 48 hours.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	PSL (1996d)

B.5. Repeat dose toxicity (in vitro)

TEST SUBSTANCE	Notified chemical
METHOD	In vitro toxicology screening test to predict repeated dose toxicity potential
Cell Type/Cell Line	H4IIE rat hepatoma cells
Vehicle	Cremophor ELP
Concentration Range in Main Test	0-1 mg/mL

Remarks - Method

Limited details were provided in the study report.

Rat hepatoma (H4IIE) cells were exposed to a 48 hour equilibration and growth phase. Thereafter, the medium was replaced and the cells were exposed to 0-1 mg/mL of the test substance in 20% serum for 24 hours at 37 ºC. Each exposure was performed in replicates (n=3-6).

The cells were then analysed for the following biochemical endpoints:
Membrane integrity (α-glutathione S-transferase (GST))
Cell mass/proliferation (Propidium iodide (PI))
Mitochondrial function (adenosine triphosphate (ATP))
Oxidative stress (Total GSH),
Apoptosis (Caspase 3 activation)
Solubility

A final Ctox value was calculated from the assay results using unspecified proprietary algorithms to predict repeat dose toxicity potential in vivo.

Positive (Rotenone and Camptothecin) and negative (Cremophor ELP and DMSO) controls were run in parallel with the test substance.

The results for the notified chemical were provided in mg/ml, whereas the results for the positive controls were provided in µM. Conversion of the test substance to µM (i.e. assuming a molecular weight of 2,200 g/mol, e.g. 1 mg/mL corresponds to 454 µM) was conducted for readability purposes.

RESULTS

Test material	*Cell number* TC_{50} *(µM)*	*MemTox* TC_{50} *(µM)*	*ATP* TC_{50} *(µM)*	*Predicted Ctox (µM)*
Test substance	> 454	> 454	> 454	> 13
Rotenone	0.09	0.5	0.1	0.05
Camptothecin	3	> 100	1	0.1

TC_{50} = concentration that produced a half maximal response (values estimated from graphs that are not shown)
Ctox = Estimated sustained plasma concentration where toxicity would be expected to occur *in vivo*.
Memtox = membrane permeability

Remarks - Results

The results for the negative control were not provided in the study report table.

Tests for oxidative stress and apoptosis indicated that the test substance did not induce either parameter. The positive controls gave adequate results confirming the validity of the test system.

A solubility test showed that the highest soluble concentration tested was 0.03 mg/mL).

A scale of what Ctox values would correlate to high, moderate or low probability of toxicity was not provided in the study report.

The study authors note that the results are indicative of expected toxicity in a 14 day *in vivo* repeat dose screening test in rats.

CONCLUSION

The notified chemical was given a Ctox value of > 0.03mg/ml (13µM) and was therefore considered by the study authors to have a low probability of *in vivo* repeat dose toxicity effects.

TEST FACILITY

CeeTox (2013)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (10% in DMSO)
METHOD	Similar to OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Aroclor 1254-induced rat liver (S9 homogenate)
Vehicle	DMSO
Remarks - Method	0.1 mL/plate of test substance was used, with and without metabolic activation. Prepared mixtures were poured across triplicate plates, the plates incubated (2 days) and then the revertant colonies counted. Negative control: DMSO vehicle (with and without activation) Positive control: Dexon (TA98, TA100, TA1537); 2-aminofluorene (TA100), sodium azide (TA1535), 2-aminoanthracene (WP2uvrA) and 1-methylmethane-sulfonate (WP2uvrA) (all with and without activation).
RESULTS	
Remarks - Results	In no case was there a ≥ 2-fold increase in the mean number of revertants of tester strains.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	NAMSA (2000)

B.7. Comedogenicity

TEST SUBSTANCE	Notified chemical (10% in solution)
METHOD	In-house
Species/Strain	Rabbit/New Zealand albino
Number of Animals	1 male, 2 female
Remarks - Method	The test substance was liberally applied to the right ear of each animal, once daily for 3 weeks (21 applications). The left ear served as a control. Irritation was evaluated based on scores determined prior to each application and on day 22. The animals were euthanized and the ears removed and examined histologically.
RESULTS	The tissues were given a comedogenic score of zero, indicating no increase in visible follicular hyperkeratosis.
CONCLUSION	The test substance was non-comedogenic.
TEST FACILITY	PSL (1997)

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