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July 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Anionic Surfactant in Rhodacal DS-4 & DS-10

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
STD/1477	Rhodia Chemicals Pty Ltd	Anionic Surfactant in Rhodacal DS-4 & DS-10	Yes	≤ 400 tonnes per annum	Emulsifier in manufacture of coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is 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. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Acute toxicity (Category 4)	H302 - Harmful if swallowed
Skin irritation/corrosion (Category 2)*	H315 - Causes skin irritation
Eye irritation/corrosion (Category 2A)	H318 - Causes serious eye damage

*Classification in a lower category may be relevant for the notified chemical itself (100% concentration)

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:
R22: Harmful if swallowed
R38: Irritating to skin
R36: Irritating to eyes

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 2)	H401 - Toxic to aquatic life
Chronic (Category 2)	H411 - Toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that control measures are in place to minimise exposure, including the use of enclosed/automated processes and PPE, 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 reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - H302 - Harmful if swallowed
  - H315 - Causes skin irritation
  - H318 - Causes serious eye damage

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation
  - Enclosed, automated processes, where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with skin and eyes
  - Avoid breathing aerosols

- 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:
  - Coveralls
  - impervious gloves
  - goggles
  - respiratory protection if ventilation is inadequate

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

- 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 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) Section 64(1) of the Act; if
(2) additional information has become available as to the inhalation toxicity of the notified chemical.
(3) Additional information has become available on the developmental toxicity of the notified chemical.

Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from emulsifier in manufacture of coatings, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment;

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

(Material) Safety Data Sheet
The (M)SDS of the notified chemical (and products containing the notified chemical) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rhodia Chemicals Pty Ltd (ABN: 80 004 449 870)
44 Real Avenue
NORMAN PARK QLD 4170

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, import volume and analogue details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical data except for melting point, density, water solubility and particle size, and all toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Anionic Surfactant in Rhodacal DS-4 (contains the notified chemical at < 30% concentration in aqueous solution)

Anionic Surfactant in Rhodacal DS-10 (neat notified chemical, purity > 95%)

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR, FTIR, UV spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White flakes

Property	Value	Data Source/Justification
Melting Point	Decomposes without melting at > 250 °C	Measured
Boiling Point	Not determined	Expected to decomposes before boiling
Bulk Density	530 kg/m^3 at 20 °C	Measured
Vapour Pressure	4.32 x10^{-16} kPa at 25 °C	Calculated (EpiSuite)
Water Solubility	> 200 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical does not contain hydrolysable functionality
Partition Coefficient (n-octanol/water)	log Pow = 2.89 at 25 °C	Calculated (KOWWIN v1.68; US EPA, 2011). The notified chemical is surface active and thus the estimation may not adequately characterise the partitioning behaviour of the notified chemical. The notified chemical is expected to partition to phase boundaries.
Adsorption/Desorption	log K_{oc} = 2.52 at 25 °C	Calculated (KOWWIN v2.00; US EPA, 2011). The notified chemical is surface active and thus the estimation may not adequately characterise the adsorption/desoprtion behaviour of the notified chemical The notified chemical is expected to sorb to soil sediment and sludge based on its surface activity.
Dissociation Constant	Not determined	The notified chemical is a salt and is ionised in this form
Particle Size	Inhalable fraction (< 100 μm): 1.25% Respirable fraction (< 10 μm): 0.62%	Measured
Flash Point and flammability	Not determined	Not expected to be flammable based on structure
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative 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.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported in the neat form or as an aqueous solution at < 30% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100-400	100-400	100-400	100-400	100-400

PORT OF ENTRY
Melbourne, Sydney and various ports in Queensland

TRANSPORTATION AND PACKAGING
The neat notified chemical as flakes will be imported in 65 kg open head lined fibre drums. When in solution, the notified chemical will be imported in either 205 L closed head poly drums, 660 kg totes or 1000 kg totes. In either case, the notified chemical (up to 100%) will be transported from the port by road to distribution centres and reformulator warehouses. The finished products containing the notified chemical at up to 0.25% will be packaged in 5 or 20L steel containers or 1000 L IBC's and transported by road to retailers for sale to customers.

USE
The notified chemical will be used as a primary anionic emulsifier in emulsion polymerisation, particularly in the manufacture of coatings such as acrylic latex resins for paint. The notified chemical will be added to the polymerisation vessel at a concentration of 0.1-0.5% and will be present at up to 0.25% in final products.

OPERATION DESCRIPTION
The notified chemical will be imported as either the neat chemical or as part of an aqueous solution at < 30% concentration for use as an emulsifier, primarily in the manufacture of latex resins for formulation of paint products.

Formulation
The solid notified chemical will be weighed and added, under local exhaust ventilation, to a drum hoist hopper which feeds into a tank containing water. It will be added via a hatch cover located at the top of the reactor. The notified chemical will be warmed and stirred until the desired concentration is achieved and will be automatically dosed into a 5000 L batch reactor. When the notified chemical is used as a solution at < 30% concentration, it will be dosed directly into the reactor from the import containers. Once the reaction is complete the polymer emulsion containing up to 0.5% notified chemical will be fed into 205 L steel drums or 1100 L intermediate bulk containers (IBC's) via dedicated hoses fitted to specialised valves.

When used in paint manufacture, the polymer emulsion is blended with other ingredients under exhaust ventilation and using closed systems. The finished paints containing the notified chemical at up to 0.25% concentration will then be packed off by gravity feed under local exhaust ventilation into 5L steel cans, 205 L steel drums or 1000 L IBC's.

End-use
The finished paints containing the notified chemical at up to 0.25% concentration will be used by painting professionals and DIY painters. The paints may be applied by brush or roller as well as by spray.

5. 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	2	24
Plant operators polymer manufacture	8	24
QA staff	1	24
Cleaning and maintenance workers	2-8	24
Plant operators (Paint manufacture)	8	200
End use painters	8	200

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may only come into contact with the notified chemical at up to 100% concentration in the event of accidental rupture of containers.

Formulation of products

Dermal and ocular exposure of workers to the neat notified chemical or to solutions containing the notified chemical at < 30% concentration may occur during formulation when weighing and charging the mixing tanks and while performing maintenance and cleaning of equipment and drum reconditioning. Inhalation exposure is not expected unless aerosols are formed due to the low calculated vapour pressure of the notified chemical (4.32 $x10^{-16}$ kPa at 25 °C) and low percentage of inhalable particles (1.25%) of the neat solid form. 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, safety glasses and impervious gloves.

End-use

Dermal and ocular exposure to the notified chemical (at up to 0.25% concentration) may occur when applying coating products such as paints. Inhalation exposure may also occur, particularly if paint products are applied by spray. Exposure to the notified chemical is expected to be minimised through the use of PPE such as coveralls, safety glasses and impervious gloves.

6.1.2. Public Exposure

Exposure of members of the public to the notified chemical is not expected as finished products containing the notified chemical will be dried and not available for exposure. Dermal, ocular and inhalation exposure to the notified chemical (at 0.25%) may occur in DIY painters. Exposure may be minimised if PPE such as coveralls, gloves and safety goggles are used. Given the low concentration of the notified chemical in finished products, members of the public are unlikely to be exposed to any significant quantities of the notified chemical from the proposed uses.

6.2. Human Health Effects Assessment

There are no toxicological studies for the notified chemical. Information on the expected health effects of the notified chemical are based on an acceptable analogue of the notified chemical. The suitability of the analogue is based on the similar chemical structure and properties of the two chemicals.

Three full studies on the analogue have been submitted in addition to information provided in a SIDS risk assessment report (SIDS dossier).

Key results from toxicological investigations conducted on the analogue chemical are summarised below. For full details of the available studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity (22.5% solution in solution)	LD50 3.6 ml/kg
Rat, acute oral toxicity*	LD50 1086 mg/kg bw; harmful
Rat, acute dermal toxicity (47% solution)*	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity*	LC50 0.31 mg/L/4 hour; very toxic
Rabbit, skin irritation	irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation *	no evidence of sensitisation
Human, skin sensitisation – HRIPT *	no evidence of sensitisation
Rat, repeat dose toxicity *	NOAEL = 85 mg/kg/day
Mutagenicity – Ames assay*	non mutagenic
Carcinogenicity*	Non carcinogenic
Toxicity for reproduction and development - oral*	NOAEL = 350 mg/kg bw/ day parental and offspring

* Derived from SIDS summary information

Toxicokinetics, metabolism and distribution.
The SIDS assessment report for the analogue chemical indicates that its absorption, metabolism and elimination the analogue chemical have been studied in multiple species. Absorption after oral administration is rapid with a wide volume of distribution and relatively fast elimination. In contrast, the dermally administered chemical is slowly and incompletely absorbed. Information on absorption after inhalation was not available.

Acute toxicity.
The analogue chemical was found to be harmful in acute oral toxicity tests in rats. One full study report was provided (see Appendix B). This study reports an LD_{50} of 3.6 ml/kg bw (when a 22.5% solution was administered) which would translate to an LD_{50} of ~0.81 ml/kg bw for the notified chemical itself. However, the study reported minimal details and appropriate controls were not employed. More reliable data from a number of studies in the SIDS assessment report indicate that the LD_{50} lies between 1086 and 1980 mg/kg bw. At doses near the LD_{50}, clinical observations included hunched posture, piloerection, abnormal gait, lethargy, decreased respiratory rate, ptosis, diarrhoea and pallor of the extremities. For the purposes of the risk assessment, the acute oral LD_{50} is determined to be 1086 mg/kg bw.

The analogue is of low toxicity via the dermal route. The LD_{50} was determined to be > 2000 mg/kg bw as there were no deaths or significant clinical effects.

The analogue may be toxic via the inhalation route. An LC_{50} of 0.31 mg/l/4h has been established based on a non GLP study which noted deaths and clinical signs of toxicity at this dose. It was noted, however, that the real world relevance of this study may be limited given that difficult laboratory procedures were adopted in order to create respirable-sized particles. Based on the available limited data, toxicity of the analogue chemical via the inhalation route is uncertain.

Irritation and sensitisation.
In a skin irritation study provided (see appendix B), the analogue (22.5% solution) was found to be irritating to the skin of rabbits and reported a maximum value for erythema of 4. In addition, the irritancy effects of the analogue chemical are supported by multiple studies cited in the SIDS assessment report. Overall, the data indicate that the analogue causes significant irritation at doses as low as 5% in solution. Taken together these data support the conclusion that the analogue chemical is irritating to the skin.

In an eye irritation study (see Appendix B), the analogue chemical (22.5% in solution) was found to cause severe irritation to the eyes. Conjunctivae chemosis, redness and cornea opacity continued for at least 7 days after application of the chemical. However, it is noted that this was a non OECD study and the data are therefore of limited reliability. In addition, the eye irritancy effects of the analogue chemical are supported by multiple studies cited in the SIDS assessment report. Overall, the data indicate that the chemical causes significant eye irritation at doses as low as 1%. Using a weight of evidence approach, the analogue chemical is considered irritating to the eyes at concentrations > 1%, with possible irritant effects between 0.1 and 1%.

Information on the sensitisation potential of the analogue chemical has been reported in the SIDS assessment report. Results in animal and human studies show that the analogue chemical does not show any sensitisation properties at concentrations of up to 50%.

Repeated Dose Toxicity.
The SIDS assessment report cites effects from long-term oral exposure in body weight gain, kidney and liver effects and blood chemistry parameters. NOAELS from a number of well conducted gavage, feeding and drinking water studies range between 50-220 mg/kg bw/ day. For the purposes of the risk assessment, a NOAEL of 85 mg/kg bw/day has been established for the analogue chemical.

Long-term dermal exposure studies indicate that local irritation/corrosion effects are the likely cause of adverse effects noted in the study. A NOAEL cannot be estimated using these data.

There are no long-term inhalation studies on either the notified chemical or analogue chemical. However, due to the low vapour pressure of the notified chemical, irritant effects to the respiratory tract would not be expected unless aerosols are formed.

Mutagenicity/Genotoxicity.
The analogue chemical was shown to be negative in a range of gene mutation and chromosome aberration studies *in vitro* and *in vivo*.

Carcinogenicity.
The analogue chemical was shown to be negative in a number of long term carcinogenicity studies. While the quality of the studies assessed preclude a definitive assessment, taken together these data show no evidence of carcinogenicity.

Toxicity for reproduction.
There have been a number of high quality long-term multi-generational reproductive studies conducted on the analogue. NOAELS ranging from 70-350 mg/kg bw/day (the highest doses tested) have been reported with no significant reproductive effects on parental or offspring generations.

Toxicity for development
The SIDS assessment report cites varied data on the developmental effects of the analogue chemical. Some significant maternal effects have been observed in multiple species treated orally with the chemical at 100-400 mg/kg bw/day and dermally with similar doses. Effects in offspring including death, deformities, and litter loss/size were observed in multiple species at maternally toxic doses only. These effects are likely associated with the irritation effects of the chemical on skin and GI tract of the dams. Due to the wide range of quality and findings of studies, a NOAEL for specific developmental effects cannot be determined based on the available information.

Health hazard classification
Based on the available information on a suitable analogue, the notified chemical is 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. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Acute toxicity (Category 4)	H302 - Harmful if swallowed
Skin irritation/corrosion (Category 2)*	H315 - Causes skin irritation
Eye irritation/corrosion (Category 2A)	H318 - Causes serious eye damage

*Classification in a lower category may be relevant for the notified chemical itself (100% concentration)

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):
R22: Harmful if swallowed
R38: Irritating to the skin
R41: Risk of serious eye damage

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical is harmful by the oral route and irritating to the skin and eyes. Given the limited available information on the analogue chemical through the SIDS assessment report, the potential for the notified chemical to cause developmental toxicity cannot be ruled out. Long term toxicity by the inhalation route for the notified chemical is not known. However, based on the low vapour pressure, inhalation exposure is not expected unless aerosols are formed.

Reformulation
During reformulation, workers will be exposed to the neat notified chemical and will be at risk of irritant effects. Workers may also be at risk of chronic toxicity effects when handling the neat notified chemical, following long-term repeated exposure. However, provided that adequate PPE is used and engineering controls are in place to limit exposure, the risk to the health of reformulation workers is not considered to be unreasonable.

End-use
Professional painters will be exposed to the notified chemical at up to 0.25% in paint/coating products that may be applied by brush, roller or spray. Given the low concentration in the end-use products, the risk of irritation and chronic toxicity effects is low. While acute inhalation toxicity cannot be ruled out and the effects of repeated inhalation exposure to aerosols are unknown, only a fraction of the 0.25% concentration notified chemical will be present as respirable particles in spray products, and therefore available for exposure. The expected use of products containing the notified chemical in well ventilated areas (where possible) and use of appropriate PPE should further minimise the potential inhalation risk. Therefore, given the proposed use scenario and low concentration (0.25% in paint products), the risk to the health of professional painters from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
DIY painters will be exposed to the notified chemical at up to 0.25% concentration in paint products in the same mode, but to a significantly lesser extent than that of professional painters. Given the low concentration in the end-use products and the infrequent use, the risk is expected to be similar or less than for professional painters.

Other members of the public will only be exposed to the notified chemical in the form of dried paint where the chemical will be cured in a matrix and unavailable for exposure.

Therefore, the risk to the health of the public from use of the notified chemical at 0.25% in paint 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, there will be no release from this activity. During paint manufacture, accidental spills and leaks of the notified chemical (1% of the imported volume) are expected to be collected with inert material and disposed of to landfill. Residues of the notified chemical in empty containers (2% of the total imported volume) are also likely to be disposed of to landfill. Where possible, equipment washings will be collected and reused in subsequent batches, but approximately 0.5% of the import volume is anticipated to be released to the on-site waste treatment facility and then discharged to sewer.

RELEASE OF CHEMICAL FROM USE
The release of the notified chemical during end-use by professionals and DIY users is expected as a result from spills and leaks, from cleaning of equipment and from residues in empty paint containers. Spills and overspray are expected to be collected with absorbent material. The collected wastes and empty containers are expected to be disposed of to landfill. It is estimated by the notifier that up to 0.1% of import volume is expected to release to sewer during end-use from the washing of application equipment.

RELEASE OF CHEMICAL FROM DISPOSAL
Discarded end use articles containing the notified chemical within the cured paint film and residues in the containers are expected to be disposed of to landfill.

7.1.2. Environmental Fate

The notified chemical is expected to enter landfill as collected wastes and residues as well as with the substrates to which the product containing the notified chemical is applied. The majority of the notified chemical is expected to be cured within an inert polymer matrix adhering to articles following its use in coating applications. Notified chemical that is disposed of to landfill is expected to remain associated with the substrate to which it has been applied. In its cured form it is not expected to be mobile, bioavailable or biodegradable.

Based on the biodegradability study of the notified chemical, it is not ready biodegradable. However, it has a potential to degrade in the aquatic environment. The bioconcentration factor (BCF) of an analogue substance was 87 L/Kg. The analogue chemical is very similar to the notified chemical. The difference between the analogue and the notified chemical is that the latter has branching in its alkyl chain. This is unlikely to alter its physicochemical and toxicological properties to any significant degree. Hence, this analogue substance is considered applicable as read across to the notified chemical with regards to bioaccumulation. Thus the bioaccumulation potential of the analogue, and by inference, the notified chemical is low. Additionally, given the fact that the notified chemical is dispersible in water, and has surface activity, it suggests that the notified chemical is not expected to bioaccumulate. Furthermore, the bioavailability of the notified chemical in the aquatic environment is expected to be further decreased by environmental processes such as biodegradation and absorption to sediments and suspended solids in the aquatic environment. It has a tendency to sorb to surface boundaries based on its surface activity. Therefore, a significant portion of the notified chemical is expected to partition to sludge during waste water treatment processes in sewage treatment plants (STPs). Literature references indicate that the removal of this chemical type in wastewater treatment plants is greater than 85 %

(Exempt Information, 2001). The notified chemical that is released to surface waters in the treated effluent is expected to partition to suspended solids and disperse. Ultimately, the notified chemical is expected to degrade via biotic and abiotic processes in the surface waters to form water and oxides of carbon and sulphur.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in paints/coating for professionals and DIY users, a conservative release of 5% is used for the notified chemical to be released to sewer on a nationwide basis over 365 days per year. It is also assumed that 85% of the notified chemical is removed from influent by partitioning to sludge during STP processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	400,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	20,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	54.79	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	85%	Mitigation
Daily effluent production:	4,523	ml
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.82	µg/L
PEC - Ocean	0.1	mg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 103 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 notified chemical may approximate 0.687 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 3.4 mg/kg and 6.9 mg/kg, respectively.

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 1.817 µg/L may potentially result in a soil concentration of approximately 12.1 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 60.6 µg/kg and 121.2 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were provided for the notified chemical. The results from ecotoxicological investigations conducted on an analogue of the notified chemical were available in a reliable international peer reviewed document (Exempt Information, 2005) and are summarised below. Limited details of these studies were published. The analogue and the notified chemical are considered to be very similar in structure and therefore the endpoints presented below are likely to reflect the ecotoxicity of the notified chemical.

Endpoint	Result	Assessment Conclusion
Fish Toxicity (96 h)	EC50 = 3.2 mg/L	Expected to be toxic to fish
Daphnia Toxicity (48 h)	EC50 = 4.8 mg/L	Expected to be toxic to aquatic invertebrates
Algal Toxicity (72 h)	E_rC50 = 29 – 163 mg/L	Expected to be harmful to algae
Inhibition of Bacterial Respiration (72 h)	EC50 = 550 mg/L	Not expected to inhibit bacterial respiration

On the basis of the analogue data, the notified chemical is expected to be toxic to aquatic organism in the aquatic environment. Therefore, Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified chemical is formally classified as Acute Category 2; Toxic to aquatic life. Based on the acute toxicity of the analogue chemical and lack of ready biodegradability of the notified chemical, the notified chemical has been formally classified under GHS as Chronic Category 2; Toxic to aquatic life with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using the most sensitive toxicity endpoint of the analogue substance for fish. The conservative assessment factor of 500 was used since ecotoxicological data of a very close analogue substance was provided in lieu of notified chemical data.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Fish).	3.2	mg/L
Assessment Factor	500	
PNEC:	6.4	µg/L

7.3. Environmental Risk Assessment

Risk Assess□en	*PEC µg/L*	*PNEC µg/L*	
Q - River:	□□□□	6	0.□84
Q - Ocean	0.1		0.028

The Risk Quotients (Q = PEC/PNEC) for a conservative discharge scenario have been calculated to be less than 1 for both riverine and marine compartment. Based on the biodegradation study of the notified chemical, it is not expected to be ready biodegradable, however, it has a potential to biodegrade. It is also not expected to bioaccumulate. Although the notified chemical is expected to be toxic to aquatic species based on the analogue data, it is unlikely to result in ecotoxicologically significant concentrations for the assessed use pattern, and there is no unreasonable risk to the aquatic environment from the assessed use scenario.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point Decomposes without melting at > 250 °C

Method OECD TG 102 Melting Point/Melting Range.
Remarks Capillary/metal block method. Sample turned brownish-black between 250-260 °C
Test Facility Case Laboratories (2013)

Bulk Density 530 kg/m^3 at 22 °C

Method ASTM Method 501,Section 31
Test Facility Case Laboratories (2013)

Water Solubility > 200 g/L at 22 °C

Method In house method
Remarks The solubility of the test substance was determined in deionised water at 22 °C. Saturated solutions of the test substance in water could not be prepared. The test substance was soluble at 1 part test substance to 5 parts water but a viscous get is formed at 1:1 ratio. The water solubility is reported at freely soluble (>20%) ratio.
Test Facility Case Laboratories (2013)

Particle Size

Method Laser Diffraction Particle Size Analysis (internal method)

Range (µm)	*Mass (%)*
< 5.80	0.125
< 7.62	0.313
< 10.4	0.625
< 13.4	0.9375
< 15.5	1.125
< 106	1.25

Remarks Approximately 10 g of test substance was weighed into a 106 µm sieve and placed on a shaker for 10 minutes. The portion of the test substance that went through the sieve was submitted for particle size distribution analysis using a Laser Diffraction Particle Size Analyzer.
Test Facility Case Laboratories (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue 1 (22.5% in solution)

METHOD: In house method
- Species/Strain: Rat/Sprague Dawley
- Vehicle: Not stated- assumed to be corn oil
- Remarks - Method: 5 groups of 5 male and female rats were dosed once by oral gavage. Feed and water were provided ad-libitum after dosing and the animals observed daily for 14 days post dosing. No control group was included in the study.

RESULTS

Group	*Number and Sex of Animals*	*Dose ml/kg bw*	*Mortality*
I	5F/5M	3.0	3/10
II	5F/5M	3.5	3/10
III	5F/5M	3.75	7/10
IV	5F/5M	4.0	7/10
V	5F/5M	4.5	8/10

- LD50: 3.6 ml/kg bw
- Signs of Toxicity: Signs of toxicity noted included pulmonary haemorrhage in 2 animals in group I, 3 in group II, 7 in group III, 6 in group IV and 8 in group V. Decreased body weights were noted in most of the animals that died during the study. However, no statistical analysis was performed and no comments relating to body weights were made by the study authors..
- Effects in Organs: No other effects were recorded.
- Remarks - Results: The data provided were insufficient for a conclusive LD_{50} value to be determined. The study reports an LD_{50} value of 3.6 ml/kg bw. This is equivalent to 0.81 ml/kg bw of the analogue chemical.

CONCLUSION: The analogue chemical is estimated to be harmful via the oral route.

TEST FACILITY: PSL (1980a)

B.2. Irritation – skin

TEST SUBSTANCE: Analogue 1 (22.5% in solution)

METHOD: In house method
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 6
- Vehicle: Not stated- assumed to be corn oil
- Observation Period: 72 hours
- Type of Dressing: Occlusive.
- Remarks - Method: The trunks of rabbits were clipped and two 2.5cm^2 gauze patches placed over either intact or abraded skin on each rabbit. Under each patch 0.5ml of the test material was applied and the gauze secured with adhesive tape. The entire trunk of each animal was then wrapped in rubberised elastic cloth. The rabbits were immobilised for 24 hours, after which time the patches were removed.

RESULTS

Lesion	*Mean Score**		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	Abraded	*unabraded*			
Erythema/Eschar	3	2.94	4	> 72 h	4
Oedema	1.3	1.2	2.2	> 72 h	0.3

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

Remarks - Results: The irritation scoring system was not defined. The data provided only included averaged primary skin irritation scores. The observation period was not sufficient to determine possible corrosive potential.

CONCLUSION: The analogue chemical is irritating to the skin.

TEST FACILITY: PSL (1980b)

B.3. Irritation – eye

TEST SUBSTANCE: Analogue 1 (22.5% in solution)

METHOD: Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain: Rabbit/New Zealand White
Number of Animals: 9
Observation Period: 7 days
Remarks - Method: 0.1 ml of test material was placed on the inverted lower lid of one eye of each rabbit. The upper and lower lids were held together for 1 second to prevent the loss of material. The treated eyes of three rabbits were irrigated with 20 ml of lukewarm water 30 seconds after the instillation of the test material. The eyes of the remaining six rabbits were not irrigated.
Observations were made at 24, 48, and 72 hours and 4, and 7 days.

RESULTS

Lesion	*Mean Score**		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	Washed	*unwashed*			
Conjunctiva: hypermia	1.3	1.3	2	> 7 d	2
Conjunctiva: chemosis	1.7	2.42	4	> 7 d	2
Conjunctiva: discharge	0.7	1.3	3	> 7 d	2
Corneal opacity	1.7	1.7	2	> 7 d	2
Iridial inflammation	0	0.1	1	> 7 d	0

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

CONCLUSION: The notified chemical is irritating to the eye.

TEST FACILITY: PSL (1980c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 302 B Inherent Biodegradability: Modified Zahn-Wellens Test
Exposure Period	28 days
Analytical Monitoring	DOC analysis
Remarks - Method	A brief test summary only was provided
RESULTS	
Remarks - Results	50.8% biodegradation in 28 days
CONCLUSION	The notified polymer is not readily biodegradable. Greater than 20% loss in DOC is considered as an evidence of inherent biodegradability.
Test Facility	Rhodia (1997)

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