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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Oxirane, methyl-, polymer with oxirane, ether with 2,4,7,9-tetramethyl-5-decyne-4,7-diol (2:1)

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Swift & Company Ltd (ABN: 44 000 005 578)
Level 1 372 Wellington Rd
CLAYTON VICTORIA 3170

NOTIFICATION CATEGORY
Limited-small volume: Polymer with NAMW < 1000 (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Monomer constituents and percentages
Spectral data
Molecular weight information
Confidential details of use
Impurities
Molecular and structural formula

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

Melting point
Boiling point
Density
Vapour pressure
Water solubility
Hydrolysis as a function of pH
Partition coefficient
Adsorption/desorption
Dissociation constant
Particle size
Flash point
Flammability limits
Autoignition temperature
Explosive properties.
Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
US TSCA
EU EINECS
Japan ENCS
China SEPA
Canada DSL (notification submitted but not on inventory as at 12/11/05)
South Korea ECL
PROD INV

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Oxirane, methyl-, polymer with oxirane, ether with 2,4,7,9-tetramethyl-5-decyne-4,7-diol (2:1)

OTHER NAME(S)
Ethoxylated propoxylated 2,4,7,9-tetramethyl-5-decyne-4,7-diol

MARKETING NAME(S)
Surfynol 2502

CAS NUMBER
182211-02-5

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) < 1000
Weight Average Molecular Weight (Mw) < 1000
High percentage of low molecular weight species < 500

METHODS OF DETECTION AND DETERMINATION

Remarks IR and GPC data were provided.

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Two residual monomers were present at levels below the cut-offs at which the notified polymer would be rendered a hazardous substance.

DEGRADATION PRODUCTS
No detailed examination of degradation products has been carried out. Degradation, decomposition or depolymerisation of the notified polymer would only be expected under the following conditions:

In the event of fire, combustion products of pyrolysis (oxygen limited) are likely to include miscellaneous hydrocarbons and oxides of carbon.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Production and formulation operations take place in closed systems and storage is in sealed vessels. Losses of additives due to volatility are therefore likely to be minimal.

The notified polymer is a component of a mixture which will be form a hardened paint. Losses due to volatility, exudation or leaching are not expected to occur after this time.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia (> 95%).

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

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

USE
The notified polymer is used in coating, ink and adhesive applications for industrial and do-it-yourself (DIY) applications. It is estimated that adhesives will contribute less than 10%, and coatings/ inks will

contribute the remaining share.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Swift and Company Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be transported by road or rail in sealed cans, pails, drums or totes.

5.2. Operation description

Typical use activities will include formulation of coatings, inks or adhesives and their application. These will be performed by industrial or DIY end users. There are currently no customers in Australia, therefore the market share from each activity has been estimated. It is assumed that adhesives will contribute less than 10%, and coatings/ inks will contribute the remaining share.

Formulation of Coating, Inks and Adhesives

Formulation of the coating/ink/adhesive involves transfer from import containers to a mixing vessel, addition of other components, blending all components together and drumming off. These processes are typically enclosed and largely automated.

Workers will connect a vacuum hose line to the drums from which the polymer solution, containing greater than 95% polymer, is pumped to the blender. All operations that involve transfer are carried out under exhaust ventilation.

Occasionally formulations of coatings/inks/adhesives may occur in batch mixers where addition of the polymer solution is semi-automated. Filtration, drum and pail filling are automated and metered processes and worker intervention is not required unless the filling line requires adjustment.

The polymer is blended with other ingredients. These may include water, resin, pigments, solvents, defoamers and other additives. The final concentration of the coating/ink/adhesive is < 5% (w/w). The blended product will be sampled for laboratory analysis.

End use application

Application of Coatings

Coatings containing the notified polymer are expected to be sold and used by the industry as well as professional and DIY users. Coatings will be applied to metal, wood or plastic.

Prior to application, the coating will be stirred and poured into trays. Coatings will be applied by spray, roller or brush. Mixing and spraying is conducted in spray booths where the overspray is collected within the spray booth by its filtering system or on masking materials (e.g. Kraft and newspaper). For roller and brush applications the coatings may be mixed and applied either manually or automatically. Coating will either occur in an industrial environment with bunding to contain any release or in an area designed for coating with newspaper for containing release.

Application of Inks

Inks containing the notified polymer will be applied only in an industrial/commercial environment predominantly by flexographic printing. The ink will either be manually transferred to the flexographic printer, or transferred using a closed line transfer process. The ink will then be automatically applied to the substrate, wood, metal, paper, board or plastic, at a specified rate of application.

Application of Adhesives

Adhesives containing the notified polymer will be applied in either an industrial environment or by DIY end users requiring pressure sensitive applications. The adhesive may be applied manually from a tube in a contained area, where any release can be limited to paper surrounding the application area. Robotics may be used to apply the adhesive in industrial environment. The adhesive can be applied to metal, wood, plastic or glass, for example when labelling bottles.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
(a) Transport and Warehousing Personnel not expected to be exposed. Only potential for exposure occurs from accident e.g. dropping of container	10	1 hour/day	200 days/year
(b) Blending			
- high speed dispersing	40	4 hours/day	30 days/year
- makeup	40	2 hours/day	30 days/year
- QC testing	10	8 hours/day	30 days/year
- filling into containers	40	8 hours/day	30 days/year
(c.1) Coating application			
- addition to coater trays and mixing	1000's	6 hours/day	200 days/year
-application by spray, roller or brush	1000's	4 hours/day	200 days/year
- cleaning of equipment	1000's	2 hours/day	200 days/year
(c.2) Ink application			
- transfer to printing press and printing	40	8 hours/day	30 days/year
- cleaning of printing equipment	40	2 hours/ day	30 days/year
(c.3) Adhesive application			
- application of adhesive	1000's	6 hours/day	200 days/year
- cleaning of equipment	1000's	1 hour/day	200 days/year

Exposure Details

Transport and Storage

Waterfront, transport and warehouse workers are not expected to be exposed to the notified polymer except in the case of an accident involving spillage of the Surfynol 2502 containing the notified polymer at a concentration greater than 95%.

Formulation of Coating, Ink and Adhesive

During formulation there is possible dermal and ocular exposure of workers to drips, spills and splashes of notified polymer or formulated coating/ink/adhesive containing greater than 95% of the notified polymer prior to formulation and less than 5% of the notified polymer post formulation. Such exposure could occur during charging of the mixing tank, taking QC testing samples and when plant and equipment is cleaned or maintained. Engineering controls such as metered dosing and enclosed mixing tanks are expected to be in place to minimise dermal/ocular exposure. Personal protective equipment (PPE) is expected to be worn by workers during this process – coveralls, goggles and impervious gloves.

During filling of cans, possible dermal/ocular exposure to coating/ink/adhesive containing < 5% of the notified polymer may result from drips and spills when connecting filling lines, or during equipment malfunction. Workers will wear coveralls, goggles and impervious gloves.

Maintenance workers and laboratory staff may also encounter dermal/ocular exposure during equipment maintenance and testing processes. To minimise exposure, coveralls, goggles and gloves are worn.

Inhalation exposure during formulation or filling of coating/ink/adhesive is unlikely as aerosols are not expected to be formed and exhaust ventilation systems are in place to control exposure to other components of the products.

End use application- Coating

Workers exposed during end use of the formulated coatings will mostly consist of industrial personnel preparing and applying the formulated coatings to surfaces (e.g. automotive parts), and cleaning equipment after use.

The final concentration of the notified polymer in coatings will be < 5%, reducing the potential for worker exposure to the notified polymer. Dermal exposure is possible during preparation of coating, which involves stirring, transfer and dilution steps.

Spraying
Aerosols may be formed during spray application and therefore inhalation exposure may be possible. To minimise exposure during end use, the coating is diluted and applied in a well ventilated, down draft spray booth with an effective fume extraction system. Workers also wear anti-static footwear and flame retardant overalls, impervious gloves, eye protection and an air fed breathing mask or respirator if local exhaust is inadequate. For manual application by spraying the applicator will wear appropriate personal protective equipment including a respirator. Any overspray will be contained on kraft and newspaper and disposed of when dry.

Spray coating may be carried out without the full range of controls mentioned above, increasing exposure. Worker exposure to the notified polymer in dried coatings is likely to be minimal, as the polymer will be encapsulated as part of the cured coating film.

Roller and Brush application
For roller and brush application the dermal exposure may occur as the result of drips or spills or during manual application. This exposure will be minimised by the use of appropriate personal protective equipment including gloves, coveralls and safety glasses. For automatic application using roller and brush the only exposure will result from drips or spills. There is not expected to be any inhalation exposure as the application occurs in a ventilated area and the polymer is not highly volatile.

End use application- Inks

All inks are likely to be applied in an industrial/commercial setting and contain the notified polymer at a concentration of < 5%. The only likely exposure from ink application is the result of spills or drips during the transfer of material. This will be minimised by the use of appropriate personal protective equipment including gloves, coveralls and safety glasses. There is unlikely to be any exposure through the inhalation pathway as the polymer is not expected to be highly volatile.

Following application the polymer is contained within the printed ink on the substrate and there is not likely to be any further exposure to the polymer.

End use application- Adhesives

The final concentration of the notified polymer in adhesives will be < 5%, reducing the potential for worker exposure to the notified polymer. Dermal or ocular exposure is possible during application of the pressure adhesives resulting from drips or spills. This exposure will be minimised by the use of appropriate personal protective equipment including gloves, full body protection and safety glasses. There is unlikely to be any inhalation exposure as the polymer is not likely to volatilise. Any application is likely to occur under natural or exhaust ventilation, further preventing any exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Surfynol 2502 is not intended to be manufactured in Australia. During formulation it is expected that approximately 1% (< 10 kg) of the notified polymer will be spilt. These spills will be contained within bunding and disposed of by a licensed waste contractor. Small amounts (< 1%; < 10 kg) will be present in washes after equipment cleaning. These washes will undergo a process of flocculation

during which time the polymer will be removed. Approximately 1% (< 10 kg) of the notified polymer may remain as residue in the drums.

RELEASE OF CHEMICAL FROM USE

During industrial use it is expected that approximately 1% (< 10 kg) of the notified polymer will be spilt. These spills will be contained within bunding and disposed of by a licensed waste contractor. Small amounts (< 1%; 10 kg) will be present after equipment cleaning. These washes will undergo a process of flocculation during which time the polymer will be removed. Approximately 1% (< 10 kg) of the notified polymer may remain as residue in the drums.

If half (< 500 kg) of the total import amount of polymer is used in paint then the expected release pattern would be as follows. Assuming that 20% (< 100 kg) of the paint containing the notified polymer is expected to be used by roller or brush applications with the other 80% (< 400 kg) being spray painted.

When the coating is applied by spraying it is expected that approximately 20% of this amount (< 400 kg) would result in 80 kg as overspray. At industrial sites the overspray will be captured in the spray booth and on Kraft paper. The spray will then harden and be disposed of by a licensed waste contractor. Minimal release to sewer is expected from spray booths. Brushes, rollers, paint trays and spray equipment used for painting would require cleaning with mineral turpentine or paint thinners whilst water based paints would be washed with water. Waste generated from these clean up operations, including residual paint remaining in the cans is estimated at up to 3% of brush and roller applications (< 100 kg) resulting in up to 3 kg of the notified polymer present in the paint being released to the environment. Professional painters using enamel based paints may have solvent retention containers where solvent wash up liquid can be disposed of in an authorised manner, however water based paints are likely to be discharged to sewer.

For DIY applications waste generated as overspray during spray painting will be contained on newspaper and Kraft paper, allowed to harden and will be disposed of as domestic waste. Waste generated from clean up operations, including residual paint remaining in the cans is also estimated to account for loss to the environment of up to 3% of the notified polymer present in the paint. This is likely to be disposed of to sewer. In most cases empty paint cans containing dried paint residues would probably be disposed of as household garbage although some may go to authorised paint collection depots.

Assuming that approximately half (< 500 kg) of the total import quantity is used in ink applications it is expected that approximately 1% (< 5 kg) will require disposal from cleaning of printing equipment and other operations. The printed material is expected to be disposed of at the end of its useful life. If the ink is applied to paper products then approximately 50% is expected to be recycled (Nolan - ITU).

Similarly for adhesive applications it is expected that 1% of the maximum 10% (< 100 kg) of the total import quantity will require disposal from cleaning of equipment and other operations. This will result in a maximum of 1 kg requiring disposal.

5.5. Disposal

The notified polymer will be disposed of to landfill, incineration and sewage treatment plants. Disposal to landfill is through household garbage collection or through industrial disposal by licensed waste contractors. Empty drums may be incinerated and the washing from rollers and brushes are likely to result in the notified polymer being released to the sewer. Paper products with ink containing the notified polymer applied thereon are likely to be landfilled, incinerated or recycled. During recycling the notified polymer is expected to be released to sewer.

5.6. Public exposure

The resultant coatings and adhesives will mainly be used for industrial applications but would also be available for the public to purchase for D.I.Y. applications. DIY applicators will be exposed to the notified polymer in coatings or adhesives at concentrations less than 5%. Exposure will be further minimised by the use of appropriate personal protective equipment during application.

General members of the public, apart from D.I.Y. applicators would only experience possible exposure to the Polymer in Surfynol 2502 in the event of a possible spill during transportation

however this is unlikely. With use, the notified polymer is encapsulated within a coating/ink/adhesive film and therefore is unlikely to pose any significant hazard to public health.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Light yellow liquid

Melting Point/Freezing Point -70ºC
Remarks According to the MSDS

Boiling Point 367ºC at 101.3 kPa
Remarks According to the MSDS

Density 1000 kg/m^3
Remarks According to the MSDS

Vapour Pressure 0.0027 kPa at 20ºC.
Remarks According to the MSDS

Water Solubility ≥ 597 mg/L
Remarks According to the environmental tests performed at concentrations between 0 and 597 mg/L the polymer was water soluble, as observed by clear test solutions and no visible precipitate. Foam was formed suggesting surfactant formation.

Hydrolysis as a Function of pH Not Determined
Remarks The structure contains no functional groups that are likely to undergo hydrolysis.

Partition Coefficient (n-octanol/water) Not Determined
Remarks The polymer is likely to be soluble in both water and octanol based on its surfactant nature. A partition coefficient test is not valid for surfactants.

Adsorption/Desorption Not Determined
Remarks The polymer has polar and non polar sections, which will give it surfactant properties. The polymer is more likely to sorb to soil due to these properties.

Dissociation Constant
Remarks There are no acid or base groups to undergo dissociation.

Particle Size
Remarks The polymer is a liquid at room temperature.

Flash Point 174ºC
Remarks According to the MSDS

Flammability Limits
Remarks Not expected to be a flammable liquid based on structure.

Autoignition Temperature
Remarks Not expected to autoignite below boiling point.

Explosive Properties
Remarks Not expected to explode based on structure.

Reactivity

Remarks Stable under normal conditions. Avoid contact with dehydrating agents, reactive metals, materials reactive with hydroxyl compounds and oxidising agents (according to the MSDS)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, eye irritation	severely irritating
Genotoxicity – bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/ Wistar albino
Vehicle	Test substance administered as supplied
Remarks - Method	No amendments to the protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	2000	0
2	5 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	Instances of anogenital area soiling, dyspnea and brown staining/ wetness of the nose/ mouth were noted during the observation period. Body weight changes were normal in 9/10 animals. One female lost weight during the second week of the observation period.
Effects in Organs	Necropsy results were normal.
Remarks - Results	All animals survived the 2000 mg/kg oral dose.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	MB Research Labs (1998a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rabbit/ New Zealand white
Vehicle	Test substance administered as supplied
Type of dressing	Semi-occlusive.
Remarks - Method	No amendments to the protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	2000	0
2	5 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Dermal reactions were well defined at 24 hours, absent to barely perceptible on day 7 and absent on day 14.
Signs of Toxicity - Systemic	Diarrhoea and soiling of the anogenital area were the only abnormal physical signs noted during the observation period.
Effects in Organs	Necropsy results were normal in 9/10 animals. Liver abnormalities were noted in one animal. Body weight changes were normal.

Remarks - Results	All animals survived 2000 mg/kg dermal application.

CONCLUSION The notified polymer is of low toxicity via the dermal route.

TEST FACILITY MB Research Labs (1998b)

7.3. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M
Observation Period	21 d
Remarks - Method	No amendments to the protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	2	1.3	2	7 d	0
Conjunctiva: chemosis	2	2	2	3	7 d	0
Conjunctiva: discharge	2	2	2	3	3 d	0
Corneal opacity	2	2	2	2	21 d	2**
Iridial inflammation	1	1	1	1	3 d	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
**Pannus

Remarks - Results	Corneal opacity, noted in 3/3 eyes, persisted to day 21. Iritis, noted in 3/3 eyes, cleared by day 7. Conjunctival irritation, noted in 3/3 eyes, cleared by day 14. There were no abnormal physical signs noted during any observation period.

CONCLUSION The notified polymer is severely irritating to the eye due to signs of irreversible damage to eyes.

TEST FACILITY MB Research Labs (1998c)

7.4. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 and TA100 *E. coli*: WP2uvrA
Metabolic Activation System	A liver microsomal preparation (S9-mix) prepared from rats pretreated with a compound known to induce an elevated level of these enzymes.
Concentration Range in Main Test	a) With metabolic activation: 0. 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 0. 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Dimethyl sulphoxide; test substance added as solution
Remarks - Method	No significant protocol deviation

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test	> 5000	> 5000	> 5000	Negative
Present				
Test	> 5000	> 5000	> 5000	Negative

Remarks - Results: The test substance caused no visible reduction in the growth of the bacterial background lawn at any dose level. The test substance was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. No test substance precipitate was observed on the plates at any of the doses tested in either the presence or absence of S9-mix.
No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

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

TEST FACILITY: SafePharm Laboratories (2002)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified polymer

Remarks - Results: No test data were provided, however the notifier has indicated that a biodegradation screening test showed little or no biodegradation over 28 days.

CONCLUSION: The notified polymer cannot be classed as readily biodegradable.

8.1.2. Bioaccumulation

Not Tested

Remarks - Results: The notified polymer is water soluble and is therefore unlikely to bioaccumulate

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: YAC-93A-973//16337-8 (notified polymer)

METHOD: U.S. Environmental Protection Agency method797.1400 (2) static.
Species: Rainbow Trout *Oncorhynchus mykiss*
Exposure Period: 96 h
Auxiliary Solvent: None specified
Water Hardness: 130 - 160 mg $CaCO_3$/L
Analytical Monitoring: Visual observation; Test Substance HPLC.

Remarks – Method: A static range finding test was conducted using single tests on an unspecified number of trout, by subjecting the trout to nominal concentrations of the test substance of 0.0 (control), 0.1, 1.0, 10, 100, and 1000 mg/L. After 96 h complete mortality was observed in the 1000 mg/L test concentration and loss of equilibrium was observed in the 100

mg/L test concentration.
The main test was conducted by subjecting duplicate treatments of 10 fish to nominal concentrations of the test substance of 0.0 (control), 31.3, 62.5, 125, 250, 500 mg/L of the test substance. Dead fish were removed when observed.
Fish 33 – 43 mm and 0.357 – 1.039 g blotted wet weight.
Temperature 12 ± 2°C
16 hours light and 8 hours dark with 30 minute transition period.
Light intensity was approximately 764 lux.
Dissolved oxygen 9.0 – 9.7 (89 – 92%) throughout the test period.
pH 7.8 – 8.4
Conductivity at initiation 305 µS/cm
Total organic carbon (TOC) and suspended solids were < 1.0 and 0.3 mg/L respectively.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control (0)	< 5.6	20	0	0	0	0
31.3	33.5	20	0	0	0	0
62.5	75.7	20	0	0	0	0
125	147	20	0	0	0	0
250	290	20	20	20	20	20
500	597	20	20	20	20	20

LC50	206 mg/L at 96 hours*.
LOEC	147 mg/L at 96 hours.
Remarks – Results	*LC50 estimated from geometric mean of 2 results. Fish treated with 147 mg/L of test substance were observed to be darkly discoloured, resting on the bottom or floating on the top of the tank they also displayed a loss of equilibrium and irregular respiration. A value of 5.3 mg/L of O_2 (57% saturation) was measured at 48 hours in one replicate of the 147 mg/L treatment. Gentle aeration was commenced in all treatments at that time. Concentrations of the test substance appeared to be stable throughout the 96 hour exposure period. All test solutions appeared clear with no visible precipitate or surface film. At initiation a slight foam was observed on the surface of the 125, 250, 500 mg/L test solutions

CONCLUSION — The test substance is practically non-toxic to fish

TEST FACILITY — ABC Laboratories, Inc (1998a)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE — YAC-93A-973//16337-8 (notified polymer)

METHOD — U.S. Environmental Protection Agency method 797.1400 (2) static.

Species	Water flea *Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None specified
Water Hardness	130 - 160 mg $CaCO_3$/L
Analytical Monitoring	Visual observation; Test Substance HPLC.
Remarks - Method	A static range finding test was conducted using single tests on an unspecified number of daphnia by subjecting the daphnia to nominal concentrations of the test substance of 0.0 (control), 0.1, 1.0, 10, 100, and 1000 mg/L. After 48 hours complete immobility (mortality) was observed at a concentration of 1000 mg/L.

The main test was conducted by subjecting four replicate treatments of 5 daphnids to nominal concentrations of the test substance of 0.0 (control), 31.3, 62.5, 125, 250, 500 mg/L of the test substance.
Temperature 20 ± 2°C
16 hours light and 8 hours dark with 30 minute transition period.
Light intensity was approximately 750 lux.
Dissolved oxygen 7.8 – 8.5 (90 - 98%) throughout the test period.
pH 8.4 – 8.6
Conductivity at initiation 313 µS/cm
Total organic carbon (TOC) and suspended solids were < 1.0 and 0.0 mg/L respectively.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
Control (0)	<5.60	20	0	0
31.3	28.7	20	0	0
62.5	70.2	20	0	6
125	134	20	0	8
250	234	20	0	8
500	533	20	0	20

LC50 167 mg/L at 48 hours
NOEC 28.7 mg/L at 48 hours
Remarks - Results

Sublethal effects observed effects observed in the 134, 234 and 533 mg/L treatments at 48 h. Observed effects included quiescence and trailing extraneous material. One daphnid was found floating on the surface of the control at 24 h but all daphnids were observed to be normal at 48 h. Concentrations of the test substance appeared to be stable throughout the 48 hour exposure period. All test solutions appeared clear with no visible precipitate or surface film.

CONCLUSION The test substance is practically non-toxic to daphnia

TEST FACILITY ABC Laboratories, Inc (1998b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE YAC-93A-973//16337-8 (notified polymer)

METHOD U.S. EPA TSCA Environmental Effects Testing Guidelines (2)
Species *Selenastrum capricornutum.*
Exposure Period 96 hours
Concentration Range Nominal: 0 - 400 mg/L
Actual: < 2.80 – 410 mg/L
Auxiliary Solvent None specified
Water Hardness Not Specified
Analytical Monitoring Cell count; Test Substance HPLC.
Remarks - Method A static range finding test was conducted using single tests on an unspecified amount of alga by subjecting the algae to nominal concentrations of the test substance of 0.0 (control), 0.1, 1.0, 10, 100, and 1000 mg/L. There was no inhibition at concentrations of 0.1 and 1.0 mg/L.
The main test was conducted by subjecting triplicate treatments of approximately 1×10^4 cells/mL to nominal concentrations of the test substance of 0.0 (control), 12, 25, 50, 100, 200 and 400 mg/L of the test substance. An abiotic replicate was also run at a nominal concentration of 400 mg/L, to determine if the test substance was incorporated into the

algal biomass over the exposure period.
Temperature 22 – 23°C
Initial pH 7.4 – 7.6; final pH 8.1 – 9.4
Conductivity at initiation 305 µS/cm
Total organic carbon (TOC) and suspended solids were < 1.0 and 0.3 mg/L respectively.

RESULTS

Test Substance Actual Concentration mg/L	*Mean Cell Numbers at 96 h× 10^4*	*% Inhibition at 96 h*
Control	145	-
15	165	0
26	127	12
52	126	13
103	97	33
206	27*	81
410	1.7*	100

* Statistically significant

Growth EC50: 128 mg/L at 96 hours
EC50 95% confidence limit of EC50 116 – 140 mg/L
The NOEC after 96 hours of concentration was 103 mg/L

Remarks - Results: Recovery of the abiotic controls was 447 mg/L or 112% demonstrating that the test substance was not incorporated into the algal biomass over the exposure period. Concentrations of the test substance appeared to be stable throughout the 48 hour exposure period. Test solutions of 15 – 103 mg/L appeared clear with no visible precipitate or surface film but the 206 and 410 mg/L test solutions appeared to have a hazy white colouration. At 24 and 48 hours all solutions appeared clear and colourless, but at 72 and 96 hours the 15 – 103 mg/L remained clear but with a green tint. At 96 hours the 206 mg/L solution also became tinted green but remained clear. The 410 mg/L solution remained clear and colourless.

CONCLUSION: The test substance is practically non–toxic to algae.

TEST FACILITY: ABC Laboratories, Inc (1998c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Assuming approximately half of the notified polymer is used in industrial coatings; a maximum of 3% (30 kg) of the notified polymer is expected to be released to sewer via this route. A further 1% (10 kg) of the notified polymer is expected to be released from spray booths, cleaning of spray equipment from industrial and DIY applications.

If approximately half of the notified polymer is used in ink applications (500 kg) of which half again is used for paper products with 50 % of that amount being released to sewer from recycling operations then a further 12.5% (125 kg) is released to sewer. The usage pattern will result in a maximum of 165 kg of the notified polymer entering sewers throughout Australia in a realistic worst case scenario. The Predicted Environmental Concentration at sewage outfall is 0.16 µg/L. (This is calculated from 165 kg released over 260 working days resulting in 0.63 kg per day. Assuming a population of 20.5 million persons consuming 200 L per day then the PEC is calculated as 0.63 kg ÷ (20.5×10^6) ÷ 200.)

Other items having adhesive material or ink thereon, containing the notified chemical are likely to be disposed of to landfill at the end of their useful lives.

The notified polymer is likely to only be slightly mobile in landfill as it has surfactant properties but is water soluble. The notified polymer is likely to undergo eventual abiotic and biotic decomposition to landfill gases including methane and oxides of carbon; and water vapour.

If incinerated the notified polymer is likely to be fully combusted to form oxides of carbon and water vapour. In the aquatic compartment it is likely to be relatively persistent but is likely to adsorb to sediments where it will eventually degrade by biotic and abiotic processes.

9.1.2. Environment – effects assessment

Organism	Duration	End Point	Toxicity mg/L
Fish	96 hours	LC 50	206
Water Flea	48 hours	LC 50	167
Algae	96 hours	EC 50 Growth	128

The predicted no effect concentration (PNEC) is 1.28 mg/L. This is calculated from the lowest end point value which is the EC50 for algae and divided by a safety factor of 100 (as end points exist for three trophic levels).

9.1.3. Environment – risk characterisation

The risk quotient (RQ) may be calculated by dividing the PEC by the PNEC. (0.16 µg/L ÷ 1.28 mg/L) This results in a RQ of < 0.01 at sewage outfall. Based on the RQ the notified polymer does not pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Formulation

Incidental dermal and ocular exposure to the notified polymer could occur during weighing and addition of the notified polymer to the mixing vessel, particularly if addition is manual. Exposure to the notified polymer in the formulated product during packing is low due to its low concentration (< 5%) in the formulated product.

End Use

Exposure to the notified polymer during end use application will be limited due to the low concentration of the notified polymer (< 5%).

9.2.2. Public health – exposure assessment

Exposure to the notified polymer may occur during use of formulated coating and adhesive products, however, exposure is expected to be low due to the low concentration of polymer in the products (up to 5%). Therefore, DIY enthusiasts may experience frequent and prolonged dermal exposure to the imported product containing the notified polymer. Personal protective equipment may not necessarily be used during coating and adhesive applications.

As the notified polymer is supplied solely to industry when used in inks, public exposure to the notified polymer through this use is not expected.

9.2.3. Human health – effects assessment

Acute toxicity

The notified polymer is of low acute toxicity via the oral and dermal route. The notifier provided a summary report of an analogue chemical tested for inhalation toxicity. 5 male and 5 female rats were exposed for 1 hour in a chamber using 5% analogue chemical. Ocular and nasal irritation as well as reduction in spontaneous activity was noted in all animals at the end of the 1-hour exposure period. These symptoms disappeared within 3 hours. All rats survived the 1-hour exposure and the 14-day observation period. The acute inhalation LC50 is estimated to be ≥ 20

mg/L/1hr for the analogue chemical in rats.

Irritation
Based on the studies provided in rabbits the notified polymer is considered to be severely irritating to the eyes since ocular lesions were present at the end of observation period. No skin irritation study was provided. However, it is likely that the notified polymer has the potential to be a skin irritant.

Genotoxicity
The notified polymer tested was not mutagenic to bacterial cells in a reverse mutation study with and without metabolic activation.

Based on the available data, the notified polymer is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). The following risk phases for the notified polymer are recommended:
Xi: Irritant
R41: Risk of serious damage to eyes

9.2.4. Occupational health and safety – risk characterisation

Formulation
As the notified polymer is a severe eye irritant and incidental dermal and ocular exposure may occur during weighing and addition of the polymer to the mixing vessel, eye protection is required during these processes. The risk is low during blending as the process is enclosed and largely automated with little potential for exposure. During filling and packaging processes, the risk of eye irritation arising from exposure to the notified polymer is acceptable provided that workers use PPE. At 5% the notified polymer is irritating to the eyes. Inhalation exposure to the notified polymer is considered to be low due to low vapour pressure and it is further reduced by the use of PPE.

End Use
The risk to workers handling formulated products containing the notified polymer is acceptable given that workers will use PPE. At 5% the notified polymer is irritating to the eyes and eye and skin protection is recommended during end use applications. During spray application, the risk of exposure to aerosols is minimised by the use of PPE. Inhalation exposure to the notified polymer is considered to be low due to low vapour pressure and spraying is expected to occur in spraying booths.

9.2.5. Public health – risk characterisation

DIY enthusiasts may be exposed when using the coating and adhesive product frequently for a prolonged period (several hours). Due to the low concentration (< 5%) of the notified polymer in coating and adhesive products and its low acute toxicity, the risk of adverse health effects is considered to be low provided that users have skin and eye protection. However, appropriate personal protective equipment is recommended for DIY enthusiasts because the notifier polymer is an eye irritant at 5%. Inhalation exposure to the notified polymer is considered to be low due to low vapour pressure and it can further reduced by the use of PPE.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Xi: Irritant
R41: Risk of serious damage to eyes
S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S39: Wear eye/face protection

and

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Serious eye damage/eye irritation	1	Cause serious eye damage

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified polymer:
  - Xi: Irritant
  - R41: Risk of serious damage to eyes

- The following safety phases for the notified polymer are recommended:
  - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  - S39: Wear eye/face protection

- Use the following risk phrases for products/mixtures containing the notified polymer:

- ≥ 10%: R41
- 5% ≤ concentration ≤ 10%: R36

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in coating, ink and adhesive product:
  - Avoid contact with skin and eyes
  - Avoid splashes and spills
  - Wash eye promptly if exposed
  - Do not breathe spray

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in coating, ink and adhesive product:
  - Suitable protective clothing
  - Eye/face protection
  - Suitable gloves
  - Suitable respirators where inhalation exposure is possible

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced and in the formulated paint product:
  - Avoid generation of aerosols during paint formulation and preparation
  - Spray application should be carried out in an enclosed automated spray booth

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken by D.I.Y. applicators to minimise exposure to formulation containing the notified polymer:
  - Avoid contact with skin and eyes
  - Do not breathe spray

Disposal

The notified polymer should be disposed of by authorised landfill. If the notified polymer is part of a paint product allow to harden before disposal.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment such as diking of the product. Absorb using inert material such as vermiculite or sand and collect and transfer to suitable labelled containers for disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment 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 notified polymer is included in products for consumer use at concentrations ≥5%

or

(2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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