File No: LTD/1267

30 October 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Surfynol MD20

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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
MULGRAVE VIC 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:

Chemical name
CAS number
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)
Philippines PICCS

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Surfynol MD20

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 Spectra, GPC Spectra and MALDI Spectra data were provided.

3. COMPOSITION

DEGREE OF PURITY
High

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%, while coatings/inks 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	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 MD20 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 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 minimized 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 minimized 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 minimized 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 MD20 is not intended to be manufactured in Australia. During reformulation it is expected that approximately 1% (up to 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%; up to 10 kg) will present after equipment cleaning. These washes will undergo a process of flocculation during which time the polymer will be removed and disposed of to landfill. Approximately 1% (up to 10 kg) of the notified polymer may remain as residue in the drums. This will be disposed of by licensed contractor to landfill or incinerated.

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 minimized 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 MD20 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 20°C and 101.3 kPa	Liquid colourless
Melting Point/Freezing Point	The polymer is a liquid at room temperature
Boiling Point	275°C at 100 kPa

Remarks According to the MSDS

Density 1000 kg/m^3 (temperature unspecified)

Remarks According to the MSDS

Vapour Pressure 0.8 kPa at 21°C.

Remarks According to the MSDS, however this value is expected to be lower due to the polymer's high molecular weight.

Water Solubility The notified polymer is likely to be slightly soluble (0.1 – 10 mg/L), based on the polymer's structural formula. However the actual solubility may be higher than this range as treatments of up to 1010 mg/L were prepared during ecotoxicity tests though it is not clear as to whether this was all in solution.

Hydrolysis as a Function of pH Not tested

Remarks The notified polymer does not contain any groups likely to undergo hydrolysis. The polymer's limited solubility will further reduce the likelihood of hydrolysis.

Partition Coefficient (n-octanol/water) Not Tested

Remarks Estimated at >6 from Rekker Method.
TEST FACILITY Rogaland Research (2001)

Adsorption/Desorption – screening test Not Tested

Remarks The notified polymer is expected to be slightly soluble and has a high estimated log Kow value. It is therefore likely to bind strongly to the organic components of soil.

Dissociation Constant The notified polymer does not contain any groups likely to dissociate.

Particle Size The polymer is a liquid at room temperature.

Flash Point 130°C (pressure unspecified)

Remarks According to the MSDS

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

Autoignition Temperature Not expected to autoignite below boiling point.

Explosive Properties 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)

ADDITIONAL TESTS

Viscosity 210 mPa.s (temperature unspecified)

Remarks According to the MSDS

7. TOXICOLOGICAL INVESTIGATIONS

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

*The notifier claims that "YBC-34B-003/Q020 was the initial batch of the polymer and contains a high proportion of chemical byproducts. Process changes have subsequently been made to the process. YBY-GHJ-023/Q20 was produced following process changes, and results for YBY-GHJ-023/Q20 are consistent with those for the polymer being introduced into Australia. Therefore the information provided on YBC-34B-003/Q020 has not been used in the risk assessment as the polymer is not representative of that being introduced into Australia."

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (YBC-34B-003//Q020) (including ~ 30% by-products)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
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	3 M	2000	0
2	3 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	Instances of diarrhoea, anogenital area soiled and wet, and red staining of the nose/mouth area were noted during the observation period. Body weight changes were normal.
Effects in Organs	Necropsy results were normal in 5/6 animals. Darker than normal adrenals were observed in one animal.
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 (2002a)

7.2.1 Irritation – skin

TEST SUBSTANCE	Notified polymer (YBY-GHJ-023//Q020 Lot#TT-0502-061) (High purity notified polymer)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Vehicle	Test substance administered as supplied
Observation Period	14 days
Type of Dressing	Semi-occlusive.
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			
Erythema/Eschar	0	0	0	0	-	0
Oedema	0	0	0	0	-	0

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

Remarks - Results

3 minute exposure: There was no erythema or oedema noted at 60 minutes following patch removal.
1 hour exposure: Erythema was absent to barely perceptible at 1, 24, and 48 hours, absent to well defined at 72 hours, and absent by days 7 and 14.
4 hour exposure: There was no erythema or oedema noted at any time period.
Systemic observations: There were no abnormal physical signs noted during the observation period.
Body weights: all body weight changes were normal.

CONCLUSION

The notified polymer is slightly irritating to the skin after 1 hour of exposure.

TEST FACILITY

MB Research Labs (2002b)

7.2.2 Irritation – skin

TEST SUBSTANCE

Notified polymer (YBC-34B-003//Q020) (including ~ 30% by-products)

METHOD

OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3M
Vehicle: Test substance administered as supplied
Observation Period: 14 days
Type of Dressing: Semi-occlusive.
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			
Erythema/Eschar	2	2	2	2	7d	0
Oedema	1.7	1	1	2	7d	0

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

Remarks - Results

3 minute exposure: Erythema and oedema was absent at 1 hour following patch removal.
1 hour exposure: Erythema was absent to barely perceptible at 1 hour following patch removal, barely perceptible at 24 hours, barely perceptible to well defined at 48 hours, well defined at 72 hours and absent to barely perceptible on day 7. By day 14, erythema was absent. Oedema was absent at 1 hour following patch removal, barely perceptible at 24, 48 and 72 hours, and absent on days 7 and 14.
4 hour exposure: Erythema was absent to barely perceptible at 1 hour following patch removal, well defined at 24, 48 and 72 hours, absent to barely perceptible on day 7, and absent by day 14. Oedema was absent to barely perceptible at 1 hour following patch removal, barely perceptible to well defined at 24 hours, barely perceptible at 48 hours, barely perceptible to well defined at 72 hours, and absent to barely perceptible on day 7. Oedema was absent by day 14.
Systemic observations: There were no abnormal physical signs noted

during the observation period.

CONCLUSION — The notified polymer is irritating to the skin.

TEST FACILITY — MB Research Labs (2002c)

7.3.1 Irritation – eye

TEST SUBSTANCE — Notified polymer (YBC-34B-003//Q020) (including ~ 30% by-products)

METHOD — EPA Health Effects Testing Guidelines, OPPTS Series 870.2400, final guideline, August 1998.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Observation Period	7 days
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	1.7	1.3	1.7	2	72 h	0
Conjunctiva: chemosis	1	0.7	1.3	2	72 h	0
Conjunctiva: discharge	0.3	0.7	0.7	1	48 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results — There was no corneal opacity or iritis noted at any observation period. Conjunctival irritation, noted in 3/3 eyes, cleared by day 7.
There were no abnormal physical signs noted during the observation period.

CONCLUSION — The notified polymer is slightly irritating to the eye.

TEST FACILITY — MB Research Labs (2002d)

7.3.2 Irritation – eye

TEST SUBSTANCE — Notified polymer (YBY-GHJ-023//Q020 Lot#TT-0502-061) (High purity notified polymer)

METHOD — OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	1M, 2F
Observation Period	72 hours
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	0.7	0.7	1	1	72 h	1
Conjunctiva: chemosis	0.7	0.7	1	1	72 h	1
Conjunctiva: discharge	0.3	0	0	1	24 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results	There was no corneal opacity or iritis noted at any observation period. Conjunctival irritation, noted in 3/3 eyes, cleared by 72 hours in 2/3 eyes. There were no abnormal physical signs noted during any observation period.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	MB Research Labs (2002e)

7.4. Genotoxicity – bacteria

TEST SUBSTANCE	Surfynol MD20
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, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S-9 mix prepared in-house from the livers of male Sprague-Dawley rats
Concentration Range in Main Test	a) With metabolic activation: 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Dimethyl sulphoxide
Remarks - Method	No significant protocol deviations.

RESULTS

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

Remarks - Results	The test substance caused no visible reduction in the growth of the bacterial background lawn at any dose level. However, a slight reduction in the frequency of revertant colonies was noted in several tester strains initially at 1500 µg/plate. The sensitivity of the bacterial tester strains to this type of toxicity of the test substance varied between strain type, exposures with and without S9-mix and experiment number. The test substance was, therefore, tested up to maximum recommended dose level of 5000 µg/plate, A slight, oil precipitate was observed at and above 1500 µg/plate with an associated opaque film present at 5000 µg/plate. These observations did not prevent the scoring of revertant colonies. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, wither with or without metabolic activation.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories (2005)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	YBC-34B-003// Q20 (notified polymer including ~ 30% by-products.)
METHOD	OECD TG 306 A Marine Closed Bottle Method.
Inoculum	None added to natural seawater
Exposure Period	28 Days
Auxiliary Solvent	Acetone
Analytical Monitoring	Oxygen meter.
Remarks - Method	The test substance was dissolved in acetone and applied to glass fibre filters. The filters were subjected to sea water, with salinity of 34 ‰. Nutrients were added, and thiourea was added to inhibit nitrification. A control was run using acetone on glass filters but no test substance. Sodium benzoate was run as a reference and a further test was conducted using sodium benzoate and the test substance to investigate inhibition of microbial growth. Temperature 20°C

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	4	7	75
14	1	14	81
21	2	21	76
28	4	28	92

Remarks - Results	The time taken to reach 50% of the final oxygen uptake of the reference substance was approximately 5 days. This indicates that the bacterial activity in the test system (sea water) was normal. The oxidation of the reference in the inhibition test was 83% (average) after 28 days compared with 92% for the reference substance alone. This indicates that the test substance does not inhibit microbial growth.
CONCLUSION	The test substance is not readily biodegradable in natural seawater.
TEST FACILITY	Rogaland Research (2001)

8.1.2. Bioaccumulation

TEST SUBSTANCE	Not tested
Remarks - Method	Log Pow was estimated by the Rekker method as >6. The notified polymer is likely to be slightly soluble in water and has a high estimated log Pow indicating that it is likely to bioaccumulate. The molecular weight of the polymer is high, which will reduce the likelihood of crossing biological membranes but cannot be regarded as so high as to remove the possibility of crossing biological membranes. However limited aquatic exposure will reduce the potential for the polymer to bioaccumulate.

8.2. Ecotoxicological investigations

The notifier claims that "YBC-34B-003/Q020 was the initial batch of the polymer and contains a high proportion of chemical byproducts. Process changes have subsequently been made to the process. YBY-GHJ-023/Q20 was produced following process changes, and results for YBY-GHJ-023/Q20 are consistent with those for the polymer being introduced into Australia. Therefore the information provided on YBC-34B-003/Q020 has not been used in the risk assessment as the polymer is not representative of that being introduced into Australia."

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	YBY-GHJ-023/Q020 (High purity notified polymer)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static
Species	Rainbow Trout *Oncorhynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None Specified
Water Hardness	80 - 100 mg $CaCO_3$/L
Analytical Monitoring	Daily Observation; Test substance Gel Permeation Chromatography (GPC) and Refractive Index (RI).
Remarks – Method	A range finding test was conducted using single tests on five 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 for 48 h. The main test was conducted by subjecting duplicate treatments of 10 fish to nominal concentrations of the test substance of 0.0 (control), 0.625, 1.25, 2.5, 5.0, 10 mg/L of the test substance. These were prepared from a stock 400 mg/L stock solution in Moderately Hard Reconstituted Water (MHRW). Size 5 ± 1.0cm Temperature 14 ± 1°C Photoperiod: 16 hours light and 8 hours dark. Dissolved oxygen 4.8 – 8.0 mg/L throughout the test period. pH 7.0 – 7.6 Conductivity 240 - 260 µmhos/cm throughout the test

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0.0 (control)	0.438	20	0	0	0	0
0.625	ND	20	0	0	0	0
1.25	0.636	20	1	10	10	10
2.5	1.242	20	0	2	3	3
5.0	2.341	20	0	7	8	8
10	4.525	20	20	20	20	20

ND = Not Determined

LC50	1.65 mg/L at 96 hours. (95% Confidence Limit 1.42 – 1.92 mg/L)
Remarks – Results	There were no recorded observations to whether there was cloudiness or precipitation at any concentration. Replicates with less than 6.0 mg/L of oxygen had both treatments aerated. The mean of the pre–exposure and post exposure concentrations measurements was used as the actual concentration for each treatment. Probit was used for the calculations.
CONCLUSION	The notified polymer is toxic to Rainbow Trout.
TEST FACILITY	Biological Monitoring Inc. (2003a)

8.2.1.a Acute toxicity to fish

TEST SUBSTANCE	YBY-GHJ-023/Q020 (High purity notified polymer)

METHOD	OECD TG 203 Fish, Acute Toxicity Test - static
Species	Rainbow Trout *Oncorhynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None Specified
Water Hardness	80 - 100 mg $CaCO_3$/L
Analytical Monitoring	Daily Observation; Test substance Gel Permeation Chromatography (GPC) and Refractive Index (RI).
Remarks – Method	A range finding test was conducted using single tests on five 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 for 48 h. The main test was conducted by subjecting duplicate treatments of 10 fish to nominal concentrations of the test substance of 0.0 (control), 0.3125 0.625, 1.25, 2.5, 5.0 mg/L of the test substance. These were prepared from a stock 200 mg/L stock solution in MHRW. Size 5 ± 1.0cm Temperature 14 ± 1°C Photoperiod: 16 hours light and 8 hours dark. Dissolved oxygen 5.8 – 8.3 mg/L throughout the test period. pH 6.9 – 7.6 Conductivity 240 - 260 µmhos/cm throughout the test

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0.0 (control)	0.207	20	0	0	0	0
0.313	ND	20	0	0	0	0
0.625	ND	20	0	0	0	0
1.25	ND	20	0	0	0	0
2.5	1.864	20	0	0	0	0
5.0	2.902	20	12	20	20	20

ND = Not Determined

LC50	2.33 mg/L at 96 hours. Interpolated from 2 results (95% Confidence Limit 1.86 – 2.90 mg/L)
NOEC	1.86 mg/L at 96 hours
Remarks – Results	There were no recorded observations to whether there was cloudiness or precipitation at any concentration. Replicates with less than 6.0 mg/L of oxygen had both treatments aerated. The mean of the pre–exposure and post exposure concentrations measurements was used as the actual concentration for each treatment. Probit was used for the calculations.

CONCLUSION	The notified polymer is toxic to Rainbow Trout.
TEST FACILITY	Biological Monitoring Inc. (2003b)

8.2.1.b Acute toxicity to fish

TEST SUBSTANCE	YBY-GHJ-023/Q020 (High purity notified polymer)

METHOD	OECD TG 203 Fish, Acute Toxicity Test - static
Species	Rainbow Trout *Oncorhynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None Specified
Water Hardness	80 - 100 mg $CaCO_3$/L
Analytical Monitoring	Daily Observation; Test substance Gel Permeation Chromatography (GPC) and Refractive Index (RI).
Remarks – Method	A range finding test was conducted using single tests on five 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 for 48 h.

The main test was conducted by subjecting duplicate treatments of 10 fish to nominal concentrations of the test substance of 0.0 (control), 0.625, 1.25, 2.5, 5.0 and 10 mg/L of the test substance. These were prepared from a stock 200 mg/L stock solution in MHRW.
Size 5 ± 1.0cm
Temperature 14 ± 1°C
Photoperiod: 16 hours light and 8 hours dark.
Dissolved oxygen 5.1 – 8.7 mg/L throughout the test period.
pH 7.0 – 7.7
Conductivity 240 - 250 µmhos/cm throughout the test

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0.0 (control)	0.441	20	0	0	0	0
0.625	ND	20	0	0	0	0
1.25	ND	20	0	0	0	0
2.5	1.286	20	0	0	0	0
5.0	2.357	20	0	9	12	12
10	3.790	20	19	20	20	20

ND = Not Determined

LC50	2.16 mg/L at 96 hours.
NOEC	1.29 mg/L at 96 hours
Remarks – Results	There were no recorded observations to whether there was cloudiness or precipitation at any concentration. Replicates with less than 6.0 mg/L of oxygen had both treatments aerated. The mean of the pre – exposure and post exposure concentrations measurements was used as the actual concentration for each treatment. Probit was used for the calculations.

CONCLUSION — The notified polymer is toxic to Rainbow Trout.

TEST FACILITY — Biological Monitoring Inc. (2003c)

8.2.1.c Acute toxicity to fish

TEST SUBSTANCE — YBY-GHJ-023/Q020 (High purity notified polymer)

METHOD

Species	Rainbow Trout *Oncorhynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None Specified
Water Hardness	80 - 100 mg $CaCO_3$/L
Analytical Monitoring	Daily Observation; Test substance Gel Permeation Chromatography (GPC) and Refractive Index (RI).
Remarks – Method	A range finding test was conducted using single tests on five 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 for 48 h. The main test was conducted by subjecting duplicate treatments of 10 fish to nominal concentrations of the test substance of 0.0 (control), 0.625, 1.25, 2.5, 5.0 and 10 mg/L of the test substance. These were prepared from a stock 160 mg/L stock solution in MHRW. A reference substance (copper sulphate) was also run. Size 5 ± 1.0cm Temperature 14 ± 1°C Photoperiod: 16 hours light and 8 hours dark. Dissolved oxygen 3.0 – 7.2 mg/L throughout the test period. pH 6.9 – 7.6

Conductivity 240 - 250 µmhos/cm throughout the test

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0.0 (control)	0	20	0	0	0	0
0.625	0.24	20	6	10	10	10
1.25	0.48	20	0	0	0	0
2.5	0.95	20	0	0	3	3
5.0	1.90	20	10	19	19	20
10	ND		20	20	20	20

ND = Not Determined

LC50	1.21 mg/L at 96 hours. (95% Confidence Limit 1.09 – 1.35 mg/L)
NOEC	<0.625 mg/L at 96 hours.
Remarks – Results	There were no recorded observations to whether there was cloudiness or precipitation at any concentration. The concentrations of the nominal concentrations of 0.625, 1.25 and 2.5 mg/L could not be detected and were instead estimated based on an average 38% recovery of the nominal 5.0 mg/L treatment. Replicates with less than 6.0 mg/L of oxygen had both treatments aerated. The mean of the pre–exposure and post exposure concentrations measurements was used as the actual concentration for the nominal 5.0 mg/L treatment. Although the LC50 of the reference substance was not recorded it was similar to in house results. Probit was used for the calculations.

CONCLUSION — The notified polymer is moderately toxic to Rainbow Trout.

TEST FACILITY — Biological Monitoring Inc. (2003d)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE — YBY-GHJ-023/Q020 (High purity notified polymer)

METHOD — OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None specified
Water Hardness	80 - 100 mg $CaCO_3$/L
Analytical Monitoring	Daily Observation; Test substance Gel Permeation Chromatography (GPC) and Refractive Index (RI).
Remarks - Method	A range finding test was conducted using single tests on ten daphnids, 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 for 24 h. The main test was conducted by subjecting quadruplicate treatments of 5 daphnids to nominal concentrations of the test substance of 0.0 (control), 31.25, 62.5, 125, 250, 500 and 1000 mg/L of the test substance. These were prepared from a stock 1000 mg/L stock solution in MHRW. A reference substance (sodium chloride) was also run. Temperature 20 ± 1°C Photoperiod: 16 hours light and 8 hours dark. Dissolved oxygen 7.0 – 7.4 mg/L throughout the test period. pH 7.5 – 7.9 Conductivity 265 - 290 µmhos/cm throughout the test

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*

Nominal	*Actual*		*24 h*	*48 h*
0.0 (control)	Not Detected	20	0	0
31.25	18.0	20	0	2
62.5	34.4	20	3	12
125	80.5	20	6	17
250	128.6	20	9	20
500	ND	20	9	20
1000	ND	20	18	20

ND = Not Determined

LC50	37.1 mg/L at 48 hours (95% Confidence Limit 29.1 – 46.5 mg/L)
LOEC	18.0 mg/L at 48 hours
Remarks - Results	There were no recorded observations to whether there was cloudiness or precipitation at any concentration. The mean of the pre–exposure and post exposure concentrations measurements was used as the actual concentration for each treatment. Probit was used for the calculations.

CONCLUSION — The notified polymer is harmful to daphnia.

TEST FACILITY — Biological Monitoring Inc. (2003d)

8.2.2.a Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE — YBC-34B-003// Q20 (notified polymer including ~ 30% by-products.)

METHOD

Species	Marine Copepod *Acartia Tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not Specified
Analytical Monitoring	Daily Observation
Remarks - Method	Water available fractions (WAF) of the test substance were prepared by stirring the substance in dilution water for 20 h and allowing settling for 4 h. Samples for testing were taken from the mid of the water phase. The test was conducted by subjecting quadruplicate treatments of 5 copepods to nominal concentrations of the test substance of, 0.3, 0.6, 0.99, 1.81, 3.18, 5.81 and 9.97 mg/L WAF of the test substance. Six replicate controls (0.0) and six replicate reference substance (1.0 mg/L 3,5-dichlorophenol) were also run. Temperature 20 ± 2°C Photoperiod: 16 hours light and 8 hours dark. Dissolved oxygen 6.5 – 7.8 mg/L throughout the test period. pH 8.2 – 8.4 Salinity 34 ‰

RESULTS

Concentration mg/L		*Number of* Copepod	*Mortalities*	
Nominal	*Actual*		*24 h*	*48 h*
0.0 (control)		30	1	2
0.3		20	1	2
0.6		20	1	2
0.99		20	1	1
1.81		20	0	3
3.18		20	2	13
5.81		20	6	15
9.97		20	13	19
Reference		30	5	14

ND = Not Determined

LC50	3.1 mg/L WAF at 48 hours (95% Confidence Limit 2.5 – 3.9 mg/L)
NOEC	1.81 mg/L WAF at 48 hours
Remarks - Results	There were no recorded observations to whether there was cloudiness or

precipitation at any concentration The lethality of the reference substance was 47%, which was within the accepted range of 20 – 80%). Probit was used for the calculations.

CONCLUSION — The test substance is moderately toxic to *Acartia Tonsa*.

TEST FACILITY — Rogaland Research (2001),

8.2.2.b Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE — YBC-34B-003// Q20 (notified polymer including ~ 30% by-products.)

METHOD — Paris Commission (ParCom) Guideline 1994 Test - static.

Species	Marine Amphipod *Corophium volutator*
Exposure Period	10 Days
Auxiliary Solvent	Acetone
Water Hardness	-
Analytical Monitoring	Visual Observation
Remarks - Method	Appropriate amounts of test substance were dissolved in acetone (20 mL). The solution was added to 150 g dry sediment. The acetone was evaporated and 500 g of damp sediment and 150 mL of sea water were added to the dry sediment and mixed for 3 h. The sediment was divided into 3 portions of approximately 200 g of sediment and 400 mL of sea water was added. Triplicate treatments of ten animals were subjected to each concentration of 263, 587, 1350, 3020 mg/kg of dry sediment. A control (0.0) and a reference substance (23.4 mg/kg fluoranthene) were also run. A sample of damp sediment was analysed for water content and all concentrations were calculated as mg/kg of dry sediment. The treatments were continuously aerated. Temperature 15 ± 2°C Dissolved oxygen 97 – 103%. pH 8.1 - 8.2. Salinity 34‰ Silt:96% Organic Content 2.5%

RESULTS

Concentration mg/kg Nominal	*Number of* Marine Amphipod	*Mortalities 10 days*
0.0 (control)	30	2
263	30	3
587	30	20
1350	30	29
3020	30	30
Reference	30	24

LC50	490 mg/kg at 10 days (95% Confidence Limit 406 – 587 mg/kg)
NOEC	263 mg/kg at 10 days
Remarks - Results	The lethality of the reference substance was 80%, which was within the accepted range of 20 – 80%). Probit was used for the calculations.

CONCLUSION — The test substance is practically non-toxic to Marine Amphipod

TEST FACILITY — Rogaland Research (2001)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE — YBY-GHJ-023/Q020 (High purity notified polymer)

METHOD — OECD TG 201 Alga, Growth Inhibition Test.

Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 63.13 - 1010 mg/L
Auxiliary Solvent	None specified
Water Hardness	Not specified.
Analytical Monitoring	Daily counting using hemacytometer
Remarks - Method	A range finding test was conducted using single tests of alga containing approximately 1×10^4 cells/mL, by subjecting the alga to nominal concentrations of the test substance of 0.1007, 1.007, 10.07, 100.7, and 1007 mg/L for unspecified time. Triplicate treatments of approximately 1.0×10^4 cells/mL, were subjected to nominal concentrations of 0.0 (control), 63.13, 126.25, 252.5, 505.0, 1010 mg/L. These were prepared from a 1010 mg/L stock solution prepared in algae culture media Triplicate reference ($CdCl_2$) substance were also run at concentrations of 0.0 (control) 12.5, 25, 50, 100, 200 mg/L. Temperature 23 ± 2°C Photoperiod continuous light. pH 7.0 – 9.6

RESULTS

Growth		*Growth*	
Test Substance	*Inhibition*	*Reference Substance*	*Inhibition*
mg/L	*%*	*µg/L*	*%*
0	0	0	0
63.13	26	12.5	6
126.25	45	25.0	9
252.5	74	50.0	33
505	92	100	93
1010	100	200	100

ErC50: 129.9 mg/L (95% Confidence Limit 112.3 – 148 mg/L)

Remarks - Results	There were no recorded observations to whether there was cloudiness or precipitation at any concentration The ErC50 (growth) of the reference substance was 51.5 µg/L, which was within the accepted 95% confidence limits of 18.96 – 141.4 µg/L. Probit was used for the calculations.
CONCLUSION	The notified polymer is practically non - toxic to *Selenastrum capricornutum*
TEST FACILITY	Biological Monitoring Inc. (2002)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	YBC-34B-003// Q20 (notified polymer including ~ 30% by-products.)
METHOD	NS-EN ISO 10253, 1998
Species	Marine Alga *Skeletonema costatum*
Exposure Period	72 hours
Concentration Range	Nominal: 0.3 – 9.97 mg/L
Auxiliary Solvent	None
Water Hardness	Not specified.
Analytical Monitoring	Fluorescence
Remarks - Method	Water available fractions (WAF) of the test substance were prepared by stirring the substance in natural seawater for 20 h and allowing settling for 4 h. Triplicate treatments of approximately 2000 cells/mL, were subjected to nominal concentrations of 0.0 (control), 0.3, 0.6, 0.99, 1.81, 3.18, 5.81, and 9.97 mg/L WAF. Triplicate reference (3,5-dichlorophenol

1.5 mg/L) substance were also run.
Temperature 20 ± 2°C
Photoperiod continuous light >50 µE/m^2.
pH 8.2 – 8.6
Salinity 34 ‰

RESULTS

Concentration mg/L WAF	Fluorescence at 0 h (unspecified units)	Fluorescence at 72 h (unspecified units)
0 (Control)	0.09	65
0.3	0.09	59
0.6	0.08	48
0.99	0.07	1
1.81	0.05	0
3.18	0.07	0
5.81	0.06	0
9.97	0.09	0
Reference	0.08	0.9

ErC50: 0.9 mg/L WAF (95% Confidence Limit 0.77 – 1.0 mg/L)
NOEC 0.6 mg/L WAF
Remarks - Results The reference substance showed 68% inhibition, which was within the accepted range. The cell density of the blank increased by more than a factor of 16, which was considered valid. Calculated using the computer program TOXEDO, which assumes a logarithmic normal distribution.

CONCLUSION The test substance is highly toxic to *Skeletonema costatum*

TEST FACILITY Rogaland Research (2001)

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 (highest toxicity to species)	Duration	End Point	Toxicity mg/L
Fish	96 hours	LC 50	1.21
Daphnia	48 hours	LC 50	37.1
Freshwater Algae	72 hours	EC 50 Growth	130

A predicted no effect concentration (PNEC) is 12.1 µg/L. The PNEC is calculated from the lowest end point value which is the EC50 for marine 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 ÷ 12.1 µg/L). This results in a RQ of 0.01 at the sewage outfall. Based on the RQ the polymer does not pose an unacceptable risk to the aquatic environment. Although no PEC was calculated for sediments it is expected to be very low. As the notified polymer is practically non–toxic to the sediment dwelling species tested the polymer is not expected to pose an unacceptable risk to the sedimentary 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 application will be limited due to the low concentration of the notified polymer (< 5%). Inhalation exposure is possible during spraying, however, the user is likely to use a respirator.

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%). 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 in this use of inks and is consumed during the printing process, 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 route.

Irritation

Based on the studies provided in rabbits the notified polymer is considered to be slightly irritating to eyes and skin.

Repeated Dose Toxicity and Toxicity for reproduction

The notifier provided summaries of an impurity (residual monomer present at up to 15% in the polymer) tested for repeated dose and reproduction study in the MSDS. Adult rats and their offspring were orally administered in the diet at the following concentrations 0, 500, 1000 and 2000 mg/kg/day for 91 days. Little size at birth and mean weanling weights were decreased in

the 2000 mg/kg/day group. After 91 day on test, a significant increase in liver weights with accompanying microscopic changes was observed in both sexes in the high dose group. The oral No-Observed-Effect-Level was 1000 mg/kg/day for the reproduction and repeated dose study. Rats were orally administered in the diet for 28 days at concentrations of 0, 750, 1500, 3000 and 6000 ppm. No adverse effects were seen at any of the dose levels. The oral No-Observed-Effect-Level was 600 ppm. The substance was administered orally to dogs in gelatin capsules at dose level of 0, 200, 400 and 600 mg/kg/day for 91 days. All dogs survived for the duration of this study with few clinical signs. The only adverse effect observed was an increase in liver weight at 400 and 600 mg/kg/day.

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 not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Formulation
As the notified polymer is slightly irritating to eyes and skin and incidental dermal and ocular exposure may occur during weighing and addition of the polymer to the mixing vessel, skin protection is recommended 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 irritation arising from exposure to the notified polymer is acceptable provided that workers use PPE. 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 polymer is not expected to be irritating to eyes and skin. The workers should avoid skin and eye contact with the product containing notified polymer. 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. However, appropriate personal protective equipment is recommended for DIY enthusiasts because the notifier polymer is slightly irritating to eyes and skin. 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 not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

No GHS classification for human health or the aquatic environment is appropriate.

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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