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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Uralac ZW5209P/ZW5210P

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**Director
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FULL PUBLIC REPORT**Uralac ZW5209P/ZW5210P****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Swift and Company Limited
Level 1, 372 Wellington Road
MULGRAVE VIC 3170

NOTIFICATION CATEGORY

Standard: Polymer with NAMW < 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

- Chemical identity
- Identity of monomers
- Impurities
- Adjuvants and additives
- GPC data
- Spectral Data

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

- Water solubility
- Hydrolysis as a function of pH
- Partition coefficient
- Absorption/desorption
- Flash point
- Acute dermal toxicity
- Repeat dose toxicity
- Induction of germ cell damage
- Chromosome damage
- Algae growth inhibition
- Ready biodegradation
- Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Not known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Uralac ZW5209P/ZW5210P

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL Gel Permeation Chromotography
METHOD Infra red Spectrophotometry
Remarks
TEST FACILITY DSM Resins bv, Analytical Department (2003)

3. COMPOSITION

DEGREE OF PURITY
>99%

DEGRADATION PRODUCTS
Not available

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None expected

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer is imported in 25 kg bags or boxes at a concentration of 100%. The reformulated powder coating containing the notified polymer at a concentration of 8% will be transported to professional spray painters in 25 kg bags or boxes.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	25	25	25	25	25

USE

The notified polymer will be used a component of industrial powder coatings.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

IDENTITY OF MANUFACTURER/RECIPIENTS **Non-Confidential**

The notified polymer will be reformulated as a component of a powder coating at several sites in Australia. At present only one Victorian reformulator has been identified however up to 5 reformulators may use the notified polymer in the future. The reformulation sites are all located in metropolitan Sydney or Melbourne except for one located in Bowral NSW.

The reformulated powder coating product will be distributed for use by professional spray painters throughout Australia.

TRANSPORTATION AND PACKAGING

The notified polymer is not a classified as a Dangerous Good under the Australian Code for the Transport of Dangerous Goods by Road and Rail. Coatings containing the notified polymer are also not classified as Dangerous Goods.

The notified polymer in its pure form and the powder coating containing the notified chemical at 8% will be transported in 25 kg plastic bags or boxes. The notified polymer is imported in shipping containers by sea and transported in both concentrated and reformulated forms by road and rail.

5.2. Operation Description

The notified polymer is imported in 25 kg containers and transported to up to five reformulating sites within Victoria and NSW.

At the reformulating site the notified polymer is manually transferred in to a mixing hopper using metal scoops or by pouring from bags. This transfer takes place within a weigh booth equipped with local exhaust ventilation. Blending of the notified polymer with other raw materials takes place in a sealed mixer fitted with an exhaust extraction system. The resulting dry coating mixture is then extruded, milled and packaged using automated processes.

At the application facility the electrostatically charged powder coating particles are sprayed onto earthed metal objects by means of a spray gun. The method of application varies between facilities. The powder coatings are applied either through a fully automated application lines, by manual spray or, in some cases a combination of both automatic and manual processes.

In the automated application lines the metal articles to be sprayed hang from metal hooks and pass automatically through a spray booth to the curing ovens. Air flow in these booths is directed to the bottom of the booth. In a fully automated application line the powder coating is applied by automatic spray guns. Alternatively, workers stand outside the booths with only their hands holding the spray guns entering the booth through apertures. Other spray booth designs in common use include walk-in open fronted booths in which objects are manually sprayed. The air flow in these booths is directed horizontally by local ventilation from behind the worker and towards the article being sprayed. Articles are usually moved manually into the booth for spraying and then to the ovens for curing.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Polymer Importation			
Dockside workers	2	2 hrs/day	20 days/year
Transport and Warehouse			
Transport	2	2 hrs/day	40 days/year
Warehousing Personnel	2	2 hrs/day	20 days/year
Powder Coating Formulation			
Maintenance Personnel	2	1-2 hrs/day	20 days/year
Laboratory Personnel	5	1-2 hrs/day	20 days/year
Powder Coating Application			
Professional Tradesmen	10 000	8 hrs/day	240 days/year

Exposure Details

Import, Transport and Storage

Import, transport and storage workers will handle sealed bags or boxes containing the notified polymer. Workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Coating formulation

There is potential for inhalation and dermal exposure to the notified polymer during weighing and decanting or scooping the polymer into the mixing vessel for dry blending. Incidental dermal and inhalation exposure may also occur during transfer of the dry powder coating to the extruder and subsequent milling, grinding and packaging processes, however, the powder coating contains only 8% notified polymer. The above operations are conducted in a contained area with local exhaust ventilation and workers will wear anti-static overalls, non-insulating gloves, anti-static footwear and dust respirators or air fed respiratory equipment.

Intermittent exposure to the notified polymer may occur during quality testing and product evaluation. All testing activities will be performed within a controlled laboratory fitted with extraction system. Laboratory personnel will wear laboratory coat, gloves, safety glasses and dust mask, as required.

Maintenance workers may be exposed to dusts containing the notified polymer left on the machinery they are required to service. Maintenance workers will wear gloves and disposable masks when cleaning and servicing machinery.

Powder coating application

The potential for inhalation, dermal and ocular exposure to the notified polymer exists when opening the bags containing the notified polymer, loading of powder coating into a hopper and application of powder coating and disposal of empty containers. All spraying is performed in a spray booth fitted with local exhaust and dust extraction system to prevent dust build-up. Where manual application is in use, the direction of airflow comes from behind the operator.

Where spraying is performed by a fully automated there is no human involvement within the spray booth and therefore no exposure. Operators using the method of spraying articles with their forearms through apertures in the spray booth may be dermally exposed to the notified polymer as some degree of skin contact is required with the spray gun to ensure good earthing. Workers use a cowl to cover the hand or cut out the palm of a glove to allow contact and may therefore be dermally exposed. Potential exposure is greatest where walk in or open fronted booths are used.

Incidental exposure may also occur during the use of industrial vacuum cleaners to remove dust from the booths and extraction units, and the emptying of residual coating into containers for curing and disposal.

After curing, the notified polymer is bound within the polymer matrix and is unavailable for exposure.

5.4. Release

RELEASE OF CHEMICAL AT REFORMULATION SITE

Release of the notified polymer into the environment during transport, storage, preparation and packaging of the final powder coating is expected to be minimal, except in the event of accidental spills. During the reformulation process there will be engineering controls (eg ventilation, filters and bunding) in place to contain and entrap any released or spilt notified polymer. It is estimated that annually up to 1.4% (350 kg) of the notified polymer will be released due to spills, filter residues and equipment cleaning. This amount may be significantly less due to reuse of collected material.

It is estimated that 0.2% (50 kg) of the imported notified polymer will be disposed of in the empty import containers.

RELEASE OF CHEMICAL FROM USE

Release of the notified polymer to the environment during application of the powder coating is expected to be minimal. In industrial applications, spraying systems are closed systems with exhaust extraction systems designed to trap excess dust and coating powder, with the trapped material being recovered and reused. Equipment cleaning is done with dust-tight vacuum cleaners and this material is also collected for re-use or disposal. It is estimated that losses due to overspray and the cleaning of application equipment would be less than 2.4% (2% overspray), approximately 600 kg annually.

Less than 1% will be disposed of in empty coating containers, i.e. approximately 250 kg annually.

No release of the notified polymer is expected once the coatings are applied and cured. Upon curing the polymer is incorporated into the polymer matrix where it will become inert.

5.5. Disposal

Waste notified polymer or coating not recycled is collected and sent to landfill sites or incinerated at both reformulation sites and end usage sites. Both import and coating containers will be disposed of to landfill. Thus approximately 1250 kg of notified polymer will be disposed of to landfill across Australia.

5.6. Public exposure

There are no consumer uses for the notified polymer and therefore, it is not available to the public.

After application, the notified polymer on the surface of the coated article is not bioavailable as it is bound within the polymer/paint matrix after curing. Members of the public are unlikely to be in contact with the notified polymer and the potential for public exposure is minimal.

6. PHYSICAL AND CHEMICAL PROPERTIES

Full test reports were not available for the notified polymer.

Appearance at 20°C and 101.3 kPa White granular solid without specific odour.

Glass Transition Temperature 75 °C

METHOD DSM Coating Resins TM 2076
Remarks
TEST FACILITY DSM Coating Resins (2002)

Density 1115-1125 kg/m³

METHOD Not provided
Remarks
TEST FACILITY DSM Coating Resins (2002)

Vapour Pressure <0.1 kPa

METHOD Not provided
Remarks
TEST FACILITY Not provided

Water Solubility <10 mg/L at 20°C

METHOD Ten (10) mg of ground test material was stirred in 1 L of water for 4 hours at room temperature. Visual examinations were undertaken at the start and after 4 hours and the amount of dissolved material was estimated.
Remarks No change in appearance was observed after 4 hours, thus it was concluded that the water solubility was less than 10 mg/L.
TEST FACILITY This test was very qualitative and is only an indication of water solubility. Not specified.

Hydrolysis as a Function of pH Not provided.

Remarks Due to low water solubility, the polymer is not expected to hydrolyse under environmental conditions (pH 4-9) in spite of the presence of groups which are potentially hydrolysable.

Partition Coefficient (n-octanol/water) Not provided.

Remarks The notifier has indicated that this is likely to be high since the polymer is hydrophobic.

Adsorption/Desorption Not provided.

Remarks Expected to adsorb to soil.

Dissociation Constant Not applicable.

Remarks No groups present which are able to dissociate.

Particle Size Granular particles

Flash Point Not determined.

Remarks Not expected to be flammable based on its molecular weight and structure.

Flammability Limits Not determined

Remarks The notified polymer is not flammable and is non volatile.
TEST FACILITY

Autoignition Temperature >400 °C

METHOD Not provided

Remarks

TEST FACILITY Not provided

Explosive Properties Not determined

Remarks No explosive properties are predicted based on the structure.

Reactivity

Remarks The notified polymer is stable.

7. TOXICOLOGICAL INVESTIGATIONS

Screening test for the following toxicological end-points were provided. Screening tests are performed using a smaller number of animals than are recommended in the respective test guideline.

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral	LD50 > 2000 mg/kg bw - low toxicity
Rat, acute inhalation LC50 ... mg/L/4 hour	LC50 > 7.23 mg/L /4 hour -low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	not sensitising
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified Polymer
METHOD	EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	Propylene glycol
Remarks - Method	The observation period is shorter than recommended in the test guideline.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	3F	2000	0
II	3M	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	Bodyweight gain of the animals during the 8 days of the study period was considered to be normal.

CONCLUSION	The oral LD50 value of the notified polymer for both male and female rats was considered to exceed 2000 mg/kg body weight. The notified chemical is of low toxicity via the oral route.
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TEST FACILITY	Notox (2000a)
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7.3. Acute toxicity - inhalation

TEST SUBSTANCE	Notified polymer
METHOD	EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation).
Species/Strain	Rats/Sprague Dawley
Vehicle	
Method of Exposure	Nose only exposure.
Exposure Period	4 hours
Physical Form	solid aerosol (particulate).
Particle Size	6.1 µm (MMAD)
Remarks - Method	

RESULTS

	<i>Number and Sex of Animals</i>	<i>Concentration mg/m³</i>	<i>Mortality</i>
	5M/5F	7230	0
LC50	> 7.23 mg/L		
Signs of Toxicity	8/10 animals exhibited chromodacryorrhoea (porphyrin secretion from the nose and eyes) immediately after exposure. Animals recovered by the next day and remained healthy for the rest of the 14-day observation period. A lower weight gain in the first week of exposure was recorded and may be attributed to a reduced wellbeing after the exposure.		
Effects in Organs	Post mortem examination revealed white areas at the edges of the lungs in 4 males and 3 females. Similar areas were also, however, observed in a spare unexposed male animal, therefore it can be concluded that these findings are not test substance related.		
Remarks - Results			
CONCLUSION	The notified polymer is of low toxicity via inhalation.		
TEST FACILITY	Austrian Research Centre Seibersdorf (2001)		

7.4. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White (SPF quality)
Number of Animals	1
Vehicle	Moistened with water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	The number of animals used in the study is less than recommended in the test guideline.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	0.33	1	24 hours	0
<i>Oedema</i>	0	0	-	0

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

Remarks - Results	Four hours of exposure to 0.5 grams of notified polymer resulted in very slight erythema and no oedema in the treated skin-area of the rabbit which had resolved in 48 hours. Following exposure, sticky remnants remained present at the treated skin area after removal of the test substance.
CONCLUSION	The notified polymer is slightly irritating to skin.
TEST FACILITY	Notox (2000)

7.5. Irritation – eye

TEST SUBSTANCE	Notified polymer
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METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	1
Observation Period	72 hours
Remarks - Method	The number of animals used in the study is less than recommended in the test guideline.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Value at End of Observation Period</i>
<i>Conjunctiva: redness</i>	0	1	1 hour	0
<i>Conjunctiva: chemosis</i>	0	0	-	0
<i>Conjunctiva: discharge</i>	0	0	-	0
<i>Corneal opacity</i>	0	0	-	0
<i>Iridial inflammation</i>	0	0	-	0

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

Remarks - Results	Instillation of 60 mg of notified polymer (0.1 mL) resulted in irritation of the conjunctivae, which consisted of redness for after 1 hour only.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	Notox (2000a)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified polymer		
METHOD	OECD TG 406 Skin Sensitisation – Magnusson and Kligman		
Species/Strain	Guinea pig/		
PRELIMINARY STUDY	Maximum Non-irritating Concentration:		
	intradermal:	20%	
	topical:	50%	
MAIN STUDY			
Number of Animals	Test Group: 10		Control Group: 5
Vehicle	Propylene glycol		
INDUCTION PHASE	Induction Concentration:		
	intradermal:	20%	
	topical:	50%	
Signs of Irritation			
CHALLENGE PHASE			
1 st challenge	topical:	50%	
2 nd challenge	topical:	50%	
	topical:	20%	
Remarks - Method	The number of animals used in the study is less than recommended in the test guideline.		

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after:</i>			
		<i>1st challenge</i>		<i>2nd challenge</i>	
		<i>24 h</i>	<i>48 h</i>	<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	50%	7/10	7/10	0/10	0/10
	20%	-	-	0/10	0/10

<i>Control Group</i>	50%	2/5	2/5	0/5	0/5
	20%	-	-	0/5	0/5

Remarks - Results

Following the first challenge, skin reactions of grade 1 were observed in six experimental and two control animals in response to the 50% test substance concentration. A skin reaction grade 4 and scabs were seen in the test substance treated skin site of one experimental animal. No skin reactions were evident after the second challenge exposure in the experimental and control animals. The skin reactions observed after the first challenge were considered to be signs of non specific irritation.

CONCLUSION

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

TEST FACILITY

Notox (2000)

7.8. 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.

Species/Strain *S. typhimurium*: TA98, TA100

Metabolic Activation System S9

Concentration Range in Main Test a) With metabolic activation: 3-5000 µg/plate.
b) Without metabolic activation: 3-5000 µg/plate.

Vehicle Dimethylsulfoxide

Remarks - Method No preliminary cytotoxicity test was conducted. Only two strains of *S. typhimurium* were used in the study.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>	Not reported	None	3330	None
<i>Present</i>	Not reported	None	3330	None

Remarks - Results

The test substance precipitated in the top agar at concentrations of 3330 and 5000 µg/plate. The bacterial lawn was not reduced at all concentrations tested and no decrease in the number of revertants was observed.

CONCLUSION

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

TEST FACILITY

Notox (2000b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

Not provided.

Due to its large molecular weight and chemical nature, the notified polymer is not expected to be readily biodegradable.

8.1.2. Bioaccumulation

Not provided.

Due to its molecular weight species distribution, the notified polymer is not expected to be bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – static.
Species	Zebra fish
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	None
Remarks – Method	Oxygen and pH were monitored daily. The test solution (100mg/L) was prepared by stirring for 30 minutes followed by 2 minutes of ultrasonic wave treatment. The final solution was a homogeneous suspension with undissolved white particles.

RESULTS

Concentration mg/L		Number of Fish	Mortality				
Nominal	Actual		3 h	24 h	48 h	72 h	96 h
0		7	0	0	0	0	0
100		7	0	0	0	0	0

LC50 >100 mg/L at 96 hours.
 NOEC (or LOEC) 100 mg/L at 96 hours.
 Remarks – Results The variations observed in pH and oxygen concentration were within an acceptable range.

No abnormal behaviour or mortality was observed during the study.

CONCLUSION Under the test conditions the notified polymer is practically non-toxic to fish.

TEST FACILITY Notox (2000c)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction

Species	Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static. <i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	None
Remarks – Method	Duplicates were run for the control and 100 mg/L. The test solution (100mg/L) was prepared by stirring for 30 minutes followed by 2 minutes of ultrasonic wave treatment. The final solution was a homogeneous suspension with undissolved white particles. Oxygen concentration and pH were measured at the start and end of the study.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
0 (control)	-	20	0	1
100	-	20	0	10

LC50	100 mg/L at 48 hours
Remarks – Results	The pH and oxygen concentration results were within acceptable ranges. At 100 mg/L particles and deposits were observed throughout the study. At the end of the study the immobile daphnia in 100 mg/L were observed to have particles adhered to them. The immobile daphnid in 0 mg/L (control) was observed to be shedding its skin.

CONCLUSION	Under the study conditions the LC ₅₀ appears to be 100 mg/L, thus indicating that the notified polymer is practically non-toxic to daphnia. However, the presence of particles indicates physical damage may have occurred to the daphnia.
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TEST FACILITY	Notox (2000d)
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8.2.3. Algal growth inhibition test

Not provided.

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Not provided.
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9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Very little environmental exposure of the notified polymer is expected under normal usage as the polymer is not expected to enter soil or aquatic compartments. Most of the polymer will be incorporated into the polymer matrix of coatings, which upon curing become inert. Once incorporated into the coating formulation, the notified polymer is expected to be immobile in the environment. At the end of their useful life, the substrates coated with the polymer are likely to be either recycled, incinerated or placed into landfill.

As a worse case scenario, up to 1250 kg of notified polymer could be generated for disposal each year. However, in most industrial coating operations, it is expected that all excess powder

will be recovered and re-used.

Incineration will destroy the polymer and convert it to water vapour and oxides of carbon. The polymer is slightly water soluble and not volatile, hence, if placed in landfill, it is expected to be immobile and to only slowly degrade along with the substrates onto which it is deposited.

9.1.2. Environment – effects assessment

In ecotoxicological studies, the findings were fish 96 h $LC_{50} > 100$ mg/L and daphnia 48 h $LC_{50} = 100$ mg/L (probably a physical effect). The results indicate that the notified polymer is practically non-toxic to aquatic organisms. The PNEC (lowest LC_{50} /safety factor) using a safety factor of 1000 (since there is only data for two trophic levels) is 0.1 mg/L (100 µg/L).

No release of the notified polymer into the aquatic environment is expected either during formulation or application. Should the notified polymer enter the aquatic environment through accidental spills, it is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate.

9.1.3. Environment – risk characterisation

The notified polymer is not expected to pose a significant risk to the environment. The usage patterns indicate that the levels of release of the polymer to the environment will be low. It is difficult to calculate a PEC as under normal usage there will be little release into the aquatic or soil environments. The majority of the notified polymer will be combined with other coating components to form a very high molecular weight and stable coating, which will be inert.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Coating formulation

Inhalation and dermal exposure to the notified polymer may occur during weighing and decanting or scooping the polymer into the mixing vessel for dry blending. However, local exhaust ventilation is provided during weighing and the polymer is expected to be in granular form, thereby minimising inhalation of polymer dust. Incidental dermal and inhalation exposure to the powder coating containing 8% notified polymer may occur during formulation, however, the process is largely enclosed. Maintenance workers may experience occasional skin contact when cleaning and servicing machinery.

Intermittent exposure to the notified polymer may occur during quality testing and product evaluation, however, these activities will be performed within a controlled laboratory fitted with extraction system.

Powder coating application

Spray applicators may experience incidental dermal and inhalation exposure, particularly during manual application, e.g. during touch-up operations. Exposure during application in a spray booth is likely to be low as the booths are specially designed to minimise exposure. No exposure will occur when fully automated spraying processes are used.

Incidental exposure may also occur during general clean-up operations.

After curing of the applied powder coating, the notified polymer is bound within the paint matrix and is unavailable for exposure.

Import, Transport and Storage

Workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

9.2.2. Public health – exposure assessment

Members of the public are unlikely to come into contact with the notified polymer unless there is an accident during transport or storage. The public will be exposed to painted car body parts, however, at this stage, the notified polymer is bound within the paint matrix and not available

for exposure.

9.2.3. Human health - effects assessment

Due to its high molecular weight distribution the notified polymer is largely not expected to cross biological membranes. However there is potential for molecules in the lower MW fraction to be absorbed.

Limited toxicological data were available for the notified polymer. Most data were for screening studies only. The notified polymer was found to be of low acute oral toxicity with LD₅₀ for the rat determined to be >2000 mg/kg using the limit test method. A primary skin irritation study using the notified polymer resulted in only slight erythema and no oedema, with erythema resolving within 48 hours. A primary eye irritation study resulted in irritation of the conjunctiva for 1 hour only.

A skin sensitisation study on Guinea pigs revealed no evidence of reactions indicative of skin sensitisation to the notified polymer.

Acute inhalation toxicity was determined to be greater than 7.23 mg/L with this concentration failing to induce mortality in any of the 10 rats. Eight of the 10 animals exhibited chromodacryorrhoea immediately after exposure but recovered by the next day and remained healthy for the rest of the 14-day observation period.

No genotoxic effects were observed in vitro in a Bacterial Reverse Mutation Test.

Hazard classification for health effects.

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, 2002). However, the results for skin irritation, eye irritation, skin sensitisation and oral toxicity were obtained from studies using less animals (skin and eye irritation, skin sensitisation), or a shorter observation period (oral toxicity), than recommended in the respective test guidelines.

9.2.4. Occupational health and safety – risk characterisation

Import, Transport and Storage

The notified polymer is imported in 25 kg boxes or bags which remain sealed until reaching the reformulation site. No significant risk to workers involved in the importation, transport and storage of notified polymer, prior to reformulation, is envisaged.

Coating formulation

The notified polymer is of low toxicity and exposure to the notified chemical is expected to be mitigated by engineering controls and safety measures including use of appropriate personal protective equipment by workers. The OHS risk presented by the notified chemical during powder coating formulation is expected to be low.

Powder coating

Powder coating is largely an automated process with well established engineering controls in place to mitigate exposure. Some workers involved in the manual spraying of articles by may have some skin exposed during application due to the requirement to make direct contact with the spray gun, however, the notified polymer is of low toxicity and is present in the coating formulation at only 8%. The OHS risk presented by the notified chemical during application is therefore considered to be low, given the low toxicity of the chemical, the low concentration of the notified chemical, the automated process and engineering controls, and use of appropriate personal protective equipment.

Following curing of the paint, the polymer will be cross-linked with other paint components to form a high molecular weight stable film. In this form, the polymer is essentially unavailable for absorption and thus the health risk to workers from the notified polymer after paint curing would be negligible.

9.2.5. Public health – risk characterisation

The notified polymer and the emulsion containing it are not freely available to the public. The low likelihood of exposure to the notified polymer and the low toxicity of the notified polymer suggest that the notified polymer will not pose a risk to public health when used in the proposed manner.

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*.

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.

- This notified polymer would not be classified under this system.

10.2. Environmental risk assessment

The polymer 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 negligible concern to public health when used in the intended 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, 2002). 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, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS**CONTROL MEASURES****Occupational Health and Safety**

- The use of the product containing the polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999b) where appropriate.

- Hand-held spraying requires a higher level of personal protective equipment than use within a spray-booth. Workers should wear goggles, impervious gloves and respiratory equipment suitable for use with all components of the formulation.
- Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- The level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m³.
- 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.

Environment

- The following control measures should be implemented by the reformulator and coating user to minimise environmental exposure during formulation and use of the notified chemical:
 - A regular and strict cleaning and maintenance program of process and extraction equipment.

Disposal

- The notified polymer should be disposed of to landfill or by incineration.

Emergency procedures

- Spills/release of the notified polymer should be handled by containment and collection. If not contaminated then the material should be recycled. If contaminated then it should be placed in a labelled sealable container ready 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 Subsection 64(1) of the Act; if
 - the importation volume exceeds 25 tonnes per annum notified chemical; or
- or
- (2) Under Subsection 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.

If secondary notification is recommended, the following data should be provided:

- full physico-chemical data set, and
- algae toxicity data and report.

13. BIBLIOGRAPHY

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