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

FULL PUBLIC REPORT

Ajisper PB-82 Series

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FULL PUBLIC REPORT

Ajisper PB-82 Series

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Toyo Ink Australia Pty Ltd (ABN: 29 006 294 837)
29 Garden Street
Kilsyth VIC 3137

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other names, CAS number, Molecular Formula, Structural Formula, Molecular Weight, Polymer Constituents, Spectral Data, Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Hydrolysis as a Function of pH; Partition Coefficient; Absorption/Desorption; Dissociation Constant; Particle Size; Flammability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

US EPA: PMN (2000)
Korea KICI (2000)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Ajisper PB-82 series (for example, PB-821, PB-822. Grades within the series differ slightly in the purification processes used, raw material quality, etc. PB-822 is a generic grade in the series).

METHODS OF DETECTION AND DETERMINATION

METHOD Infrared spectroscopy and High Pressure Liquid Chromatography

Remarks Spectral data was provided

3. COMPOSITION

DEGREE OF PURITY

> 99%

DEGRADATION PRODUCTS

Degradation by hydrolysis may generate complex polymer mixtures that may contain monomers and other related chemicals.

Thermal decomposition products may include fumes containing CO, CO₂, NO_x, and HCN gases.

Fire conditions may also result in decomposition.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Loss of monomers is expected to be negligible during normal use of the polymer.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported into Australia in a powdered form (concentration >99%) for further formulation, or as a component of paints, coatings or inks (concentration <5%). No manufacture will occur in Australia.

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>	0.1	0.5	1.0	1.5	2.0

USE

The notified polymer will be used as a pigment dispersing agent in paints, coatings and inks, for example, in the automotive industry, in liquid crystal displays, and paper and plastic products. It is estimated that approximately 50% of the import volume will be used in ink products and the remaining 50% in paints/coatings.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer and products containing it will initially be stored and then distributed, mainly by road, from the notifier's site in Melbourne.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in polyethylene bags contained within carton boxes. Transport of the notified polymer will be mainly by road.

5.2. Operation description

Reformulation

During reformulation of the notified polymer into final products, the notified polymer (concentration >99%) will be transferred to a mixing vessel using automated processes, or possibly by manual means. During mixing with other ingredients, the vessel is likely to be sealed. QC samples are expected to be taken from the vat during the final stages of the batch production. The final mixture will be transferred into containers such as plastic bottles (1L, 5L, or larger) using automated processes. Final products contain the notified polymer at concentrations < 5%.

End use

Ink products containing the notified polymer (at concentrations <5% in formulated and imported products) will be used industrially. Printing processes are expected to be varied.

Paint and coating products containing the notified polymer are intended mainly for industrial applications. It is expected that most will be applied by robotic sprayers and industrial rollers, with smaller amounts being applied by conventional sprayers, rollers and brushes.

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>
Transportation and storage	1	2 hours/day	5 days/year
Warehouse	1	1 hour/day	10 days/year
End use	~500	2.5 hours/day	5 – 150 days/year

Exposure Details

Exposure of workers to the notified polymer (at concentrations >99% or <5%) during transport and storage will only occur in the event of an accidental spillage. Workers may wear protective clothing during these operations.

Reformulation

There is potential for dermal, ocular and inhalation exposure to the undiluted form of the notified polymer when transferring into the mixing vat for reformulation. Exposure to the notified polymer may also occur during mixing. Exposure would be minimised if local exhaust extraction is used and if workers wear personal protective equipment such as gloves, safety glasses, respiratory protection and protective industrial clothing. Dermal and ocular exposure that may occur during QC sampling and transfer of the final product into storage containers or packaging containers should be minimised by similar means.

End use

During end use applications, the notified polymer will be present at a maximum concentration of 5%.

When used in printing applications, dermal and ocular exposure to the notified polymer may occur for a short duration due to the mainly automated processes. However, exposure should be minimised by workers wearing gloves and eye protection during direct handling procedures.

During spray and roller/brush application of the coatings and paints, dermal and ocular exposure to the notified polymer may occur. Exposure should be reduced by working in well-ventilated areas, performing spray procedures in spray booths or with robotic sprayers, and/or by wearing personal protective equipment such as gloves, safety glasses, respiratory protection and protective industrial clothing.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer is manufactured outside of Australia. Spills will only occur if the packaging is breached. The polymer is a powdered solid and can be easily collected for re-use or disposal. Reformulation will occur in Australia by adding the notified polymer as a component of coatings or inks. No environmental release is expected except from empty packaging and cleaning of equipment. As the notified polymer is present as powdered flakes minimal amounts (0.1%; 2 kg per annum) are expected to remain in packaging. Consequently the release from sites is expected to be very low (~1%; < 20 kg per annum). This is expected to be disposed of by licensed waste disposal.

RELEASE OF CHEMICAL FROM USE

The notified polymer is used as a component in paint, coating, and ink. The notified polymer is not volatile, so when the final products are dried, it will remain in dried solid phase. It is expected that approximately 50% (1.0 tonne) of the notified polymer will be used in paints and coatings with the remaining 1.0 tonne being used in ink products. Of the ink products the major use will be on plastic sheets, meaning that less than 50% (<0.5 tonne) will be used in printed paper products. In Australia, approximately 50% of paper products are recycled (NOLAN-ITU, 2001) with the remainder being landfilled or possibly incinerated.

Paint products are intended mainly for industrial applications. It is expected that most will be applied by robotic sprayers and industrial rollers, with smaller amounts being applied by conventional sprayers, rollers and brushes. Industrial spray applications are efficient and wastage is expected to be approximately 10%. The overspray is expected to be captured in spraybooth washings. Similarly, wastage from industrial rollers is expected to be minimal (< 1%) from cleaning and maintenance. Any other applications are expected to be done by professional painters and as such virtually all waste is expected to be collected (eg. on newspaper, in spraybooth washings, etc) for correct disposal, with only minor amounts (< 5%) being diluted and flushed to sewer from cleaning of equipment. The vast majority of the paint containing the notified polymer will be used for its intended use as a coating and will share the same fate as the coated product.

5.5. Disposal

Waste notified polymer and paint containing the notified polymer is expected to be disposed of by licensed waste disposal and may be incinerated, where possible.

Printed paper products with ink containing the notified polymer will be recycled, landfilled or possibly incinerated at the end of their useful lives. Similarly, coated and printed products at the end of their useful lives will be landfilled, with metal products possibly also undergoing metal recycling.

5.6. Public exposure

Products containing the notified polymer will not be sold to the public. The public may come into contact with the notified polymer during use of products that have been coated or printed with coatings, paints or inks containing the notified polymer eg. in the automotive industry, liquid crystal displays, paper and plastic products, etc. However, on such products the notified polymer should be bound within a matrix after curing and is unlikely to be bioavailable. Therefore, exposure to the public is expected to be negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Light yellow wax/flakes

Melting Point/Freezing Point 25 - 52°C (Onset temperature ~ 51 °C)

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Differential Scanning Calorimetry
TEST FACILITY	NOTOX (2005a)

Boiling Point Not observed

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Boiling was not observed below the temperature at which reaction or decomposition commenced.
TEST FACILITY	NOTOX (2005a)

Density 1140 kg/m³ at 19.8 – 20.3°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY	NOTOX (2005b)

Vapour Pressure $1.1 \pm 0.2 \times 10^{-5}$ kPa at 20°C

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure. Static Technique with tests conducted at 38.31, 33.04 and 25.38°C.
TEST FACILITY	NOTOX (2005c)

Water Solubility 35.1 mg/L at 20°C

METHOD	OECD TG 120 Solution/Extraction behaviour of Polymers in Water.
Remarks	Analytical method: Total Organic Carbon (TOC) for a polymer concentration of 10g/L, and assuming carbon content of 66.4% (w/w). Gravimetric analysis was used to confirm the result. A value of 117.2 mg/L was obtained, but this includes losses from the extraction procedure.
TEST FACILITY	Chemex (2005)

Hydrolysis as a Function of pH Not tested

Remarks	The notified polymer contains functional groups that may undergo hydrolysis under extreme temperature and pH conditions. The polymer will contain a range of oligomers and polymers with varying water solubility and susceptibility to hydrolysis.
Partition Coefficient (n-octanol/water)	Not tested
Remarks	The polymer will contain a range of oligomers and polymers with varying water solubility and octanol solubility.
Adsorption/Desorption	Not tested
Remarks	The polymer will contain a range of oligomers and polymers with varying affinity for organic carbon.
Dissociation Constant	Not tested
Remarks	Contains cationic groups expected to show typical acidity with pKa of ~ 10. The polymer will contain a range of oligomers and polymers, which will have slightly different ratios of labile protons to molecular weight. A single dissociation constant is therefore not appropriate.
Particle Size	Not determined
Remarks	As the notified polymer is of a waxy/flaky consistency, it is not expected to generate particles of inhalable or respirable size.
Flash Point	Could not be determined
METHOD	EC Directive 92/69/EEC A.9 Flash Point, Pensky Martens Closed Cup
Remarks	No flammable vapour/air mixture was produced in the test vessel at temperatures below boiling point, which was visually observed to occur at 136°C.
TEST FACILITY	NOTOX (2005d)
Flammability Limits	Not determined
Remarks	Not expected to be flammable, based on the flash point determination.
Autoignition Temperature	450°C
METHOD	92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY	NOTOX (2005e)
Explosive Properties	There are no bond groupings present that are known to confer explosive properties.
Reactivity	
Remarks	Stable under normal conditions of handling and storage.

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Acute oral LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating

Rabbit, eye irritation
Guinea pig, skin sensitisation – adjuvant test
Genotoxicity – bacterial reverse mutation

moderately irritating
no evidence of sensitisation
non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE Ajisper PB-822

METHOD Test method not stated (only a summary report was provided)

Species/Strain Mice/ICR

Vehicle Olive oil

Remarks - Method Test substance was dissolved in olive oil, using heat, to give concentrations of 2.5% and 5% w/v. The dose volume used was 4mL/100g. Olive oil was used in the control group. Mice were observed for acute toxic signs up to 2hr after administration, changes of clinical signs were investigated at approximately 6hr after administration, and once daily up to day 7 after administration.

No statement of Good Laboratory Practice (GLP).

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5 male	Control	0
II	5 male	1000	0
III	5 male	2000	0

LD50 >2000 mg/kg bw

Signs of Toxicity No animals died during the observation period.
No changes in clinical signs were observed.
There were no significant changes in body weight.

Effects in Organs No changes in necropsy were observed.

CONCLUSION The notified polymer is of low toxicity via the oral route, under the conditions of the test.

TEST FACILITY Not stated

7.2. Irritation – skin

TEST SUBSTANCE Ajisper PB-822

METHOD Test method not stated (only a summary report was provided)

Species/Strain Rabbit, details not provided

Number of Animals 4 animals treated with the test substance; 4 animals treated with a positive control substance (5% SLS solution).

Vehicle The test substance (solid) was melted in a hot bath prior to application to skin.

Observation Period 1 week

Type of Dressing Not stated

Remarks - Method The test substance (dose not stated) was applied to rabbit skin and covered with a patch (type of dressing, size of the test site, and exposure period not stated). Irritation was observed 24, 48, 72 hours and 1 week after removal of the patch.

Positive control animals were treated in a similar fashion.

No statement of Good Laboratory Practice (GLP).

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	0.4	2	1 week	0
<i>Oedema</i>	0	0	0	0

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

Remarks - Results

Pronounced erythema was observed in 1 rabbit at 24 and 48 hours after removal of the patch. Mild erythema was observed in 1 rabbit 72 hours after removal of the patch. Skin irritation was no longer observed 1 week after application, although desquamation was noted in one rabbit.

All positive control animals had severe oedema and scabbing 24 hours after removal of the patch. Oedema gradually recovered and was no longer present after 1 week. The severity of the scabbing remained unchanged after 1 week of observation.

CONCLUSION

The notified polymer is slightly irritating to the skin under the conditions of the test.

TEST FACILITY

Not stated

7.3. Irritation – eye

TEST SUBSTANCE

Ajisper PB-822

METHOD

Species/Strain
Number of Animals
Observation Period
Remarks - Method

Test method not stated (only a summary report was provided)

Rabbit/New Zealand White

Three

1 week

Test substance (0.1mL or 0.1g) was administered to one eye of each animal (exposure duration was not stated). Observations of irritation effects were made 1, 24, 48, 72, 96 hours, and one week after instillation.

No statement of Good Laboratory Practice (GLP).

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva</i>	2	2	0	4	96 hr	0
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	0	0	0

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

Remarks - Results

All animals showed moderate conjunctival redness and two of the three animals showed a large amount of discharge one hour after administration. Two of the three animals showed moderate conjunctival redness 24, 48 and 72 hours after administration. Irritation disappeared after 96 hours and remained unchanged after 1 week.

CONCLUSION

The notified polymer is moderately irritating to the eyes under the conditions of the test.

TEST FACILITY

Not stated

7.4. Skin sensitisation

TEST SUBSTANCE	Ajisper PB-822
METHOD	Test method not stated (only a summary report was provided)
Species/Strain	Guinea pig, details not provided
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
Remarks - Method	Minimal information about the testing method has been provided. No statement of Good Laboratory Practice (GLP). Elicitation concentration: 10% acetone solution Sensitisation concentration: 100%
RESULTS	
Remarks - Results	Minimal details have been recorded. The report states that 0% of the animals were sensitised at 24 and 48 hours.
CONCLUSION	The report concluded that the notified polymer is not a skin sensitiser.
TEST FACILITY	Not stated

7.5. Genotoxicity – bacteria

TEST SUBSTANCE	Ajisper PB-822		
METHOD	Test method not stated (only a summary report was provided)		
Species/Strain	Pre incubation procedure		
Metabolic Activation System	<i>S. typhimurium</i> : TA98, TA100		
Concentration Range in Main Test	S9 mix		
Vehicle	a) With metabolic activation: 10 - 5000 µg/plate		
Physical Form	b) Without metabolic activation: 10 - 5000 µg/plate		
Remarks - Method	Not stated		
	Not stated		
	48 hour incubation		
RESULTS			
<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Resulting in: Genotoxic Effect</i>
<i>Absent</i>			
Test 1 (TA100)	>5000	>625*	Negative
Test 2 (TA98)	>5000	>313*	Negative
<i>Present</i>			
Test 1 (TA100)	>5000	>625*	Negative
Test 2 (TA98)	>5000	>313*	Negative
* A white deposit was observed. The quantity of deposit increased with increasing concentrations of test substance.			
Remarks - Results	No substantial increases in the number of revertant colonies were seen in both strains tested, either in the presence or absence of metabolic activation.		
	The positive controls (2-aminoanthracene(+S9); Furylamide (-S9)) demonstrated the sensitivity of the test system.		
CONCLUSION			
	The notified polymer was not mutagenic to bacteria under the conditions		

of the test.

TEST FACILITY

Not stated

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted

8.1.2. Bioaccumulation

The polymer has a high molecular weight and is unlikely to cross biological membranes. It is therefore not expected to bioaccumulate.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Up to 500 kg of the notified polymer will be used on printed paper products. It is expected that approximately half of the paper products will be recycled, with the paper being de-inked at the end of the useful lives of the paper products. Assuming that the entire amount of polymer is released to sewer during de-inking and that none is removed in the sewage treatment plant (STP), this results in a worse case scenario of 250 kg (per annum) of the polymer being released from STPs throughout Australia annually.

Paints and coatings are expected to account for the remaining 1 tonne of the notified polymer. Most of this is expected to be used in industrial applications. The wastage from such applications is expected to be small, but if a worst case scenario is assumed, where approximately 5% is flushed to sewer from cleaning of equipment, spills and incomplete removal from spraybooth washings, then 50 kg will enter STPs per annum.

The total amount entering sewers throughout Australia is expected to be 300 kg per annum over 260 working days. The worst case predicted environmental concentration (PEC) can therefore be estimated as 0.28 µg/L ($300 \text{ kg} \div (200 \text{ L per person per day} \times 20.5 \text{ million persons} \times 260 \text{ days})$). The actual amount is expected to be considerably lower as the notified polymer is expected to be incorporated into the cured paint or ink. This is likely to be removed in the sewage sludge.

The remainder of the notified polymer is expected to share the same fate as the products on which the ink or paint is used. At the end of their useful lives the products will be landfilled, enter metal recycling or possibly be incinerated.

In landfill the notified polymer is expected to eventually undergo degradation by biotic and abiotic processes to form landfill gases including methane, ammonia, oxides of nitrogen, oxides of carbon and water vapour.

The notified polymer will be thermally decomposed by incineration or during metal recycling to form oxides of carbon and nitrogen; and water vapour.

9.1.2. Environment – effects assessment

The notified polymer contains both cationic sites and anionic sites. Polycationic polymers that are soluble are known to display toxicity to aquatic organisms (Boethling and Nabholz 1997).

Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. The toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups (Nabholz *et al.* 1993). However, as no toxicity data were submitted a predicted no effect concentration (PNEC) cannot be calculated.

9.1.3. Environment – risk characterisation

Although a risk quotient (RQ) cannot be calculated by dividing the PEC by the PNEC, the aquatic exposure of the notified polymer is expected to be low with a PEC of less than 0.28 µg/L. The notified polymer is therefore unlikely to show an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Dermal, ocular and inhalation exposure (to powder formulation) to the notified polymer may occur during reformulation into final products, particularly when handling high concentrations of the notified polymer (>99%) such as when opening containers, during transfer of the imported product into the blending vessel and mixing. However, worker exposure should be reduced by local exhaust ventilation and the use of personal protective equipment. Overall, exposure to the notified polymer during reformulation is expected to be low.

In end use products, the notified polymer will be present at concentrations < 5%. When used in printing inks, dermal exposure to the notified polymer is expected to be low due to the mainly automated processes involved. Wearing of personal protective equipment when handling the product directly may further lower worker exposure.

When used in paints and coatings, dermal, ocular and inhalation exposure to the notified polymer may occur. Protective measures are likely to vary widely depending on the type of product in which the notified polymer is contained (water based or solvent based), the surface to which it is applied, the application site, and the application method (spray, roller/brush). Exposure may be reduced by the use of mechanical ventilation, and personal protective equipment such as vapour masks, breathing protection, protective clothing, etc. During spray operations, exposure would be significantly reduced when performed in spraybooths or if robotic sprayers are used. The low concentration of the notified polymer in final products (< 5%) may mitigate concerns associated with worker exposure to the notified polymer during end use applications.

9.2.2. Public health – exposure assessment

The notified polymer is present in a number of products that the public are likely to come into contact with occasionally, such as products in the automotive industry, liquid crystal displays, paper and plastic products, etc. However, the notified polymer is unlikely to be bioavailable as it becomes encapsulated within a polymer matrix during curing. Therefore the level of public exposure is expected to be minimal.

9.2.3. Human health – effects assessment

A number of summary reports of toxicological studies were provided. Only brief details of the test methods were provided and no statement of compliance with Good Laboratory Practice was noted.

The notified polymer was of low acute oral toxicity in mice (LD50 > 2000 mg/kg bw).

The notified polymer was found to be slightly irritating to the skin of rabbits. It was moderately irritating to the eyes of rabbits, although the severity does not meet the NOHSC criteria for classification as an eye irritant. It was not found to be a skin sensitiser based on the study provided, however, this conclusion was based on a summary test report containing limited study details. The notified polymer contains a functional group of concern, and as such it may possess skin sensitisation properties. However, the polymer has a high number average molecular weight

(Mn) of >1000, relatively low levels of low molecular weight species, and is unlikely to cross biological membranes.

The notified polymer was found to be non-mutagenic.

Based on the available data, the notified polymer cannot be 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

The notified polymer is expected to be of low toxicity but may possess irritant properties.

The potential risk of eye irritation and skin sensitisation effects exists when handling the imported products containing >99% of the notified polymer, particularly during weighing and transfer into the blending vessel when reformulating into final products. However, the risk should be minimised by the short exposure duration to the imported product containing >99% of the notified polymer, and the use of local exhaust ventilation and PPE, such as eye protection, gloves and protective clothing.

The potential risk of skin sensitisation also exists during end use of the products containing <5% of the notified polymer, particularly during painting and coating applications. End use applications should take place under local exhaust ventilation or in a well-ventilated area and workers should wear PPE to minimise skin exposure.

The particle size of the imported powder has not been provided. As such, inhalation exposure to the notified polymer as a powder at concentrations >99% may occur, particularly during reformulation processes. The notifier should ensure that exposure to dust is below the NOHSC exposure standard of 10mg/m³ (inspirable dust) (NOHSC, 1995).

Overall the risk to workers can be considered low if appropriate controls are in place at all workplaces where the notified polymer is handled or used, especially where spray application occurs.

9.2.5. Public health – risk characterisation

When present in consumer products, the notified polymer will be encapsulated within a polymer matrix and will not be bioavailable. As such, the risk of adverse effects to the public is considered to be minimal.

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*.

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 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

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Local exhaust ventilation during reformulation and packaging.
 - Ventilation during paints and coating operations.
 - Local exhaust ventilation should be in place during all spraying operations.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid skin and eye contact.
 - Avoid inhalation exposure to imported powder formulation.
 - Spray operations should be according to the NOHSC National Guidance for Spray Painting (1999).
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Safety glasses, gloves and protective industrial clothing during reformulation and end uses.

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 polymer 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

Disposal

- The notified polymer should be disposed of by licensed waste disposal with incineration where permitted.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical collection such as sweeping or vacuuming. Transfer to suitable containers for re-use if practicable or disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;
 - additional data becomes available regarding skin sensitisation;
- or
- (2) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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