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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Melapur 200 *and* Polymer in Exolit OP 1312

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Director
NICNAS

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FULL PUBLIC REPORT

Melapur 200 *and* Polymer in Exolit OP 1312

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)
235 Settlement Road
Thomastown VIC 3074

and

Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
675 Warrigal Road
Chadstone VIC 3148

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; CAS number; Molecular Formula; Structural Formula; Molecular Weight; Purity; Identity and % weight of toxic or hazardous impurities; Identity of non-hazardous impurities; Identity and % weight of additives/adjuvants; Import Volume; Identity of Reformulating Sites; Spectral Data; Methods of Detection and Determination; Polymer Weight Percentage and Ingredients; Number Average Molecular Weight; Residual Monomers/Other Reactants; Low Molecular Weight Polymer; Degradation Products; Loss of Monomers, Additives and Impurities; Specific Use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/678

NOTIFICATION IN OTHER COUNTRIES
EU (EINECS) – exempt
China (IECSC) – (2004)
Japan (ENCS) – (Register No. (5)-1024 & (1)-422)
Korea (KECI) – (2002) (Register No. 2001-3-1669)
USA (TSCA) – listed (confidential section)
Philippines (PICCS) - exempt
Canada (DSL) – limited – Schedule VI

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Polyphosphoric acids, compounds with melamine
Polyphosphoric acids, 1,3,5-triazine-2,4,6-triamine salt
1,3,5-triazine-2,4,6-triamine, polyphosphate
TKA 40287

MARKETING NAME(S)
Melapur 200 (> 95% notified polymer, name used by Ciba Specialty Chemicals Pty Ltd)
Exolit OP 1312 (< 40% notified polymer, name used by Clariant (Australia) Pty Ltd)

CAS NUMBER
218768-84-4 (this number represents only the Marketing Name Melapur 200)

SPECTRAL DATA

METHOD ^{31}P NMR spectroscopy
TEST FACILITY DSM Research (1997)

METHOD Infrared spectroscopy
TEST FACILITY Ciba Specialty Chemicals Inc.

METHODS OF DETECTION AND DETERMINATION

METHOD The notified polymer can be characterised by infrared spectroscopy and ^{31}P NMR. Typical spectra have been provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 110	< 110	< 110	< 110	< 110

USE
Flame retardant for plastic material for furniture, electrical housings and electrical components.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne or Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)
235 Settlement Road
Thomastown VIC 3074

Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
675 Warrigal Road
Chadstone VIC 3148

TRANSPORTATION AND PACKAGING
Ciba Specialty Chemicals Pty Ltd will import Melapur 200 (> 95% notified polymer in a powder form) by sea to Melbourne in 20 kg polyethylene-lined fibreboard cartons. It will then be transported by road directly to Ciba's warehouse in Thomastown, Victoria where it will be stored until required by customers.

Clariant (Australia) Pty Ltd will import Exolit OP 1312 (< 40% notified polymer in a solid form) by

air or sea to Sydney or Melbourne in 25 kg cardboard boxes with PE liner. It will then be transported by road to a contract warehouse until required by customers.

5.2. Operation description

The notified polymer will be weighed and added into a blending vessel where it is mixed with other ingredients. This is likely to occur manually with workers scooping or pouring the notified polymer into weighing containers or feeders. The resulting mixture containing the notified polymer at < 20% will then be hot-melt extruded and pelletised. During the hot-melt extrusion process, the notified polymer becomes encapsulated within the polymer matrix.

The plastic pellets will then be packaged, perhaps using automated processes, into 25kg bags, 500kg bulk bags or boxes, or plastic bags. The pellets will then be transported to customer sites.

At the customer sites, the pellets may be mixed with further ingredients into the hopper of an injection moulding machine. Once heated, the polymer melt will be injected into a mould to form the shape of the required plastic article, containing the notified polymer at concentrations < 20%.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
CIBA SPECIALTY CHEMICALS			
Transport drivers	1 – 4	75 mins per trip	5 - 10 days per year
Warehouse operators	4 – 6	30 mins per unload or load	30 - 50 days per year
Weighing/blending operators	2 – 4	10 - 15 minutes per day	80 - 100 days per year
Extrusion plant operators	2 – 4	30- 40 minutes per day	80 - 100 days per year
Laboratory technician	1 - 2	10 - 20 minutes per day	80 - 100 days per year
CLARIANT			
Warehouse/ Stores personnel	8	1 hour per day	100 days per year
Production operators	20	4 hours per day	100 days per year
Production supervisors	4	4 hours per day	100 days per year
Quality control personnel	4	4 hours per day	100 days per year

Exposure Details

Dermal, ocular or inhalation exposure to the notified polymer may occur during production of pellets, particularly when workers manually transfer the notified polymer into the blending vessel. The maximum concentration at which the notified polymer will be present during these processes is > 95%. Exposure should be minimised by the exhaust ventilation in place in such areas, and personal protective equipment including respiratory protection, gloves, safety glasses and overalls. Similar means of protection will be in place during extrusion, pelletising, and packaging operations. Following the extrusion process, the notified polymer is bound within a matrix.

Worker exposure to the notified polymer during injection moulding of the final plastic products should be minimal, as the notified polymer should remain encapsulated within the polymer matrix. Local exhaust ventilation is used to capture any fugitive emissions from the notified polymer when heated, and workers wear gloves and eye protection. The maximum concentration at which the notified polymer will be present during these processes is < 20%.

5.4. Release

RELEASE OF CHEMICAL AT SITE

There will be no release in Australia due to manufacture, as the notified polymer will not be manufactured here.

Release to the environment during shipping, transport and warehousing will only occur through

accidental spills or leaks of the plastic-lined fibreboard carton. This is expected to be minor due to the robust packaging of the material.

RELEASE OF CHEMICAL FROM USE
CIBA SPECIALTY CHEMICALS
Small quantities of the notified polymer could be lost during preliminary mixing with polymer and other components prior to extrusion of the compound, and all of this is likely to be collected and placed into landfill. Small spills of chemical would be swept up and be either returned to the mix or be disposed with other factory waste to landfill. It is expected that the mixing and extrusion operation would be performed using vacuum extraction/filtration so that any particulate matter released to the air during operations would be captured and retained on the filters, and all solid material retained on the filters also placed into landfill.

Residues of the substance will be retained in import containers after emptying for use in production. It is estimated that up to 1% (100 kg) may remain in each bag after emptying, which will be disposed of to landfill with the packaging.

On occasions the extrusion equipment would be cleaned out and some solid scrap material would be removed from the equipment and also placed into landfill, as would any of the granulated compound lost during packaging.

Apart from spills, no release of the notified polymer during dry mixing of the compound with polymer, filler and other materials is expected during injection moulding of the final articles. However, it is possible that some scrap plastic may be produced during finishing of the final products. All such waste would be placed into landfill.

While no details of likely release of the notified polymer are available, large releases are not expected. If it is assumed that 2% is lost during compound preparation and a further 3% lost as scrap and waste from injection moulding, then total losses associated with manufacturing activities are 5%, which, based on a maximum import volume of 10 tonnes per annum, amounts to an annual release of up to 500 kg, all placed into landfill.

CLARIANT
It is possible that quantities of the new substance may be consigned to waste during preparation of masterbatch grades containing the notified polymer.

Residues of the substance will be retained in containers after emptying for use in production. It is estimated that up to 0.2% may remain in each container after emptying. The residue will be disposed in closed containers to regulated landfills.

During the extrusion process, some waste may be generated by spillage of powder prior to incorporation into polymer. This waste (up to 0.1%) will be collected by sweeping/ vacuuming and consigned to waste. Residues will not be washed or collected with water.

During start up and after a batch run, a further quantity of the notified substance will be incorporated into waste purged polymer. This quantity (up to 0.2% of a batch) of the notified substance will be immobilised in the carrier polymer. The purged polymer may be either reprocessed or consigned to waste.

All waste quantities of the new substance (up to 0.5% of the substance or a maximum of 500 kg per annum) will be disposed of via a licensed waste disposal company to an approved landfill. No quantities of the notified substance will be released to the sewer or waste water systems.

5.5. Disposal

It is intended that all of the imported substance will be used in the preparation of plastic products. The need for disposal of the substance will be limited and would only be required if spillage occurred or residues from production processes exist. Waste from manufacturing of plastic articles will be deposited into landfill and enclosed within a polymer matrix with only small quantities resulting from spills of the polymer left in the free state.

Disposal procedures should be in accordance with Government regulations. It is recommended that waste substance should be disposed of via a licensed contractor.

The majority of the notified polymer will share the fate of the plastic article into which it has been incorporated. At the end of their useful life it is anticipated that the majority of the articles will be disposed of to landfill.

5.6. Public exposure

Public exposure to the notified polymer during transportation is unlikely except in the case of an accident. The maximum concentration of notified polymer to which the public may be exposed is >95%.

The notified polymer will be present in a variety of end use consumer products at concentrations < 20%. In such products the high molecular weight of the notified polymer and its encapsulation within the polymer matrix renders it non-bioavailable. Therefore, public exposure to the notified polymer during use of such products is expected to be negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White, fine crystalline powder with no odour.

Melting Point The test substance did not melt between 25°C and 400°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	RCC Ltd (2005a)

Boiling Point The test substance did not boil between 25°C and 400°C.

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The boiling point of melamine tri-phosphate (smallest unit of the polymer) was estimated to be approximately 498 °C using the Meissner's method (Lyman et al. 1990). This estimation does not account for the ionic nature of the chemical.
TEST FACILITY	RCC Ltd (2005a)

Density 1790 kg/m^3 at 19.5°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Density was determined using a pycnometer; the reference gas was helium.
TEST FACILITY	RCC Ltd (2005b)

Vapour Pressure << 8.0 Pa at 25°C

METHOD	OECD TG 104 Vapour Pressure (Estimation Method). EC Directive 92/69/EEC A.4 Vapour Pressure (Estimation Method).
Remarks	The vapour pressure was calculated for melamine tri-phosphate (smallest unit of the polymer) and used the estimate of the boiling point mentioned above. This calculation does not account for the polymeric or the ionic nature of the polymer and is only considered to be a rough estimate.
TEST FACILITY	RCC Ltd (2005c)

Water Solubility ~2% of the polymer is water soluble/extractable at 20°C

METHOD	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water. EC Directive 92/69/EEC A.20 Solution/Extraction Behaviour of Polymers in

Water.

Remarks Flask Method.
The extractability was quantified by gravimetric analysis of the dried undissolved material, which tends to overestimate the extractability of the polymer. Polymers consist of a range of different species having different molecular weights and hence different water solubilities. The percentage of water soluble/extractable polymer species in the notified polymer is ~2%. This may be explained by the dissolution of lower molecular weight species present in the polymer, while the higher molecular weight fractions, being of lower solubility, remain undissolved.

TEST FACILITY RCC Ltd (2005d)

Hydrolysis as a Function of pH Not Determined

Remarks The hydrolysis of the notified polymer was not determined as a suitable analytical method for the polymer could not be determined due to the lack of solubility of the notified polymer in organic solvents.

The notified polymer contains functional groups that are susceptible to hydrolysis. However, hydrolysis of these moieties is not expected to be rapid under environmental conditions.

TEST FACILITY RCC Ltd (2005e)

Partition Coefficient (n-octanol/water) log Pow < -2.3.at 20ºC

Remarks Determined from the ratio of the solubility of the notified polymer in n-octanol (< 1.062 mg/L based on visual assessment) and water (based on the solvent extractability into water and using a water solubility of 200 mg/L).

TEST FACILITY RCC Ltd (2005f)

Adsorption/Desorption Not Determined

Remarks The adsorption/desorption of the notified polymer was not determined due to the lack of solubility of the notified polymer in organic solvents precluding the development of a method of analysis for the notified polymer.

The charged nature of the polymer would indicate that it is likely to bind to minerals in soils and sediments.

TEST FACILITY RCC Ltd (2005g)

Dissociation Constant Not Determined

Remarks The submission claims that due to the insolubility of the notified polymer in water, the dissociation constant could not be determined experimentally.

pKa is estimated to be < 5 based upon literature values of its constituent monomers.

TEST FACILITY RCC Ltd (2005h)

Particle Size

METHOD Performed on a Sympatec Helos instrument.

Range (μm)	*Mass (%)*
5	57.73
9	75.10
18	92.78
25	98.91

Remarks Details of the test method were not available to the notifier.

TEST FACILITY Hsosokawa (1999)

Flash Point Test not conducted as the notified polymer is a solid.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified substance could not be ignited with a flame during a contact time of approximately 2 minutes.
TEST FACILITY RCC Ltd (2005i)

Autoignition Temperature The substance does not auto-ignite at temperatures up to 400°C.

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY RCC Ltd (2005j)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The molecular structure of the notified substance indicates no risk of rapid decomposition. The oxygen balance was not considered relevant for evaluation of explosive properties and there was no exothermic peak when measuring exothermic decomposition energy.
TEST FACILITY RCC Ltd (2005k)

Reactivity Expected to be stable under normal environmental conditions.

Remarks Oxidising properties have not been tested for this substance. Based on the chemical structure of the notified substance, we do not expect this substance to show oxidising potential. The product is likely to be incompatible with strong acids, strong bases and strong oxidising agents. The product is stable under normal storage and temperature conditions. Static discharges should be avoided, as there is a risk of dust explosion if an air-dust mixture forms. In the event of thermal decomposition or burning, the likely decomposition products are oxides of carbon, oxides of nitrogen (NOx), oxides of phosphorus and hydrogen cyanide.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating

7.1. Acute toxicity – oral

TEST SUBSTANCE Melapur 200

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/HanRcc:WIST (SPF)
Vehicle Purified water
Remarks - Method Limit test.
The test substance was diluted in purified water to a concentration of 0.2g/mL and administered by oral gavage at a dosage of 10mL/kg.
No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3F	2000	0
II	3F	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	No deaths occurred during the study.
Effects in Organs	No clinical signs were observed during the course of the study. The body weights of the animals were within the range commonly recorded for this strain and age.
Remarks - Results	None

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

TEST FACILITY — RCC (2005l)

7.2. Acute toxicity – oral

TEST SUBSTANCE — Melapur 200

METHOD	No mention of compliance with international test guidelines.
Species/Strain	Wistar Rats
Vehicle	1% aqueous carboxymethylcellulose
Remarks - Method	Screening test (only study summary provided). Each test animal received a single oral dose of the test substance in 1% aqueous carboxymethylcellulose at a dose level of 2000mg/kg body weight and dose volume of 10mL/kg body weight. Animals were observed daily and macroscopic examination was performed after 8 days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3M or F	2000	0
II	3M or F	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	No deaths occurred during the study.
Effects in Organs	No clinical signs were observed during the course of the study. Body weight gain of the animals during the 8 day study period was considered normal.
Remarks - Results	None

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

TEST FACILITY — NOTOX (1998)

7.3. Irritation – skin

TEST SUBSTANCE — Melapur 200

METHOD	No mention of compliance with international test guidelines.
Species/Strain	Albino Rabbit (New Zealand White)
Number of Animals	One male
Vehicle	Test substance moistened with water.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.

Remarks - Method A sample of 0.5g of test substance was moistened with water and applied to the skin of the rabbit. After 4 hours the test substance was removed and the animal was observed for an additional 72 hours.

RESULTS

Lesion	*Mean Score* Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1			
Erythema/Eschar	0	0	0	0
Oedema	0	0	0	0

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

Remarks - Results None

CONCLUSION The notified polymer is non-irritating to the skin.

TEST FACILITY NOTOX (1998)

7.4. Irritation – eye

TEST SUBSTANCE Melapur 200

METHOD No mention of compliance with international test guidelines.
Species/Strain Albino Rabbit (New Zealand White)
Number of Animals One male
Observation Period 72 hours
Remarks - Method A sample of 38.6mg (volume of approx. 0.1mL) of test substance was instilled in the conjunctival sac of one eye of the rabbit. The exposure duration is unknown. The other eye remained untreated and served as a reference control.

RESULTS

Lesion	*Mean Score* Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1			
Conjunctiva: redness	0.33	2	48hr	0
Conjunctiva: chemosis	0	1	24hr	0
Conjunctiva: discharge	0	1	24hr	0
Corneal opacity	0	0	0	0
Iridial inflammation	0	0	0	0

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

Remarks - Results All irritation effects were completely reversed within 48 hours.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY NOTOX (1998)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

No data available

8.2.2. Acute/chronic toxicity to aquatic invertebrates

No data available

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Melapur 200
METHOD	US EPA, OPPTS 850.5400 (Static)
Species	*Selenastrum Capricornutum*
Exposure Period	96 hours
Concentration Range	0.1, 0.3, 0.5, 1.0 and 3.0 mg/L
Auxiliary Solvent	None
Water Hardness	Not given
Remarks - Method	A stock solution with a nominal concentration of 50 mg/L was prepared. Undissolved material was observed in the stock solution after stirring for 50 minutes. The test concentrations were prepared by taking aliquots from the stirred stock solution and adding to test vessels. Undissolved material was also noted in the test media.
RESULTS	
Remarks - Results	No inhibitory effects were observed in the test concentrations when compared with the control. The 96-hour EC50 value for the notified substance was determined to be greater than 3.0 mg/L. The NOEC was determined to be 3.0 mg/L.
CONCLUSION	The notified polymer is not toxic to algae at nominal concentrations of up to 3 mg/L.
TEST FACILITY	Aqua Survey, Inc. (2000)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

An aquatic PEC is not able to be determined due to the limited release to the aquatic environment.

Although very little of the notified polymer is likely to be released to the water compartment, the relatively high average molecular weight (>10,000 g/mol) and charged nature of the polymer indicates low potential for bioaccumulation.

9.1.2. Environment – effects assessment

The only ecotoxicity available for the notified polymer is algal toxicity (LC50 > 3 mg/L, NOEC = 3 mg/L). As undissolved material was observed in all test concentrations the notified polymer is not toxic to algae up to the limit of its solubility.

9.1.3. Environment – risk characterisation

The fate of the majority of the notified polymer will share that of the polymer matrix in which it will be incorporated and ultimately be disposed of to landfill at the end of its useful lifetime. A small amount of the free polymer (100 kg per annum) will be disposed of to landfill along with empty import packaging. The charged nature and low volatility of the polymer would suggest that it would not be expected to be mobile in landfill. As the polymer matrices are broken down by the slow biological and abiotic processes operative in landfills, the polymer will be liberated

and then slowly attacked and degraded by the soil bacteria. During biodegradation under aerobic conditions, the notified polymer would eventually be mineralised to water and oxides of carbon, nitrogen and phosphorous. Hydrogen cyanide may also be formed. Given the proposed use pattern very little of the notified polymer is expected to be incinerated.

The majority of the notified polymer will be incorporated as a flame retardant polymer used for a range of equipment. During the lifetime of the equipment there is little potential for the polymer to bloom to the surface of the plastic from where it may be dispersed. Any material that may migrate to the surface of the plastic in which it is contained (bloom) is not expected to be volatile due to its ionic form. Further, the rate of emission from the blooming process is likely to be low due to the high molecular weight and charged nature of the notified polymer. This release will be extremely dispersed, occurring throughout Australia and not expected to pose an environmental risk at the proposed levels of import.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The maximum concentration of the notified polymer in the imported product is > 95%. Dermal, inhalation or ocular exposure to the notified polymer may occur during the production of pellets, particularly during manual transfer of the imported product into the blending vessel and during mixing. However, worker exposure should be reduced by local exhaust ventilation and the use of personal protective equipment. Worker exposure after the hot-melt extrusion process is expected to be minimal as the notified polymer becomes encapsulated within the polymer matrix and is not bioavailable. Similarly, worker exposure during manufacture of the final plastic products via injection moulding is low.

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 furniture and electrical equipment. However, the notified polymer is unlikely to be bioavailable as it becomes encapsulated within a polymer matrix during the hot-melt extrusion process and is of a high molecular weight. Therefore the level of public exposure is expected to be minimal.

9.2.3. Human health – effects assessment

The notified polymer was of low acute oral toxicity in rats (LD50 > 2000 mg/kg bw). It was found to be non-irritating to the skin of rabbits, and slightly irritating to the eyes of rabbits.

Based on the available data, the notified chemical 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

The data provided suggest that the notified polymer is of low acute oral toxicity, and is not irritating to skin. It has the potential to cause slight eye irritation, therefore, the risk of worker eye irritation exists when handling the imported products containing either > 95% or < 40% of the notified polymer, particularly during manual weighing and transfer into the blending vessel when pellets are produced. However, this risk should be mitigated by the use of local exhaust ventilation and personal protective equipment, including eye protection. Subsequent operations will involve products containing the notified polymer at lower concentrations (< 20%), and more importantly the notified polymer will be encapsulated within a polymer matrix after the hot-melt extrusion process. In addition, given the chemical nature of the polymer (NAMW > 10000 and low level of low molecular weight species), the OHS risk of adverse health effects can be considered to be low.

9.2.5. Public health – risk characterisation

The data available on the health effects of the notified polymer indicate a low hazard. When present in end use 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 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 (and products containing the notified polymer) provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicants.

11.2. Label

The labels for the notified polymer (and products containing the notified polymer) provided by the notifier were 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.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid generating and breathing dust.
  - Avoid skin and eye contact.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Respiratory protection, gloves, safety glasses and overalls during weighing and transfer of the notified polymer.
  - Gloves and eye protection during other operations involving the notified polymer.

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.

Disposal

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

Emergency procedures

- Spills/release of the notified polymer should be contained, collected and stored 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 Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000; or

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.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

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