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

FULL PUBLIC REPORT

Bionolle Series #1000

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**Director
NICNAS**

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FULL PUBLIC REPORT

Bionolle Series #1000

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Bio-Deg Mouldings Pty. Ltd. (ABN: 40 090 078 489)
3 Crane Court
Toowoomba, QLD, 4350

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
Spectral Data

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Partition co-efficient
Adsorption/desorption
Dissociation constant

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

USA, Japan

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

PBS (#1001), PBS (#1903), PBS (1903G)

MARKETING NAME(S)

Bionolle Series (#1000) Natural

METHODS OF DETECTION AND DETERMINATION

METHOD	IR Spectroscopy
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3. COMPOSITION

DEGREE OF PURITY

>99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None at detectable levels.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None at detectable levels.

ADDITIVES/ADJUVANTS

None

DEGRADATION PRODUCTS

The notified polymer degrades in the presence of water in a non-radical manner to form an acid and unsaturated low molecular weight oligomer.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The polymer contains only trace levels of residual monomers.

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 but will be imported by Wharf into Brisbane and Melbourne and potentially Sydney at a concentration of 100%. It will be transported by road for storage at a warehouse until required for manufacturing.

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>	40	90	230	460	920

USE

The notified polymer will be imported at 100% concentration as Bionolle series #1000 it will be used in the industrial manufacture of biodegradable plant pots for commercial (landscaper gardeners, plant nursery staff) and consumer (resulting from the sale of plants using these pots to the public at garden nurseries) use and will be present at a concentration of up to 70%. The notified polymer may also be potentially used for the manufacture of coffins and furniture (such as chairs and tables).

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Brisbane and Melbourne and potentially Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

Bio-Deg Mouldings Pty. Ltd. (ABN: 40 090 078 489)

3 Crane Court

Toowoomba, QLD, 4350

The products containing the notified polymer will be manufactured in Melbourne, Victoria.

TRANSPORTATION AND PACKAGING

The notified polymer (100% concentration) is transported by road in 20 kg paper bags lined with polyethylene from the port of entry to storage in a warehouse. The notified polymer is transported by road in its original packaging to the manufacturing/formulation facility.

5.2. Operation description

The notified polymer is not manufactured in Australia.

Blending

The notified polymer (100%) will be transported by forklift, as required, from the warehouse to the

production area. It is expected that all weighing, blending, extrusion operations are undertaken under local exhaust ventilation. In some cases the notified polymer and components will be crushed in a hammer mill generating a fine powder prior to mixing. Alternatively, the notified polymer will be transferred manually from bags to the hopper directly where it is combined with other ingredients and mixed in a combination hopper that is fully enclosed. The resulting mixture is heated to 220°C until molten.

Moulding

Once molten the resultant mixture containing (50-70% notified polymer) is moulded as required into pre-cast moulds by injection moulding or a continuous piece by extrusion moulding. It is expected that the moulding processes are largely automated. Injection moulded products are then removed from moulds after cooling. Extrusion moulded products are typically carried along a conveyor, cooled and cut to the desired length. Moulded products are packaged by manual and/or automated means for transportation.

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>
Transport and Warehousing	2-4	1-2 hours	1 day/month
Process Operators (Reformulation, Moulding, Quality Control and Cleaning)	3-5	6-8 hours	2 days/month

Exposure Details

Transport and Warehousing

Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the imported product containing the notified polymer (up to 100%). During transport and warehousing, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Blending and Extrusion

The main routes of exposure to the notified polymer (up to 100%) are dermal and accidental ocular and inhalation exposure during weighing, crushing and adding the notified polymer to the moulding machine.

Exposure is expected to be greatest when the polymer is crushed and mixed with other ingredients prior to addition to the hopper compared with direct addition of the introduced pellet to the hopper.

It is possible that dermal and accidental ocular and inhalation exposure may occur if manual intervention is required during the moulding process. Production operators and supervisors will have intermittent exposure to the notified polymer when cleaning the equipment in general. Quality control personnel will have intermittent exposure when sampling batches of the extrusion and/or final products containing the notified polymer. Dermal and inhalation exposure may also occur during removal of products containing the notified polymer from moulds and conveyor, cutting and packaging operations.

All workers involved in handling the imported product and formulated powder coatings will wear personal protective equipment (PPE) such as safety glasses, gloves, protective clothing and dust masks, if necessary. The weighing, batching, extruding and moulding operations occur under local exhaust ventilation (LEV).

5.4. Release

RELEASE OF CHEMICAL AT SITE

There will be no environmental release due to the manufacture of the notified polymer as this will occur overseas. Release during transport is low due to its pelletised form and packaging. If spilt due to an accident the material will be easily contained and collected.

Blending and Extrusion

Release of the polymer during the article manufacturing process will be due to the following possibilities:

Spills	– up to 0.01%, recycled
Off cuts and out of specifications material	– up to 0.01%, recycled or landfill
Equipment cleaning	– up to 0.01%, landfill
Residual in import packaging	– up to 0.01%, landfill

During the extrusion process to incorporate the notified polymer into plastic grades, some waste may be generated by spillage prior to incorporation into the plastic. The bulk of the spilt material or original off-cuts will be re-used in the process of moulding. Any discarded material (spilt or other) will be collected and disposed of to landfill or possibly by incineration.

The process equipment will be washed between batches.

Import containers will be shaken into the feed hopper and then sent to landfill still containing minimal residues.

RELEASE OF CHEMICAL FROM USE

Current use will be in as plant pots (concentration of 50-70% of the notified polymer), with the estimated life of the pots being 18-48 months. The pots maybe planted with the plant or disposed of by composting or to landfill. The pots are likely to be dispersed over a wide range of Australia. Composting in various compost mediums may take up to 9 months. Amounts released to soil over time and after composting will depend on life of each product. Ultimately all of the notified polymer will degrade to oligomers, water and oxides of carbon and nitrogen.

In future, other possibly manufactured articles will generally end up buried in the ground across Australia or disposed of to landfill, where the fate of the polymer is the same as above.

5.5. Disposal

Spilt material and off-cuts and out-of specification material will be sent to landfill if it is contaminated and cannot be reprocessed. This accounts for up to 184 kg annually (if the maximum annual import is 920 tonnes). A further 92 kg will go to landfill in empty import packaging. Any material disposed of to landfill may also be disposed of via incineration with the generation of water and oxides of carbon.

5.6. Public exposure

No manufacture of the notified polymer will take place in Australia. The potential for exposure of the general public to Bionolle Series #1000 during normal industrial storage, handling, transportation and manufacturing processes will be minimal. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of public exposure.

The notified polymer will be imported neat and will be used industrially for preparation of plastic plant pots containing the notified polymer (50-70% notified polymer) and in the moulding of furniture designed (% notified polymer unspecified) for public use products. Widespread dermal exposure to the plastic plant pots and furniture is expected, however the notified polymer is bound in the plastic and is not available for exposure under normal conditions of use.

6. PHYSICAL AND CHEMICAL PROPERTIES

The Department of the Environment and Heritage undertook modelling (using EpiWin (v3.12)) of a very simple form of the notified polymer (i.e. the repeating units were taken up to 6 times so that the molecular weight was only 3533). While this does not approach the size of the polymer it does indicate its likely physico-polymer behaviour.

Appearance at 20°C and 101.3 kPa	White particle as pellet figure
Melting Point/Freezing Point	114-115 °C

Remarks	Test report not supplied. Data from technical data sheet.		
Glass Transition Temperature	-32 °C		
Remarks	Test report not supplied. Data from technical data sheet.		
Density	1260 kg/m ³ at 25°C		
Remarks	Test report not supplied. Data from technical data sheet.		
Vapour Pressure	Not determined.		
Remarks	The notified polymer is expected to have a low vapour pressure given the high molecular weight.		
Water Solubility	Insoluble		
METHOD	In-house procedure.		
Remarks	1 g of notified polymer was immersed in 10 mL of water for one month at room temperature and was reported to be insoluble.		
TEST FACILITY	Showa Highpolymer.		
Water Solubility	8x10 ⁻³⁸ mg/L (estimation)		
METHOD	EpiWin (v3.12)		
Remarks	This estimate indicates that it is not water soluble,		
TEST FACILITY	DEH		
Hydrolysis as a Function of pH	Not determined. The polymer does contain functional groups that may hydrolyse at high temperatures and pH.		
	When the notified polymer is placed at 65°C under high moisture conditions (in sterilized sawdust, water content 65%), the molecular weight decreased over time.		
	Time	0 weeks	2 weeks
			8 week
	PBS	10.8x10 ⁻⁴	3.16x10 ⁻⁴
			0.596x10 ⁻⁴
	Thus indicating that hydrolysis did occur at high temperatures.		
TEST FACILITY	R. Ishioka, Y. Ichikawa		
Partition Coefficient (n-octanol/water)	Log K _{ow} = 21.91 (estimate)		
Method	Modelled using EpiWin (v3.12)		
Remarks	Indicates the polymer is hydrophobic and will partition out of the water phase and into soil or sediments.		
Adsorption/Desorption	Log k _{oc} = 10 (estimate)		
Method	Modelled using EpiWin (v3.12)		
Remarks	Indicates the polymer will adsorb to soil or sediments and will be immobile.		
Dissociation Constant	The notified polymer does not contain any acidic or basic functionalities.		
Particle Size	Not determined.		
Remarks	Test report not supplied. The notified polymer as imported is in pellet form (cylindrical diameter 3 -5 mm).		
Flash Point	Not determined.		
Remarks	The notified polymer is expected to be a low volatility solid.		

Flammability The material is reported to burn if sufficient heat is applied. The flames will usually self extinguish and when burning produces little smoke.

Remarks The notified polymer combusts to form oxides of carbon. The MSDS reports an oxygen index of 22.2-22.5

TEST FACILITY Queensland Fire and Rescue Authority Report (2001)

Autoignition Temperature Not determined.

Remarks Not expected to autoignite below 280°C. Information obtained from MSDS.

Thermal Stability

METHOD Not reported

Remarks For temperatures of $\leq 200^{\circ}\text{C}$, the molecular weight decreased slowly and heat deterioration for a short period of time can be negligible. When the temperature is $\geq 200^{\circ}\text{C}$, the pyrolysis rate increases gradually. When the temperature is $\geq 250^{\circ}\text{C}$ a considerable decrease in molecular weight occurs. However when polyester is subjected to heating for a short period of time, such as heating experienced during a typical moulding process, then heat deterioration is not significant, i.e., the polyester remains stable, until the temperature reaches approximately 280°C .

TEST FACILITY R. Ishioka, Y. Ichikawa

Explosive Properties Not explosive.

Remarks From examination of the structure, there are no chemical groups that would infer explosive properties.

TEST FACILITY Urban, P.G *et al.* (1999)

Reactivity

Remarks The notified polymer is expected to be stable during blending and moulding activities. The notified polymer is resistant to water, aliphatic hydrocarbons, castor oil, mineral oil, turpentine oil, salad oil, etc. It will undergo hydrolysis with a strong acid and strong base. It is not permeable to oxygen but permeable to steam and alcoholic vapour.

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw, low toxicity
Rabbit, eye irritation	slightly irritating
Human, skin irritation	slightly irritating
Genotoxicity – bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague Dawley
Vehicle	Corn oil
Remarks - Method	Statement of GLP. Protocol variations included: Volume administered was 2 mL/100 g (1 mL/100 g recommended)

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5 males	5000	0/5
II	5 females	5000	0/5

LD50	>5000 mg/kg bw
Signs of Toxicity	Clinical signs of toxicity noted were red staining of the face (occurred in one male on Day 11 and Day 12), soft stool and wet or yellow stained urogenital area. The occurrence of a red stained face in one male may be due to lack of water from Day 10 to 12 during the study period. All other signs of toxicity had reversed at the end of the observation period in surviving animals.
Effects in Organs	There were no remarkable organ or necropsy findings during the study period.
Remarks - Results	There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period.

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

TEST FACILITY Hazelton (1994)

7.2. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Observation Period	8 days
Remarks - Method	Statement of GLP. No significant protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
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	1	2	3			
<i>Conjunctiva: redness</i>	2.0	0.7	0.3	2	> 72 hour, < 8 days	0
<i>Conjunctiva: chemosis</i>	0	0	0	1	< 24 hours	0
<i>Conjunctiva: discharge</i>	0	0.7	0	2	< 72 hours	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0.3	1	< 24 hours	0

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

Remarks - Results	Redness of the conjunctiva was observed during the first hour after administration of the test-item in all animals and continued until the 24 hour examination in one animal, the 48 hour examination in one animal and the 72 hour examination in the remaining animal. Slight discharge was also observed in all three animals at the one hour examination; the discharge continued in one animal up to the 48 hour examination. One hour after treatment slight swelling was noted in one animal and iritis was noted in all animals.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	Pharmaco (1994)

7.4. Irritation – skin (human volunteers)

TEST SUBSTANCE	Notified polymer (unknown concentration)
METHOD	Unspecified
Species/Strain	Human volunteers
Number of Volunteers	20
Vehicle	None
Observation Period	24 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No full study report supplied. No statement of GLP.
RESULTS	
Remarks - Results	From the summarised data provided the notified polymer was slightly irritating on the basis of increased deepened furrows. The notified polymer did not cause erythema, edema or papule.
CONCLUSION	Based on the summarised information provided the notified polymer is slightly irritating to the skin.
TEST FACILITY	JSCH (1995)

7.3. Genotoxicity – bacteria

TEST SUBSTANCE	Low molecular weight oligomer corresponding to the notified polymer.
METHOD	Ministry of Labor, Japan (Standards for Mutagenicity test using Microorganisms , 1997)
	Pre incubation procedure
Species/Strain	<i>S. typhimurium</i> : TA1538, TA1535, TA98, TA100 <i>E. coli</i> : WP2uvrA (pKM101)
Metabolic Activation System	Not specified
Concentration Range in Main Test	In the main study 5,000 mg/plate or the lowest dose at which inhibition of bacterial growth was observed in the dose-finding study was used as the highest dose, followed by 6 dose level with a common ratio of 2.
Vehicle	Dimethyl sulfoxide

Remarks - Method	No full study report was provided. No statement of GLP.
RESULTS	
Remarks - Results	The summarised report stated that no significant increase in revertant colonies was observed with or without metabolic activation. No results were sited.
CONCLUSION	Based on the summarised information provided the notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Safety Evaluation Centre (undated).

8. ENVIRONMENT

8.1. Environmental fate

Very brief summary sheets were provided for the biodegradation studies, so details of the studies could not be confirmed.

8.1.1.a Ready biodegradability

Test Substance	Notified polymer										
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).										
Inoculum	Activated sludge										
Exposure Period	52 days (this is twice as long as the exposure period in TG 301C)										
Auxiliary Solvent	Unknown										
Analytical Monitoring	BOD meter										
Remarks - Method	Reference substance – aniline Temperature 24-26°C Treatments consisted of 30 mg SS/L of the inoculum and 100 mg SS/L of test substance. The BOD of the supernatant was used to determine the level of biodegradation.										
RESULTS	<table><thead><tr><th>Time (days)</th><th>Percent degradation Notified polymer</th></tr></thead><tbody><tr><td>7</td><td>2</td></tr><tr><td>14</td><td>3</td></tr><tr><td>28</td><td>6</td></tr><tr><td>52</td><td>7</td></tr></tbody></table>	Time (days)	Percent degradation Notified polymer	7	2	14	3	28	6	52	7
Time (days)	Percent degradation Notified polymer										
7	2										
14	3										
28	6										
52	7										
Remarks - Results	No data for the reference substance was presented, so the validity of the test could not be determined.										
CONCLUSION	The results indicate that the test substance is not readily biodegradable in activated sludge.										
TEST FACILITY	Safety Evaluation Centre (undated).										

8.1.1.b Biodegradability in Compost

TEST SUBSTANCE	Notified polymer
METHOD	ISO 14855 (this appears to be similar to OECD TG 302C Inherent Biodegradation: modified MITI)
Test medium	Compost
Exposure Period	90 days (this is three times the exposure period in TG 302C)
Auxiliary Solvent	Unknown
Analytical Monitoring	Unspecified
Remarks - Method	Reference substance – cellulose Temperature – 56-60°C A measured amount of test substance (25 g) and compost (400 g) were mixed and placed in a compost vessel. An air flow of greater than 1 mL/min was maintained throughout the study. The CO ₂ generated was collected and the amount generated determined. The percentage of degradation was calculated by: Percentage degradation = (BCO-B)/TCO x 100, where, BCO = yield of CO ₂ by test substance B = yield of CO ₂ by compost

TCO = Theoretical yield of CO₂ if 100% decomposition

RESULTS	No results provided
Remarks - Results	By day 7 the reference material reached 40% degradation and by day 14 is was 60%, these results indicate the test conditions were valid as per ISO 14855.
CONCLUSION	The test substance is said to have reached a degradation of greater than 60% in the 90 day period, therefore it is degradable in compost.
TEST FACILITY	Safety Evaluation Centre (undated).

8.1.1.c Biodegradability in soil-suspended aqueous solution

TEST SUBSTANCE	Notified polymer
METHOD	ISO 14851
Test medium	Soil suspension
Exposure Period	90 days
Auxiliary Solvent	Unknown
Analytical Monitoring	BOD meter
Remarks - Method	Reference substance – aniline Temperature – 30°C A measured amount of non-sterile, fertile soil (10 g) was suspended in 100 mL of test medium (ISO medium), then allowed to settle for 15 minutes after which the supernatant liquid decanted and filtered. The inoculum was then prepared as follows. Treatments: <ol style="list-style-type: none"> 1. Blank: 95 mL ISO medium + 5 mL soil suspension 2. 0.01 mL Aniline + 95 mL ISO medium + 5 mL soil suspension 3. 10 mg notified polymer + 95 mL ISO medium + 5 mL soil suspension 4. 10 mg notified polymer + 95 mL ISO medium + 5 mL soil suspension 5. 100 mL ISO medium + 5 mL soil suspension The BOD of the supernatant was used to determine the level of biodegradation.

RESULTS	
Remarks - Results	By day 7 the reference material reached 60% degradation.
CONCLUSION	The test substance is said to have reached a degradation of greater than 60% in the 90 day period, therefore is degradable in an aqueous soil suspension.
TEST FACILITY	Safety Evaluation Centre (undated).

8.1.1.c Biodegradability in field studies

Remarks	Australia small scale field trials have been undertaken by the notifier. Results of these trials indicated different levels of degradation. <u>1. Torrington Landscape</u> The trial at Toowoomba Queensland, was conducted for 17 weeks with the results as follows – <ul style="list-style-type: none"> • Pot 1: reasonable breakdown, expected to last 1 more month. • Pot 2: faster break-down with root penetration through walls and bottom – approximately 60% pot degradation.
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- Pot 3: almost completely gone with root penetration approximately 90% pot degradation.

2 Earth Life Pty Ltd

- Pots marked (1): Planted with seedlings in commercial potting mix on 20/9/04, by 10/11/04 all pots showed signs of splitting.
- Pots marked (11): Planted with seedlings in commercial potting mix on 20/9/04, by 10/11/04 none of the pots showed signs of splitting.
- Opaque pots: Planted with seedlings in commercial potting mix on 20/9/04 by 17/12/04 all treated pots were splitting, while the controls showed no signs of degradation.

No study details were provided (including concentration of notified polymer in pots used). Only poor quality copies of progress reports and photographs were supplied, from which it was not possible to confirm the notifier's claims of pot degradation.

Based on the draft international standard (ISO-16929, 2002)

8.1.2. Bioaccumulation

No bioaccumulation study was undertaken. However, it is not expected to bioaccumulate due to its molecular weight.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted. Non-ionic polymers of high NAMW are of low concern to the aquatic environment.

There is the possibility that notified polymers degradation products may be toxic. It would be expected that the polymer would degrade to smaller molecules such as the major starting polymer constituents which are not toxic to the environment.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority of the notified polymer will be incorporated in manufactured articles, with less than 0.5% of the imported volume going to landfill as wastes during the production stage. Most of the manufactured articles will end up buried across Australia, whereby the polymer will degrade to oligomers, water and oxides of carbon and nitrogen.

9.1.2. Environment – effects assessment

No ecotoxicological data was provided, however non-ionic polymers of high NAMW are of low concern to the aquatic environment..

9.1.3. Environment – risk characterisation

While the notified polymer will be released to the terrestrial environment, it is unlikely to be released to the aquatic compartment. It is estimated that the life of the pot is 18-48 months and in compost, and therefore in landfill and when buried, the article/ notified polymer is estimated to degrade in 9 months. However during this time the estimated log K_{oc} and water solubility indicate that the polymer will adsorb to soil and will not be mobile. The fugacity results of the EpiWin (v3.12) indicate that 99.5% of the notified polymer released to the environment will partition to soil/sediment.

The Biowin (v4.0) for the likely degradation products indicate they will readily degrade.

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

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified polymer is imported as a solid pellet in 20 kg lined bags. Transport or warehouse workers can be exposed in the event of accidental breach of the containers.

The main operations during which inhalation, dermal and accidental ocular exposure can occur is during weighing, crushing and adding the notified polymer to the moulding machine. This exposure is controlled by the use of LEV and dust masks if required. Some dermal or ocular exposure can occur and will be controlled by the use of impervious gloves and safety goggles. Once the powder has been added to the mixing vessel, it is in a closed system and exposure should be precluded. In addition, the notified polymer is encapsulated within a matrix and should not be bioavailable. Therefore, exposure during subsequent moulding operations should also be precluded.

Exposure is expected to be greatest when the polymer is crushed and mixed with other ingredients prior to addition to the hopper compared with direct addition of the introduced pellet to the hopper.

All workers involved in handling the notified polymer are expected to wear personal protective equipment (PPE) such as safety glasses, gloves, protective clothing and dust masks, if necessary in accordance with the instructions specified on the MSDS. The weighing, batching, extruding and moulding operations are expected to occur under local exhaust ventilation (LEV).

Overall, on the basis of the engineering controls, industrial hygiene, safe work practices and personal protective equipment occupational exposure to the notified polymer is determined to be low.

9.2.2. Public health – exposure assessment

Widespread public exposure, primarily dermal to products containing the notified polymer will occur, however the notified polymer is incorporated in a solid matrix and is not available for exposure under normal conditions of use.

Overall, public exposure to the notified polymer is determined to be low.

9.2.3. Human health – effects assessment

The notified polymer is of low acute oral toxicity, slightly irritating to the eye and skin and not mutagenic. Based on these studies, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

The notified polymer is of high molecular weight, typically polymers (MW>1000) are unlikely to cross biological membranes and hence the polymer is likely to be of low hazard. However, the notified polymer belongs to a class of polymers (high molecular weight, insoluble) which have been linked with irreversible lung damage.

9.2.4. Occupational health and safety – risk characterisation

The risk to workers from dermal and ocular exposure is considered to be low due to the limited exposure expected and the predicted hazard of the polymer via these routes. Any risk of slight irritant effects would be mitigated by the use of PPE.

There is a risk of lung damage where inhalation of respirable particles can occur. This is most likely when the polymer is crushed prior to addition to the hopper. The risk of lung overloading is considered to be low if activities that generate dust such as crushing, weighing, cutting are conducted in the presence of LEV and workers wear appropriate PPE.

Overall, due to the limited exposure expected and the likely low hazard of the notified polymer the risk to workers is expected to be low.

9.2.5. Public health – risk characterisation

Due to the intermittent exposure expected and the likely low hazard of the notified polymer the risk to the public is expected to be low.

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 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.

The MSDS should include a statement highlighting the potential health effects from inhalation of dust or respirable particles.

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 chemical as introduced, during cutting or when dust is generated:
 - Local exhaust ventilation
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
 - Avoid skin and eye contact

- Avoid breathing dust
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Gloves
 - Safety goggles
 - Coveralls
 - Dust masks
- 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 to landfill or by incineration.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment and collected (via sweeping generally) and then placed in labelled containers 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.

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