File No: STD/1135

May 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in ISOCURE 1 AL xx486

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Polymer in ISOCURE 1 AL xx486

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ashland Pacific Pty Ltd (ABN 47 000 075 641) of 7 Sir Thomas Mitchell Road, Chester Hill NSW 2162

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Polymer identity
Composition
Use details
Import volume
Identity of sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point/Boiling point
Specific gravity/density
Vapour pressure
Hydrolysis as a Function of pH
Absorption/Desorption
Dissociation Constant
Particle size
Flash Point
Flammability Limits
Autoignition temperature
Explosive properties
Reactivity

Acute oral toxicity
Acute dermal toxicity
Acute inhalation toxicity
Skin Irritation
Eye Irritation
Skin sensitization

Induction of point mutations
Induction of germ cell damage
Chromosome damage

Fish, Acute toxicity
Daphnia sp., Acute Immobilisation/Reproduction
Alga, Growth Inhibition Test

Ready biodegradation
Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Commercial Evaluation Permit Application for Polymer in ISOCURE I AL XX 486

NOTIFICATION IN OTHER COUNTRIES
US 1985

2. IDENTITY OF POLYMER

MARKETING NAME(S)
ISOCURE 1 AL xx486

MOLECULAR WEIGHT
< 1000

3. COMPOSITION

DEGREE OF PURITY
>95%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia by sea in 21,000 L dedicated isotanks as a solution component of the commercial product ISOCURE 1 AL xx486 at a concentration of up to 60%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<300	<300	<300	<300	<300

USE
Resin binder for metal sand casting.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Toll manufactures warehouse Victoria

TRANSPORTATION AND PACKAGING
The notified polymer will be imported at <60% in the product ISOCURE 1 AL xx486 in 21,000 L dedicated isotanks. It will be transported by road from the wharf directly to the toll manufacturer and bulk storage site. At the storage site the product containing the notified polymer will be transferred via automated transfer lines to 30,000 L intermediate bulk holding tanks and then to dedicated 5,000 L IBCs for road transport to the customer site.

5.2. Operation description

Importation, transport and storage
The notified polymer will be imported as a resin solution in 21,000 L dedicated isotanks and transported by road to the toll manufacturer bulk storage site. At the bulk storage site the resin solution from isotanker will be transferred by means of automated transfer lines to 30,000 L intermediate bulk

holding tanks. From these tanks 5000 L IBC's will be filled by means of automated transfer lines and sent by road to customer site(s).

This transfer will be conducted in a purpose-built area that is bunded and supplied with local and general ventilation. Workers will connect up transfer lines and operate valves and pumping equipment. The equipment is purpose built and does not require cleaning between transfer operations. Workers involved in the transfer operation will wear protective clothing and footwear, eye protection and polymer resistant gloves.

Core manufacture, packaging and assembly
On arrival at the customer's site, the resin solution is transferred from the IBC's to 10,000 L onsite enclosed holding/storage tanks. The transfer will take place in a purpose-build, bunded and ventilated pumping room. One trained operator will connect the transfer lines and operate the valves and pumping equipment. It is envisaged that this operation will take place once per week. Workers in the pumping room will wear protective clothing, eye protection (chemical goggles or safety glasses fitted with side shield), polymer resistant gloves and safety footwear.

The resin solution containing the notified polymer will be pumped by means of automated transfer lines to an enclosed mixing vessel from the storage tank when required. In the mixing vessel, the resin will be mixed with clean, dry sand as well as other components to form the core sand/binder mixture (containing <2% notified polymer). The mould or tooling contains the negative image of the core, consists of two parts which are split vertically. These come together and the fluid sand/binder mixture is injected into the mould under pressure. A gassing plate descends and connects to the mould. The binder is cured by passing an amine catalyst, in a vapour form over the sand. The core then hardens. The mould is purged with air to remove any residual amine. The tooling is split to reveal the core. This is then placed onto a conveyer by a robotic arm. And is transferred to the package assembly and filling areas. Once the package is assembled, the molten metal is then filled into the cavities of the core and mould to form the metal casting. Once the package has cooled and the metal has hardened, the package is then solution heat treated within an oven. The core sand/binder structure disintegrates within the oven leaving the metal engine block with the hollow internal cavities. The sand is reclaimed and cleaned for reuse. The resin is totally destroyed during sand reprocessing which involves a high temperature furnace. Any gasses and vapours from the entire process are trapped by scrubbers and cyclones. The plant utilises state-of-the-art cleaner production technologies to minimise wastes and emission from the plant.

The various core making machines, ovens, package assembly machines, package filling and casting finishing lines are automated, enclosed and supplied with local and general ventilation to minimise worker exposure to polymer agents. The core-making machine is totally contained within a cabinet and workers are not required to enter the cabinet while the machine is in operation. The machine is designed to stop if the cabinet is opened.

Plant operators will only need to intervene in the manufacturing process when equipment malfunctions, or during routine maintenance. The process will be stopped and purged prior to workers entering the enclosed system. Workers outside of the enclosure will wear protective coveralls, chemical goggles or safety glasses fitted with side shield and safety boots. Workers who will be entering the enclosure will also ware a suitable respirator and suitable gloves as necessary.

The finished metal casting, which does not contain the notified polymer, is transported to industrial metal fabricators Australia-wide for use as required.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration Hours/day*	*Exposure Frequency Days/year*
Transport and warehouse	4-8	2	50
Plant operators (transfer operation)	4-8	2-4	50

Plant operators (core making/package assembly)	8-16	8-12	260

Exposure Details

Importation, transport and storage
Dockworkers will unload the 21,000 L isotanks (< 60% notified polymer) from the ship and then load them onto trucks for road transport to the bulk storage site. During import, transport and storage operations, dermal, inhalation and accidental ocular exposure to up to 60% notified polymer is possible through leaks and spillages when connecting and disconnecting transfer lines and during cleaning of the equipment and any accidental spills. Operators will typically wear personal protection equipment such as goggles, gloves, impervious work clothing and a respirator, as required.

Core manufacture, packaging and assembly
During core manufacturing processes, dermal, inhalation and accidental ocular exposure to up to 60% notified polymer is possible when connecting and disconnecting transfer lines which pump the imported solution into the mixing vessel. Once formulated into the finished core, the notified polymer will be cured into an inert matrix and hence unavailable for further exposure. As the core sand/binder structure disintegrates within the oven leaving the metal engine block with the hollow internal cavities, worker exposure to the notified polymer via means of reclaimed sand is not expected.

Dermal, inhalation and accidental ocular exposure to up to 60% notified polymer is possible during cleaning of the equipment and any accidental spills and if workers are required to intervene in the core manufacturing process and enter the manufacturing cabinet. Operators will typically wear personal protection equipment such as goggles, gloves, impervious work clothing and a respirator, as required.

All workers have access to the Material Safety Data Sheet.

Exposure to the notified polymer by means of finished metal casting is not expected because the notified polymer is only used in a cured form in the sand-cast, which is destroyed during the high temperature casting process.

5.4. Release

RELEASE OF POLYMER AT SITE
As the notified polymer will not be manufactured in Australia there will be no release due to this activity.

Environmental release of the notified polymer may occur during importation, storage and transportation, due to accidental spills, leaks and catastrophic mechanical failure during a transport accident. However, generally this will be very low due to engineering controls (eg. specialised transport containers), personnel training and emergency clean-up procedures. Spilt material will either be disposed of or recollected and retained for use. It is estimated that less than 1% will be lost due to spills (i.e. less than 3 tonne/year of notified polymer).

RELEASE OF POLYMER FROM USE
Mixing of the resin solution, containing the notified polymer, and the sand is done using automated, closed, systems with the potential for drips and spillage to occur only at the times of manual connection and disconnection of hose/pump lines. Thus the environmental release of the notified polymer is minimal, i.e. less than 1% due to spills (less than 3 tonne/year of the notified polymer).

During the high temperature furnace-casting process the notified polymer will be destroyed therefore there will be none in the used sand.

5.5. Disposal

Contaminated/unusable spilt material will be contained and absorbed with vermiculite or other absorbent material and then placed in labelled containers for disposal via a licensed waste contractor, presumably to landfill.

5.6. Public exposure

The notified polymer will be for industrial applications and it will not be sold to the public. In addition, the notified polymer is used as a manufacturing aid and polymer will not be present in any products which will be sold to the public. The risk to the public will be minimal.

6. PHYSICAL AND POLYMER PROPERTIES

The notified polymer is produced in solution in petroleum solvent and as such is never isolated. The notified polymer will only be imported as Polymer in ISOCURE 1 AL xx486.

The following physico-polymer properties are for either the major component (Analogue A) of the notified polymer or the Polymer in ISOCURE 1 AL xx486.

Appearance at 20ºC and 101.3 kPa Clear amber liquid
(Polymer in ISOCURE 1 AL xx486)

Melting Point/Freezing Point Not applicable

METHOD
Remarks Imported only as a liquid Polymer in ISOCURE 1 AL xx486
TEST FACILITY

Boiling Point >230ºC

METHOD
Remarks Analogue A
TEST FACILITY European Union (2003)

Density 1090 kg/m^3 at 25ºC

METHOD
Remarks No report submitted. In-house methodology provided consistent with OECD TG 109 Density of Liquids/EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY

Vapour Pressure 0.02 kPa at 38ºC

METHOD
Remarks Vapour pressure of solvent in product ISOCURE 1 AL xx486.
TEST FACILITY

Water Solubility 484 mg/L at 23±1ºC

METHOD OECD TG 105: Water Solubility.
Remarks Flask Method. The test substance (400 mg Polymer in ISOCURE 1 AL xx486) was added to reverse osmosis water (150 mL) and mixed over a 3-day period. Tests were conducted on three concentrations (2 reps of each). The water concentration was measured daily by size exclusion chromatography and compared against calibration standards in the range ~30-3000 mg/L. pH of the test solution was 5.0.
TEST FACILITY Analytical Services & Technology 2004(a)

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer does not contain any groups, which are hydrolysable.

Partition Coefficient (n-octanol/water) Log Pow = 1.07 at 23±1°C

METHOD OCED 107 Partition Co-efficient (n-octanol:water).

Remarks	Shake flask method. The test substance (400-600 mg Polymer in ISOCURE 1 AL xx486) was added to equilibrated saturated reverse osmosis water:octanol solutions (50 mL). Tests were conducted on three concentrations (2 reps of each) and results averaged. Liquid phases analysed by size exclusion chromatography and compared against calibration standards in the range ~30-3000 mg/L. Using a 3 day shake flask method, the average solubility of the test substance (192-257 g) in 1-octanol (150 mL) was 875 mg/L at 23±1°C.
TEST FACILITY	Ashland SCC. (2004a-b)

Partition Coefficient (n-octanol/water) Log Pow = 1.70 at 23±1°C

METHOD	OCED 107 Partition Co-efficient (n-octanol:water).
Remarks	Shake flask method. The test substance (400-600 mg Polymer in ISOCURE 1 AL xx486) was added to equilibrated saturated reverse osmosis water:octanol solutions (50 mL). Tests were conducted on three concentrations (2 reps of each) and results averaged. Liquid phases analysed by size exclusion chromatography and compared against calibration standards in the range ~30-3000 mg/L. Using a 3 day shake flask method, the average solubility of the test substance (192-257 g) in 1-octanol (150 mL) was 875 mg/L at 23±1°C.
TEST FACILITY	Analytical Services & Technology 2004(b)

Adsorption/Desorption Not determined

Remarks	Due to its water solubility and partition coefficient, the notified polymer is expected to have a low adsorption/desorption coefficient and is likely to be mobile in soils and partition into the water column.

Dissociation Constant Not determined

METHOD	
Remarks	The polymer does not contain any groups that are expected to dissociate in the environmental pH range of 4 – 9.
TEST FACILITY	

Particle Size Not applicable

METHOD	
Remarks	Imported only as a liquid polymer formulation
TEST FACILITY	

Flash Point 72ºC

METHOD	
Remarks	For product ISOCURE 1 AL xx486.
TEST FACILITY	

Flammability Limits Not determined

METHOD	
Remarks	Not applicable based on the flash point for product Polymer in ISOCURE 1 AL xx486.
TEST FACILITY	

Autoignition Temperature 429ºC

METHOD	
Remarks	For the product Polymer in ISOCURE 1 AL xx486.
TEST FACILITY	

Explosive Properties Not determined

METHOD
Remarks Not considered explosive.
TEST FACILITY

Reactivity Not expected to be reactive.

Remarks Product ISOCURE 1 AL xx486 will not undergo hazardous polymerisation.

ADDITIONAL TESTS

Viscosity 20 cps at 25ºC

METHOD OECD TG 114 Viscosity of Liquids.
Remarks For product ISOCURE 1 AL xx486.
TEST FACILITY No reports submitted

n-octanol Solubility 875 mg/1000 g in 1-octanol at 23°C

METHOD OECD TG 105 Solubility in 1-octanol.
Remarks Flask method
TEST FACILITY Analytical Services & Technology 2004(c)

7. TOXICOLOGICAL INVESTIGATIONS

No toxicity data were submitted. The notified polymer is produced in solution in petroleum solvent.
The following toxicological investigations are for the major component (Analogue A) of the notified polymer and relies upon the European Union risk assessment of Analogue A.

A summary of the toxicology investigations and findings undertaken by the European Union for Analogue A are described below (European Union 2003).

Endpoint and Result [+]	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rat, acute inhalation LC50 (>0.21 mg/L/6 hour)	Low toxicity
Rat, <repeat inhalation> -2 and 13 weeks	NOAEL 10 mg/m^3
Rabbit, skin irritation	slightly irritating
Human, skin irritation - case reports	irritating
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation – unspecified test	equivocal evidence
Human, skin sensitisation – case reports	evidence of sensitisation
Rat, repeat dose <dietary - oral> toxicity – 2 years.	NOAEL = 74 mg/kg
Genotoxicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – *in vivo* <mouse bone marrow micronucleous>	non genotoxic
Endrocrine disruption <*in vivo* and *in vitro* screening assays>	equivocal evidence
Developmental and reproductive effects <rat F2 generation>	no evidence
Developmental and reproductive effects <rat multi-generation>	NOAEL (developmental) = 50 mg/kg/day LOAEL (maternal) = 160 mg/kg/day NOAEL (foetal) = 640 mg/kg/day
Developmental and reproductive effects <mouse continuous breeding>	LOAEL (developmental) =300 mg/kg/day NOAEL (maternal) = 250 mg/kg/day NOAEL (foetal) = 1,000 mg/kg/day
Carcinogenicity	no evidence of carcinogenicity

[+] Full study reports are contained in European Union Risk Assessment Report (European Union 2003).

Acute toxicity
No useful information is available on the effects of single exposure to the analogue (Analogue A) in humans. Oral LD50 values beyond 2,000 mg/kg are indicated in the rat and mouse, and dermal LD50 values above 2,000 mg/kg are evident in the rabbit. Few details exist of the toxic signs observed or of target organs. For inhalation, a 6-hour exposure to 170 mg/m^3 (the highest attainable concentration) produced no deaths in rats; slight and transient slight nasal tract epithelial damage was observed. These data indicate that the analogue is of low acute toxicity by all routes of exposure relevant to human health.

Irritation
Limited human anecdotal information of uncertain reliability is available from written industry correspondence suggesting that workers handling the analogue (Analogue A) have in the past experienced skin, eye and respiratory tract irritation. It cannot be determined whether the reported skin reactions were related to skin sensitisation or irritation. A well-conducted animal study shows that the analogue is not a skin irritant. A well-conducted animal study shows that the analogue is an eye irritant; effects persisted until the end of the study (day 28 post instillation) in 1 of 3 rabbits. Overall, taking into account the animal and human evidence, the analogue has the potential to cause serious damage to the eyes.

Slight and transient nasal tract epithelial damage was observed in rats exposed to the analogue dust at 170 mg/m^3 for 6 hours. Slight local inflammatory effects in the upper respiratory tract were observed in rats exposed to 50 mg/m^3 and 150 mg/m^3 of the analogue in 2 and 13 week repeat inhalation studies, but were not observed at 10 mg/m^3 in the same studies. Increased duration of exposure did not increase the severity of the response at 50 and 150 mg/m^3. Taken together with anecdotal human evidence, these data suggest the analogue has a limited respiratory irritation potential.

Based on the above evidence, the analogue is not found to be corrosive. The analogue is classified in the List of Designated Hazardous Substances as an irritant to skin and eyes (NOHSC 1999).

Sensitisation
There are several reports of patients with dermatitis responding to the analogue (Analogue A) in patch tests. However, it is unclear whether the analogue or related epoxy resins were the underlying cause of the hypersensitive state. Anecdotal information indicates skin inflammation in workers handling the analogue, although given the uncertain reliability of this information no conclusions can be drawn from it. In animals, a skin sensitisation test performed to current regulatory standards is not available. The available studies are negative, but the test reports lack detail and no reliable justifications were given for the choice of concentrations used. In the study using the highest challenge concentration, 50% in a guinea pig closed-patch test, a sensitisation rate of 12.5% was obtained. It is possible that the concentrations used in all the available studies were not sensitised and a greater response might have been obtained with higher induction and challenge concentrations. Based on the findings from the most robust study, the analogue may possess a skin sensitisation potential, albeit a limited one. The analogue in the presence of UV light can also elicit skin responses in humans, and reproducible positive results for photo-sensitisation have been obtained in mouse ear swelling tests. Mechanistic studies in mice have suggested this is an immune-mediated process. Therefore, examination of the available human and experimental animal studies leaves the picture somewhat unclear as to whether one or more of the following are properties of the analogue; (1) orthodox skin sensitisation (2) photo-sensitisation (3) the analogue eliciting a response in people previously skin sensitised to another substance (e.g. epoxy resins).

Overall, it is clear that skin reactions can be a potential consequence of repeated skin exposure in humans. Thus, taking all of these data available into account, the analogue is considered capable of producing skin sensitisation responses in humans. There are no data from which to evaluate the potential of the analogue to be a respiratory sensitiser.

The analogue is classified in the List of Designated Hazardous Substances as a substance that may cause sensitisation by skin contact (NOHSC 1999).

Repeat Exposure
No useful information on the effects of repeated exposure to the analogue (Analogue A) in humans is available. Experimental studies are available in rats, mice and dogs.

In rat inhalation studies, the principal effect of repeated exposure was the same as observed following a single exposure: slight upper respiratory tract epithelium inflammation. Very slight to slight inflammation and hyperplasia of the olfactory epithelium were observed in rats following exposure to 50 mg/m3 (6 hours/day, 5 days/week for 13 weeks). There was no significant increase in the severity of these effects on the olfactory epithelium in animals exposed to 150 mg/m3. A NOAEL of 10 mg/m3 was identified in rats in this 13-week study.

Dietary studies in rats produced a decrease in body weight gain and minor changes in the weights of several organs at higher doses probably of no toxicological significance, especially given the absence of other related pathological findings. However, in one study in male rats, reductions in the weight of several reproductive organs and testicular toxicity was seen following dietary exposure to 235 mg/kg for 44 days. A NOAEL was not established from this study. Although these effects on the reproductive organs have not been seen in any other robust repeated dose toxicity study in rats or mice (including a 2-year study in F344 rats), the severity of effects was generally dose-related and therefore cannot be disregarded. The only other finding was an inconsistent observation of caecal enlargement in some 90-day studies. The caecal enlargement was observed at 25 mg/kg and above and was without any associated histological abnormalities. In addition, it was not observed in a 2-year study at doses up to about 140 mg/kg or a multi-generation study at doses up to 500 mg/kg/day. Consequently, this is not regarded as a toxicologically significant observation of relevance to humans. A NOAEL of 74 mg/kg has been established for rats from a 2-year study.

Dietary studies in mice indicated that the liver is a target organ in this species, with changes being observed in the size and nucleation state of hepatocytes in 2-year and 90-day studies. The incidence and severity of these treatment-related multinuclear giant hepatocytes was greater in males than in females, and it was not possible to identify a no effect level for males. The effect was observed at all dose levels used in males from 120 mg/kg. In females, a no-effect level of 650 mg/kg was identified for these cellular changes in the 2-year study. The only other findings in mice were significant reductions in body weight gain at dose levels of approximately 650 mg/kg/day and above. Thus, LOAELs of 120 mg/kg in males for multinuclear giant hepatocytes and 650 mg/kg in females for a reduction in body weight gain of unknown magnitude were identified in a 2-year study.

In a 90-day dietary study in dogs, a no effect level of approximately 80 mg/kg was identified, with increases in relative liver weight being the only other finding observed at approximately 270 mg/kg: in the absence of histopathology this finding is of doubtful toxicological significance.

There are no animal data available for repeated dermal exposure.

Mutagenicity
No human data regarding mutagenicity are available. However, the analogue (Analogue A) appears to have demonstrated aneugenic potential *in vitro*, positive results being observed without metabolic activation in a micronucleus test in Chinese hamster V79 cells and in a non-conventional aneuploidy assay in cultured Syrian hamster embryo cells. Additionally, in cell-free and cellular systems there is information that shows the analogue disrupts microtubule formation. The analogue has been shown to produce adduct spots in a post-labelling assay with isolated DNA and a peroxidase activation system, but it does not appear to produce either gene mutations or structural chromosome aberrations in bacteria, fungi or mammalian cells in vitro. However, some deficiencies in the conduct of these studies have been noted and the negative results cannot be taken as entirely conclusive. The analogue does not appear to be anuegenic in vivo, since a recently conducted, standard mouse bone marrow micronucleus test has given a negative result.

The analogue was negative in a briefly reported dominant lethal study in rats but, given the limited details provided, this is not regarded as an adequate negative result. The only other data

in somatic cells in vivo are from a 32P-postlabelling assay, which showed that the analogue is capable of producing DNA adduct spots in rat liver following oral administration. These adduct spots were not characterised fully.

Considering all of the available genotoxicity data, and the absence of significant tumour findings in animal carcinogenicity studies (see below), it does not appear that the analogue has significant mutagenic potential *in vivo*. Any aneugenic potential of the analogue seems to be limited to in vitro test systems and is not of concern. The relevance of the finding that the analogue can produce rat hepatic DNA adduct spots in a post-labelling assay is not entirely clear. However, given the absence of positive results for gene mutation and clastogenicity in cultured mammalian cell tests, it seems unlikely that these are of concern for human health.

Carcinogenicity
There are no human data contributing to the assessment of whether or not the analogue (Analogue A) is carcinogenic. In animals, a dietary carcinogenicity study in two species is available: F344 rats and B6C3F1 mice. A small increased incidence of leukaemias was seen in male and female F344 rats along with increases in the frequency of mammary gland fibroadenomas in male rats. These increases were not statistically significant, were slight and in a strain prone to these tumours.

An increased incidence in benign Leydig cell tumours seen in male rats was within historical control limits. In mice, a small increased incidence in lymphomas was observed in males, but was not statistically significant and there was no dose-related trend. No increased incidence in any tumour type was observed in female mice. Overall, all of these tumour findings in rats and mice are not considered toxicologically significant. Consequently, it is concluded that the analogue was not carcinogenic in this study in both species. No inhalation or dermal carcinogenicity studies are available, although in repeat exposure inhalation toxicity studies, the analogue did not exhibit properties that raise concern for potential carcinogenicity. Only minimal inflammation was seen in the upper respiratory tract at 50 mg/m3 in a 13-week study and the severity did not increase up to concentrations close to the maximum attainable concentration in the experimental system used, 150 mg/m3. Taking into account all of the animal data available the evidence suggests that the analogue does not have carcinogenic potential.

Reproduction
No human data are available. The analogue (Analogue A) has been shown to have endocrine modulating activity in a number of in vitro and in vivo screening assays. The potency of this activity in these assays generally ranged from 3 to 5 orders of magnitude less than that of oestradiol. No significant oestrogenic activity has been observed with the analogue glucuronide in vitro. The available data also indicate that there is a marked strain difference in the response to the analogue in rats. However, there are no data to indicate the underlying reasons for such differences.
It should be noted that these studies investigating endocrine modulating activity are essentially screening tests and many of them employ experimental protocols, which have not undergone any international validation. However, the first phase of the validation of the uterotrophic assay in indicates that this model is robust and reproducible across laboratories. Whilst this assay can be used to identify oestrogenic activity and can be an early screening test, its use for risk characterisation purposes is still a matter for discussion. In addition, many of the available in vivo studies have used parenteral routes of exposure, the relevance of which are uncertain with respect to relevant routes of human exposure.

The effects of the analogue on fertility and reproductive performance have been investigated in three good quality studies: two generation and multi-generation studies in the rat, and a continuous breeding study in the mouse. Although no effect on fertility was seen in the rat two-generation study, low-dose levels were employed (0.2-200 µg/kg/day). In the multi-generation study, an effect on fertility (reduction in litter size) was seen in all three generations at the top dose of 500 mg/kg. Although this effect was seen only at a dose level causing parental toxicity (a reduction in body weight gain (>13%) in both sexes and renal tubule degeneration in females only), it is not clear whether or not the finding could be a secondary consequence of parental toxicity, or a direct effect of the analogue.

In the light of this uncertainty, and given that an adverse effect on fertility has been seen in the mouse, it is prudent to assume that the analogue may be having a direct effect on fertility in this study. No effects on fertility were seen at 50 mg/kg. The continuous breeding study in the mouse provides some evidence that the analogue can cause adverse effects on fertility. In the F0 generation, no effects on fertility were seen at 300 mg/kg/day, but at dose levels of approximately 600 mg/kg/day and above, reductions in the numbers of litters produced, litter size and numbers of live pups per litter were observed in each of the 4-5 litters produced. These effects were observed in the absence of significant parental toxicity. In contrast, no adverse effects on fertility were observed in the single litter tested at each dose level from the F1 generation. A statistically significant and dose-related decrease in epididymal weight was seen at all doses in the F1 generation. However, the significance of this finding is uncertain given that there was no effect on fertility in this generation, and where an adverse effect on fertility was seen (in the F0 generation), there was no effect on epididymal weight. In spite of the uncertainty, the epididymis is associated with sperm transport and storage, and any reduction in the weight of this organ would be of concern. Although no effects were seen in the two-generation rat study, it is not considered suitable for use in the risk characterisation due to the low-dose levels employed (0.2-200 µg/kg/day). However, this data combined with that for the multi-generation study does provide a comprehensive dose-response range for effects on fertility in the rat. In addition, comparing the rat and mouse data it can be seen that similar toxicological profiles were observed for effects on fertility; effects were seen in both species at approximately the same dose level (i.e. reductions in litter size at 500 mg/kg/day in the rat and at 600 mg/kg/day in the mouse). Consequently, it is considered that the NOAEL of 50 mg/kg/day identified in the rat multi-generation study is also likely to produce no adverse effects in mice for which there is only a LOAEL of 300 mg/kg/day (for a small but statistically significant decrease in epididymal weight in F1 males only). Therefore, the NOAEL of 50 mg/kg/day identified from the multi-generation study will be used for risk characterization purposes, in relation to effects on fertility.

No evidence that the analogue is a developmental toxicant was observed in standard development studies in rats and mice. In rats, a maternal LOAEL and foetal NOAEL of 160 and 640 mg/kg/day, respectively, were identified. In mice, maternal and foetal NOAELs were 250 and 1,000 mg/kg/day, respectively. In a rat multi-generation study, a statistically significant decrease in mean pup body weight gain, with concomitant delays in the acquisition of developmental landmarks (vaginal patency and preputial separation) was observed at 500 mg/kg on post-natal days 7-21 in males and females of all generations (F1-F3). These decreases in pup body weight gain and delays in development were seen in the presence of maternal toxicity. No maternal toxicity and no treatment-related effects were reported in the offspring of animals exposed to 50 mg/kg. However, additionally, some studies have investigated the potential of the analogue to affect male reproductive tract development in rats and mice. Conflicting results have been reported in these studies, in both species. In mice, adverse effects on male reproductive tract development (an increase in prostate weight in two studies and a reduction in epididymis weight in one study) have been reported at dose levels in the range 2–50 µg/kg.
However, these results have not been reproducible in two other studies, one of which included additional dose levels, and using larger group sizes compared with those used in either of the two studies showing effects. It is noted that in contrast to the studies showing effects on the male reproductive tract, the studies that did not find an effect of the analogue also did not show any effects of DES. Furthermore, no functional changes in reproductive parameters or reproductive organ development were observed in a recent rat two-generation study using similar dose levels. The reasons for the differences in these results are unclear. Recent evidence from one study suggests that there are differences in the sensitivity of different mice strains to the effects of oestrogens, which may be related to the selection of strains for large litter size. This difference in sensitivity may in part explain some of the differences in the current database, although the relevance of these rodent strain differences in relation to human health remains unclear.

Overall, in standard developmental studies in rodents, there is no convincing evidence that the analogue is a developmental toxicant. However, the available and apparently conflicting data from studies conducted using low doses (in the µg/kg range) do raise uncertainties. Overall, the studies reporting effects at low doses are not dismissed by NICNAS and are regarded as equivocal. It is concluded that a provisional NOAEL of 50 mg/kg/day for developmental effects, derived from the rat multi-generation study, should be used in the risk characterisation in the interim, whilst awaiting the outcome of further investigations of the analogue, with the aim

of identifying those scenarios which may be of concern irrespective of the outcome of the further testing.

The notified polymer contains 4% phenol impurity. Phenol is classified in the List of Designated Hazardous Substances at concentrations equal to or more than 1% and less than 5% as follows: Harmful (Xn); R21 - Harmful in contact with skin/R22 - Harmful if swallowed; R36 - Irritating to eyes/R38 - Irritating to skin (NOHSC 1999).

8. ENVIRONMENT

8.1. Environmental fate

Environmental fate data for proposed analogues were submitted. However, these analogues are not acceptable since their structures are not closely related to the notified polymer. Therefore the data are not presented in the assessment report.

8.2. Ecotoxicological investigations

Ecotoxicity data for proposed analogues were submitted. However, these analogues are not acceptable since their structures are not closely related to the notified polymer. Therefore the data are not presented in the assessment report.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

A small amount of the notified polymer (up to 6 kg/annually) will be released to the environment due to spills during transport, storage and use. These will be disposed of via a licensed waste contractor presumably to landfill where the notified polymer may be mobile but will gradually degrade by abiotic and biotic processes to water and oxides of carbon.

Due to the way the notified polymer is used the majority will be destroyed during use, whereby releasing water and oxides of carbon.

A Predicted Environmental Concentration (PEC) calculation is not possible.

9.1.2. Environment – effects assessment

No ecotoxicity data were provided, therefore a predicted no effect concentration (PNEC) for aquatic ecosystems cannot be estimated.

9.1.3. Environment – risk characterisation

The aquatic risk quotient (RQ = PEC/PNEC) cannot be determined. However, the notified polymer is not expected to be released to the aquatic compartment. Therefore the proposed use does not represent a risk to the aquatic environment.

Overall, the environmental risk from the proposed use of the notified polymer is expected to be low. However, due to the uncertainty of toxic effects to fish and other aquatic organisms the notified polymer should be prevented from entering waterways.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Skin contact to up to 60% notified polymer during the connection and disconnection of transfer hoses will be the main route of exposure although inadvertent eye contact and inhalation exposure during transfer/ pumping operations from the isotanks to the holding/storage tanks and mixing vessel is also possible. Given the molecular weight of the notified polymer, absorption

through intact skin cannot be excluded.

All workers handling the notified polymer wear PPE such as protective clothing and footwear, eye protection, polymer resistant gloves and respiratory protection, as required. All workers will have access to the Material Safety Data Sheet. Plant operations will occur under local exhaust ventilation and by means of fully automated and enclosed system for transfer, core making, and packaging and assembly operations.

Transport, Storage and Supply
Exposure to the notified polymer (up to a concentration of 60%) is not expected during transport, storage and supply provided the isotanks containing the notified chemical remain intact. Transport, storage and supply workers would only be exposed to the notified chemical in the event of an accidental spill or breach of the 200 L steel drums. The nature of the packaging used for transport, i.e. steel drum, minimises the likelihood of release or loss of the notified chemical.

Plant Operations (transfer operations)
Exposure to the notified polymer to up to 60% may occur during transfer of the imported product containing the notified polymer from the isotanks into the storage and mixing vessel via residual or leaking solution from transfer hoses, fittings, and/or pumps. Exposure to the notified polymer will be limited through the use of transfer lines (under local exhaust ventilation) and the use of PPE such as chemical goggles or safety glasses fitted with side shield, polymer resistant gloves, protective clothing and respiratory protection, as required.

Plant Operations (core making/packaging and assembly)
Mixing of the notified polymer into the manufactured core composite occurs mechanically in a closed system and under local exhaust ventilation and thus exposure is limited. Exposure to the notified polymer and core composite containing the notified chemical is controlled through the use of automatic equipment, engineering control measures, such as a fully contained cabinet and the use of PPE such as chemical goggles or safety glasses fitted with side shield, polymer resistant gloves, protective clothing and respiratory protection, as required. Inhalation exposure is expected to be low given the use of local exhaust ventilation and general exhaust ventilation at the plant. Workers are not required to enter the core making cabinet while the machine is in operation – with the machine designed to stop if the cabinet is opened.

Once the sand core is made and the metal is cast, the core composite containing the notified polymer is destroyed in the high temperature metal casting process. All gases and vapours trapped are scrubbed at the plant site and the core-making sand is subsequently re-used. Consequently dermal, eye and inhalation exposure to the notified polymer during core making is expected to be low under the conditions described.

Once the metal casting is made, negligible residue of the notified polymer is expected on the surface of the finished metal casts. This is because the notified polymer is destroyed during the casting process. Exposure to the notified polymer is not expected when handling (packaging and assembling) the finished casting as no residual polymer nor residual constituents are expected on or in the finished metal cast.

Exposure to odours and vapours generated during the casting operation undertaken at high temperatures is expected to be low, given that casting ovens are under exhaust extraction and the resulting vapours and gases will be trapped by scrubbers and cyclones.

Maintenance and Engineering
Maintenance and engineering workers will have limited exposure to the notified polymer to up to 60% notified polymer by skin and respiratory contact if they are required to intervene in the core making and metal casting operation or during routine maintenance. If this is required, the process will be stopped and the cabinet purged (unspecified conditions) prior to workers entering the enclosed system. The operation will occur under local exhaust ventilation. Workers entering the unit will wear respiratory protection and gloves. Workers outside the unit will wear chemical goggles or safety glasses fitted with side shield, protective clothing. There is a potential for limited respiratory exposure to vapours of the notified polymer, phenol residue and any break down products of the notified polymer by workers outside the unit under such

circumstances if purging is incomplete.

Overall, any dermal, eye and respiratory exposure to the notified polymer and from contact with contaminated equipment is expected to be low given mediation by the use of PPE such as chemical goggles or safety glasses fitted with side shield, polymer resistant gloves, protective clothing and respiratory protection and the undertaking of the operations under local exhaust ventilation and in a fully enclosed and automated systems.

Exposure the notified polymer is expected to be low (transfer and core making) and negligible (packaging and assembly). There is a potential for inadvertent respiratory exposure by workers to vapours of the notified polymer, phenol residue and polymer breakdown products if entering and outside the cabinet if intervention and entry into the confined space is required. While such operations occur under local exhaust ventilation, the extent of purging under such situations will be important in further limiting such exposure.

9.2.2. Public health – exposure assessment

The notified polymer will not be sold to the public. Metal castings, manufactured by means of the notified polymer containing resin in a sand dye cast, are expected to contain negligible residues of the notified polymer on the surface of the casting. This is because the notified polymer is totally destroyed the high temperature production of the metal casting. Any gasses and vapours from the metal casting manufacturing process are to be trapped by scrubbers and cyclones at the metal casting site. .

Exposure to the notified polymer during transport is not expected unless the isotanks are accidentally breached. The use of isotanks as the preferred transport container, is expected to limit such situations. The notifier recommends in the event of accidental releases, small spills may be absorbed onto any adsorbent material. Large spills are to be dealt with by emergency personnel (equipped with protective equipment to protect skin, eyes and the respiratory tract) to prevent spreading.

Exposure to the notified polymer is, therefore, assessed as negligible due to the destruction of the notified polymer at high temperature during the metal casting process and the trapping of off-gases and vapours at the metal casting site.

9.2.3. Human health – effects assessment

Toxicological data for the notified polymer was not submitted. The human health effects assessment relates to the analogue and relies upon an assessment undertaken by the European Union (European Union 2003). In conjunction with the phenol residue, the analogue is accepted as a worst-case scenario as it is a major component of the polymer.

The key health effects of exposure to the notified polymer and phenol residue are eye and respiratory tract irritation, skin sensitisation, repeat dose toxicity to the respiratory tract, potential effects on the liver and equivocal effects on reproductive toxicity (i.e., developmental toxicity by virtue of the analogue relied upon by the notifier). By virtue of the molecular weight of the notified polymer, dermal absorption is predicted.

Further investigations are needed to resolve the uncertainties surrounding the potential for the notified polymer to produce adverse effects on development at low doses. This is due to the reliance of the notifier on worst-case scenario analogue data.

By analogue, it is expected that the notified polymer will be absorbed orally with no significant bioaccumulation potential.

The notified polymer is considered to be of low acute toxicity. The presence of phenol residue indicates it is harmful in contact with skin and if swallowed and is a skin irritant. In addition, it is expected to be an eye irritant and is irritating to the respiratory tract. By analogue, it is predicted that the notified polymer can produce skin sensitisation responses in humans. There is

no information on respiratory sensitisation potential.

Repeated inhalation studies in rats of the analogue indicate slight inflammation of the upper respiratory tract epithelium, with a NOAEL of 10 mg/m3 in a 13-week study. In a 2-year dietary study, a NOAEL of 74 mg.kg-1.day-1 has been established for rats. In mice, the liver is the target organ, with a LOAEL (2-year study) of 120 mg.kg-1.day-1 in males and a NOAEL of 650 mg.kg-1.day-1 in females.

The notified polymer (by analogue) is considered not to have mutagenic potential *in vivo* nor carcinogenic potential.

Further work is required to resolve the uncertainties surrounding the potential for the notified polymer by analogue to produce adverse effects on development at low doses. In the interim, a provisional NOAEL of 50 $mg.kg^{-1}.day^{-1}$ should be used in the risk characterisation as a worst-case scenario.

The nature of the phenol residue the notified polymer as introduced will be harmful to the skin and if swallowed and irritating to the eyes and skin.

Based on the available data, the notified polymer is classified as a hazardous substance in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC 2004). The classification and labelling details are:

Harmful (Xn) and Irritant (Xi)

Risk Phrases:
R21/22 - Harmful in contact with skin/ if swallowed
R36/38 - Irritating to eyes and skin
R43 - May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

Based on the toxicity data provided for the notified polymer, the notified polymer is a slight skin irritant and a severe eye irritant with the potential for adverse eye effects such as swelling and discoloration of the eye up to three days post exposure. In addition, the notified polymer is expected to be harmful in contact with skin and if swallowed and may cause sensitisation by skin contact.

All workers have access to the MSDS. The MSDS recommends workers wear chemical goggles or safety glasses fitted with side shield, impervious work clothing, boots and neoprene or PVC gloves, and a respirator as required that meets the requirements of AS 1715.

Import, storage and handling
Exposure to the notified polymer (up to 60% notified polymer) during transport and storage is not expected unless the packaging is accidentally breached. Therefore, on the basis of good work practices and safety-handling measures and the use of steel isotanks to limit accidental breaches, the notified chemical as introduced is unlikely to pose a significant occupational health and safety risk when used in the proposed manner.

Core manufacture, packaging and handling
Workers who have the highest potential for dermal, ocular and respiratory exposure to the notified polymer (up to a concentration of 60%) during routine operations is predicted to be workers involved in transfer operations such as connecting and disconnecting transfer lines and when adjusting transfer pumps and valves, as required. Such exposure, however, will be limited by the use of PPE such as eye protection (chemical goggles or safety glasses fitted with side shield), protective clothing, chemical resistant gloves and safety footwear. Any potential inhalation exposure will be limited by the use of fully enclosed operations undertaken under local exhaust ventilation and the use of respiratory protection as required. .

Exposure by workers to the notified polymer during core manufacture is not expected because

the mixing of the notified polymer into the sand mixture during core manufacture occurs within a fully enclosed system under local exhaust ventilation. Workers will wear PPE. Consequently, exposure to the notified polymer during core manufacture is predicted to be low and risk to workers during this activity is assessed as low.

The notified polymer is destroyed during the metal casting process. Consequently, exposure to the notified polymer during packaging and handling is predicted to be negligible and risk to workers during this activity is assessed as negligible.

Plant operators may need to intervene when equipment malfunctions or during routine maintenance. However, under such circumstances the process will be stopped and purged prior to workers entering the enclosed system. Exposure under such incidental circumstances will be further limited by the use of PPE such as a suitable respirator and suitable gloves, chemical goggles or safety glasses fitted with side shield, and protective coveralls and be undertaken under local exhaust ventilation. It is noted employers are responsible for adherence to the NOHSC Exposure Standards for Atmospheric Contaminants as may arise from any of the constituents of the notified polymer as introduced (NOHSC 1995).

It is noted that the notified polymer may cause sensitisation by contact with skin. Employers may wish to consider health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation. Individuals who become sensitised should not continue to handle the notified polymer.

In conclusion, on the basis of good work practices and safety-handling measures such as the automated nature of the core making process under local exhaust ventilation and with PPE including chemical goggles or safety glasses fitted with side shields, impervious work clothing, safety gloves and safety boots and respiratory protection as required, the risk to workers involved in core making operations is assessed to be low.

End-use
Following destruction of the notified polymer during metal casting, the risk to workers handling the final finished metal products is expected to be negligible.

9.2.5. Public health – risk characterisation

The notified polymer is not available to the general public and negligible residue of the notified polymer is expected on the surface or in the finished metal castings. This is because the notified polymer is totally destroyed in the production of the metal casting. The sand used in the casting process is re-used on site. Scrubbers and cyclones trap any gasses and vapours from the metal casting manufacturing process.

Consequently, negligible public exposure (direct and by secondary exposure) to the notified polymer by the dermal, ocular, oral and respiratory route is predicted as a result of the use and manufacture of the metal castings by means of the notified polymer.

Therefore, the notified polymer is considered unlikely to pose a significant public health risk when used in the proposed manner.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are: …

Harmful (Xn) and Irritant (Xi)

Risk Phrases:
R21/22 - Harmful in contact with skin/ if swallowed
R36/38 - Irritating to eyes and skin
R43 - May cause sensitisation by skin contact;

Safety Phrases:
S28 - After contact with skin, wash immediately with plenty of soap and water
S37 – Wear suitable gloves
S39 –Wear eye/face protection
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

and

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Polymers (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Eye Irritant	2A	Causes eye irritation
Sin Irritation	2	Causes skin irritation
Skin sensitisation	1	May cause an allergic skin reaction
Acute toxicity - oral	4	Harmful if swallowed
Acute toxicity - dermal	4	Harmful in contact with skin

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 manner proposed.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer (as introduced) 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 applicant.

11.2. Label

The label for the notified polymer (as introduced) 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Polymers Standards Sub-committee should consider the following health hazard classification for the notified polymer:
  - Xn (Harmful) and Xi;(Irritant)
  - R36/38 (Irritating to Eyes/Skin)
  - R43 (May cause sensitisation by skin contact)
  - R21/22 (Harmful in contact with skin and if swallowed)

- Use the following risk phrases for products/mixtures containing the notified polymer:

  - ≥1%: Xn; R43 (May cause sensitisation by skin contact)
  - ≥20%: Xi; R36/38 (Irritating to Eyes/Skin)
  - ≥25%: Xn; R21/22 (Harmful in contact with skin and if swallowed)

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer [as introduced for use]:

  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer [as introduced for use]:

  - Safe work practices to avoid entry to confined space where vapour may have collected

  - Atmospheric monitoring of constituents of the notified polymer to ensure compliance with the *Exposure Standards for Atmospheric Contaminants in the Occupational Environment* (NOHSC 19995).

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer [as introduced for use]:

  - Safety glasses (eye/face protection)

  - Respiratory protection

  - Chemical resistant gloves

  - Protective clothing

  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.

Health Surveillance

- Employers may wish to consider health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation. Individuals who become sensitised should not continue to handle the notified polymer.

Environment

- The following control measures should be implemented by the importer and the users to minimise environmental exposure during (manufacture, formulation, use) of the notified polymer:
  - The material should be stored in bunded areas
  - All process equipment, including holding and fed tanks, should be in bunded areas with only process drains present, if any.

Disposal

- The notified polymer should be disposed of by licensed waste contractors or secure landfill or preferably incineration, where possible, in line with State and Territory Authorities.

Storage

- The following precautions should be taken [by the Notifier and recipients] regarding storage of the notified polymer as introduced:
  - Store in a well ventilated area

Emergency procedures

- Spills/release of the notified polymer should be handled by containment, collected with appropriate absorbent material (eg vermiculite) then placed in labelled containers ready for disposal.

12.1. Secondary notification

The Director of 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 importation volume exceeds 300 tonne per annum notified polymer; or
- use of the polymer changes in such a manner as to significantly increase discharge of the notified polymer to the aquatic environment, the hazard should be reassessed and the full report on the toxicity of the notified polymer may be required in order to conduct a more comprehensive environmental assessment.
- additional information becomes available as to any adverse environmental and health effects of the notified chemical and analogue.

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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