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

FULL PUBLIC REPORT

**Benzene, 1,3-bis(1-isocyanato-1-methylethyl)-, homopolymer, polyethylene glycol
mono-Me-ether-blocked**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

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Director

Chemicals Notification and Assessment

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FULL PUBLIC REPORT**Benzene, 1,3-bis(1-isocyanato-1-methylethyl)-, homopolymer, polyethylene glycol mono-Me-ether-blocked****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

P.D. Plastics (Aust) Pty Ltd (ABN 42 091 476 505)
762 Arthurs Seat Road
Arthurs Seat VIC 3936

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (PMN P95-0180)

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

Benzene, 1,3-bis(1-isocyanato-1-methylethyl)-, homopolymer, polyethylene glycol mono-Me-ether-blocked

OTHER NAME(S)

Polymer of poly(oxy-1,2-ethanediyl), α -methyl- ω -hydroxy and oligomeric carbodiimide of benzene 1,3-bis(1-isocyanato-1-methylethyl)-

MARKETING NAME(S)

Lupragen VP 9238
Elastostab H01

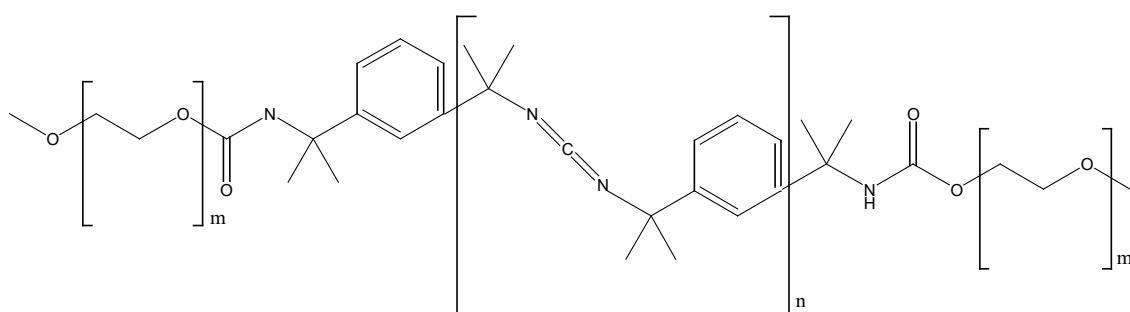
CAS NUMBER

197098-60-5

MOLECULAR FORMULA

$[(C_{14}H_{16}N_2O_2).(C_2H_4O)_nCH_4O]_n$

STRUCTURAL FORMULA



n = 4, m = 11

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	1179
Weight Average Molecular Weight (Mw)	1862
Polydispersity Index (Mw/Mn)	1.58
% of Low MW Species < 1000	11.11
% of Low MW Species < 500	7.56

SPECTRAL DATA

ANALYTICAL METHOD Infrared Spectroscopy

Remarks A characteristic spectrum was obtained and the assigned peaks were consistent with the structure. IR peaks at 3000, 2575, 2125, 1725, 1475, 1375, 1250, 1225, 1150, 1100, 960, 700 and 625 cm⁻¹.

3. COMPOSITION

DEGREE OF PURITY
77%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

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

Chemical Name	Poly(oxy-1,2-ethanediyl), α-methyl-ω-hydroxy-
CAS No.	9004-74-4 Weight % 11

ADDITIVES/ADJUVANTS
None

POLYMER CONSTITUENTS

Chemical Name	CAS No.	Weight % starting	Weight % residual
Benzene, 1,3-bis(1-isocyanato-1-methylethyl)-	2778-42-9	51.43	0.01
Poly(oxy-1,2-ethanediyl), α-methyl-ω-hydroxy-	9004-74-4	48.57	11

DEGRADATION PRODUCTS
None known

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

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a component of fully formulated thermoplastic polyurethane (TPU) base pellets (natural compound). The imported pellets contain approximately 2% notified polymer.

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>	2	2	2	2	2

USE

Stabiliser for acidic hydrolysis of thermoplastic polyurethanes.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Not stated

IDENTITY OF MANUFACTURER/RECIPIENTS

P.D. Plastics (Aust) Pty Ltd (ABN 42 091 476 505)
762 Arthurs Seat Road
Arthurs Seat VIC 3936

TRANSPORTATION AND PACKAGING

The imported pellets measuring 5 mm long × 3 mm wide will be packed in heavy duty 25 kg multilayer polyethylene bags. Following importation, transport workers will deliver the pellets to customers ready for forming into plastic articles or for manufacture of masterbatch. The masterbatch will be transported to the customer sites by road.

5.2. Operation Description

No repackaging of the product occurs in Australia. However, the base pellets may be compounded with other raw materials to form compounded coloured plastic pellets known as masterbatch. The plant operator manually weighs out the base pellets and transfers the requisite amount into plastic bags. The base pellets and other ingredients including a concentrated dye are transferred into a mixer. The mixer is sealed during mixing. After mixing, the extruder operator releases the mixture from the sealed dispenser into the extruder, or the mixer may open directly into the extruder below through a sealed tube. In the extruder, the mixture is melted and extruded through die holes in long spaghetti-like strings, passes through a cooling water bath into a pelletiser and classifier, which cuts the strings into pellets, which are graded and conveyed to a hopper for storage. A quality control technician scoops a portion of the masterbatch into a sample container for testing. The quality of the pellets is tested against a battery of quality control tests using standard laboratory procedures. Following quality control testing, a packaging operator will bag the masterbatch into a 25 kg capacity drum, ready for distribution to customers.

Alternatively, the base pellets are manually transferred into a dispenser and will be extruded using similar extrusion process described above to form a colourless plastic article. The base pellets may also be mixed with the masterbatch before being mechanically lifted or conveyed to a hopper extruded as above to form coloured plastic articles. The extruded plastic articles are formed and trimmed as required.

In an injection process, the base pellets and masterbatch are either vacuum transferred or manually tipped into the feeding hopper on the injection-moulding machine. The mixed pellets are then fed into the barrel of the machine by gravity. Once heated, the melted pellets are moulded to form the shape of the plastic article, then cooled within the closed mould, prior to ejection into a suitable receptacle. Extruded or injection-moulded plastic articles will contain less than 1% notified polymer.

5.3. Occupational exposure

Approximately 20 process workers will have the potential for exposure to the notified polymer on a regular basis (maximum duration of exposure of 8 hours/day, 30 days/year). The pellet is transferred either by automatic suction pumps or manually tipping the contents of the bag into the dispenser of the extruder machine or to the feeding hopper on the injection-moulding machine.

The notifier indicates that the manufacture of plastic articles involves a highly automated process. Skin contact may occur when opening containers and manually charging the polymer masterbatch into the heat-moulding machine. However, worker exposure is not anticipated since the notified polymer is encapsulated within the TPU masterbatch and would not be available for exposure.

Workers handling the pellets containing the notified polymer will wear protective equipment including gloves, safety glasses and overalls. The moulding machines are enclosed and the process areas are fitted with local exhaust ventilation to capture fugitive vapours from the heated plastic pellets.

Waterside, warehouse and transport and storage workers (5 workers, duration of exposure of 20 hours/year or 10 days/year) are unlikely to be exposed to the notified polymer unless the packaging is breached.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a component of fully formulated TPU pellets and will be used to produce moulded or extruded plastic articles. There will be no environmental exposure associated with the manufacture of the notified polymer in Australia.

The manufacture of plastic articles involves a highly automated process and moulding machines that are enclosed. Any spillage will be contained within bunded areas. Any spilled or reject material (TPU pellets or plastic scrap containing the polymer) during the manufacture of the masterbatch or moulded articles, will be regularly regranulated and reprocessed. Regranulated product unsuitable for reuse (containing less than 20 kg of the notified polymer/annum) is bagged and disposed of in landfill as normal industrial waste via a waste contractor.

Up to 0.2% of the imported pellets (containing less than 10 kg of the notified polymer) is expected to be released as waste due to residue in import containers and spills during the production of masterbatch and moulded or extruded plastic articles. Up to 200 kg per year of plastic scrap (containing less than 2 kg of the notified polymer) may be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer will be incorporated into moulded or extruded plastic articles, which will be disposed of to landfill at the end of their useful lives.

5.5. Disposal

Although the notified polymer is a viscous liquid, it is imported into Australia in a form of pellets. Spilled or reject material (TPU pellets or plastic scrap containing the polymer) during manufacture of masterbatch or moulded articles will be collected and reused. Regranulated product unsuitable for reuse is bagged and disposed of in landfill as normal industrial waste via a waste contractor. Packaging should be emptied as far as possible, and disposed of to a licensed waste landfill site.

5.6. Public exposure

During manufacture of formed plastic articles by injection and extrusion, any spillage will be contained within bunded areas. Public exposure during the injection and extrusion process is negligible.

The notified polymer in plastic articles is expected not to be biologically available. Public exposure through contact with articles made from the polymer is expected to be negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Pale yellowish viscous liquid

Freezing Point <5°C

Remarks Test report not provided.

Density 1100 kg/m³ at 25°C

Remarks Test report not provided.

Vapour Pressure 3 X 10⁻⁶ mbar at 20°C

Remarks Test report not provided.

Water Solubility > 0.35 g/L at 25 °C

Remarks The water solubility was mentioned to be greater than 2.0 g/L in the MSDS, however, a test report was not provided. The above value is based on the observations made during the determination of the partition coefficient (summarised below). The maximum concentration of the test substance measured in the water phases was 351.2 mg/L. In the absence of a test report to support the claim that the water solubility is greater than 2 g/L, the maximum value measured during the partition coefficient determination is selected as the lower limit of water solubility.

Test Facility Accordingly, the test substance is moderately soluble (Mensink *et al.*, 1995).
BASF Aktiengesellschaft (1999).

Hydrolysis as a Function of pH The test substance can be considered to be very rapidly hydrolysing at pH 4, fairly hydrolysing at pH 7 and moderately hydrolysing at pH 9.

Method OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> (°C)	<i>t</i> ^{1/2} hours
4	5	<<1
4	20	<<1
7	35	75
7	20	208
7	20	210
9	50	527

Remarks The buffer solutions were prepared by dissolving 200 mg of the test substance in 100 mL at each pH tested. Acetonitrile (0.5 mL) was added to prevent foaming. The solutions were filled in vials and maintained at the particular test temperature and samples were injected at given time intervals.

Two injections were made immediately and 1 hour after dissolving the test substance in buffer solution that was temperate at 5°C and 20°C. Detailed observations were made at pH 7 and 9 at the given temperatures and the mean *t*^{1/2} values are listed above. Test solutions were analysed using a modular HPLC system with UV/Vis-detector.

The report indicated that as the separation power of the chromatographic system allowed only for peak 1 separation of the hydrolysis products and no significant change in hydrolysis behaviour was expected for the other peaks, only half lives and time constants for peak 1 were calculated. As the chemical behaviour of all species in the mixture is similar, this assumption was accepted as valid.

The test substance can be considered to be very rapidly hydrolysing at pH 4, fairly hydrolysing at pH 7 and stable at pH 9 (Mensink *et al.*, 1995).

Test Facility BASF Aktiengesellschaft (1999)

Partition Coefficient (n-octanol/water) log Pow at 25°C = 0.4 to 2.9 (Pow = 2.5 to 882)

Method OECD TG 107 Partition Coefficient (n-octanol/water), Shake Flask Method.
Remarks Two standard solutions were made in water (pH 6.4 and octanol saturated) and 3 samples from each were shaken until equilibration with octanol (saturated with water). The water phases were separated by centrifuging at 13000 rpm for 1 hour and injected after dilution with water as appropriate. The octanol phases were diluted with acetonitrile (1:25). The 12 samples were analysed by HPLC and the concentrations were determined by the method of external standard.

The report indicated that as the chromatogram of the test substance showed a distribution of several peaks, the log Pow was determined for the single peaks. Due to background peaks, low chromatographic resolution and bad signal-to-noise ratio only peaks 1 to 9 were evaluated. The content was determined by LC area %. The first peak corresponded to log Pow = 0.4; all other peaks gave log Pow values in the range of 2.1 to 2.9.

The results indicate a low affinity for the organic phase and component of soils and sediments.

Test Facility BASF Aktiengesellschaft (1999)

Adsorption/Desorption Not determined

Remarks The moderate water solubility and relatively low P_{ow} may indicate a potential for mobility in soil.

Dissociation Constant pKa >10

Method OECD TG 112 Dissociation Constants in Water.
Remarks The report indicated that a titration was not possible with either NaOH or HCl. As the structure of the test substance has no acidic or basic groups no measurable pKa value was expected and the report concluded that the pKa was greater than 10.
Test Facility BASF Aktiengesellschaft (1999)

Particle Size Not determined

Remarks The notified polymer will be imported as plastic pellets measuring 5 mm long × 3 mm wide.

Viscosity 1.0 - <6.0 mPa.s at 25°C

Remarks Test report not provided.

Flash Point 230°C

Remarks Test report not provided.

Autoignition Temperature 380°C

Remarks Test report not provided.

Explosive Properties

Not explosive

Remarks Test report not provided.

Stability Testing

Thermally decomposes at >250°C.

Remarks Test report not provided.

Reactivity

Remarks The notified polymer is stable under normal conditions. However, the notified polymer reacts with acids and oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

A limited toxicity data set was submitted in support of the notification for the notified polymer. The data are summarised below.

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

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test. EC Directive 92/69/EEC B.1tr Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	Aqua Bidest
Remarks - Method	No significant protocol deviations.

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	3/sex	2000	None

LD50 >2000 mg/kg bw
Signs of Toxicity None
Effects in Organs No macroscopic abnormalities observed at necropsy.
Remarks - Results All animals gained weight in the course of the study.

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

TEST FACILITY BASF Aktiengesellschaft (1997a).

7.4. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 males and 1 female

Vehicle None
 Observation Period 72 hours
 Type of Dressing Semi-occlusive.
 Remarks - Method No significant protocol deviations.

RESULTS

Remarks - Results All scores for erythema/eschar or oedema were zero.

CONCLUSION The notified polymer is non-irritating to skin.

TEST FACILITY BASF Aktiengesellschaft (1997b).

7.5. Irritation - eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
 EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
 Species/Strain Rabbit/New Zealand White
 Number of Animals 3/females
 Observation Period 72 hours
 Remarks - Method No significant protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0.3	1.0	0.3	2	48 hours	0
<i>Conjunctiva: chemosis</i>	0.3	0	0	1	24 hours	0
<i>Conjunctiva: discharge</i>	0	0	0	0	0	0
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	0	0	0

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

Remarks - Results Mild to moderate redness of the conjunctiva was observed at 1- and 24-hour observation periods in all animals, and persisted up to 48 hours in 1 animal. Chemosis was also observed in all animals at 1-hour observation period, and persisted up to 24 hours in 1 animal. All animals appeared normal at 72-hour observation period.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY BASF Aktiengesellschaft (1997c).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
 EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
 Plate incorporation procedure/Pre incubation procedure
 Species/Strain *S. typhimurium*:
 TA1535, TA100, TA1537, TA98.
E. coli: WP2 uvrA.
 Metabolic Activation System Arochlor 1254-induced rat liver S9 fraction.
 Concentration Range in a) With metabolic activation: 0 to 5000 µg/plate.

Main Test	b) Without metabolic activation: 0 to 5000 µg/plate.
Vehicle	Water
Remarks - Method	No significant protocol deviations. Two independent experiments using standard plate test and pre-incubation test with and without metabolic activation were conducted in triplicate.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate)</i>	<i>Resulting in:</i>	
	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>			
Test 1 (Standard Plate Test)	2500 (TA1537)	None	None
Test 2		None	None
<i>Present</i>			
Test 1 (Standard Plate Test)	5000 (TA1535)	None	None
Test 2		None	None

Remarks - Results	<p>No precipitation was observed. In Test 1, toxicity as evidenced by a slight decrease in the number of colonies was observed in TA1535 without metabolic activation, and in TA1537 with metabolic activation.</p> <p>No significant increases in the numbers of revertant colonies were seen in any strain, either in the presence or absence of metabolic activation.</p> <p>Appropriate positive controls induced marked increases in the number of revertant colonies, indicating that the test system responded appropriately.</p>
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CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
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TEST FACILITY	BASF Aktiengesellschaft (1997d).
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8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Annex of EEC Directive 92/69 Manometric Respirometry Test corresponding to OECD TG 301F and ISO Standard 9408.
Exposure Period	Municipal activated sludge from wastewater treatment plants
Auxiliary Solvent	28 days
Analytical Monitoring	None
Remarks - Method	Dissolved organic carbon (DOC)
	In addition to the test substance (test concentration = 100 mg/L), blank samples and samples containing a reference substance (aniline) were tested. Abiotic elimination in a test assay containing the test substance and demineralised water was also measured.

RESULTS

<i>Day</i>	<i>Test substance</i>	<i>% degradation</i>	<i>Reference Substance</i>
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7	6	33
14	11	73
21	12	75
28	13	75

Remarks - Results

Primary biodegradation was not calculated since the concentrations of the test substance at the end of the test were higher in the inoculated medium than in the blank test with water. The test was regarded valid as the OECD criteria for test validation including the degradation of the reference substance were fulfilled.

The report indicated that abiotic processes e.g. hydrolysis may take place at the test conditions and especially in alkaline environments. Based on the HPLC data it was concluded that the test substance is not stable in alkaline conditions and may hydrolyse to the urea derivative at the carbodiimide bond. The pH of the samples containing the test substance in the biodegradability study varied between 7.5 and 9.4. It should be noted that the above conclusion contrasts with that of the hydrolysis as a function of pH test (Section 6.6), where the test substance was found to be stable at pH 9.

CONCLUSION

The test substance is not readily biodegradable according to the OECD criteria requiring > 60% within 10 days of commencement.

TEST FACILITY

BASF Aktiengesellschaft (1998).

8.1.2. Bioaccumulation

If there is any release to the aquatic compartment bioaccumulation is not expected due to the moderate water solubility, high molecular weight (>1000) and the low log P_{ow} of the notified polymer (Connell, 1990).

8.2. Ecotoxicological investigations**8.2.1. Acute/chronic toxicity to aquatic invertebrates**

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static

Species

Daphnia magna

Exposure Period

48 hours

Auxiliary Solvent

None

Water Hardness

Standard M4 medium used.

Analytical Monitoring

Spectrophotometric analysis

Remarks - Method

Concentration control analyses were conducted with test solutions of 100 and 12.5 mg/L at the start and end of the test.

RESULTS

Concentration (Test Substance) mg/L Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
Control	20	0	0
100	20	0	1
50	20	0	0
25	20	0	0
12.5	20	0	0

LC50

> 100 mg/L at 48 hours

NOEC (or LOEC)

> 50 mg/L at 48 hours

Remarks - Results	The test water temperature, oxygen content and pH were satisfactorily maintained. The measured concentration of the test substance was between 94.4% and 97% at the beginning of the test and between 96.8% and 100% at the end of the test. The results are expressed in terms of the nominal values.
CONCLUSION	The test substance is practically non-toxic to daphnia.
TEST FACILITY	BASF Aktiengesellschaft (2001).
8.2.2. Inhibition of microbial activity	
TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test ISO Standard 8192
Inoculum	Activated sludge from laboratory wastewater treatment plants fed with municipal and synthetic wastewater.
Exposure Period	30 minutes
Concentration Range	
Nominal	1000 mg/L
Remarks – Method	Test concentrations of the reference substance (3,5-dichlorophenol) were 1, 10 and 100 mg/L.
RESULTS	
EC50	> 1000 mg/L
NOEC	> 1000 mg/L (Highest concentration tested)
Remarks – Results	No significant effect on respiration was observed at the test concentration used. The EC50 of the reference substance was 6.5 mg/L (within the required range of 5 to 30 mg/L), thus validating the test.
CONCLUSION	The test substance does not cause significant inhibition of the respiration rate of activated sludge at concentrations much greater than expected in the sewer.
TEST FACILITY	BASF Aktiengesellschaft (1997e).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Almost all of the notified polymer will be used to manufacture various injection moulded and extruded articles. Once moulded, the notified polymer is expected to be inert and is unlikely to pose a risk to the environment.

It is anticipated that majority of wastes generated during the manufacture of the masterbatch and injection moulded articles will be collected, reground and reused in the moulding process. Up to 12 kg per year of the notified polymer is expected to be disposed of to landfill as waste in the form of TPU pellets or scrap/reject material resulting from the manufacturing processes. At the end of their useful lives, the moulded and extruded articles manufactured using the notified polymer will also be disposed of to landfill as inert solid waste.

In landfill, the polymer contained in the plastic articles/scrap or TPU pellets is expected to be immobile due to its inert state. Although not expected to be ready biodegradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified polymer due to abiotic or slow biotic processes to give water vapour and oxides of carbon and

nitrogen.

The moderate water solubility and relatively high molecular weight indicates a low potential for bioaccumulation (Connell, 1990).

The very limited exposure to the aquatic compartment makes it very difficult to calculate a meaningful predicted environmental concentration (PEC).

9.1.2. Environment – effects assessment

The results of one aquatic toxicity test are listed below.

<i>Organism</i>	<i>Duration</i>	<i>End Point</i>	<i>mg/L</i>
Daphnia	48-h	EC50	>100

Aquatic toxicity data were provided only for one trophic level. The predicted no effect concentration (PNEC) for aquatic ecosystems was not determined, due to the small amount of the notified polymer expected to be released to the aquatic environment as a result of the proposed use, and the low toxicity to daphnia.

9.1.3. Environment – risk characterisation

Almost all of the notified polymer imported will eventually be disposed of to landfill in the form of wastes from the masterbatch and plastic articles manufacturing process, residues in empty containers, and injection moulded and extruded articles at the end of their useful lives. In landfill, the notified polymer bound to the TPU pellets, plastic articles or scrap can be expected to be immobile and eventually degrade to give water vapour and oxides of carbon and nitrogen.

It is not possible to determine a realistic PEC value to assess the risk to aquatic organisms, since the use pattern of the notified polymer will result in negligible exposure to the aquatic environment. Also, due to the limited release to water, it is unlikely that the polymer would exist at levels which could accumulate and pose a threat to aquatic organisms or to bioaccumulate. Based on the proposed use pattern, the release of the notified polymer to the environment is expected to be very low. Abiotic or slow biotic processes are expected to be largely responsible for the eventual degradation of the notified polymer as it is not readily biodegradable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Dermal, ocular and inhalation exposure to dust when opening bags, weighing and charging plastic pellets containing the notified polymer may occur during masterbatch production, extrusion and moulding process. However, such exposures are expected to be low since the notified polymer is encapsulated in the compounded plastic pellets and the particle size of the base pellet and masterbatch containing the notified polymer is above the inspirable and respirable range as set out in National Occupational Health and Safety Commission (NOHSC) *Guidance Note on the Interpretation of Exposure Standards for Atmospheric Contaminants in the Occupational Environment* (NOHSC, 1995).

Additionally, protective equipment (gloves, safety glasses and overalls) will be used to prevent dermal and ocular exposure and engineering controls (local exhaust ventilation) are in place to capture fugitive emissions during processing. The possibility of exposure is lessened further during extrusion and moulding process with the use of enclosed and automated process.

During further processing into finished articles, the notified polymer is bound within a polymer matrix, and is not available for separate exposure.

Exposure to waterside, warehouse and transport workers is low considering the handling of sealed packages of products containing the notified polymer.

9.2.2. Public health – exposure assessment

Exposure of the general public as a result of transport, formulation of masterbatch and disposal of articles containing the notified polymer is assessed as being negligible. Public exposure to

the notified polymer may occur as a result of dermal contact with plastic products containing the notified polymer. However the amounts to which the public may be exposed is considered to be negligible since the notified polymer is trapped within the polymer matrix. Very small amounts migrate to the surface of plastic products and it is present in end-use plastic products at low concentrations.

9.2.3. Human health - effects assessment

A limited toxicity data set was submitted in support of the notification for the notified polymer. The notified polymer exhibited very low acute oral ($LD_{50} > 2000$ mg/kg) toxicity in rats. It was not irritating to skin and slightly irritating to the eye of rabbits. Eye irritation effects were limited to redness and chemosis of the conjunctiva and were reversible within 72 hours. The notified polymer was not mutagenic in bacteria.

On the basis of data supplied, the notified polymer would not be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

9.2.4. Occupational health and safety – risk characterisation

The notified polymer will be imported as a component of formulated base pellet ready for forming into plastic articles, or will be mixed and extruded with other ingredients to form a masterbatch for use in plastic manufacture. In both forms (base pellet or masterbatch), the notified polymer is encapsulated in the polymer matrix and is not likely to be available for exposure. Exposure during extrusion and moulding will also be precluded due to the elevated temperatures used, and the enclosed and automated moulding processes. Exposure, if any, is limited to large pellets or formed articles containing approximately 2% notified polymer. While the pellet size reduces inhalation exposure, dust and fumes may be present. The exposure standard of 10 mg/m^3 in general for dust should be observed.

Due to the low hazard of the notified polymer and the low exposure, particularly the low potential for ocular exposure, the risk posed by the notified polymer to occupational health and safety is low.

9.2.5. Public health – risk characterisation

Public contact to the notified polymer will only occur following accidental exposure from a spill and from touching plastic products containing the notified polymer. However, public exposure is assessed as negligible because the notified polymer will be encapsulated within the plastic products from which it is not expected to leach, and hence is not expected to be dermally absorbed. The potential for public exposure to the notified polymer during all phases of its life cycle is considered to be negligible.

The risk from public exposure to the notified polymer is considered negligible since the notified polymer is present at low concentration in the pellets and plastic articles, is expected to be of low hazard and is largely trapped within the polymeric matrix of the plastic articles.

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 a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

For the environment it is not possible to categorise the notified polymer according to the Globally Harmonised System (GHS) for the Classification and Labelling of Chemicals (UN, 2003).

10.2. Environmental risk assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a component of plastic articles.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer.
 - overalls, safety glasses and PVC or rubber gloves.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified polymer should be incinerated in a suitable incineration plant observing local authority regulations.
- The waste material containing the notified polymer should be disposed of to landfill.

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(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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