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

FULL PUBLIC REPORT

Polymer in Elastopor H 1129/5/0

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FULL PUBLIC REPORT**Polymer in Elastopor® H 1129/5/0****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

BASF Australia Ltd (ABN 62 008 437 867)
500 Princes Highway
Noble Park Vic 3174

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:

CHEMICAL NAME

OTHER NAMES

CAS NUMBER

MOLECULAR FORMULA

STRUCTURAL FORMULA

MOLECULAR WEIGHT

SPECTRAL DATA

PURITY

IMPURITIES/RESIDUAL MONOMERS

ADDITIVES/ADJUVANTS

POLYMER COMPOSITION

LOW MOLECULAR WEIGHT SPECIES

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

MELTING POINT/BOILING POINT

DENSITY

VAPOUR PRESSURE

HYDROLYSIS AS A FUNCTION OF PH

PARTITION CO-EFFICIENT

ADSORPTION/DESORPTION

DISSOCIATION CONSTANT

PARTICLE SIZE

FLASH POINT

FLAMMABILITY LIMITS

AUTOIGNITION TEMPERATURE

EXPLOSIVE PROPERTIES

REACTIVITY

ACUTE DERMAL TOXICITY

ACUTE INHALATION TOXICITY

REPEAT DOSE TOXICITY

INDUCTION OF POINT MUTATIONS

CHROMOSOME DAMAGE

INDUCTION OF GERM CELL DAMAGE

DAPHNIA, ACUTE IMMOBILISATION/REPRODUCTION

ALGAL, GROWTH INHIBITION TEST

READY BIODEGRADATION

BIOACCUMULATION

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Notified to USA (1987) and Canada (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Elastopor H 1129/5/0 (60-80% notified polymer)

Terate 2541 V (70-85% notified polymer)

The end-use customer will receive and use the blended product Elastopor H 1129/5/0.

METHODS OF DETECTION AND DETERMINATION

METHOD Liquid Chromatography

TEST FACILITY Test Facility A (2001)

3. COMPOSITION

DEGREE OF PURITY

>89%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

All hazardous impurities and residual monomers are present at below the relevant cut offs for classification of the notified polymer solution as a hazardous substance.

DEGRADATION PRODUCTS

No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

Thermal decomposition may release toxic fumes containing products of combustion such as carbon monoxide and carbon dioxide.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No losses by volatilisation, exudation or leaching are expected from the polymer.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. In the first year of introduction it will be imported as a component of a blended polyol product Elastopor H 1129/5/0 (60-80% notified polymer) containing flame retardant, surfactants and stabilisers. After this the importation of the blended product will cease and the notified polymer will be imported as the polymer solution Terate 2541 V (70-85% notified polymer) for reformulation in Australia.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED POLYMER (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>	100 – 1000	100 – 1000	1000– 2000	1000– 2000	1000– 2000

USE

Polyol component for production of rigid polyurethane foam.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Melbourne (Terate 2541 V)

Sydney (Elastopor H 1129/5/0)

IDENTITY OF MANUFACTURER/RECIPIENTS

The imported polymer solution Terate 2541 V will be stored in a contract warehouse in Melbourne until required for formulation at the BASF Altona site.

The imported blended polyol product Elastopor H 1129/5/0 will be stored at a contract warehouse in Sydney prior to distribution to one customer in Sydney.

TRANSPORTATION AND PACKAGING

Both the polymer solution and blended polyol product will be imported in 1000-kg intermediate bulk containers (IBC), and transported by road. When the product is formulated in Australia it will be transported to the customer site in Sydney in a 20 tonne bulk road tanker.

5.2. Operation description

Formulation of blended polyol product

Production operators unload the IBCs containing the imported polymer solution Terate 2451 V (70-85% polymer) into the general chemical store where they are kept until transfer to the formulation area.

In the formulation area the production operators connect hoses to the valves on the IBCs and the polymer solution is pumped directly into the blending tank. Flame retardant, surfactants and stabilisers are also added to the tank and the mixture is blended to give the product Elastopor H 1129/5/0. A quality control sample is taken once during the blending. The contents of the tank are then transferred directly into a dedicated bulk road tanker and transported by road to the polyurethane manufacturing site in Sydney.

Use of blended polyol product for polyurethane manufacture

At the customer site, the blended product Elastopor H 1129/5/0 (60-80% notified polymer) is pumped from the bulk road tanker or the imported IBCs into a bulk storage tank prior to use.

Polyurethane foam panels are made by reacting two-component systems. Component A is typically an isocyanate and Component B is a polyol or polyether. During the manufacture of polyurethane foam panels, the notified polymer will be directly added from the bulk storage tank to a foam mixing line together with 2 catalysts, the isocyanate and a blowing agent. The polyurethane foam panel is manufactured using highly automated five metering feed heads and enclosed processes. The foam manufacture takes place into an empty steel shell on a moving conveyor system. The panels are removed from the conveyor system and placed in racks for curing. Typical curing time is 24 hours. The notified polymer is incorporated into the polyurethane foam at < 50% concentration. The manufactured insulation panels are delivered directly to construction sites for incorporation into the building structure, e.g. cool stores.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
<u>Terate 2541 V</u>			
Transport and storage	5	30 mins/day	4-8 days/month
Store person	3	30 mins/day	2-4 days/month
Formulation operator	3	200 mins/day	2-3 days/month
Quality Control	2	20 mins/day	2-3 days/month
<u>Elastopor H 1129/5/0</u>			
Storage and transport	2	75 mins/week	48 weeks/year
Warehouse	3	90 mins/week	48 weeks/year

Store person	1	6 – 8 hours/week	48 weeks/year
Process Operator	1	40 hours/week	48 weeks/year

Exposure Details

Transport and storage

Transport and storage workers would only be exposed to the notified polymer in the event of a spill or an accidental breach of packaging.

Formulation of blended polyol product

Dermal contact, and limited ocular and inhalation exposure to the notified polymer is possible during certain formulation processes, such as: connecting intermediate bulk containers of the polymer solution (70-85% concentration) by transfer hose to the blending tank; connecting hoses from the tank to the bulk road tanker; and taking quality control samples. However, exposure to significant amounts of the notified polymer is limited because of the personal protective equipment (protective aprons, gloves, boots, face shield) worn by workers.

Use of blended polyol product for polyurethane manufacture

Dermal contact, and limited ocular and inhalation exposure to the notified polymer is possible when handling and connecting intermediate bulk containers of the polyol blend containing the notified polymer (60-80% concentration) by transfer hose to the bulk storage tank. Skin contact from spillages of the polyol blend is also possible when changing the hose between containers.

The manufacturing process for polyurethane foam is highly automated and enclosed. However, it is possible that skin contamination to the notified polymer may occur if pumps and metering devices malfunction during foam manufacture. Skin and eye contamination during cleaning and repair of the equipment may also occur. Operators will wear chemical resistant gloves, impervious protective clothing, splash goggles or safety glasses with side-shields. Organic cartridge respirators will also be worn if vapour or misting occurs. Local exhaust ventilation is in place to minimise vapour or misting. Since isocyanate is used during foam manufacture, special precautions on the safe handling of isocyanate will also be observed.

There is no potential for direct exposure to the notified polymer after foam manufacture, since the notified polymer is entrained into the foam.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. It will either be imported as a formulated product, or as a component of a polymer solution for blending into a formulated product. This formulated product will be used for the manufacture of rigid polyurethane foam for use in insulation panels for the construction industry. Environmental release of the notified polymer is unlikely to occur following accidental spillage of imported containers containing the notified polymer during importation (shipping), handling, storage or domestic transportation due to established emergency response procedures and environmental controls. Directions are provided on the label and Material Safety Data Sheet for handling, bundled storage, emergency response and spill clean up to minimise the environmental impact of a spill incident. Imported container size (1000 kg) and construction specifications (metal/plastic IBCs) will also limit the extent of a spill.

Prior to the proposed formulation in Australia, containers holding the notified polymer will be transported directly from the Sydney port facility to the contracted warehouse for storage. The containers will then be delivered direct to the customer site for decanting into a bulk storage tank prior to blending into a rigid polyurethane foam product. Blending is mostly undertaken using automated pumping and mixing procedures in enclosed systems and spillage is not expected.

The polymer solution used for local formulation in Australia will be imported at a level of 40-60 IBCs per month. The empty IBCs will be cleaned out on site with water. Expected residues are at a maximum of 1 kg per IBC (1/1000 = 0.1%). The notifier indicates that based on the worst case of 60 IBCs per month (720 per annum) it is expected that approximately 504-612 kg of the polymer will be

discharged per annum to effluent. However, based on the maximum import volume of 2000 tonnes, it is expected that there will be up to 2 tonnes of the notified polymer per year that will be discharged to effluent at the Altona site. After blending, the contents of the blending tank will be drummed into a 20 tonne bulk road tanker, which will transport the blended product directly to the customers in Sydney. The tankers will not be cleaned during the blending runs.

During incorporation of the notified polymer and manufacture of polyurethane foam products, water is not used in the process and generation of aqueous waste streams containing the notified polymer is not anticipated. Off-specification products and scrap materials (1-2% of the import volume of the notified polymer) is likely to be sent to landfill for disposal. Prior to the proposed formulation in Australia, imported containers are not rinsed after use at the customer site, but are collected by an approved container reconditioning contractor for reconditioning and/or disposal. The collected IBCs are likely to be cleaned with the use of solvents due to the low miscible nature of the product. It is expected each empty IBC will contain less than 1 kg of product remaining when taken from the customer site to the approved container reconditioning contractor. As the product will contain 60-80% notified polymer, we would expect each empty IBC to contain 0.6-0.8 kg prior to cleaning. Therefore, in a year this will amount to < 800 kg per annum entering the waste stream from empty IBCs. The solvent cleaning mixture containing the notified polymer will be taken off-site for incineration.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be entrained in the rigid foam panel and tends not to leach, and the foam product containing the notified polymer will be protected from exposure to water by the outer steel sheet lining. Degradation of the foam matrix may occur, usually giving a friable dusty surface, if exposed to sunlight over a long period; however, the foam products will be protected by the outer steel sheet lining. No information on the stability of the finished foam product or long term fate of the notified polymer in finished foam products is available for this submission. Foam products containing the notified polymer will have widespread use in the construction industry (e.g. cool stores), mostly in the developed areas in Australia.

5.5. Disposal

Prior to the proposed formulation in Australia, residues of the notified polymer in emptied imported IBCs will not be rinsed but will be collected by an approved container reconditioning contractor for either disposal, recycling or IBC reconditioning. However, in the formulation process residues from the emptied imported IBCs will be discharged to effluent. No wastewaters containing the notified polymer are generated during manufacture of foam products. A small quantity of waste may be generated after each foam batch is produced (e.g. < 100 kg/annum) which will be reused in the next batch or collected by waste disposal contractor for solid waste disposal. Products containing the notified polymer will have widespread disposal in Australia at the end of their useful life and waste finished products will be mostly sent to landfill for disposal.

5.6. Public exposure

Public exposure during polyurethane manufacture is expected to be negligible. Public exposure to formed polyurethane can occur during the construction stage of public buildings (e.g. cool stores). At this stage, the notified polymer is contained within the polyurethane matrix and the potential for public exposure to the notified polymer is therefore considered to be negligible.

The potential for exposure of the public to the notified polymer during normal industrial storage, handling and transportation is negligible, except in the case of an accident. The robust packaging will protect the contents from being released during normal handling.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Amber liquid with amine-like odour (Elastopor H 1129/5/0)
Freezing Point	< 0°C (Elastopor H 1129/5/0)

METHOD	Not disclosed. Information provided by notifier
Remarks	Solidification temperature.
Boiling Point	Not determined.
Remarks	The notified polymer is never isolated from the solution.
Density	> 1000 kg/m ³ at 20°C (Elastopor H 1129/5/0)
METHOD	DIN 51757
Remarks	Value given on MSDS. Study report not provided.
Vapour Pressure	< 1.0 kPa at 20°C (Elastopor H 1129/5/0)
METHOD	Not disclosed
Remarks	Value given on MSDS. Study report not provided.
Water Solubility	48 g/L at 20°C
METHOD	OECD TG 105 Water Solubility.
Remarks	On the basis of the preliminary test, a shake flask method was used to determine the solubility of the notified polymer at pH 1, 7 and 10 and in n-octanol. Test solutions were prepared and mixed at 30°C for 24, 48 and 72 h. Prior to analysis by liquid chromatography the test solution was removed from shaker and was kept at 20°C for 24 h, with occasional stirring. The notified substance was partially soluble in water and n-octanol and the total amount of product dissolved in a given solvent was dependent on the notified polymer/solvent ratio and the amount of residual monomer in the product. The solubility of the notified polymer, minus the residual monomer, was determined to be 48 g/L in water and 294 g/L in octanol.
TEST FACILITY	Test Facility A (2001)
Hydrolysis as a Function of pH	
Remarks	The notified polymer is expected to hydrolyse to a slight extent in the environmental range of pH 4 – 9. The rate of hydrolysis appears to be higher under alkaline conditions.
TEST FACILITY	Test Facility A (2001)
Partition Coefficient (n-octanol/water)	log Pow ~0.8
Remarks	Based on results from water solubility study (solubility in n-octanol = 294 g/L)
TEST FACILITY	Test Facility A (2001)
Adsorption/Desorption	Koc = 10
Remarks	An estimated Koc of 10 based on EPIWIN calculations indicates that the notified polymer is likely to be mobile in soil. However, the notifier indicates that on the basis of the structure, the notified polymer is likely to associate with the soil matrix and is expected to be immobile in soil as indicated in the Level III Fugacity Model where the notified polymer (where the monomer number = 1) will partition principally to soil.
Dissociation Constant	Not determined.
Remarks	As the notified polymer contains no dissociative functional groups, it is not expected to dissociate under normal environmental conditions.
Particle Size	Not applicable

Remarks	The notified polymer is never isolated from the solution.
Flash Point	>110°C (Elastopor H 1129/5/0)
METHOD	DIN 51758
Remarks	Value given on MSDS. Study report not provided
Flammability Limits	Not determined
Remarks	Based on the flash point of a 60-80% solution of the notified polymer, the notified polymer is not expected to be a flammable liquid.
Autoignition Temperature	Not determined
Remarks	The notified polymer is not expected to autoignite under normal conditions of use.
Explosive Properties	
Remarks	Expected to be stable under normal conditions of use. The notified polymer contains no functional groups that would infer explosive properties.
Reactivity	
Remarks	The polymer and polymer solution are expected to be stable under normal conditions of use. The notified polymer is not expected to have oxidising properties. The imported product containing the notified polymer is likely to be incompatible with acids, oxidising agents. An exothermic reaction is likely to occur when the imported product is reacted with isocyanates. There are no known conditions that are likely to contribute to the instability of the notified polymer. Thermal decomposition of the notified polymer may release toxic fumes containing products of combustion such as carbon monoxide and carbon dioxide.

7. TOXICOLOGICAL INVESTIGATIONS

A full suite of toxicological data for the notified polymer was not submitted. For the reasons detailed below, it was concluded that the polymer in Elastopor H 1129/5/0 is of low toxicological concern and only an acute oral toxicity study, an irritation study and a sensitisation study were required for this polymer.

A polyester with a molecular weight less than or equal to 1000 is a polymer of low concern under *the Act* if it is made from prescribed reactants. The notified polymer is a polyester constructed from two prescribed reactants and one reactant that is not prescribed. The reactant not on the prescribed list is structurally related to a prescribed reactant. The notified polymer does not contain any high or moderate concern reactive functional groups.

An organism must absorb a chemical in order to cause an adverse health effect. The ability of a molecule to pass through biological membranes and therefore be absorbed by organisms generally decreases with increasing molecular weight. It is generally accepted that polymers with MW exceeding 1000 are unlikely to pass through biological membranes (Anliker et al., 1988 and Connell DW, 1989). Whilst the molecular weight is < 1000, the notified polymer is a relatively large molecule and as such absorption through the skin is therefore expected to be low.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral	LD50 >5.0 mL/kg bw, low toxicity
Rat, acute dermal	not performed.
Rat, acute inhalation	not performed.
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation –non-adjuvant test.	no evidence of sensitisation.
Rat, repeat dose toxicity	not performed.
Genotoxicity – bacterial reverse mutation	not performed.
Genotoxicity – in vitro	not performed.
Genotoxicity – in vivo	not performed.

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (~90% purity)
METHOD	In house method.
Species/Strain	Rat/ Sprague-Dawley (CrI: CD®(SD)BR VAF/Plus®)
Vehicle	Test substance administered as supplied.
Remarks - Method	No significant deviations from OECD TG 401 Acute Oral Toxicity – Limit Test

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5M	5.0	2
II	5F	5.0	0

LD50	>5.0 mL/kg bw
Signs of Toxicity	Signs of toxicity included urine stains of the abdominal fur, excess salivation, chromodacryorrhea, chromorhinorrhea and laboured breathing. These signs were noted during week 1 only. Two males were found dead (one on Day 1 and one on Day 3) probably due to dosing accidents. All surviving animals had favourable weight gains throughout the end of the 14 days observation period.
Effects in Organs	The two males that died were found to have test material in the thoracic cavity. There were no other remarkable necropsy findings.
Remarks - Results	It was determined by this study that the acute median lethal oral dose of the notified substance in rats is greater than 5.0 mL/kg bw. Based on a density value of > 1000 kg/m ³ this would equate to a LD50 value greater

than 5.0 g/ kg bw.

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

TEST FACILITY Hoechst-Roussel (1995a)

7.2. Irritation – skin

TEST SUBSTANCE Notified polymer (~90% purity)

METHOD In house method
 Species/Strain Rabbit/New Zealand White
 Number of Animals 3M, 3F
 Vehicle Test substance administered as supplied
 Observation Period 72 h
 Type of Dressing Occlusive
 Remarks - Method The only significant protocol deviation from OECD TG 404 Acute Dermal Irritation/Corrosion was an increase in the number of animals used for this study (Six used as opposed to the three required in OECD 404) and the use of an occlusive dressing.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	0.06	1	24 h	0
<i>Oedema</i>	0	0	0	0

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

Remarks - Results At 24 hours postdosing, very slight erythema was noted in one animal. No other signs of erythema, eschar or oedema were noted in any of the animals throughout the 72-hour observation period.

CONCLUSION The notified polymer is slightly irritating to skin.

TEST FACILITY Hoechst-Roussel (1995b)

7.3. Irritation – eye

TEST SUBSTANCE Notified polymer (~90% purity)

METHOD In house method.
 Species/Strain Rabbit/New Zealand White
 Number of Animals 3M, 3F
 Observation Period 96 h
 Remarks - Method The only significant protocol deviation from OECD TG 405 Acute Eye Irritation/Corrosion was an increase in the number of animals used for this study (Six used as opposed to the three required in OECD 405)

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
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<i>Conjunctiva: redness</i>	0.3	1	< 96 h	0
<i>Conjunctiva: chemosis</i>	0	0	0	0
<i>Conjunctiva: discharge</i>	0	1	< 24 h	0
<i>Corneal opacity</i>	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	0

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

Remarks - Results	Slight conjunctival inflammation was observed in all six test animals one hour after instillation. Slight conjunctival discharge was observed in two of the animals one hour after instillation, but this had resolved 24 hours after instillation. The number of animals affected decreased over the test period, with no animals affected 96 hours after instillation.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	Hoechst-Roussel (1995c)

7.4. Skin sensitisation

TEST SUBSTANCE	Notified polymer (~90% purity)
METHOD	In house method.
Species/Strain	Guinea pig/Hartley-derived albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 5M, 5F Control Group: 5M, 5F
INDUCTION PHASE	Induction Concentration: topical: 100%
Signs of Irritation	Slight, patchy erythema (score of \pm) was observed in 7 of the 10 animals.
CHALLENGE PHASE	
1 st challenge	topical: 100%
Remarks - Method	The only significant protocol deviations from OECD TG 406 Skin Sensitisation – Buehler were: <ol style="list-style-type: none"> 1. The number of animals in the test group was only half the number required by OECD TG 406 (20 animals required). 2. The dermal grading system included an additional rating of \pm, (score of 0.5) for slight, patchy erythema.

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after:</i>			
		<i>1st challenge</i>		<i>2nd challenge</i>	
		<i>24 h</i>	<i>48 h</i>	<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	100%	2/10	0/10		
<i>Control Group</i>	100%	3/10	1/10		

Remarks - Results	The only signs of dermal irritation observed were slight, patchy erythema (a dermal grading score of \pm). This was observed after 24 hours in 2 of the 10 test animals and 3 of the 10 control animals. Therefore, there was no significant difference between test and control animals. A rechallenge was not performed. The positive control confirmed the sensitivity of the test.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY Springborn Laboratories, Inc. (1995)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.1.2. Bioaccumulation

The notified polymer's relatively high molecular weight and the low Kow of 0.8 suggests that it is unlikely to cross biological membranes and bioaccumulate (Connell 1989).

8.2. Ecotoxicological investigations

8.2.1(a). Acute toxicity to fish

TEST SUBSTANCE	Notified polymer (~90% purity)
METHOD	TSCA Environmental Effects Testing Guideline 797.1400.
Species	Bluegill sunfish (<i>Lepomis macrochirus</i>)
Exposure Period	96 h
Auxiliary Solvent	acetone
Water Hardness	74 mg CaCO ₃ /L
Analytical Monitoring	None
Remarks – Method	No significant protocol deviations. The acute toxicity of the notified polymer to bluegill sunfish was conducted in a 96-h test under static condition. Nominal concentrations of 1.25, 2.5, 5.0, 10.0 and 20.0 mg/L and controls were used in the treatment. All treatments were duplicated resulting in a total of 20 bluegill per treatment. Mortality and any abnormalities in the behaviour or physical appearance of the fish were also noted. Temperatures, pH and dissolved oxygen were measured in each replicate daily with surviving fish.

RESULTS

Concentration mg/L Nominal Actual	Number of Fish	Mortality			
		24 h	48 h	72 h	96 h
Control	20	0	0	0	1
Solvent control	20	0	1	1	1
1.25	20	0	0	1	4
2.50	20	0	0	2 ^b	3
5.00	20	0	0	2	2
10.0	20	0	0	1 ^b	3
20.0	20	0	1 ^a	2	3

a one fish appeared dark in colouration

b one fish appeared lethargic

LC50	> 20.0 mg/L at 96 hours.
NOEC	20 mg/L at 96 hours.
Remarks – Results	During the test solutions at concentrations ≥ 10.0 mg/L were cloudy and undissolved chemical was observed at 20.0 mg/L. In addition, a film was observed on the surface of the water at 10.0 mg/L. Test solutions at concentrations ≤ 10 mg/L remained clear and colourless throughout the test. Mortality of bluegill fish exposed for 96 h to the notified polymer ranged from 10% at 5 mg/L to 20% at 1.25 mg/L. No significant sublethal effects were observed. Temperatures, pH and dissolved oxygen were within acceptable levels during the test.

CONCLUSION The notified polymer is considered to be at most slightly toxic to bluegill

sunfish.

TEST FACILITY Toxikon Environmental Sciences (1995a)

8.2.1(b). Acute toxicity to fish

TEST SUBSTANCE Notified polymer (~90% purity)

METHOD TSCA Environmental Effects Testing Guideline 797.1400.

Species Juvenile sheepshead minnow (*Cyprinodon variegatus*)

Exposure Period 96 h

Auxiliary Solvent Acetone

Water Hardness Not provided

Analytical Monitoring None

Remarks – Method The acute toxicity of the notified polymer to juvenile sheepshead minnow was conducted in a 96-h test under static condition. Nominal concentrations of 1.25, 2.5, 5.0, 10.0 and 20.0 mg/L and controls were used in the test. All treatments were duplicated resulting in a total of 20 fish per treatment. Mortality and any abnormalities in the behaviour or physical appearance of the fish were also noted. Temperatures, pH and dissolved oxygen were measured in each replicate daily with surviving fish.

RESULTS

Concentration mg/L Nominal Actual	Number of Fish	Mortality			
		24 h	48 h	72 h	96 h
Control	20	0	0	0	0
Solvent control	20	0	0	0	0
1.25	20	0	0	0	0
2.50	20	0	0	0	0
5.00	20	0	0	0	0
10.0	20	0	0	0	0
20.0	20	0	0	0	0

LC50 > 20.0 mg/L at 96 hours.

NOEC 20 mg/L at 96 hours.

Remarks – Results At test initiation, solutions at concentrations ≥ 5.0 mg/L were cloudy and had a film on the surface of the water. In addition to the surface film and cloudiness, undissolved chemical was also present at 20.0 mg/L. After 48 h of exposure, solutions at ≥ 5.0 mg/L were cloudy, a film was visible on the surface at concentrations ≥ 10.0 mg/L and undissolved chemical was observed at 20.0 mg/L. At termination undissolved chemical still remained at 20.0 mg/L indicating all test compound was not in solution at concentration ≥ 20 mg/L. Mortality of sheepshead minnow was zero percent in the control and all test concentrations. Temperatures, pH and dissolved oxygen were within acceptable levels during the test.

CONCLUSION The notified polymer is considered to be at most slightly toxic to sheepshead minnow.

TEST FACILITY Toxikon Environmental Sciences (1995b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer (~90% purity)

METHOD TSCA Environmental Effects testing Guideline 797.1930

Species Mysid (*Mysidopsis bahia*)

Exposure Period	96 h
Auxiliary Solvent	Acetone
Water Hardness	Not provided
Analytical Monitoring	None
Remarks - Method	The acute toxicity of the notified polymer to mysid was conducted in a 96-h test under static saltwater conditions. Based on the range-finding test, nominal concentrations of 1.25, 2.5, 5.0, 10.0 and 20.0 mg/L and controls were used in the test. All treatments were duplicated resulting in a total of 20 mysid per treatment. Mortality and any abnormalities in the behaviour or physical appearance of mysid were also noted. Temperatures, salinity, pH and dissolved oxygen were measured in each replicate daily with surviving mysid.

RESULTS

<i>Concentration mg/L Nominal</i>	<i>Number of mysid</i>	<i>Mortality</i>			
		<i>24 h</i>	<i>48 h</i>	<i>72 h</i>	<i>96 h</i>
Control	20	0	0	0	0
Solvent control	20	0	0	0	0
1.25	20	0	0	0	0
2.50	20	0	0	0	0
5.00	20	0	0	0	0
10.0	20	0	0	0	0
20.0	20	0	0	0	0

LC50	> 20.0 mg/L at 96 hours.
NOEC	20 mg/L at 96 hours.
Remarks – Results	<p>Due to the high mortality response and insolubility of the test substance during the range finding tests, a further test was conducted to determine if the mortality was linked to the presence of the undissolved substance. The results suggest that the mortality observed in the range-finding tests may have been either due to the physical effects of the undissolved test substance present on the bottom of the test chambers where the mysids reside or due to direct ingestion of the undissolved test substance.</p> <p>Similar solution behaviours were observed in the test concentrations as for sheepshead minnow during the test. Mortality of mysids was zero percent in the control and all test concentrations. Temperatures, salinity, pH and dissolved oxygen were within acceptable levels during the test.</p>
Conclusion	The notified polymer is considered to be at most slightly toxic to mysids.
TEST FACILITY	Toxikon Environmental Sciences (1995c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer is considered to be highly soluble in water. Its low partition coefficient of 0.8 indicates that it is likely to partition to the aqueous phase. The low calculated Koc value of 10 indicates that it is likely to be mobile in soils. As the notified polymer will be entrained in

the rigid foam panel and protected from exposure to water by the outer steel sheet lining, it is expected that the environmental exposure of the notified polymer will be low.

All of the residues generated during cleaning of the empty IBCs used in the foam manufacture will be incinerated leading to predominantly air emission of oxides of carbon and water. No wastewaters containing the notified polymer are generated during manufacture of foam products. A small quantity of waste (< 100 kg/annum) will be generated after each foam batch is produced. This will be reused in the next batch or collected by waste contractor for solid waste disposal. However, in the formulation process at the Altona site, residues from the emptied IBCs (up to 2 tonnes) will be discharged to effluent corresponding to 2000 kg/260 working days = 7.70 kg/day. Based on an effluent discharge at an average daily rate of 361 ML/day at the Western Treatment Plant in Victoria (Social and Environment Report 2004-05), this will amount to approximately 7.7 kg/361 ML ~ 21 µg/L.

Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the PECs of the notified polymer in rural areas and coastal water may approximate 21 and 2.1 µg/L, respectively.

SIMPLETREAT modelling is not possible due to the lack of an accurate vapour pressure result. However, the high water solubility suggests that virtually all will be retained in the water column.

Partitioning to biosolids in STPs Australia-wide is unlikely to occur assuming negligible attenuation in sludge during the STP process due to the high water solubility.

The effluent re-use (eg. irrigation purposes) concentration of the notified polymer may potentially approximate 21 µg/L, assuming virtually all remains in solution during the STP process. STP effluent re-use for irrigation occurs at Western Treatment Plant. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m³). Using these assumptions, irrigation with a concentration of 21 µg/L may potentially result in a soil concentration of approximately 2.1 mg/kg assuming accumulation of the notified polymer in soil for 10 years under repeated irrigation.

The worst-case PECs values are summarised below:

Sewage effluent/coastal city = 2.1 µg/L

Sewage effluent/rural areas = 21 µg/L.

Soil concentrations following 10 years irrigation with effluent = 2.1 mg/kg.

Products containing the notified polymer at the end of their useful life will be mostly disposed of by landfill. It is anticipated that prolonged residence in an active landfill will eventually degrade the notified polymer via biotic and abiotic processes.

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate that the notified polymer is at most slightly toxic to aquatic life. The sensitive species mysid (*Mysidopsis bahia*) where the acute EC50 is > 20 mg/L will be used as the toxicological end point.

<i>Organism</i>	<i>Duration</i>	<i>Endpoint</i>	<i>Concentration (mg/L)</i>
Bluegill sunfish (<i>Lepomis macrochirus</i>)	96 h	LC50	> 20
Sheepshead minnow (<i>Cyprinodon variegates</i>)	96 h	LC50	> 20
Mysid (<i>Mysidopsis bahia</i>)	96 h	EC50	> 20

The Predicted No Effect Concentration (PNEC) is > 20 µg/L, using a safety factor of 1000 and

the acute 96 h EC50 for mysid of > 20 mg/L.

9.1.3. Environment – risk characterisation

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	21	>20	<1.1
Q - Ocean:	2.1	>20	<0.11

The risk quotients indicate an acceptable risk for both marine and freshwater organisms given that the PNEC value is >20 µg/L. Further, this is a worst case scenario without taking movement to sludge into account in the STP and the Western Treatment Plant only releases to Port Phillip Bay. The ecotoxicity data provided and the relatively low release to water during the formulation process indicate that there is unlikely to be an environmental risk in the aquatic compartment.

Limited environmental release of the notified polymer is anticipated during the manufacture of the finished product. Even in the case of accidental spillage, there are established emergency responses and environmental controls to minimise exposure. Residues remaining in containers are expected to be recovered and disposed of by incineration or landfill. Therefore, the notified polymer is unlikely to pose an environmental risk under the proposed use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The major route of exposure to workers involved in formulation and polyurethane foam production is expected to be dermal. Dermal exposure may occur when connecting transfer hoses between intermediate bulk containers of polymer solutions, blending or storage tanks, and tankers, as well as during cleaning and repair of the equipment. Limited ocular and inhalation exposure is also possible during these processes. The exposure of the workers is expected to be low due to the automated and enclosed nature of most of the formulation and foam production processes, as well as the use of PPE and local exhaust ventilation.

After foam manufacture there is no potential for worker exposure as the notified polymer is contained within the polymer matrix.

9.2.2. Public health – exposure assessment

Public exposure to the notified polymer is expected to be negligible as it is used only in industrial settings. During its use in the construction industry the polymer is contained within the polyurethane matrix and will therefore not be available for public exposure.

9.2.3. Human health – effects assessment

Based on the molecular weight of the majority of the polymer species, the lack of moderate or high concern reactive functional groups and the similarity in structure to polyesters meeting the definition of a polymer of low concern, the notified polymer is considered to be of low toxicity. This is supported by the results of an acute toxicity study in rats, irritation studies in rabbits and a skin sensitisation study in guinea pigs.

Acute toxicity

In an acute oral toxicity study conducted on a ~90% solution of the notified polymer an LD50 of >5.0 mL/kg bw was found. The notified polymer is therefore considered to be of low acute oral toxicity. No dermal toxicity study had been conducted on the notified polymer. However, dermal absorption through the skin is expected to be low. No inhalation toxicity study had been conducted on the notified polymer. However, due to the predicted low vapour pressure, the form of the notified polymer (solution) and the low acute oral toxicity of the notified polymer, it is unlikely that atmospheric concentrations of the notified polymer would be high enough to cause an adverse effect in humans.

Irritation and Sensitisation.

Based on a skin and eye irritation study conducted on a ~90% solution of the notified polymer, the notified polymer is considered to be slightly irritating to skin and slightly irritating to the eye. In a skin sensitisation study conducted on a ~90% solution of the notified polymer, the notified polymer was found to not induce skin sensitisation.

9.2.4. Occupational health and safety – risk characterisation

The exposure of the workers during the formulation of the blended polyol product and during polyurethane foam manufacture is limited due to the automated and enclosed nature of the processes, as well as the use of PPE and local exhaust ventilation. In addition, the notified polymer is expected to have a low toxicity, although it was shown to be a slight skin and eye irritant. Therefore, the risk to workers is expected to be low. However, due to the slight skin and eye irritancy potential of the notified polymer personal protective equipment (protective eyewear, protective clothing and impermeable gloves) should be worn during processes when dermal and ocular exposure are possible (i.e. when connecting transfer hoses and during cleaning and repair of the equipment).

9.2.5. Public health – risk characterisation

Public exposure to the notified polymer is expected to be negligible and therefore the risk to public health is also expected to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS**10.1. Hazard classification**

Based on the limited data available the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

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

10.2. Environmental risk assessment

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

10.3. Human health risk assessment**10.3.1. Occupational health and safety**

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

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET**11.1. Material Safety Data Sheet**

The MSDS of Terate 2541 V and Elastopor H 1129/5/0 (products containing the notified polymer) provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the

responsibility of the applicant.

11.2. Label

The labels for Terate 2541 V and Elastopor H 1129/5/0, containing the notified polymer, were provided by the notifier. The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in the products Terate 2541 V and Elastopor H 1129/5/0:
 - Avoid skin and eye contact
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the products Terate 2541 V and Elastopor H 1129/5/0:
 - Chemical resistant gloves
 - Protective clothing
 - Safety goggles

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

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

Disposal

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

Storage

- The following precautions should be taken regarding storage of the notified polymer:
 - The notified polymer solution should be stored separate from acids, oxidising agents and isocyanates.

Emergency procedures

- Spills/releases of products containing the notified polymer should not be released to waterways, stormwater, soils or sewerage system.
- Spills/leaks of product should be contained by applying absorbent materials to the spill and/or pumping to labelled sealable container(s). Scoop absorbed substance into labelled sealed containers. Carefully collect all spill/leftover residues. Remove contaminated soil and place in labelled sealable containers for appropriate disposal. Clean contaminated surfaces with an excess of water and contain and collect all wash waters for appropriate disposal. Wash equipment and clothing after clean-up and contain wash waters for appropriate disposal and dispose of used personal protection

equipment appropriately. Dispose of all wastes in a manner consistent with local waste management regulations.

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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