File No: NA/260

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Ixol B 251

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Ixol B 251

1. APPLICANT

Australian Urethane Systems Pty Ltd of 5 Prince William Drive SEVEN HILLS NSW 2147 has submitted a standard notification statement in support of their application for an assessment certificate for Ixol B 251.

2. IDENTITY OF THE CHEMICAL

Trade Name:	Ixol B 251
Method of Detection and Determination:	infrared (IR) spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark brown, viscous liquid with a slight ether-like odour
Melting Point:	< -100°C
Boiling Point:	> 160°C (decomposition)
Specific Gravity:	1.58
Vapour Pressure:	0.47 kPa at 20°C
Water Solubility:	450 $g.kg^{-1}$
Partition Co-efficient (n-octanol/water):	log K_{ow} = 0.2 (calculated)
Hydrolysis as a Function of pH:	no significant hydrolysis (independent of pH)

Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	196°C
Flammability Limits:	non-flammable
Autoignition Temperature:	350°C
Explosive Properties:	none
Reactivity/Stability:	stable up to 50°C

Comments on Physico-Chemical Properties

The presence of hydroxyl groups on the notified chemical enables it to hydrogen bond with water and as a result imparts water solubility (1). The solubility was determined gravimetrically by equilibrating the product, Ixol B251, with water then separating and removing the water under vacuum at 50°C for 50 hours.

The notified chemical does not contain any functional groups which are likely to undergo hydrolysis in the environmental pH range (pH 4-9).

Because of its high water solubility and relatively low partition coefficient, the chemical is not expected to adsorb to organic matter and sediments to any great extent. High mobility in water and soil is expected.

The substance does not contain any groups likely to gain or lose a proton in the environmental pH range.

4. PURITY OF THE CHEMICAL

Degree of Purity:	99.85%
Toxic or Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	none
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as part of the components of a fire-retardant polyurethane foam used for insulation in buildings. The foam may also be sprayed externally onto buildings and coated. The notified chemical will be imported neat in 200 L drums at a rate of less than 100 tonnes per annum for the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be transported by road to the notifier's premises. Transport and storage of the drums containing the notified chemical should not result in worker exposure except in the event of an accident.

The notified chemical will be reformulated at the notifier's premises. For reformulation to occur at a site other than that of the notifier, a secondary notification will be required (see section 15 below).

Reformulation occurs in a stainless steel vessel. The vessel is charged by fitting a valve with a rotating outlet, to the drum, and allowing the material to flow into the tank. The valve is then rotated which prevents spillage from dripping, until the drum is placed back on a storage pallet. Following mixing with other chemicals, in such a way to avoid splashing, the resultant blend is filled into 200 litre drum. The potential for exposure during these operations is expected to be limited given the precautions taken.

During end use, the polyurethane foam is produced by mixing the blend together with isocyanate in a machine and applying to the space to be filled or on to building surfaces. Possible applications for the foam are as insulation in building construction when fire retardancy is important. The drum containing the blend is placed near the machine, the bung removed and a transfer pump placed in position and locked into the 50 mm bung. When the drum is empty, the standard procedure is to unlock the collar and withdraw the pump, which has liquid free external sides. Limited dermal and ocular exposure to residues is possible during these operations.

Dermal, ocular and inhalational exposure to the notified chemical is possible when spraying polyurethane foam while the foam is still in the form of a liquid. It is recommended that this operation should only be carried out using approved person protective equipment.

7. PUBLIC EXPOSURE

No public exposure is expected as a result of transport and storage of the notified chemical following importation except in the event of an accident. Exposure of the public as a result of industrial use is likely to be negligible. Minor public exposure may result from disposal of unused polyurethane foam.

8. ENVIRONMENTAL EXPOSURE

Release

At the reformulation site, the drums are stored on a pallet in a pre-allocated space i a pallet racking system. There is limited opportunity for release to the environment during the reformulation and repackaging process. Decanting of the liquid into 205 drums for dispatch to end users is carried out using a closed pipe and pumping system. The empty drums and residue of Ixol B251 are disposed of by way of recyclers. If the drums cannot be reused, they are crushed and landfilled.

Most environmental exposure comes from *in situ* spraying of the polyurethane insulation foams. These will be used both internally (mainly for void filling in steel, brick or some other media where both physical and UV access is eliminated) or externally (onto walls and external roofs of poultry sheds or industrial buildings or tanks). All external applications will be coated with a high grade coating (i.e. urethane, acrylic, polyester or poly vinyl ester). The insulation foams will be applied using commercially available types of spray pour machines. The mixture containing the notified chemical and isocyanate are mixed in a mixing chamber within the gun before being expelled. The mixture (including the notified chemical) reacts with the isocyanate to form the inert fully crosslinked foam (2).

Release through this process will come as a result of spillage during pouring from drums, vapour and/or overspray, and cleaning of application equipment. Spillage procedures are outlined in the material safety data sheet (MSDS), which are to dike large quantities of liquid with sand or earth, and remove the product with an inert absorbent. When spraying *in situ* structures, spraying is carried out at close range, and the foam stabilises quickly. Therefore release to the environment will be contained. Application equipment is seldom cleaned, as usually another grade or type of system is pumped through the machine. If cleaning does take place, oil or similar material is used as a flushing agent, and this material is collected in drums and disposed of via authorised liquid waste disposal companies. Empty drums of the Ixol B251/mixture are either returned to the supplier for refilling, or sold to drum recyclers.

It is possible to divide flame retardants into groups of additive and reactive chemicals. Reactive flame retardants are incorporated into the polymeric material by covalent bonding between the polymer and the flame retardant, while additive flame retardants are only mixed with the polymer. This second type may migrate out of the products and cause a diffuse contamination of indoor and outdoor environments during the whole lifetime of the product. Reactive flame retardants are immobilised in the products and thus not of the same concern for environmental contamination (3). As the notified chemical will be covalently linked to the foam matrix it can be classed as a reactive flame retardant. Hence, release through rigid polyurethane foams (PUR products) once *in situ*, or as waste will be low.

The combustion of the imported product or the PURs and PUIRs (polyurethane foams modified by isocyanurate rings) containing the notified chemical may release toxic gases, including hydrogen chloride (HCl), hydrogen bromide (HBr) and

carbon monoxide. Additionally, highly toxic chlorinated and brominated dibenzodioxins and dibenzofurans, formed through the *de novo* synthesis (4, 5), may be released when either the imported product or PURs and PUIRs containing the fire retardant are burned. The amount produced is dependent on the concentration of the fire retardant in the final product, and the temperature of the fire. Combustion of the PURs and PUIRs may also release hydrogen cyanide (HCN).

Fate

The majority of the notified chemical will share the same fate as the PURs and PUIRs into which it has been incorporated. It is anticipated that these products will be disposed of to landfill at the end of their useful life, along with the building materials to which they have been applied. Being a reactive flame retardant, ie. one which is incorporated into the polymeric material by covalent bonding, the likelihood of release to the environment through this method of disposal is low.

The notifier has outlined disposal procedures as to "Comply with local and national regulations. Dispatch the product to an authorised hazardous waste incinerator". Due to the possibility of combustion releasing toxic gases, landfill would be a preferred option for the ultimate fate of waste imported product.

The substance was examined for biodegradation potential using EEC Directive 92/69, Part C.4-E (Closed Bottle Test), and OECD Test Guideline 301D. The results were 16% biodegradation after 28 days (6). Hence, the chemical can not be classified as readily biodegradable.

The company states there are no data for bioaccumulation. Despite the presence of bromines, the high water solubility and low partition coefficient of the notified chemical indicate that it is unlikely to bioaccumulate (7).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Ixol B 251

Test	*Species*	*Outcome*	*Reference*

acute oral toxicity	rat	LD_{50} = 1 337 mg.kg^{-1}	(8)
skin irritation	rabbit	non-irritant	(9)
eye irritation	rabbit	moderate irritant	(10)
skin sensitisation	guinea pig	non-sensitiser	(11)

9.1.1 Oral Toxicity (8)

Species/strain:	rat/Wistar
Number/sex of animals:	5 **males** per dose group
Observation period:	14 days
Doses/Method of administration:	0, 625, 1 250, 2 500 and 5 000 mg.kg^{-1} by stomach tube

Clinical observations: no signs were observed in control and animals treated with 625 $mg.kg^{-1}$; for 1 250 $mg.kg^{-1}$ moderate to severe signs (mostly) with onset between 6 and 24 hours after dosing were as for 2 500 $mg.kg^{-1}$ except that twitches, diminished righting reflex and salivation were not observed; for 2 500 $mg.kg^{-1}$ moderate to severe signs with onset mostly between 1.5 and 6 hours after dosing were as for 5 000 $mg.kg^{-1}$ except for dispersion and open mouth but including catatonia, salivation and diminished grooming; for 5 000 $mg.kg^{-1}$, 10 to 30 minutes after dosing, mostly moderate to severe dispersion in cage, apathy, twitches, decreased respiration rate, decreased alertness and startle response, decreased locomotor activity, diminished righting reflex, abnormal posture and gait, piloerection, abnormal touch response, paralysis, open mouth, positional passivity, decreased limb and body tone and hypothermia were observed

Mortality:

Dose ($mg.kg^{-1}$)	**625**	**1 250**	**2 500**	**5 000**
Mortality	0/5	3/5	4/5	5/5

Morphological findings: for rats that died as a result of treatment, irritation of the gastro-intestinal tract, pale liver, congested lymph nodes and red spots on the lungs; one surviving rat of the 2 500 $mg.kg^{-1}$ dose group had a slightly enlarged liver and a slightly irritated fundus

Test method: not specified

LD_{50}: 1 337 (863 - 2 070) $mg.kg^{-1}$

Result: the notified chemical was of moderate acute oral toxicity in rats

Dermal Toxicity

not provided

9.1.2 Inhalation Toxicity

not provided

9.1.4 Skin Irritation (9)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3
Observation period:	72 hours
Method of administration:	0.5 g applied under occlusive patch for 4 hours
Test method:	according to OECD guidelines (12)
Result:	the notified chemical was not irritating to the skin of rabbits

9.1.5 Eye Irritation (10)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	72 hours
Method of administration:	0.1 mL into the conjunctival sac of one eye

Draize scores (13):

	Time after instillation											
Animal	***1 hour***		***1 day***		***2 days***		***3 days***		***7 days***	
Cornea	***o***[a]	***a***[b]	***o***[a]	***a***[b]	***o***[a]	***a***[b]	***o***[a]	***a***[b]	***o***[a]	***a***[b]
1	1[1]	4	2	4	2	2	1	1	0	0
2	0	0	2	3	1	2	1	1	0	0
3	0	0	0	0	0	0	0	0	0	0
Iris	no scores above zero									
Conjunctiva	***r***[c]	***c***[d]	***d***[e]	***r***[c]	***c***[d]	***d***[e]	***r***[c]	***c***[d]	***d***[e]	***r***[c]	***c***[d]	***d***[e]	***r***[c]	***c***[d]	***d***[e]

1	1	0	0	2	1	1	2	1	0	2	0	0	1	0	0
2	1	0	0	2	3	0	2	2	0	1	0	0	0	0	0
3	1	0	0	2	1	0	1	1	0	1	0	0	1	0	0

[1] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Test method: according to OECD guidelines (12)

Result: the notified chemical was moderately irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (11)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 20 test and 20 control animals

Induction procedure: 3 pairs of injections (0.1 mL) into the scapular region:

- Freund's Complete Adjuvant (FCA) 1:1 with water;
- 0.25% notified chemical in 5% (v/v) acetone in Alembicol D;
- 0.25% notified chemical a 1:1 mixture of 5% (v/v) acetone in Alembicol D and FCA

after one week, neat notified chemical was placed on the same area of skin for 48 hours under occlusive dressing

Challenge procedure: two weeks following topical induction, challenge was performed with 5% (v/v) andocclusive dressing for 24 hours

Challenge outcome:

	Test animals			***Control animals***		
Challenge concentration	***24 hours****	***48 hours****	***72 hours***	***24 hours***	***48 hours***	***72 hours***
5%	0/20**	0/20	0/20	0/20	0/20	0/20
10%	0/20	0/20	0/20	0/20	0/20	0/20

* time after patch removal
** number of animals exhibiting positive response

Test method: according to OECD guidelines (12)

Result:	the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity

not provided

9.3 Genotoxicity

9.3.1 Micronucleus Assay in the Bone Marrow Cells of the Mouse (14)

Species/strain:	mouse/Swiss
Number and sex of animals:	5/sex/dose group
Doses:	0, 750, 1 500 and 3 000 $mg.kg^{-1}$
Method of administration:	gavage; vehicle: 1% tragacanth
Test method:	similar to OECD guidelines (12)
Result:	no increase in the proportion of micronucleated bone marrow polychromatic erythrocytes was observed following treatment of mice with the notified chemical

9.4 Overall Assessment of Toxicological Data

The notified chemical was of moderate acute oral toxicity in rats (LD_{50} = 1 337 $mg.kg^{-1}$). It was not a skin irritant in rabbits but was a moderate eye irritant and was not a skin sensitiser in guinea pigs. The

notified chemical was negative in a mouse micronucleus test.

The notifier did not provide all the data required by the Act and variation of schedule requirements was requested for acute dermal toxicity, repeat dose and clastogenicity. The variations were allowed on the basis that the chemical would only be used at the notifier's premises and that engineering controls were sufficient to control exposure.

The notified chemical would be classified as hazardous according to the National Commission's *Approved Criteria for Classifying Hazardous Substances* (15) in relation to acute oral toxicity.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Results of ecotoxicity tests are summarised in the table below. The tests were carried out to OECD Test Methods (12).

Species	***Test***	***Concentrations[a] ($mg.L^{-1}$)***	***Result ($mg.L^{-1}$)***	***Reference***

Guppy (*Poecilla Reticulata*)	96 h acute	0, 125, 250, 500, 750, 1000	LC_{50} = 560 NOEC = 250	(16)
Water Flea (*Daphnia magna*)	48 h acute	0, 63, 125, 250, 500, 1000	EC_{50} = 520 NOEC = 250	(17)
Algae (*Selenastrum capricornutum*)	96 h growth	0, 125, 250, 500, 750, 1000	E_RC_{50} > 1000 E_BC_{50} = 880 NOEC = 250	(18)
Bacteria (*Pseudomonas Putida*)	16 h	875	> 875	(19)

[a]All concentrations are nominal concentrations except for Bacteria which was estimated.

Sub-lethal effects were observed in the 96 hour fish toxicity test. These effects were hypo-activity and uncontrolled movements. Hypo-activity was observed for all fish at the two highest concentrations after 3 hour. One or two fish exhibited hypo- activity after longer periods at the lower concentrations. Uncontrolled movement was exhibited by one or two fish at the two highest concentrations after 3 hour.

No sublethal effects were observed in the other toxicity studies.

The notified chemical can be classified as practically non-toxic to fish, algae and water fleas. While no ecotoxicity figures were provided for concentrations required to impede reproduction in Water Fleas, it is unlikely that Ixol B 251 would be classed as toxic from the figures provided. Also, the chemical does not appear to inhibit the ability of bacteria cell multiplication, so it should not effect the ability ofbacteria to biodegrade other waste materials.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified chemical will be incorporated into PURs or PUIRs. The environmental hazard posed by the chemical is rated as low when manufactured into foam products as the chemical will be incorporated into the foam matrix, which will be disposed of to landfill at the end of it useful life.

The combustion of the PURs or PUIRS containing the notified chemical may release toxic gases which can be a source of environmental exposure. This is further elucidated in the environmental release section.

Worst case scenario is as follows: with the highest predicted level of importation of 100 tonnes, this equates to 330 drums (205 litres each) a year, i.e. less than an average of one per day. With 93.5% of the notified chemical in the drums, this equates to 192 litres of chemical per drum. The reformulation site is situated in Seven Hills, NSW, so any spillage will enter the Sydney sewer network. With an accidental spillage of one drum while being moved to the blending operation, a

maximum of 192 litres could enter the sewer, which will dilute to a concentration of approximately 64 ppm (based on 300 megalitres per day output from the sewer). This concentration would be further diluted in receiving waters and despite the relatively high concentration this is well below the observed toxic levels (see above). No account is taken of loss through vaporisation before entering the sewer. In addition, due to the viscosity of the liquid, containment of spillages is made easier. With adequate bunding and procedures to contain spillages, the risk of water contamination should be greatly reduced.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is expected to be harmful by the oral route and is assumed to be harmful by the dermal route in the absence of other information. It is not likely to be a skin irritant but may be a moderate eye irritant. It is not likely to be skin sensitiser. A negative mouse micronucleus assay suggests limited genotoxic potential and a quantitative structure-activity analysis provided by the notifier suggested a low genotoxic potential. In the absence of a repeat dose study, it is assumed that the notified chemical is harmful on repeated or prolonged exposure on the basis of the acute oral toxicity data and physico-chemical properties.

When mixing and dispensing the fire-retardant blend for use in polyurethane foams, exposure is not expected to be high as precautions are taken to avoid drips and spills. The actual mixing itself is not expected to result in splashing or spills given that the components are viscous, the tank is large and blades of the mixer turn slowly. Some exposure may be possible during cleaning of apparatus and connectors, in which case personal protective equipment as described below should be worn.

During end use of the notified chemical, precautions are taken to minimise exposure from pump residues. However, rags used to minimise drips when transferring pumps from one drum to another may be a source of exposure unless disposed of correctly. When spraying foam, precautions are required to be taken, including the use of personal protective equipment, to minimise exposure to isocyanate.

There is a risk of toxic effects to workers involved in reformulation and end use of the notified chemical from acute exposure or repeated or prolonged exposure. There is also a risk of eye irritation.

The risk of adverse public health effects is negligible. Where there may be minor public exposure to foams which have been disposed of, the chemical is bound within a polyurethane polymer matrix and is not bioavailable.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed during reformulation, equipment cleaning and end use:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (20) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (21);
- Industrial clothing should conform to the specifications detailed in AS 2919 (22);
- Impermeable gloves or mittens should conform to AS 2161 (23);
- All occupational footwear should conform to AS/NZS 2210 (24);
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for landfill disposal. Wastes containing the notified chemical should be consigned to landfill in preference to incineration due to the potential release of toxic gases. During cleanup the above personal protective equipment should be worn;
- Good personal hygiene should be practised to minimise the potential for ingestion particularly as the notified chemical is classified as harmful via the oral route;
- A copy of the relevant MSDS should be easily accessible to employees.

All labels on formulations containing the notified chemical at a level greater than 25%, the risk phrases: “Harmful in contact with skin”, “Harmful if swallowed” and “Danger of serious damage to health by prolonged exposure” should be used. For

formulations containing greater than 10% but less than 25% of the notified chemical, the phrase “Danger of serious damage to health by prolonged exposure” is required.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (25).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. In addition, under subsection 64(1) of the Act, secondary notification shall be required if reformulation of the notified chemical is to occur at other than the notifier’s premises.

16. REFERENCES

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
o reaction to light, haemorrhage, gross destruction	2 severe