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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer E 1211

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer E 1211

1. APPLICANT

International Sales and Marketing Pty Ltd of 262 Highett Road HIGHETT VIC 3190 has submitted a limited notification statement in support of their application for an assessment certificate for the polymer E 1211.

2. IDENTITY OF THE CHEMICAL

Polymer E 1211 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae have been exempted from publication in the Full Public Report and the Summary Report

The notified chemical contains no hazardous impurities at levels necessary to classify it as as a hazardous substance (1). Therefore, information on the purity of the chemical has been exempted from publication in the Full Public Report and the Summary Report.

Trade name:	E 1211
Method of detection and determination:	the following analytical spectra were provided: Infrared Spectroscopy (IR) used for identification; ^{1}H-NMR, ^{13}C-NMR and ^{29}Si-NMR spectra were provided to determine structure; Gel Permeation Chromatography (GPC) used to determine molecular weight and weight distribution

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	a colourless to yellow liquid
Odour:	characteristic (not specified)
Boiling Point:	not determined
Glass-transition Temperature:	not determined

Density:	1019 kg/m^3 @ 25°C
Vapour Pressure:	not determined, expected to be low
Water Solubility:	not available
Surface Tension:	32.1 mN/m and 29.7 mN/m at 20°C at concentrations of 1 g/L and 10 g/L, respectively
Fat Solubility:	not determined
Partition Co-efficient (n-octanol/water): log P_{ow}	not determined
Hydrolysis as a function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant:	pK_a not applicable
Flash Point:	110°C
Flammability Limits:	not determined
Combustion Products:	SiO_2, CO_2, H_2O
Autoignition Temperature:	not determined
Explosive Properties:	not determined
Reactivity/Stability:	stable under room conditions
Particle size distribution:	not applicable

Comments on physico-chemical properties

The melting and boiling points of the notified substance have not been determined. This is acceptable due to the polymeric nature of the substance.

The attempted determination of the water solubility of the polymer, following a procedure corresponding to the OECD Guideline 105, failed due to the surface activity (please see below). The notified polymer was found to be miscible with water in any proportion by forming opaque micellar solutions. At higher concentrations, the mixture a milky white and no phase separation was observed.

The surface tension of aqueous solutions of the polymer was determined by the ring tensiometer method following OECD Guideline 115. The low surface tension

obtained for aqueous polymer solutions confirmed the surface active property of the polymer.

The notifier claims that there is no hydrolysis of the polymer expected in the normal pH range of 4-9. However, the polymer will undergo hydrolysis at pH < 2 and pH > 11 and high temperatures (> 90^{o}C). Although considered generally stable in the environment, significant cleavage of siloxane bonds by hydrolysis can occur in certain soil types and at a range of pH values, producing water soluble dimethyl-silanediol as the major product (1). Small amounts of low molecular weight, volatile cyclics may also result under certain conditions (2).

The data for partition coefficient and adsorption/desorption are not available. This is acceptable due to the surface active property of the polymer.

4. PURITY OF THE CHEMICAL

Degree of purity: 76%

Toxic or hazardous impurity/impurities: none

Additive(s)/Adjuvant(s):

. **Chemical name:** dipropylenglycol
CAS No.: 26265-71-8
Weight percentage: ≅ 5%

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia but imported at a total estimated quantity of 60 tonnes per annum as the pure chemical for the next five years. The notified polymer will be used as a surfactant (foam stabiliser) in the manufacture of polyurethane. It will be added to the polyurethane system up to 2%.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported as a liquid at a concentration of 70% in 200 litre sealed drums, shipped in 20 foot containers, containing approximately 78 drums. From the wharf, containers are transported by road to stores. The drums are unpacked and stored in racks in bunded areas, until delivered to customers by trucks. One truck driver and one storeman will be involved in the above operations of the notified polymer. Direct contact with the notified polymer is envisaged only in the event of drum breakage.

The notified polymer is pumped from drums to a mixing head via a hose for mixing with other ingredients for approximately 4 hours per day for 5 days a week. The mixing will be carried out under local exhaust ventilation. One maintenance person, two machine operators and one storeman will be exposed to the notified polymer

during the above operation. The operators will monitor the flow rates, observe the quality of the finished product, and make adjustments to the blend of chemicals via a computer board key or by manually actuating a flow valve. During these operations contact will rarely be made with liquids containing the notified polymer. However, contact with the notified polymer is possible during manual connection of hoses to drums.

7. PUBLIC EXPOSURE

No public exposure to the notified polymer is expected during storage and transport except in the event of accidental spillage. However, spills are to be contained in absorbent material, which will be disposed of by incineration in accordance with local government regulations.

The notified chemical will not be sold to the general public. The public may be in contact with the foam products, but the polymer is not be available, since, it the notified polymer has a number-average molecular weight (NAMW) > 1000 and is bound to the cured foams.

Since the notified polymer is bound to the cured foam, it is likely to remain immobile in the waste foam and public exposure is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

There will be no environmental release during transport except during a major accident. Any spillage will be contained by absorbent material and after recovery will be disposed of by incineration in accordance with local regulations.

The foam manufacturing takes place in a factory designed and built according to EPA regulations. At the factory, the notified polymer is used in a continuous polyurethane foam production process in which if is incorporated into the cured polyurethane foam. The polymer waste from washing used drums will be removed and disposed of by a licensed waste handler and the drums will be recycled. The amount of waste generated at the foam manufacturing plant is estimated to be ca. 0.1% of the polymer used.

Fate

The fate of the bulk of the polymer will be tied to the fate of the finished polyurethane foam. The foam that has been treated with the polymer is expected to be used in making mattresses, furniture, and pillows. Most of the treated foam will be landfilled, either as trimmings during the making of end products or when the end products are disposed of. Solid waste containing the polymer, generated during manufacture of foam is expected to be disposed of through landfill or incineration.

The notified polymer is bound to the finished foam. It also has a high molecular weight. Therefore, the notified polymer in the waste foam disposed to landfill is likely to remain immobile. The high molecular weight will also prevent any bioaccumulation.

Some degree of clay-catalysed degradation of the polymer to linear, water soluble, low-molecular weight siloxanols may occur, this being enhanced by soil drying. Water soluble siloxanols are believed to rapidly mineralise to silicates under environmental conditions (3).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Toxicological data are not required for polymers with NAMW > 1000 under the Act. However, the following studies on acute oral toxicity, eye irritation, skin sensitisation and mutagenicity were submitted for siloxanes and silicones, di-Me, 3-hydroxypropyl Me, ethoxylated propoxylated (Abil B 8851) and acute oral toxicity, eye irritation and skin irritation for siloxanes and silicones, di-Me, 3-hydroxypropyl Me, ethoxylated (Abil B 8842). Both these chemicals are similar in composition to the notified chemical.

Table 1 Summary of the acute toxicity of Abil B 8851 and Abil B 8842

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD_{50} > 5000 mg/kg Abil B 8851	(4)
acute oral toxicity	rat	LD_{50} > 5000 mg/kg Abil B 8842	(6)
skin Irritation	rabbit	non-irritant Abil B 8842	(7)
eye irritation	rabbit	non-irritant Abil B 8851	(9)
eye irritation	rabbit	non-irritant Abil B 8842	(10)
skin sensitisation	guinea-pig	non-sensitiser Abil B 8851	(11)

9.1.1 Oral Toxicity

9.1.1.1 Oral Toxicity of Abil B 8851 (4)

Species/strain: Sprague Dawley rat

Number/sex of animals: 5 males, 5 females

Observation period: 14 days

Method of administration (vehicle): diluted solution given orally by gavage (16.0 ml/kg)

Clinical observations: pilo-erection; hunched posture; abnormal gait; decreased respiration; and increased salivation (one animal)

Mortality: no deaths

Morphological findings: no abnormalities were noted at necropsy

Test Method: based on OECD Guidelines for Testing Chemicals (5)

LD_{50}: > 5000 mg/kg

Result: low oral toxicity in the rats

9.1.1.2 Oral Toxicity of Abil B 8842 (6)

Species/strain: Sprague Dawley rat

Number/sex of animals: 5 males, 5 females

Observation period: 14 days

Method of administration (vehicle): 10% aqueous solution given orally by gavage (5000 mg/kg)

Clinical observations: no signs of systemic toxicity were noted during the study.

Mortality: no deaths

Morphological findings: no abnormalities were noted at necropsy

Test Method: based on OECD Guidelines for Testing Chemicals (5)

LD_{50}: > 5000 mg/kg

Result: low oral toxicity in the rat

9.1.2 Skin Irritation (7)

Species/strain: New Zealand White rabbits

Number/sex of animals: 6 males

Method of administration: 500 mg of Abil B 8842 applied under semi-occlusive dressing

Draize (8) Scores[i]:

Animal	Time after decontamination				
	30-60 min	1 day	2 days	3 days	7 days
ERYTHEMA					
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
5	0	0	0	0	0
6	0	0	0	0	0
OEDEMA					
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
5	0	0	0	0	0
6	0	0	0	0	0

Test Method: based on OECD Guidelines for Testing Chemicals (5)

Result: non-irritant to rabbit skin

9.1.3 Eye Irritation

9.1.3.1 Eye Irritation (9)

Chemical type: Abil B 8851

Species/strain: New Zealand White rabbits

Number of animals: 6 males

Method of administration: 0.1 ml of Abil B 8851 as a 10% aqueous solution

Draize (8) Scores

	Time after instillation									
Animal	***1 day***		***2 days***		***3 days***		***4 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	0[i]		0	0	0		-		0	
2	0		0	0	0		-		0	
3	0		0	0	0		-		0	
4	0		0	0	0		-		0	

5	0			0		0	0		0			-			0
6	0			0		0	0		0			-			0
Iris															
1		0			0			0			-			0	
2		0			0			0			-			0	
3		0			0			0			-			0	
4		0			0			0			-			0	
5		0			0			0			-			0	
6		0			0			0			-			0	
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	0	0	0	0	0	0	0	0	0	-	-	-	0	0	0
2	0	0	0	0	0	0	0	0	0	-	-	-	0	0	0
3	0	0	1	0	0	0	0	0	0	-	-	-	0	0	0
4	0	0	0	0	0	0	0	0	0	-	-	-	0	0	0
5	0	0	0	0	0	0	0	0	0	-	-	-	0	0	0
6	0	0	0	0	0	0	0	0	0	-	-	-	0	0	0

[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Test Method: based on OECD Guidelines for Testing Chemicals (5)

Result: non-irritant to rabbit eye

9.1.3.1 Eye Irritation(10)

Chemical type: Abil B 8842

Species/strain: New Zealand White rabbits

Number of animals: 6 males

Method of administration: 0.1 ml of Abil B 8842 as a 10% aqueous solution s

Draize (8) Scores

Animal	**Time after instillation**				
	1 day	**2 days**	**3 days**	**4 days**	**7 days**
CORNEA:	opacity area	opacity area	opacity area	opacity area	opacity area
1	0	0	0	0	
2	0	0	0	0	

3	0			0			0			0						
4	0			0			0			0						
5	0			0			0			0						
6	0			0			0			0						
IRIS																
1	0			0			0			0						
2	0			0			0			0						
3	0			0			0			0						
4	0			0			0			0						
5	0			0			0			0						
6	0			0			0			0						
CONJUNCTIVA	r^a	c^b	d^c	r^a	c^b	d^c	r^a	c^b	d^c	r^a	c^b	d^c	r^a	c^b	d^c	
1	0	0	0	0	0	0	0	0	0	0	0	0				
2	0	0	0	0	0	0	0	0	0	0	0	0				
3	0	0	1	0	0	0	0	0	0	0	0	0				
4	0	0	0	0	0	0	0	0	0	0	0	0				
5	0	0	0	0	0	0	0	0	0	0	0	0				
6	0	0	0	0	0	0	0	0	0	0	0	0				

[a] redness [b] chemosis [c] discharge

Test Method: based on OECD Guidelines for Testing Chemicals (5)

Result: non-irritant to rabbit eye

9.1.6 Skin Sensitisation (11)

Species/strain: Perbright Albino guinea pigs

Number of animals: 10 test, 5control

Induction procedure: three pairs of injections of 0.1 ml: Abil B 8851; Freund's Complete Adjuvant (FCA) in distilled water (1:1); Abil B 8851 in a mixture of distilled water and FCA (1:1) topical induction: at day 6, 100% Abil B 8851 for 48 hours

Challenge procedure: a challenge was conducted two weeks after induction using 100% Abil B 8851

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hrs****	***48 hrs****	***24 hrs***	***48 hrs***
100%	1/10**	0/10	0/5	0/5

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

Skin reaction after topical induction:	slight erythema and oedema were observed following intradermal injections in the test and control groups
Skin reactions after topical challenge:	no adverse reactions were found at the test material and vehicle control sites of the control or test animals at the 24-hour and 48-hour observations, except for erythema in one animal at 24-hour observation in the test group
Test Method:	based on OECD Guidelines for Testing Chemicals (5)
Result:	non-sensitiser to guinea pig skin

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (12)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 100 and TA 98
Concentration range:	8 - 5000 μg/ plate
Toxicity to bacteria:	> 5000 μg/ plate
Metabolic activation:	Arocolor 1254-induced rat liver S9-mix
Solvent:	DMSO
Test Method:	based on OECD Guidelines for Testing Chemicals (5)
Result:	no toxicity was exhibited to any of the strains of bacteria used; no significant increases in the number of revertant colonies of bacteria were recorded for any of the strains of bacteria used, at any dose level, either with or without metabolic activation. the positive controls, 2-aminoanthracene with metabolic activation and 2-nitrofluorene and sodium azide without metabolic activation produced marked increases in the number of revertant colonies.

9.4 Overall Assessment of Toxicological Data

Based on studies done and information provided by the notifier with compositionally similar chemicals (Abil B 8851 and Abil B 8842), the notified chemical may be of low acute oral toxicity in rat, a non-irritant to the skin and eye of rabbit and non-mutagenic to *Salmonella typhimurium* strains TA 1538, TA 11537, TA 100 and TA 98 in an *in vitro* bacterial reverse mutation assay.

On the basis of submitted analog data, the notified chemical would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)] in relation to acute oral toxicity, skin irritation, skin sensitisation or mutagenicity.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

According to the Act, environmental effects testing is not required for polymers with NAMW >1000 as such polymers are too large to cross biological membranes.

Reviewers have concluded that silicones partition to sediment where they are persistent, but do not exert any adverse environmental effects (13).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Most of the polymer will be disposed of to landfill or incinerated with the foam to which it is cured. Incineration of the polymer will produce oxides of carbon, silica and water with no significant environmental hazard.

A small amount of the polymer (ca. 0.1%) contained in the used drums after the foam manufacture will also be removed and disposed of by a licensed waste handler. However, if released to the environment, it may undergo some degradation releasing water soluble siloxanols. Such low-molecular weight species are either volatilised, degraded to silicates, incorporated into humus or oxidised to CO_2.

Overall, the environmental hazard of the polymer can be rated as low under proposed use and disposal methods.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No data on effects on humans (for the notified polymer) were available for assessment. However, based on results of animal studies done on structural analogues, the notified chemical is likely to exhibit low acute oral toxicity and unlikely to present a risk of eye and skin irritation or skin sensitisation to workers. In addition, adverse systemic effects (from dermal adsorption) are unlikely due to the high NAMW of the notified polymer and the levels of residual monomers are unlikely to present a health hazard. There are no hazardous impurities present in sufficient concentrations to render the polymer hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances*.

As the polymer is available in liquid form, skin and eye contact will be the main source of occupational exposure during polyurethane foam manufacture. Inhalational exposure during these activities is unlikely as the polymer vapour pressure is expected to be low and no loss to the working environment should occur as a result of the specificity of the dosing system. The use of local exhaust ventilation would further minimise worker exposure during mixing of the ingredients. However, exposure is still possible during connection and disconnection of hoses.

The risk of adverse occupational health effects is expected to be low, due to low exposure levels and low hazard of the notified polymer. Precautions against continued exposure to other ingredients should be observed.

Because the notified polymer is bound to the cured foams and has a NAMW > 1000, it is not available for absorption by dermal contact with the foam products. The proposed use of the notified chemical is unlikely to have a significant impact on public health.

13. RECOMMENDATIONS

To minimise occupational exposure to the Polymer E 1211 the following guidelines and precautions should be observed during mixing and connecting hoses:

. mixing should be carried out under local exhaust ventilation

. safe practices, as should be followed when handling any chemical formulation, should be adhered to - these include:

- minimising spills and splashes;
- practising good personal hygiene; and
- practising good housekeeping and maintenance including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal.

. It is expected that, in the industrial environment, protective clothing conforming to and used in accordance with Australian Standards (AS) 2919 (14) and protective footwear conforming to Australian/New Zealand Standard (AS/NZS) 2210 (15) should be worn as a matter of course; in addition it is advisable that when handling chemical formulations containing the notified polymer to wear chemical-type goggles (selected and fitted according to AS1336 (16) and meeting the requirements of AS/NZS 1337 (17)), impermeable gloves (AS 2161) (18) should be worn to protect against unforseen circumstances.

. a copy of the Material; Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS were provided for the polymer E 1211 was provided in an acceptable format.

This MSDS was provided by the applicant as part of their notification statement. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of the Polymer E 1211 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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16. Australian Standard 1336-1982, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.

16. Australian Standard 1337-1984. *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.

17. Australian Standard 2161-1978. *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.

[ii] 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 by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4