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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Polymer in Reactint Red X64

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by 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 in Reactint Red X64****1. APPLICANT**

APS Chemicals Ltd of 8 Abbott Road SEVEN HILLS NSW 2147 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer in Reactint Red X64.

2. IDENTITY OF THE CHEMICAL

Polymer in Reactint Red X64 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, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Trade name:	component of Reactint Red X64
Number-average molecular weight:	>1000
Maximum percentage of low molecular weight species	
(molecular weight < 1000):	<15%
(molecular weight < 500):	<1%
Method of detection and determination:	UV-Vis and infrared (IR) spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	viscous dark red liquid with a slight sweet odour
Boiling point:	>100°C (at 760 mm Hg)
Specific gravity:	1.1
Vapour pressure:	not determined
Water solubility:	>2 g/L at 25°C

Partition co-efficient (n-octanol/water):	log K _{ow} 3.2
Hydrolysis as a function of pH:	not determined
Adsorption/desorption:	not determined
Dissociation constant:	not determined
Flash point:	213°C
Flammability limits:	not determined
Autoignition temperature:	>350°C (estimate)
Explosive properties:	stable
Reactivity/Stability:	not an oxidiser, will react with isocyanates

Comments on Physico-Chemical Properties

Vapour pressure was not determined, it is expected to be low under ambient conditions due to its high boiling point and molecular weight. Hydrolysis has not been measured, it is not expected to hydrolyse as it does not contain hydrolysable chemical groups (1).

The polymer has a high water solubility. Solubility was determined by adding various quantities (10, 20 and 200 mg) of Reactint Red to 100 mL of water, all of which dissolved, as indicated by a linear increase in the absorbance of the test solution.

The partition coefficient was determined by the HPLC method (OECD Guideline 117). In calculating the value, log K_{OW} = 3.2, the slope and the gradient of the line of best fit of the reference compounds were interchanged by the notifier. Recalculating the partition coefficient using the correct line of best fit of the data gives log K_{OW} = 3.6. However, this value is based on extrapolation of the line of best fit for the reference substances and must therefore be treated with caution.

No information was provided on the adsorption/desorption properties of the polymer. The partition coefficient would indicate that the notified polymer is likely to adsorb to organic matter. This is in contrast to the polymer's high water solubility which would suggest that it is not likely to strongly adsorb to soils.

The notified chemical is normally reacted into polyurethane which is environmentally stable. Dissociation constant was not measured as the chemical is unlikely to dissociate in water as it does not contain ionisable groups. The notified polymer is not flammable. However it is combustible and can produce toxic degradation products including sulphur, nitrogen and carbon oxides.

4. PURITY OF THE CHEMICAL

Degree of purity: >92%

Toxic or hazardous
impurities: none

Non-hazardous impurities:

None of the impurities listed appear on the *Designated List of Hazardous Substances* (3); they are not listed on the Toxline database (4) or in Sax and Lewis (2).

Maximum content
of residual monomers: <8%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The polymer will be used as a colourant in the manufacture of polyurethane foams. It will be added to foams at a rate of <2% by weight. The foams are used in products such as furniture, mattresses, packaging, carpet underlay, novelty foams and toys. The colourant will replace a similar material that has been in use for over 10 years with no reported health effects. The chemical has only recently been introduced for use overseas as such there is no information available on problems associated with longterm usage.

The notified substance will not be manufactured in Australia, but will be imported at a rate of 5 tonnes per annum for the first 5 years. The substance will be imported as a component of a colourant formulation Reactint Red X64 in 55 gallon drums and 5 gallon plastic pails.

6. OCCUPATIONAL EXPOSURE

Occupational exposure can occur during transport and warehousing, repackaging and during use of the formulation containing the notified polymer to manufacture polyurethane foams. The polymer is effectively bound in the final product, polyurethane foam. Exposure could occur during shaping/cutting operations, however this will be limited as the polymer will be reacted into the polyurethane foam and be fairly inert. The notifier states that this has been demonstrated in colour extraction tests; these reports have not been sighted.

Occupational exposure during transport and warehousing will only occur through accidental release of the imported formulation, Reactint Red X64. The formulation will be imported in either, 55 gallon drums or 5 gallon pails. There will be some repackaging at the importers warehouse; 4 employees will be exposed for 1 hour/day for 50 days/year. This repackaging will be undertaken using local exhaust

ventilation.

There are 12 manufacturers of polyurethane foam in Australia who potentially may use the notified chemical. At the polyurethane manufacturing plant, the formulation containing the notified polymer will be dispensed into the polyurethane feed system either through a closed system or manually under local exhaust ventilation. The notified polymer will be handled in conjunction with more hazardous polyisocyanates. Safety measures to limit exposure to isocyanates will also reduce exposure to the notified polymer. The group of employees with the highest level of exposure to the notified polymer are the production workers who decant the formulation containing the notified polymer. They will be exposed for 8 hours/day for about 200 days/year. In addition 12 maintenance technicians may be exposed for periods of 4 hours/day for 20 days/year.

As the notified chemical is new there are no reports on health effects during use overseas.

7. PUBLIC EXPOSURE

The notified polymer will not be manufactured in Australia. The notified polymer will be repacked and distributed to about twelve companies who manufacture polyurethane foam. The notified polymer will be transported by road or rail within Australia. If accidental spillage occurs the notified polymer will be contained and cleaned up according to practices recommended in the material safety data sheet (MSDS). No public exposure to the notified polymer is expected to occur during transport or manufacture of polyurethane foam.

Although public contact with the notified polymer in polyurethane foam will occur, the notified polymer is bound to the polymers in the foam, minimising its potential for absorption.

The polyurethane foam that contains the notified polymer will be disposed of in landfills. Waste polymer (residual in drums and spillage) will be either incinerated or placed in landfills following treatment.

8. ENVIRONMENTAL EXPOSURE

Release

Environmental release during transportation will result only in the event of accidental spill or mishandling. All clean up of spills and disposal should be carried out according to the MSDS.

The notified polymer will be repacked at the notifiers warehouse into 1, 5 and 10 litre plastic bottles or pails. The empty drums, in which the notified polymer was imported, are sent to a licensed drum recycler. The notifier claims that the residual chemical in the empty drums is expected to be very low (<0.5%). The recycler will thoroughly rinse the drums with water and drain for future use. The rinsate is

released to a trade waste sewer. Empty plastic bottles or pails will either be washed and reused or disposed of to landfill.

All the notified substance is intended for use in the manufacture of polyurethane foam for use in furniture, bedding, packaging, carpet underlay and novelty foams and toys. The foam is to be manufactured at three major sites across Australia (two in Victoria and one in New South Wales). The colourant will be added to the foam machine using an enclosed automated mixing system, resulting in minimal loss of the notified polymer during foam manufacture.

When items containing the foam reach the end of their useful life, the notified polymer, bound within the foam matrix, will be disposed of to landfill or incinerated.

Fate

Most of the notified polymer is expected to be covalently bound within polyurethane foam products, with the final environmental fate being incineration or landfill.

Leaching of the polymer from landfill sites is not expected when it is bound within the inert foam matrix. Degradation of the foam in landfill sites is expected to be slow.

Any incineration of the notified polymer is expected to produce water and oxides of carbon, nitrogen and sulfur.

A small amount (<50 kg per annum) of the unreacted polymer, from spills, will be disposed of to approved landfill or incinerated by licensed waste contractors after treatment. Washings from storage drums (<50 kg per annum) will be discharged into a trade waste sewer.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Polymer in Reactint Red X64

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ 4146 mg/kg	5
skin irritation	rabbit	not an irritant	7
eye irritation	rabbit	slight irritant	9

9.1.1 Oral Toxicity (5)

<i>Species/strain:</i>	Crl:CD®(SD)BR strain rats
<i>Number/sex of animals M/F:</i>	15/15 (5/5 for each dose level)
<i>Observation period:</i>	14 days

<i>Method of administration:</i>	gavage, dose 2000, 4000 and 5000 mg/kg
<i>Clinical observations:</i>	staggered gait, hypoactivity, hunched posture, absence of righting reflex, dyspnea, staining, alopecia (urogenital area), mydriasis, lacrimation and stained urine
<i>Mortality:</i>	2000 mg/kg - 0/0, 4000 mg/kg - 0/3, 5000 mg/kg - 3/3
<i>Morphological findings:</i>	2000 mg/kg gained weight, 4000 mg/kg 1/1 lost weight, 5000 mg/kg all lost weight
<i>Test method:</i>	in accordance with OECD Guidelines for Testing Chemicals (6)
<i>LD₅₀:</i>	4146 mg/kg
<i>Result:</i>	low oral toxicity

9.1.4 Skin Irritation (7)

<i>Species/strain:</i>	New Zealand White rabbits
<i>Number/sex of animals M/F:</i>	3/3
<i>Observation period:</i>	24 hours exposure to article and observation to 72 hours
<i>Method of administration:</i>	shaved to expose skin, patch abraded and article applied under an occlusive dressing

Draize scores (8):

Time after treatment (days)	Animal #					
	1	2	3	4	5	6
Erythema						
1	¹ 0	0	0	0	0	0
3	0	0	0	0	0	0
Oedema						
1	0	0	0	0	0	0
3	0	0	0	0	0	0

¹ see Attachment 1 for Draize scales

Test method: in accordance with OECD Guidelines for Testing Chemicals (6)

Result: not a skin irritant

9.1.5 Eye Irritation (9)

Species/strain: New Zealand White rabbits

Number/sex of animals M/F: 3/3

Observation period: 7 days

Method of administration: 0.1 mL into everted lower lid of one eye, held closed for 1 second and not flushed

Draize scores (8) of unirrigated eyes:

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

¹ see Attachment 1 for Draize scales

^a opacity ^b area ^c redness ^d chemosis ^e discharge

Test method: in accordance with OECD Guidelines for Testing Chemicals (6)

Result: slight irritant

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (10)

Strains: *Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537 and *Escherichia coli* WP2uvrA

Concentration range: 6.7 - 5000 µg/ plate with or without rat liver S9

Test method: in accordance with OECD Guidelines for Testing Chemicals (6)

Result: non mutagenic in bacteria

9.4 Overall Assessment of Toxicological Data

The notified polymer has a low oral toxicity to rats and is not a skin irritant in rabbits. The notified polymer caused slight eye irritation in rabbits up to 4 days after exposure; after a period of seven days no effects were apparent. The Draize score average for iris lesions at 24 hours is 0.83, this is below the threshold value of 1 required for hazardous classification according to the *Approved Criteria for the Classification of Hazardous Substances* (11). The Draize score average for redness of the conjunctiva and oedema of the conjunctiva (chemosis) at 24 hours are 2.0 and 1.0 respectively, these are below the threshold values of 2.5 required for hazardous classification (11). In a *S. typhimurium* reverse mutation assay there was no evidence of mutagenicity with and without S9 activation. On the basis of the toxicological data provided for the notified polymer it would not be classified as hazardous based on oral toxicity to rats, skin and eye irritation to rabbits and an Ames test.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicological data were not provided, which is acceptable for polymers with number-average molecular weight (NAMW) of greater than 1000, according to the Act.

The notified substance is not expected to exhibit toxic characteristics because large polymers are not readily absorbed by biota, and being nonionic it would not overchelate minerals. Due its NAMW >1000 the polymer is not expected to cross biological membranes (12,13).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is anticipated that the amount of the notified polymer released to the environment will be low. Spills from the manufacturing process (<50 kg per annum) will be disposed of to approved landfill or incinerated by licensed waste contractors after treatment. Washings from storage drums (<50 kg per annum) will be discharged into a trade waste sewer. Foam from furniture, bedding, packaging, carpet underlay and novelty foams and toys will be disposed of to landfill or incinerated. The inert nature of the polyurethane foam means that the polymer is not expected to be mobile within landfill sites.

The hazard to the environment is restricted by the expected limited release, the low solubility in water of the polymer and its high molecular weight.

The environmental hazard posed by the polymer is rated as negligible when manufactured into foam products as the polymer will be incorporated into the foam

matrix.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer will not be manufactured in Australia. Occupational exposure to the notified polymer can occur during transport and warehousing although this will only occur during accidental release. Exposure can occur during repackaging operations but will be minimised as local exhaust ventilation is used during this operation. The main occupational exposure will occur during production of polyurethane foam for which the polymer is used as a colourant. If the polymer is dispensed manually, as opposed to a closed system, dermal, inhalational and eye exposure could occur. Local exhaust ventilation will reduce inhalational exposure, which will be limited due to the expected low vapour pressure of the notified polymer. Dermal exposure will be apparent due to the red colouration imparted by the polymer. The notified polymer is not a dermal irritant in rabbits and is unlikely to cause systemic effects as penetration through the skin is unlikely due to the notified polymer's high molecular weight. Although it is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (11), it has some potential for eye irritation and eye contact with the polymer prior to incorporation into polyurethane foam should be avoided. Since the notified polymer will be handled in conjunction with more hazardous polyisocyanates during polyurethane foam manufacture, the measures instituted to reduce occupational exposure to isocyanates will also reduce exposure to the notified polymer.

Under normal conditions of use, there will be low potential for public exposure to the notified polymer since it will be used in the manufacture of polyurethane foam. If public contact with the notified polymer does occur during accidental spillages, potential health hazards arising from acute exposure are anticipated to be low as it has a NAMW of >1000 and low acute oral toxicity, it is non-irritating to the skin and a slight eye irritant to rabbits. Whilst the public may be exposed to foam containing the notified polymer it will be bound and not dermally absorbed.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in Reactint Red X64 the following guidelines and precautions should be observed:

- during repackaging and transferral operations local exhaust ventilation to be used.
- if engineering controls and work practices are insufficient to reduce exposure to Polymer in Reactint Red X64 to a safe level, then the following personal protective equipment which conforms to Australian Standards (AS) or Australian/New Zealand Standards (AS/NZS) should be worn;

safety goggles should be selected and fitted in accordance with AS 1336 (14) to comply with AS/NZS 1337 (15).

- safe practices, as should be followed when handling any chemical formulation, should be adhered to - these include:
 - minimising spills, 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 (16) and protective footwear conforming to Australian/New Zealand Standards (AS/NZS) 2210 (17) should be worn as a matter of course; in addition it is advisable that when handling chemical formulations containing the notified chemical to wear chemical-type goggles (selected and fitted according to AS1336 (18) and meeting the requirements of AS/NZS 1337 (19)), impermeable gloves (AS 2161) (20) should be worn to protect against unforeseen circumstances.

- a copy of the MSDS should be easily accessible to employees.

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 a Material Safety Data Sheets* (21).

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. No other specific conditions are prescribed.

16. REFERENCES

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16. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing*, Standards Association of Australia Publ., Sydney, Australia.
17. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.
18. Australian Standard 1336-1982, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.
19. Australian Standard 1337-1984. *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.
20. Australian Standard 2161-1978. *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.
21. National Occupational Health and Safety Commission (1994). *National Code of Practice for the Completion of a Material Safety Data Sheets*, [NOHSC:2011(1994)], AGPS, Canberra.

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
No reaction to light, haemorrhage, gross destruction	2 severe