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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Reactive Orange TZ3931

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Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9466 **FAX (61) (02) 9577-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in Reactint Orange X96

1. APPLICANT

APS Chemicals Ltd of 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 Orange X96.**

2. IDENTITY OF THE CHEMICAL

Polymer in Reactint Orange X96 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:	Reactint Orange X96
Method of Detection and Determination:	the notified chemical is isolated by gel permeation chromatography (GPC) and identified by fourier transformed infrared (FTIR) spectroscopy and quantitatively determined by ultraviolet/visual (UV/Vis) spectral analysis

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	viscous dark orange liquid
Boiling Point:	> 100°C
Density:	1 100 kg/m^3
Vapour Pressure:	not determined
Water Solubility:	> 2 000 mg/L at 25°C

Partition Co-efficient (n-octanol/water): log P_{ow}	3.3 - 3.5 (HPLC method)
Hydrolysis as a Function of pH:	see comment below
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	270°C
Flammability Limits:	non-flammable
Autoignition Temperature:	350°C
Explosive Properties:	stable at ambient temperatures
Reactivity/Stability:	does not oxidise; may react with isocyanates to form polyurethanes during normal use

Comments on Physico-Chemical Properties

Vapour pressure of the polymer has not been measured. Because of the relatively high boiling point and high molecular weight of the polymer, it is assumed the vapour pressure will be low.

The water solubility of the chemical was tested in several solvents including water, up to a concentration of 2 000 mg/L. It was soluble at this concentration in all solvents. The Material Safety Data Sheet (MSDS) states that the product is miscible in water.

GPC results from hydrolysis testing (OECD 111) showed no statistically significant changes in the molecular weight of the colorant, or any statistically significant increase in the percentage of low molecular weight material, at pH values of 1.2, 4, 7 and 9. Hydrolysis is not expected to be a major source of degradation for the notified chemical.

The partition coefficient was determined by HPLC by comparison with a number of reference compounds, following the liquid chromatography procedure. Given the relatively high water solubility, the result seems high. There are 4 polyethylene/polypropylene glycol end chains on the molecule, and while no information is available on the chemicals surface activity, a degree of surface activity may exist. This could distort partition coefficient results.

Adsorption/desorption was not measured. Although the chemical is expected to have a high degree of miscibility, a positive dependence of soil adsorption on the length of the ethoxylate chain has been observed in experiments performed with long-chain polyethylene glycols (1). By themselves, the polyethylene/polypropylene

glycol chains contain around 12 units (typically). There are four chains on each molecule, and a degree of adsorption could be expected.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 94%

Toxic or Hazardous Impurities: none

Maximum Content of Residual Monomers: < 6.1%

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 less than 2.5% by weight. The foams are used in products such as packaging, furniture, bedding, 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 overseas and as such there is no information available on adverse effects associated with long term usage.

The notified chemical will not be manufactured in Australia, but will be imported at a rate of 5 tonnes per annum for the first five years. The notified chemical will be imported as a component of a colourant formulation Reactint Orange X96 in 55 gallon drums and 5 gallon plastic pails.

6. OCCUPATIONAL EXPOSURE

Occupational exposure may 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 encapsulated. This has been demonstrated in colour extraction tests.

Occupational exposure during transport and warehousing will only occur through accidental release of the imported formulation, Reactint Orange X96. The formulation will be imported in either, 55 gallon drums or 5 gallon pails. There will be some repacking 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. The most likely routes of exposure are dermal and inhalational.

7. PUBLIC EXPOSURE

Public exposure to the polymer in Reactint Orange X96 will occur primarily through contact with products incorporating it. As the polymer is covalently bound into the chemical structure of the polyurethane foam to which it is added at low concentrations, it will not be bioavailable due to its high NAMW.

In the event of a transport accident product containing the polymer is unlikely to be widely dispersed as its physical form is a thick liquid. The polymer is, however, water soluble so may enter the water table if it is dispersed by rain or washed from an accident site. Spilt product should be covered with absorbent material and collected in drums for disposal, preferably by incineration.

Because of its physical form, public exposure to the product following dispersal from manufacturing sites to surrounding areas is unlikely. The product has a low vapour pressure and is not heated during the polyurethane foam manufacturing process.

8. ENVIRONMENTAL EXPOSURE

Release

The chemical will be stored at the notifier's sites, from where it will be distributed to end customers. Some repacking may be carried out at these sites, but losses through this process will be minimal.

The notifier has identified three major customers where the notified product will be used as a colorant in the manufacture of polyurethane foam. It is normally added along with other colorants, at less than 2.5% by weight and is covalently reacted into the polymer. Of the major customers, two are located in Victoria, with one in New South Wales.

Release during foam manufacture can occur as a result of spillage when the polymer is decanted to holding tanks. Any spillage would be contained by

bunding, and losses through this mechanism are expected to be minimal. It is estimated that 20 to 50 kg of the chemical may need to be disposed of as the result of spillage. This will be disposed of with other liquid waste, ie. polyol and isocyanate by use of a licensed waste contractor who will either incinerate or landfill after treatment.

The majority of the notified chemical will ultimately be disposed of to landfill in a highly diffuse manner, through disposal of the foam products it is incorporated into. Release through leaching is unlikely as the polymer will be firmly incorporated into the foam matrix.

Drums containing the notified polymer are normally thoroughly drained by the polyurethane foam manufacturer, resealed and sent to a licensed drum recycler. Residual chemical in the empty drum is expected to be very low, with the notifier estimated less than 0.5% (around 25 kg per annum). The practice of the drum recycler is to rinse the drums thoroughly with water. The rinsate containing small amounts of chemical are released to a trade waste sewer.

Fate

Disposal of chemical resulting from accidental spillage will generally be by incineration, or to landfill after treatment. Incineration will release oxides of sulphur, nitrogen, carbon and hydrogen. In landfill, the chemical is not expected to exhibit mobility, based on its relatively high partition coefficient.

The polymeric colorant is reacted into polyurethane foam and consequently its fate is linked to that of the polyurethane foam. Articles made form the foam include furniture, bedding, packaging etc. Ultimately, these articles will be landfilled, where leaching of the polymer from the foam is not expected.

Any residues remaining in drums are likely to be treated by a drum recycler with rinsate containing small amounts of the chemical being disposed of to sewer. While the polymer has an environmentally significant level of water solubility, the length and number of polyethylene/polypropylene glycol chains on the molecule indicates a degree of adsorption to organic matter and sediment.

9. EVALUATION OF TOXICOLOGICAL DATA

According to the Act, toxicological data are not required for polymers with a NAMW greater than 1 000, although the data summarised below were submitted by the notifier.

9.1 Acute Toxicity

Summary of the acute toxicity of Polymer in Reactint Orange X96

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(2)

9.1.1 Oral Toxicity (2)

Species/strain:	Crl:CD®(SD)BR strain rats
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage, dose of 5 000 mg/kg administered by gavage
Clinical observations:	thin appearance, red-stained face, dark or red-stained urogenital area in all females
Mortality:	none
Morphological findings:	none
Test method:	OECD Guidelines for Testing of Chemicals (3)
LD_{50}:	> 5 000 mg/kg
Result:	low oral toxicity in a limit test

9.23 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (4)

Strains:	*S. typhimurium* TA 98, TA 100, TA 1 535, TA 1537 and *Escherichia coli* WP2*uvrA*
Concentration range:	100 - 5 000 μg/plate
Test method:	OECD Guidelines for Testing of Chemicals (3)
Result:	non-mutagenic in bacteria

9.3 Overall Assessment of Toxicological Data

The notified polymer has a low acute oral toxicity to rats (LD_{50} > 5 000 mg/kg). In a *Salmonella typhimurium* reverse mutation assay there was no evidence of mutagenicity with or without metabolic activation provided by rat liver S9.

On the basis of toxicological data provided, the notified polymer would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (5).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has not presented any ecotoxicity results for the polymer. This is acceptable as ecotoxicity tests are not required for a polymer with NAMW greater than 1 000.

The high molecular weight of the polymer suggests that it will not cross biological membranes, and will not bioaccumulate.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard during repacking and polyurethane foam production is expected to be low.

Release to sewer is only likely from the cleaning of drums, with maximum residues estimated at 25 kg per year. If all this were released to a city sewer (250 ML per day output) in one day, a concentration in the sewage treatment plant of 0.1 ppm would result. This would be further diluted in receiving waters.

In reality, the release would occur in two major cities, and over many days of the year, and a concentration in the sewage treatment plant in the low parts per billion range could be expected.

Up to 50 kg per year of the notified polymer could be lost through accidental spillage, but this would be contained within the plant by bunding, and disposed of with liquid waste. This is either incinerated, or landfilled after treatment.

Instructions in the MSDS are adequate to limit the environmental exposure from spills etc. and therefore the environmental hazard from possible accidental spills should be low.

The overall environmental hazard from the use of the polymer is rated as low.

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. Inhalational and dermal exposure can occur during repackaging operations but will be minimised as local exhaust ventilation will be used during this operation. The main occupational exposure will occur during production of polyurethane foam for which the polymer is used in a colourant. If the polymer is dispensed manually, as opposed to in a closed system, dermal, inhalation 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 dark orange colouration imparted by the polymer. The dermal irritation potential of the notified polymer is unknown but the MSDS states prolonged or repeated skin contact may cause irritation. However, it is unlikely to cause systemic effects as penetration through the skin is unlikely due to the notified polymer's high molecular weight. The MSDS also states there is some potential for eye irritation. Therefore eye contact with the polymer solution 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.

As the Polymer in Reactint Orange X96 is present in low concentration, has a high NAMW and is immobilised within the chemical matrix of polyurethane foam, the level of exposure of the public is likely to be low. The notified polymer represents a low public health risk when used in the manner proposed.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in Reactint Orange X96 the following guidelines and precautions should be observed:

- During repackaging and transferral operations local exhaust ventilation should be used;

- 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 (8) and protective footwear conforming to Australian/New Zealand Standards (AS/NZS) 2210 (9) 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 (10) and meeting the requirements of AS/NZS 1337 (11)), impermeable gloves (AS 2161) (12) should be worn to protect against unforseen circumstances.

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the Polymer in Reactint Orange X96 was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (13).

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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7. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

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9. 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.

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

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

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

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