



Polymer in Reactint Red X64

Existing Chemical

Secondary Notification Assessment

Report NA/405S

April 2003

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Preface

This assessment was carried out under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This Scheme was established by the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), which came into operation on 17 July 1990.

The principal aim of NICNAS is to aid in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals.

NICNAS assessments are conducted in conjunction with Environment Australia, which carries out the environmental assessment.

NICNAS has two major programs: the assessment of the health and environmental effects of new industrial chemicals prior to importation or manufacture; and the other focussing on the assessment of chemicals already in use in Australia in response to specific concerns about their health and/or environmental effects.

Chemicals that have been assessed as new or existing chemicals may require a reassessment of the risk of the chemical under the secondary notification provisions of the Act.

This assessment report has been prepared by the Director of NICNAS, in accordance with the Act. Under the Act manufacturers and importers of the chemical are required to apply for assessment. Applicants for assessment are given a draft copy of the report and 28 days to advise the Director of any errors. Following the correction of any errors, the Director provides applicants and other interested parties with a copy of the draft assessment report for consideration. This is a period of public comment lasting for 28 days during which requests for variation of the report may be made. Where variations are requested the Director's decision concerning each request is made available to each respondent and to other interested parties (for a further period of 28 days). Notices in relation to public comment and decisions made appear in the *Commonwealth Chemical Gazette*.

In accordance with the Act, publication of this report revokes the declaration of this chemical for secondary assessment, therefore manufacturers and importers wishing to introduce this chemical in the future need not apply for assessment. However, manufacturers and importers need to be aware of their duty to provide any new information to NICNAS, as required under Section 64 of the Act.

For the purposes of Section 78(1) of the Act, copies of assessment reports for new and existing chemical assessments may be inspected by the public at the library of the National Occupational Health and Safety Commission (NOHSC). Summary Reports are published in the *Commonwealth Chemical Gazette*, which are also available to the public at the NOHSC library.

Copies of this and other assessment reports are available on the NICNAS website. Hardcopies are available from NICNAS either by using the prescribed application form at the back of this report or directly from the following address:

GPO Box 58

Sydney

NSW 2001

AUSTRALIA

Tel: +61 (02) 8577 8800

Freecall: 1800 638 528

Fax: +61 (02) 8577 8888

Other information about NICNAS (also available on request) includes:

- NICNAS Service Charter;
- information sheets on NICNAS Company Registration;
- information sheets on Priority Existing Chemical and New Chemicals assessment programs;
- safety information sheets on chemicals that have been assessed as priority existing chemicals;
- details for the NICNAS Handbook for Notifiers; and
- details for the *Commonwealth Chemical Gazette*.

More information on NICNAS can be found at the NICNAS web site:

<http://www.nicnas.gov.au>

Other information on the management of workplace chemicals can be found at the web site of the National Occupational Health and Safety Commission:

<http://www.nohsc.gov.au>

Overview

Polymer in Reactint Red X64 was assessed as NA/405 under the NICNAS New Chemicals program in 1996 in the limited category of notification. As a result of new data becoming available, Polymer in Reactint Red X64 has now been reassessed under the secondary notification provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) relevant to existing chemicals, as more than five years has elapsed since the original assessment.

This assessment has evaluated new animal and environmental studies including a dermal sensitisation study in guinea-pigs, a 28-day repeated-dose study in rats, an in vitro chromosomal aberration test, an in vivo mammalian erythrocyte micronucleus test, a ready biodegradation study and an extraction testing report. Updated use and exposure information has been considered.

Polymer in Reactint Red X64 is imported into Australia as < 50% of the marketed product Reactint Red X64. Current and projected imports of Reactint Red X64 are < 1 tonne per year. The major use of Polymer in Reactint Red X64 is as a colorant at up to 1% for polyurethane foam systems including packaging, bedding, furniture, carpet underlay and novelty items such as foam toy balls and puzzles. A limited survey of polyurethane formulators confirmed Australian use in furniture, cushions and bedding, and possible future use in nappies, at approximate concentrations of 0.005% to 0.5%. Other uses may occur in Australia. The survey also identified the use of Polymer in Reactint Red X64 at 0.025% as a component of primer paint for engineering parts and machinery that are later coated with polyurethane elastomer.

Occupational exposure can occur during storage, transport, repackaging and formulation, and use of products made with Polymer in Reactint Red X64. The major potential route of exposure is dermal. Potential exposure to the public would occur through use of foam items coloured with Polymer in Reactint Red X64.

With an import volume of < 1 tonne per annum, and the use pattern resulting in the majority of the chemical being bound in a polymer matrix, environmental exposure is expected to be small. Release to landfill will be in a diffuse manner around the country. Release to the aquatic compartment will be negligible.

Polymer in Reactint Red X64 has low acute oral toxicity in rats (LD50 = 4818 and 4203 mg/kg bw for males and females respectively). It is not a skin irritant or skin sensitiser but is a slight eye irritant. In a 28-day repeated-dose gavage study in rats, the NOAEL was identified as 15 mg/kg bw/day based on minimal clinical signs of toxicity at 150 mg/kg bw/day. Two in vitro and one in vivo genotoxicity tests were performed with Polymer in Reactint Red X64. This chemical was negative in a reverse mutation assay in both *Salmonella typhimurium* and *Escherichia coli* and in an in vivo mouse micronucleus test. An in vitro chromosomal aberration test with Chinese hamster lung (CHL) cells was positive at one dose only in the presence of metabolic activation. Overall the chemical is not considered genotoxic on the basis of these tests.

Polymer in Reactint Red X64 is not classified as a hazardous chemical under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a). However it would be classified as a hazardous substance under the Globally Harmonised System for Hazard Classification and Labelling of Chemicals (GHS) and would require appropriate labelling if this system were adopted in Australia. Polymer in Reactint Red X64 is not specifically listed in the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (FORS, 1998), and is not expected to meet the criteria to be classified as a Dangerous Good.

Ecotoxicological data for Polymer in Reactint Red X64 were not provided, however it is not expected to exhibit ecotoxic characteristics because large polymers are not readily absorbed by biota, and as it is non-ionic it would not overchelate minerals. Reactint Red X64 containing < 50% Polymer in Reactint Red X64 was tested for biodegradability according to OECD Test Guideline (TG) 301C. In this test Reactint Red X64 was identified as non-biodegradable after 28 days with activated sludge, however, a large proportion was transformed during the study. The transformation products were not identified.

Polymer in Reactint Red X64 is a dark-coloured viscous liquid that reacts with isocyanates and becomes bound in polyurethane foams. Its water solubility is > 2 g/L. For the marketed product Reactint Red X64 the boiling point is > 100⁰C and flash point (open cup) is 213⁰C.

The risk of adverse health effects from occupational exposure to Polymer in Reactint Red X64 is considered very low, given its low hazard. It is not classified for health effects, quantities used are relatively small, and in its major use in polyurethane foams it is used in conjunction with the more hazardous isocyanates. Safety measures to limit exposure to isocyanates will in turn reduce the exposure to Polymer in Reactint Red X64. Inhalational exposure is possible in spray application of primer, but would be limited by the low concentration in this product.

Public exposure to Polymer in Reactint Red X64 could occur through consumer use of Polymer in Reactint Red X64 coloured foams, or articles made from these foams. Under normal conditions of use, there will be negligible potential for public exposure, since it will be bound in the polyurethane foam.

The highest potential risk of consumer exposure will be with children sucking or chewing foam toys containing bound Polymer in Reactint Red X64, as oral exposure could occur. Accelerated extraction test results of colorant from foam were supplied for the assessment but cannot be easily extrapolated to normal use conditions. Calculations on a reasonable worst case scenario suggest that the margin of safety may be as high as 5000, indicating low public risk.

Based on limited exposure, the risk to the environment is expected to be low. The chemical has properties that indicate it may bioaccumulate, and there are no measured ecotoxicity data available. Should import volumes significantly increase, and/or the use pattern change so that aquatic exposure occurs, this data should be provided.

Under the secondary notification provisions of the Act, manufacturers/importers of chemicals previously assessed by NICNAS are required to notify the Director of new information. New information can include an increase in quantity imported, the commencement of Australian manufacture, increased environmental exposure, and/or additional information becoming available on hazards or exposure, such as the amount of Polymer in Reactint Red X64 leached from children's toys under normal conditions of use.

Recommendations summary (see Section 12 for full recommendations)

Recommendations for occupational controls for Polymer in Reactint Red X64 are similar to those given in the 1996 New Chemicals assessment NA/405, and cover engineering controls, safe work practices, personal protective equipment (PPE) and the material safety data sheet (MSDS).

It is recommended that foam toys and foam produced for toys and coloured with Polymer in Reactint Red X64 should be tested for colorant extraction. One test is contained in the *Australian Standard for Children's toys (safety requirements) Part 3: Toxicological requirements (AS 1647.3 – 1995)* and toys should at least meet the requirements of this standard. Information on testing requirements should be included in the technical literature for Reactint Red X64.

Recommendations are also made on disposal of Polymer in Reactint Red X64 and products containing it, and on cleanup of spills.

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Acronyms and abbreviations

ALAT	alanine aminotransferase
APS	Asia Pacific Specialty Chemicals Ltd
ASAT	aspartate aminotransferase
BOD	biological oxygen demand
CAS	Chemical Abstracts Service
CHL	Chinese hamster lung
DOC	dissolved organic carbon
DNCB	2,4-dinitrochlorobenzene
EA	Environment Australia
GHS	Globally Harmonised System for Hazard Classification and Labelling of Chemicals
HPLC	high performance liquid chromatography
LC50	median lethal concentration
LD50	median lethal dose
LOAEL	lowest-observed-adverse-effect-level
MSDS	material safety data sheet
NAMW	number average molecular weight
ND	new data
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no-observed-adverse-effect-level
NOHSC	National Occupational Health and Safety Commission
OECD	Organisation for Economic Cooperation and Development
PMN	premanufacture notice (US EPA)
P/N ratio	ratio of polychromatic to normochromatic erythrocytes
PPE	personal protective equipment
pph	parts per hundred
S9	metabolic activation system
TDI	toluene diisocyanate
US TSCA	United States Toxic Substances Control Act

1. Introduction

The chemical Polymer in Reactint Red X64 (CAS Number not assigned) was assessed as a new chemical under Section 23 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) under the limited notification category.

The New Chemicals Assessment Report (NA/405) was published in August 1996. This report concluded that Polymer in Reactint Red X64 was non-hazardous according to the National Occupational Health and Safety Commission's then current *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994a). Recommendations were made relating to engineering controls during repackaging and transferral, use of personal protective equipment, safety practices when handling and Material Safety Data Sheet (MSDS). These recommendations were based on the intended use of Polymer in Reactint Red X64 as a colorant in the manufacture of polyurethane foams.

New data were supplied on Polymer in Reactint Red X64 in 2001. As five years have elapsed since the original assessment, this chemical is now being assessed as an existing chemical. The new data warranted reassessment which has been carried out under Section 68A of the Act, covering secondary notifications of existing chemicals.

Polymer in Reactint Red X64 is imported into Australia, and marketed, as a component in Reactint Red X64. Reactint Red X64 is a mixture that contains < 50% Polymer in Reactint Red X64 and a polyester polyol.

Reactint Red X64 has been imported and used in Australia since 1996.

1.1 Declaration and secondary notification

Declaration as a secondary notification was initiated when NICNAS received further studies conducted on Polymer in Reactint Red X64 that were not available during its assessment as a new chemical. The studies are:

1. Dermal sensitisation study in guinea-pigs;
2. 28-day repeated-dose study in rats;
3. In vitro chromosomal aberration test; and
4. Mammalian erythrocyte micronucleus test.

Two further studies conducted on Reactint Red X64 were received. These were:

5. Ready biodegradability; and
6. Extraction testing reports.

A notice was published in the *Chemical Gazette* of 5 February 2002 requiring all persons who introduce Polymer in Reactint Red X64 into Australia either by manufacture or import to apply for secondary notification.

1.2 Objectives

The objectives of this assessment were to review the new data made available since the publication of the 1996 new chemical assessment and where appropriate revise the original assessment to:

- characterise the hazards of Polymer in Reactint Red X64 to human health and the environment;
- characterise current and potential occupational, public and environmental exposure to Polymer in Reactint Red X64;
- characterise the risks of adverse effects resulting from exposure to workers, the general public and the environment; and
- make appropriate recommendations to control exposures and/or reduce potential health and environmental risks.

1.3 International perspective

In 1993 a premanufacture notification (PMN) for Polymer in Reactint Red X64 was made to the United States Environmental Protection Agency (US EPA). Proposed uses in the USA for the chemical (P-94-212) were as a colorant for polyurethane systems and a tyre cord lubricant. An outcome of the PMN review was a Section 5(e) Consent Order requiring the following testing to be conducted, based on expected substantial human exposure:

- 28-day oral study including a neurotoxicity function observational battery and histopathologic examination including reproductive organs;
- acute oral study;
- Ames assay; and
- mouse micronucleus assay by the intraperitoneal (IP) route of administration.

In 1999, the US EPA revoked the PMN consent order based on the results of the testing.

The Australian importer of the chemical advised that Polymer in Reactint Red X64 was approved for use in Korea in 1996 and has been sold in Europe since 1994.

1.4 Peer review

During all stages of preparation, this report has been subject to internal peer review by NICNAS and Environment Australia (EA).

2. Applicants

One company applied for secondary notification assessment of this chemical. The applicant supplied relevant information, such as toxicity and use data. Under Section 36 of the Act, the applicant was provided with a draft copy of the report for correction of errors and variation of content.

Applicant details are:

Asia Pacific Specialty Chemicals Limited (APS)

15 Park Road

Seven Hills NSW 2147

3. Chemical Identity and Composition

The following information refers to Polymer in Reactint Red X64.

Trade Names:	Component of marketed product 'Reactint Red X64' at < 50%.
USA Premanufacture notice (PMN) number:	P-94-212
Number average molecular weight (NAMW):	> 1000
Maximum percentage of low molecular weight species:	(molecular weight < 1000): < 15% (molecular weight < 500): < 1%
Maximum content of residual monomers:	< 8%
Degree of purity:	> 92%
Toxic or hazardous impurities:	none
Non-hazardous impurities:	< 8%

4. Physical and Chemical Properties

4.1 Physical state

Polymer in Reactint Red X64 is a dark viscous liquid with a slightly sweet odour at ambient temperature and pressure. Information submitted on the physical and chemical properties of Polymer in Reactint Red X64 and Reactint Red X64 is provided below.

Physical and Chemical property	Result	Substance tested
Boiling point:	> 100°C (at 760 mm Hg)	Reactint Red X64
Specific gravity:	1.1	Reactint Red X64
Water solubility:	> 2 g/L at 25°C	Polymer in Reactint Red X64
Partition co-efficient (n-octanol/water):	Log P _{ow} 3.2	Polymer in Reactint Red X64
Flash point (open cup):	213°C	Reactint Red X64
Autoignition temperature:	> 350°C (estimate)	Reactint Red X64
Explosive properties:	Stable	Not known
Reactivity/ stability:	Not an oxidiser, but will react with isocyanates	Polymer in Reactint Red X64

Although vapour pressure was not determined, it is expected to be low under ambient conditions due to its high boiling point and molecular weight. Polymer in Reactint Red X64 is not expected to hydrolyse, as it does not contain hydrolysable chemical groups (Howard, 1991).

No information was provided on the adsorption/desorption properties of Polymer in Reactint Red X64. However, the partition coefficient would indicate that it is likely to adsorb to organic matter. This is in contrast to the polymer's high water solubility that suggests it is not likely to strongly adsorb to soils.

Polymer in Reactint Red X64 is normally reacted into polyurethane, which is environmentally stable. Although the dissociation constant was not measured, dissociation in water is unlikely to occur.

Polymer in Reactint Red X64 does not contain ionisable groups. It is not flammable, however, it is combustible and can produce toxic degradation products including sulphur, nitrogen and carbon oxides.

Release of the polymer from the polyurethane foam is not expected as it is chemically bound, however, extraction testing information was supplied and discussed in Section 6.2 and 6.3.

5. Manufacture, Importation and Use

5.1 Manufacture and importation

Polymer in Reactint Red X64 is not manufactured in Australia. It is imported into Australia as a component (< 50%) of Reactint Red X64.

Since 1998, less than one tonne per year of Reactint Red X64 has been imported into Australia. Importation over the next three years is likely to remain below one tonne per year.

Reactint Red X64 is imported into Australia in 20.4 kg drums.

5.2 Repackaging, storage and transport

Repackaging of Reactint Red X64 from the 20.4 kg drums into 1 and 4 kg tins has been carried out at one site in Australia. This process has currently ceased but may occur in future.

Drums (20.4 kg) and tins (1kg or 4kg) of Reactint Red X64 are stored and distributed from facilities in New South Wales, Victoria, South Australia and Queensland.

5.3 Use

Reactint Red X64 has been in use in Australia for 5 years and replaced similar material that was in use for over 10 years. The importer advised that Polymer in Reactint Red X64 (as part of the marketed product Reactint Red X64) is added to polyurethane foams at a rate of up to 1% by weight.

Polymer in Reactint Red X64 is present in Reactint Red X64 for the intended use of colorant for polyurethane foam systems including packaging, furniture, bedding, carpet underlay and novelty items such as foam toy balls and puzzles.

5.3.1 Australian formulators survey

As part of this assessment, NICNAS conducted a survey of three companies that had recently (January to July 2002) purchased Reactint Red X64. Information on method of use, occupational exposure to, and control measures in place for Reactint Red X64 was requested.

The responses confirmed that Reactint Red X64 is used as a colorant for polyurethane foam in a variety of applications, including furniture, cushions and bedding, and may be used in babies' nappies in the future. Concentrations of Polymer in Reactint Red X64 in these products ranged from 0.005% to 0.5%. An additional use identified was as a component of primer paint used for engineering parts and machinery that are later treated with polyurethane elastomer.

As the survey was small and covered a short time span, it cannot be excluded that other polyurethane foam uses not identified (such as packaging, toys, carpet underlay etc) may also occur in Australia.

6. Exposure

Occupational, public and environmental exposure are considered below.

6.1 Occupational exposure

Occupational exposure to Polymer in Reactint Red X64 in Australia may occur during storage, transport, repackaging, formulation and use of products made with Polymer in Reactint Red X64. The major potential route of exposure is dermal.

No workplace monitoring data were available, however, there is limited potential for inhalation exposure because of Polymer in Reactint Red X64's high molecular weight and boiling point and, hence, predicted low volatility. Ingestion is not likely during occupational use.

Due to the colorant nature of this chemical, exposure is likely to be evident to exposed persons. It is anticipated that this may assist in maintaining dermal exposure to a minimum.

6.1.1 Exposure during storage and transport

Reactint Red X64 drums and repackaged containers are stored in a small number of warehouse facilities throughout Australia. The drums and tins are transported by road to user sites.

Exposure during importation, transportation, and storage of drums and tins is unlikely except in cases of accidental spills or leaks.

6.1.2 Exposure during repackaging

Repackaging of Reactint Red X64 from the 20.4 kg drums into 1 and 4 kg tins occurred at one site in Australia. Repackaging has ceased but may resume in future. Four workers were involved in repackaging for 1 h/day, 10 days/year. The use of ventilation with local exhaust during this process would reduce the potential exposure.

6.1.3 Exposure during formulation with Polymer in Reactint Red X64

The major use of Polymer in Reactint Red X64 is at polyurethane foam manufacturing plants, where the chemical is dispensed into polyurethane feed systems either through a closed or manual system under local exhaust ventilation (Figure 1). Polymer in Reactint Red X64 binds to isocyanates to form the coloured polyurethane foam. It is predicted that the present engineering controls in place to limit exposure to hazardous isocyanates will also reduce exposure to Polymer in Reactint Red X64. Although the concentration of Polymer in Reactint Red X64 used may be up to 1% by weight, data from survey respondents indicates its use at lower levels. One respondent used Reactint Red X64 containing < 50% Polymer in Reactint Red X64 at 0.01% to 0.05% in polyurethane foam, and another at 0.05% to 1.0%. This is approximately equivalent to 0.005% to 0.5% Polymer in Reactint Red X64.

In the polyurethane foam manufacture industry, workers with the highest potential for exposure to Polymer in Reactint Red X64 are production workers decanting the polymer and operating the polyurethane foam machines. Time spent in these activities is 6 h/day for up to 230 days/year, depending on the usage of the chemical. In addition to these workers, potential exposure exists for maintenance technicians. Time spent on maintenance may be up to 4 h/day for 20 days/year.

REACTINT © AUTOMATED COLOUR BLENDING SYSTEM

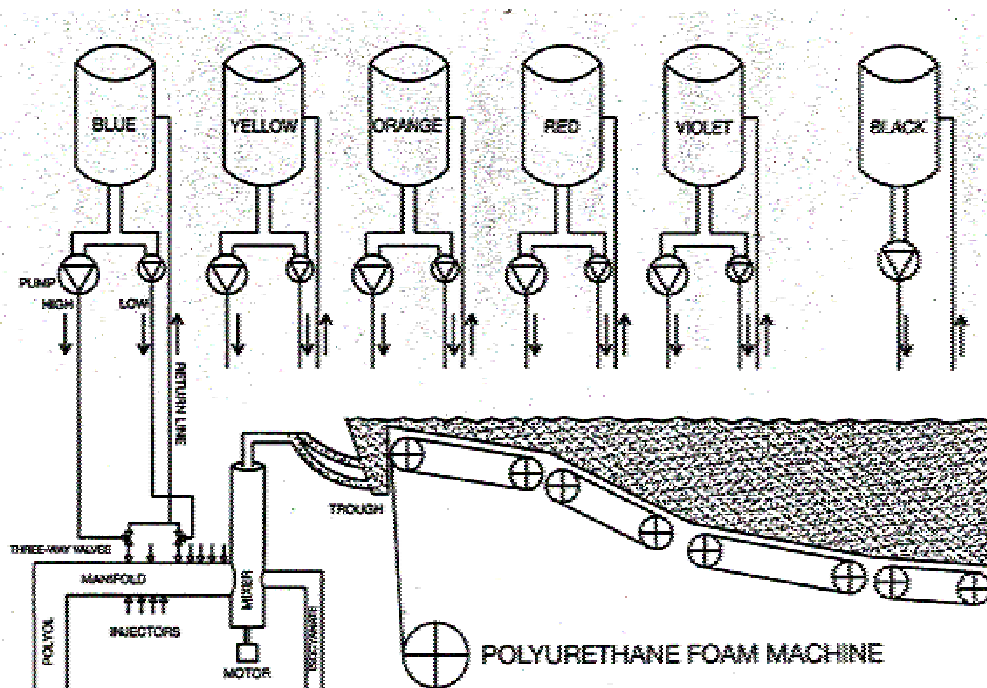


Figure 1: Polyurethane foam formulation machine involving Polymer in Reactint Red X64 (red) as a colorant

Exposure during the formulation of polyurethane foams containing Polymer in Reactint Red X64 is likely to be low. Colour extraction test results submitted during the assessment indicates that the polymer predominantly remains within the foam. Though not anticipated, potential for dermal exposure remains if partly cured material is handled. One responder to the survey indicated small samples may be manually taken from partially cured foam for laboratory testing, however formulation and curing is an automated process. Additionally, the use of extraction ventilation systems during this process will limit exposure.

One company reported formulation of a paint primer containing Reactint Red X64 at 0.05%. Reactint Red X64 is weighed directly into the containers in which the primer is sold. These containers range in size from 500 mL to 20 kg. One worker was involved in this formulation process for 2 hours/day, 10 days/year.

6.1.4 Use

Further processing of polyurethane foam containing Polymer in Reactint Red X64 into articles such as furniture is not expected to lead to occupational exposure, as the colorant has been bound into the foam.

Primer containing Polymer in Reactint Red X64 is applied to large metal machinery or small engineering parts. Application may be by brush, roller or spray. Information from end users on details of their application method was not obtained. However, the primer is applied to sand/grit blasted steel as a thin coating (50-200 microns). Potential exposure would be greatest for spray application although the low concentration used would limit exposure.

6.2 Public exposure

The potential for public exposure to Polymer in Reactint Red X64 during importation, repackaging, transport, storage, formulation and industrial use is expected to be low - limited to accidental release and repackaging/formulation emissions.

Use in a primer for engineering parts and machinery should not lead to public exposure during application if appropriate occupational controls are in place for surface coatings. The painted articles would not be a source of further public exposure once the final paint coating was applied.

Polymer in Reactint Red X64 is incorporated at levels up to 1% into polyurethane foams, many of which would be intended for public use. Some articles may involve direct skin contact during use. There is potential for dermal exposure to the public during the use of such articles, though the polymer is bound into the polyurethane foam.

Results of accelerated extraction trials of Reactint Red X64 from polyurethane foams were supplied for this assessment. The trials were for worst case scenarios and not representative of normal conditions, as solvent extraction was used with off-specification foams. For the test foams, the relative amount of toluene diisocyanate (TDI) available for reacting was decreased while at the same time up to double the level of colorant was used in the foam. Solvent extraction of 1.5 to 8.0% of Reactint Red X64 from foam was recorded, however, the highest level was believed to be associated with breakdown of the integrity of the foam. Less leaching is expected with polyurethane foams produced under normal conditions.

6.2.1 Use of toys

Polyurethane foam containing Polymer in Reactint Red X64 is used in children's toys internationally e.g. animal shapes made from foam. This use was not identified in the recent Australian survey, however, the use of foam coloured with Polymer in Reactint Red X64 for toys manufactured in and imported into Australia cannot be excluded.

Oral exposure of young children may occur through sucking or chewing these toys. Exposure by this route is likely to be higher than for scenarios involving dermal exposure described below. It is estimated that a child aged between 6 and 12 months could be exposed to 0.028 mg/kg bw/day of Polymer in Reactint Red X64 (Appendix 1). The calculations are based on the highest concentration of colorant (1%) that is expected to be used in foam. The submitted extraction tests were not considered to be directly relevant to release of the colorant, as off-specification foams and solvent extraction were used. The tests have been used as a guide in these estimates. It is considered that the extraction test results of 1.5% to 8.0% would be an overestimation. Therefore for a realistic worst case scenario it has been assumed that 1% of the colorant could be released per day, and that there is 3 hours exposure per day via the mouth. In previous studies on mouthing estimates, it has been shown that children will not mouth a single toy non-stop (Steenbekkers, 2001), therefore reducing exposure from the Polymer in Reactint Red X64 coloured toys.

Oral exposure to children is reduced by a number of factors including limited mouthing times and limited saliva volumes. However, factors increasing exposure include the child's small body weight and the flexibility of the foam. Polyurethane foam density varies from 0.03 to 0.6 g/cm³, which is equivalent to 33 to 667 cm³ for a 20 g piece of foam. At the denser end of the range, the foam will be solid, so saliva will only contact the outside of the toy. Exposure will be greater from soft foam, where saliva can permeate the foam (Watson et al, 1983).

6.2.2 Use of nappies

One formulator indicated that Polymer in Reactint Red X64 is likely to be used in the future in babies' nappies as colouring for the adhesive foam section attached to the outside front of the nappy. The concentration of Polymer in Reactint Red X64 would be between 0.025 and 0.5%. Infant urine and faeces may enhance degradation of Polymer in Reactint Red X64, although this has not been investigated. Furthermore, the dermal exposure of Polymer in Reactint Red X64 would be enhanced through broken and inflamed skin, which is common in children wearing nappies. Infants potentially exposed to Polymer in Reactint Red X64 via this route would be susceptible to chemical exposure because of their underdeveloped physiology and stage of development. As children age their ability to deal with xenobiotics improves.

However dermal exposure is likely to be limited as the coloured foam is used on the outside of the nappy and is covered by other materials (i.e. velcro and probably clothing as well).

In addition the high molecular weight would limit the potential for dermal absorption. Therefore, significant exposure to infants is not expected through this potential use in foam strips on the outside of nappies.

6.3 Environmental exposure

6.3.1 Release

Two main areas identified for potential environmental exposure to Polymer in Reactint Red X64 are accidental release and repackaging/formulation emissions.

Environmental release during transport or handling can occur in the event of accidental spillage or mishandling. All clean up of spills and disposal should be conducted according to the MSDS. It is anticipated that the amount of Polymer in Reactint Red X64 released to the environment this way will be low (< 10 kg per year).

The empty 20.4 kg drums in which Reactint Red X64 is imported are sent to a licensed drum recycler. The company advised that the residual chemical in the empty drums is expected to be low (< 0.5%). The recycler thoroughly rinses the drums with water and drains for future use. The rinsate is released to a trade waste sewer. The anticipated quantity of Reactint Red X64 expected to be released through this system is less than 10 kg per year. Empty bottles or pails are either washed and re-used or disposed of to landfill.

Local exhaust ventilation was previously identified as a requirement for formulation facilities involved in the use of Polymer in Reactint Red X64 and its incorporation into polyurethane foam. Due to these controls and the expected low volatility of Polymer in Reactint Red X64 this source of emissions is expected to be low.

Waste products such as Polymer in Reactint Red X64 coloured polyurethane foam are expected to be disposed of to landfill or incinerated. An extractability test, while not representative of environmental conditions, does demonstrate the potential for release out of the foam when disposed of to landfill. The highest release of approximately 8% Reactint Red X64 was associated with a non standard foam containing a concentration of Reactint Red X64 higher than that considered normal. This high level of release was believed to be associated with breakdown of the integrity of the foam, which may be expected after sufficient time in landfill. Assuming 4% of Polymer in Reactint Red X64 moves out of foam as a worst case, less than 50 kg per annum will be released from foam in landfill around the country.

6.3.2 Fate

Covalent bonding is expected to retain Polymer in Reactint Red X64 in the polyurethane foam matrix, with the final environmental fate being incineration or landfill.

A small amount (< 10 kg) of unreacted Polymer in Reactint Red X64 from spills is disposed of to approved landfill or incinerated by licensed waste contractors after treatment. Significant 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, and as discussed above, some migration of the chemical out of the foam may be expected. Incineration of Polymer in Reactint Red X64 is expected to produce water and oxides of carbon, nitrogen and sulphur.

Washings from storage drums (< 10 kg per year) are discharged into a trade waste sewer. Water solubility of Polymer in Reactint Red X64 is > 2g/L and dilution is likely if released to waterways.

Reactint Red X64 containing < 50% Polymer in Reactint Red X64 was tested for biodegradability according to OECD TG 301C. In this test Reactint Red X64 was identified as non-biodegradable after 28 days with activated sludge, however, a large proportion was transformed during the study. Degradability based on Biological Oxygen Demand (BOD) and Dissolved Organic Carbon (DOC) was shown to be minimal (< 5% after 28 days). However, when the residual test substance concentration was tested by High Performance Liquid Chromatography (HPLC), degradation around 40% was observed. No further studies on the transformation products were conducted.

In summary the chemical cannot be considered ready biodegradable, although the test substance did appear to be transformed through the exposure period.

Due to its NAMW > 1000, Polymer in Reactint Red X64 would not normally be expected to cross biological membranes (Anliker et al, 1988; Gobas et al, 1986). However the substance may be surface active and exhibit surfactant-like properties. Consequently, environmental behaviour can be difficult to predict. This compound has an experimentally determined Log Kow of 3.2, which suggests a bioaccumulation potential exists.

7. Evaluation of Animal Toxicological Data

Data submitted for the original new chemical assessment and the new data (denoted by ND) for the secondary notification are detailed below. All studies summarised below were conducted on Polymer in Reactint Red X64.

7.1 Acute toxicity

As part of the original assessment acute oral, skin irritation and eye irritation tests were evaluated. Summaries of these studies are presented below.

Acute toxicity

A rat acute oral toxicity study is available conducted to OECD TG 401 (Corning Hazleton Inc., 1995a). Sprague-Dawley rats, 5 per sex per group, were administered 2000, 4000 or 5000 mg/kg bw Polymer in Reactint Red X64 by gavage. No deaths or clinical signs of toxicity occurred at 2000 mg/kg bw. At 4000 mg/kg bw 3 females died and at 5000 mg/kg bw 3 males and 3 females died. Clinical signs of toxicity observed in both sexes at 5000 and 4000 mg/kg bw included staggered gait, hypoactivity, hunched posture, absence of righting reflex, red stained face, thin appearance, dyspnea, soft and/or red stool, red stained urogenital area, wet urogenital area, alopecia (urogenital area), mydriasis, lacrimation and pink urine. At necropsy, red or pink staining of connective tissue was observed throughout the body at 4000 mg/kg bw and above. The LD50 for males and females was 4818 and 4203 mg/kg bw respectively.

Skin irritation

In a well-reported study (Corning Hazleton Inc., 1995b), six New Zealand White rabbits received a 24-hour application of 0.5 mL undiluted Polymer in Reactint Red X64 to an abraded and “intact” site under an occlusive dressing. Skin reactions were noted 30 minutes and 48 hours after patch removal. No skin reactions were observed at the intact site at either observation period. In abraded animals very slight erythema was seen in 1 animal 30 minutes after patch removal. No skin reactions were seen approximately 48 hours later. The results of this study show that Polymer in Reactint Red X64 is not a skin irritant.

Eye irritation

In a study employing methodology analogous to OECD TG 405 (Corning Hazleton Inc., 1995c), six New Zealand White rabbits received a single instillation of 0.1 mL undiluted Polymer in Reactint Red X64 into the eye. The eyes were examined 1, 24, 48, and 72 h, and 7 days after instillation. No corneal opacity was seen. Injected iritis was observed in 5 animals at 1 hour post-instillation only. From 1 to 96 hour post-instillation mild to moderate conjunctival erythema and slight chemosis were observed in up to 6 animals. No signs of ocular irritation were observed on day 7 post-treatment. The mean score for conjunctival erythema and chemosis determined from all animals at the 24, 48 and 72 hour observation points were 1.4 and 0.7 respectively. The results of this study show that Polymer in Reactint Red X64 has the potential to cause slight eye irritation.

7.2 Skin sensitisation (ND)

A guinea-pig closed-patch test was submitted for assessment during the secondary notification of this chemical (Corning Hazleton Inc., 1995d). Groups of 10 Dunkin-Hartley guinea-pigs were employed in the treated and control groups. At induction, 0.4 mL undiluted Polymer in Reactint Red X64 (concentration determined in a screening test) was applied topically to test animals, for 6 hours once weekly for 3 weeks. Two weeks after the final induction treatment, a challenge concentration of 0.4 mL undiluted Polymer in Reactint Red X64 was applied to both the test and control animals for 6 hours, and observations made 24 and 48 hours after patch removal. A second challenge with 0.4 mL 75% Polymer in Reactint Red X64 was performed 1 week after the initial challenge. A positive control group of 4 animals was treated with 2,4-dinitrochlorobenzene (DNCB).

At induction, skin reactions of very faint to faint erythema were observed in all test animals. At the initial challenge, skin reactions were seen in 9/10 test animals and 8/10 control animals. Twenty-four hours after application, very faint and faint erythema was observed in 5 and 4 test animals respectively, compared to 5 and 3 control animals. At 48 hours, skin reactions were seen in 6/10 test and 6/10 control animals (very faint and faint erythema in 4 and 2 test animals respectively, compared to 5 and 1 control animals). No skin reactions were observed with the second challenge concentration of 75%. Moderate to strong erythema were observed in all animals treated with DNCB. In comparison with the Buehler test (OECD TG 406), another non-adjuvant test method, this study employed induction and challenge concentrations of 0.4 mL instead of 0.5 mL, and used DNCB, a “strong” sensitiser, instead of one of the recommended “mild/moderate” sensitisers. However, concentrations at induction and challenge were maximised, that is, undiluted Polymer in Reactint Red X64 applied topically. Consequently, it is considered that the skin sensitisation potential of Polymer in Reactint Red X64 was adequately investigated in this study.

Skin reactions were only seen in the initial challenge with 100% Polymer in Reactint Red X64. However, the observation of skin reactions of the same severity (and incidence by 48 hours) in test and control animals that generally faded between observation periods suggests an irritant rather than sensitisation reaction. Thus, overall, Polymer in Reactint Red X64 is considered not to have exhibited a skin sensitisation potential under the conditions of this study.

7.3 Repeated-dose toxicity (ND)

In a dose ranging study (Safepharm Laboratories Limited, 1997a), conducted to determine final dose levels for a 28-day study, Sprague-Dawley rats, 3 per sex per group, were dosed daily by gavage with 0, 150, 400, 550, 700 or 1000 mg/kg bw/day Polymer in Reactint Red X64 in distilled water for up to 14 consecutive days. All the animals were subject to macroscopic examination at necropsy. All animals died or were killed *in extremis* by day 6 of treatment at 700 and 1000 mg/kg bw/day. One female died at 550 mg/kg bw. Clinical signs of toxicity observed at 550 mg/kg bw/day included dehydration, generalised fur loss, hunched posture, piloerection, noisy respiration and tiptoe gait. At 400 mg/kg bw/day, one female exhibited noisy respiration on day 4 of treatment only. Compared to controls, reductions in mean body weight gain were seen in males (41%) and females (26%) at 550 mg/kg bw/day at the end of the dosing period. At necropsy dark livers were seen in animals at 700 and 1000 mg/kg bw/day, along with dark adrenals, kidneys and spleen, and enlarged stomach, at 1000 mg/kg bw/day. No treatment-related macroscopic findings were seen at 550 mg/kg bw/day (including the female that died during treatment), 400 and 150 mg/kg bw/day. Staining of the internal viscera observed in Polymer in Reactint Red X64 treated animals due to the colorant nature of the test material was not considered a toxicologically significant finding.

In the main study conducted to OECD TG 407, Sprague Dawley rats, 5 per sex per group, were dosed orally by gavage with 0, 15, 150 or 400 mg/kg bw/day Polymer in Reactint Red X64 in distilled water for 28 consecutive days. Additionally, two recovery groups, 5 per sex per dose, received 0 or 400 mg/kg bw/day test material for the same dosing schedule and were then maintained without treatment for a further 14 days. Functional performance tests including motor activity and grip strength were conducted in all non-recovery test and control animals on day 27 of treatment. Animals were sacrificed at the end of the treatment (or recovery) period and routine haematology, biochemical and urinalysis investigations conducted. All animals were subject to a complete and thorough macroscopic and microscopic examination at necropsy.

In the non-recovery groups death was only observed at 400 mg/kg bw/day; one male died on day 4 and one male died on day 22 of treatment. Clinical signs of toxicity observed in both sexes at 400 mg/kg bw/day included hunched posture, piloerection, altered respiratory rate, laboured and noisy respiration intermittently throughout the study. A decrease in overall motor activity (32%) was also seen in females at 400 mg/kg bw/day compared to controls. At 150 mg/kg/day, noisy respiration rate was seen in one male on day 25 of treatment and in two females intermittently throughout the study from day 6 and 12. Decreased respiratory rate was also seen in one of these females on day 25. No clinical signs of toxicity were seen at 15 mg/kg bw/day. At 400 mg/kg bw/day a substantial reduction in food intake was seen in males throughout treatment compared to controls, and at study termination a significant decrease in body weight gain (i.e. > 10%) was seen in these males. No significant reduction in body weight gain or food consumption was seen at ≤ 150 mg/kg bw/day, or water consumption at ≤ 400 mg/kg bw/day.

At 150 mg/kg bw/day and above, a statistically significant dose dependent increase in aspartate aminotransferase (ASAT) and bilirubin levels were seen in males (≥ 27 and $\geq 60\%$ respectively), along with an increase in alanine aminotransferase (ALAT) in females (25-95%). A statistically significant decrease in triglycerides (56-52%) was also seen in males at > 150 mg/kg bw/day. However, these changes were not dose related and are therefore not considered as treatment-related effect. Additional statistically significant increases in biochemical parameters seen at 400 mg/kg bw/day only (the top dose level) were ALAT (80%) and thyroid stimulating hormone (21%) levels in males, ASAT (20%) and bilirubin (83%) levels in females, and thyroxine levels (41-48%) in both sexes. At 400 mg/kg bw/day a statistically significant increase in white blood cell count (39-65%) was seen in both sexes, with an 80% increase in the lymphocyte sub-population being seen in females. No treatment related effects were seen on haematological or biochemical parameters at 15 mg/kg bw/day, or on urinalysis parameters at any dose level. Compared to controls, a statistically significant increase in absolute and relative liver (28-36%) and spleen weight (32-38%) was seen in females at 400 mg/kg bw/day. At necropsy, no macroscopic changes were seen in treated animals, and no histopathological indication of the cause of death was seen in males that died at 400 mg/kg bw/day. The only treatment-related effects seen were an increased incidence and severity of vacuolation of fibre tracts in the brain (notably those of the corpus callosum) and alveolar macrophage accumulation in females at 400 mg/kg bw/day compared to controls.

In the recovery group (400 mg/kg bw/day), no deaths were observed and clinical signs of toxicity showed a complete regression upon cessation of treatment. At the end of the recovery period, no treatment related effects were seen in any of the parameters investigated, while histopathological examination showed no evidence of a persistent effect for changes seen in the lung and brain at the end of the dosing period.

Overall, the results of the 14-day dose finding and 28-day studies show a clear dose dependent increase for mortality and clinical signs of toxicity at 400 and 150 mg/kg bw/day and above, respectively. Additional effects seen at 150 mg/kg bw/day in the 28-day study were small increases in ALAT in females, and ASAT and bilirubin in males. However, these relatively small increases (25-60%) in biochemical parameters are not considered toxicologically significant, as they were observed in the absence of histopathological changes to the liver (even at 400 mg/kg bw/day which produced mortalities) and were reversible in the 400 mg/kg bw/day recovery group. Therefore, a NOAEL of 15 mg/kg bw/day is identified for clinical signs of toxicity in the 28-day study. The LOAEL for these effects, occasional observations of noisy respiration and decreased respiratory rate in a few animals, is 150 mg/kg bw/day.

7.4 Genotoxicity

Two in vitro studies and one in vivo study have been conducted with Polymer in Reactint Red X64.

In vitro studies

Two in vitro studies were conducted on Polymer in Reactint Red X64. One, a reverse mutation assay in both *Salmonella typhimurium* and *Escherichia coli*, was evaluated in the original New Chemicals Assessment NA/405, and is summarised below. In addition, a new chromosome aberration study was submitted as part of the secondary notification.

In a study conducted to OECD TG 471 using direct plate incorporation (Corning Hazleton Inc., 1995e), *S. typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537, along with *E. coli* strain WP2uvrA, were incubated with up to 5000 µg/plate Polymer in Reactint Red X64 (the limit dose) with and without metabolic activation. No increase in the number of revertants was seen in any of the tested cultures. Positive controls confirmed the validity of this test. This negative result with Polymer in Reactint Red X64 was confirmed by a second independent experiment.

The genotoxic potential of Polymer in Reactint Red X64 was investigated in a chromosome aberration study employing methodology analogous to OECD TG 473 (Safeparm Laboratories Limited, 1997b). Dose levels for the main study were determined in a preliminary dose ranging study. The maximum dose levels chosen were those that did not produce significant toxicity (e.g. decreased cell count \geq 50%). In the first experiment, Chinese hamster lung cells (CHL) were exposed to 2.5-60 µg/mL Polymer in Reactint Red X64 for 6 hours with metabolic activation and 5-30 µg/mL for 6 hours without metabolic activation. Cells were harvested at 18 hours with and without metabolic activation. In the second experiment CHL cells were continuously exposed to 1.25-30 µg/mL Polymer in Reactint Red X64 in the absence of metabolic activation until harvesting at 24 and 48 hours. Both experiments scored 200 metaphases per group.

In the first experiment, a 6-hour exposure period with metabolic activation produced a statistically significant increase in the frequency of chromosome aberrations with and without gaps in the absence of significant cytotoxicity at 60 µg/mL (the top dose); 4.0, 2.5, 3.5 and 8.5 % excluding gaps at 0, 20, 40 and 60 µg/mL respectively. No increase in chromosome aberrations was observed in the absence of metabolic activation. Similarly in the second experiment no increase in chromosome aberrations was observed in the absence of metabolic activation for a 24 and 48 hour exposure period. The positive control, cyclophosphamide, induced a statistically significant increase in the frequency of aberrations with metabolic activation. No suitable positive control was used for the 6-hour exposure period without metabolic activation, though for the extended exposure periods the positive control mitomycin produced a statistically significant increase in aberrations. Overall, the test system was considered capable of detecting chemicals that caused chromosomal aberrations. Though there was an absence of a clear dose-response relationship in the frequency of chromosome aberrations, the statistically significant increase at 60 µg/mL in the presence of metabolic activation is considered evidence, albeit weak, of genotoxic activity. Consequently, Polymer in Reactint Red X64 was clastogenic in vitro in the presence of metabolic activation under the conditions of this study.

In vivo study (ND)

In a micronucleus study conducted to OECD TG 474, groups of CD-1 mice (5 per sex per dose per sampling time) received a single intraperitoneal (ip) injection of 0, 20, 40 or 80 mg/kg bw Polymer in Reactint Red X64 (Safepharm Laboratories Limited, 1997c). Bone marrow was sampled at 24, 48 or 72 hours and 1000 polychromatic erythrocytes scored for micronuclei per animal. Dose levels were determined in a preliminary range finding study.

Two males and one female died in the 72-hour sampling group at 80 mg/kg bw. Clinical signs of toxicity seen in animals at 80 mg/kg bw in the 24, 48 and 72-hour sampling groups included hunched posture, lethargy, ptosis, dehydration, emaciation, decreased respiratory rates, laboured respiration, occasional body tremors, splayed gait, tiptoe gait, ataxia and piloerection. Compared to negative controls, mean ratios of polychromatic to normochromatic erythrocytes (P/N ratio) were reduced at 80 mg/kg bw by 43, 16 and 12% at the 24, 48 and 72-hour sampling times respectively. The decrease at 24 hours was statistically significant. Although there were no dose-related trends in P/N ratio, the observation that values at 80 mg/kg bw were consistently lower than controls at all sacrifice times suggests that Polymer in Reactint Red X64 was bioavailable to the bone marrow following intraperitoneal (ip) administration. No increase in the incidence of micronuclei was observed following Polymer in Reactint Red X64 treatment, but the positive control, cyclophosphamide, gave a statistically significant increase in micronuclei. Thus, Polymer in Reactint Red X64 did not express genotoxic activity in vivo in this well conducted study.

8. Environmental effects assessment

8.1 Environmental effects summary

Ecotoxicological data were not provided. Polymer in Reactint Red X64 is not expected to exhibit toxic characteristics because large polymers are not readily absorbed by biota, and being non-ionic it would not overchelate minerals

Modelling using ECOSAR predicts a 14-day LC50 to fish in the order of 14 mg/L where a water solubility of 2000 ppm is assumed. While this is based on non-ionic surfactants found in the model database, model results such as this should be used with caution. Toxicity values for other trophic levels were not predicted.

Substances formed during degradation were not identified and their environmental effects are not known.

9. Hazard classification

This section discusses the classification of the health effects of Polymer in Reactint Red X64 according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (the Approved Criteria) (NOHSC, 1999a). The Approved Criteria are cited in the NOHSC National Model Regulations for the Control of Workplace Hazardous Substances (NOHSC, 1994a) and provide mandatory criteria for determining whether a workplace chemical is hazardous.

No human data is available. The classification for health effects is based on experimental studies (animal and in vitro tests). Only those toxicity endpoints for which new data (ND) are available for this assessment are considered for reclassification. The hazard assessment of these endpoints takes into account the new data and relevant data from the Polymer in Reactint Red X64 New Chemicals Assessment NA/405, which found the chemical non hazardous according to the 1994 Approved Criteria (NOHSC, 1994b).

9.1 Skin sensitisation

Skin sensitisation was not observed in a guinea-pig closed patch test that used undiluted Polymer in Reactint Red X64 in both the induction and challenge phase.

Classification status

Polymer in Reactint Red X64 does not meet the Approved Criteria for classification as a dermal sensitiser.

9.2 Repeated-dose toxicity

According to the Approved Criteria, a substance is classified as hazardous when substance-related deaths or serious damage (clear functional disturbances or morphological changes which have functional toxicological significance) are likely to be caused by repeated or prolonged exposure by an appropriate route. For a 28-day oral study, these effects would lead to classification as harmful (Xn) when observed at ≤ 150 mg/kg bw/day.

In the 28-day repeat-dose toxicity study clinical signs of toxicity and small increases in ALAT, ASAT and bilirubin were observed (25-60%) at 150 mg/kg bw/day. These relatively small increases in biochemical parameters are not considered toxicologically significant, as they were observed in the absence of histopathological changes to the liver (even at 400 mg/kg bw which produced mortalities) and were reversible in the 400 mg/kg bw/day recovery groups. No treatment related effects were seen at 15 mg/kg bw/day. Therefore, a NOAEL of 15 mg/kg bw/day is identified for clinical signs of toxicity in the 28-day study. The LOAEL for these effects (occasional observations of noisy respiration and decreased respiratory rate) is 150 mg/kg bw/day.

Classification status

The NOAEL for Polymer in Reactint Red X64 is 15 mg/kg bw/day based on clinical signs of toxicity occasionally observed in both sexes at 150 mg/kg bw in a 28-day study. Guidance in the Approved Criteria for classification states that clinical observations do not, by themselves, indicate “serious damage” and would not normally justify classification with the R48 risk phrase “Danger of serious damage to health by prolonged exposure”. Consequently, based on the results of the 28-day study, Polymer in Reactint Red X64 does not meet the Approved Criteria for classification with R48.

9.3 Genotoxicity

According to the Approved Criteria a substance is classified as a Category 1 mutagen if there is sufficient evidence of a casual relationship between human exposure to a substance and heritable genetic damage, Category 2 if there is a strong assumption that human exposure to the substance may result in the development of heritable genetic damage (generally on the basis of appropriate animal studies in germ cells), and Category 3 if there is evidence from appropriate studies in somatic cells in mammals in vivo (normally supported by positive results from in vitro mutagenicity tests). Furthermore, substances showing positive results only in one or more in vitro mutagenicity assays should normally not be classified.

No human data or animal studies in germ cells are available for Polymer in Reactint Red X64. In vitro, Polymer in Reactint Red X64 was negative in a well-conducted reverse mutation assay in *Salmonella typhimurium* and *Escherichia coli*. A positive result was observed in a chromosome aberration study in CHL cells in the presence of metabolic activation only. In vivo, Polymer in Reactint Red X64 was negative in a well-conducted mouse micronucleus study. Therefore, the clastogenic activity observed in vitro is not exhibited in somatic cells in mammals in vivo.

Classification status

Based on the above results Polymer in Reactint Red X64 does not meet the Approved Criteria for classification as a mutagenic substance.

10. Risk characterisation and management

Polymer in Reactint Red X64 has low oral toxicity in rats (LD50 for males and females of 4818 and 4203 mg/kg bw). It is a slight eye irritant but is not a skin irritant or a skin sensitiser. In 28-day repeat-dose testing of rats by gavage the NOAEL was identified as 15 mg/kg bw, based on slight clinical signs of toxicity at the LOAEL of 150 mg/kg bw. These were occasional observations of noisy respiration and decreased respiratory rate in a few animals. Two in vitro and one in vivo genotoxicity tests have been performed on Polymer in Reactint Red X64 and overall the chemical is not considered genotoxic on the basis of these tests.

Based on the tests submitted and the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a), Polymer in Reactint Red X64 is not classified as a hazardous chemical. As a comparison only, the classification of Polymer in Reactint Red X64 has been carried out using the assessed data against the proposed classification system for the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (OECD, 2002). This system is not mandated in Australia and carries no legal status. The classifications against the proposed GHS are shown in Appendix 2.

Due to the high NAMW of Polymer in Reactint Red X64, absorption through intact dermal tissue is likely to be limited. The inhalation potential of Polymer in Reactint Red X64 is considered low as vapour pressure is expected to be low.

Uncertainties in the risk characterisation process may arise from inadequate information, assumptions made during the process and variability in experimental conditions. Examples of uncertainties inherent in the characterisation of risk for Polymer in Reactint Red X64 include:

- It is assumed there is effective binding of the polymer to foam under normal manufacturing and use conditions;
- There are no human health effects data;
- Limited data are available on the occupational exposure and controls in different workplaces;
- For estimates of public exposure, the amount of Polymer in Reactint Red X64 able to leach from the foam over time is not characterised;
- Other assumptions made in estimating public exposure such as the weight of toys; and
- Transformation products of the polymer have not been identified.

10.1 Occupational

Potential routes of exposure to Polymer in Reactint Red X64 in the occupational setting are inhalation and dermal. Overall the exposure via both routes is expected to be low, except in the cases of accidental spillage or where primer containing Polymer in Reactint Red X64 is applied by spraying without controls in place. Exposure during transport and storage is minimal due to the enclosed packaging of Polymer in Reactint Red X64. Occupational exposure to Polymer in Reactint Red X64 may occur during repackaging and formulation, though the local exhaust extraction measures that are required during foam manufacture operations are likely to reduce this exposure to a minimum.

The major use of Polymer in Reactint Red X64 in Australia is as a colorant in polyurethane foams at levels up to 1%, but in many cases lower concentrations are used. Isocyanates are used in the production of these polyurethane foams and formulation includes both closed and semi-closed processes with personal protective equipment (PPE) such as gloves, goggles and masks being used during formulation. Having these controls in place to limit occupational exposure to the hazardous isocyanates will also in turn limit potential exposure to Polymer in Reactint Red X64 during the formulation process, as would the colorant's high molecular weight, low volatility and visible colorant properties. Once the foams are cured, contact with them for further processing should not lead to exposure, as the colorant is bound within the foam.

Polymer in Reactint Red X64 also has a minor use in metal primer at levels of 0.025%. Formulation is carried out in a partially closed manner using manual decanting into containers which are then sealed. Point extraction, and personal protective equipment (gloves, glasses and chemical filter mask) are used to limit occupational exposure. Information was not obtained from end-users of this product, however the formulator advised that it can be applied by roller, brush or spray.

There is potential for inhalation exposure through this use, especially with spray application. However, the very low concentration of Polymer in Reactint Red X64 used would limit the exposure. Exposure, primarily dermal, is possible from accidental release, but dermal absorption is expected to be low.

Because occupational exposure to Polymer in Reactint Red X64 is expected to be low, the risk of health effects from occupational exposure to Polymer in Reactint Red X64 is negligible.

10.2 Public

Indirect public exposure to Polymer in Reactint Red X64 through industrial processes or disposal is not expected, and the risk of accidental exposure to spillages in transport would be limited.

Public exposure to Polymer in Reactint Red X64 could occur through consumer use of Polymer in Reactint Red X64 coloured foams or articles made from these foams, and consequent dermal contact with the articles. Under normal conditions of use of foams, the potential for public exposure to Polymer in Reactint Red X64 is negligible, since it is expected to remain bound in the polyurethane foam.

Bedding, furniture material and carpet underlay have been identified as uses of Polymer in Reactint Red X64 coloured polyurethane foams. Concentration of Polymer in Reactint Red X64 in the foam can be up to 1%. Direct contact with the foam bedding and furniture or carpet underlay may occur. However exposure would be limited by the binding of the colorant in the foam and the expected low dermal absorption.

Exposure during the use of Polymer in Reactint Red X64 in baby nappy foams is also expected to be low because of the small amount of coloured foam on the nappy and use of the foam on the outside of the nappy. In addition, the foam is likely to be covered by other materials such as velcro and probably clothing, therefore further limiting exposure. The risk of adverse health effects due to the use of Polymer in Reactint Red X64 in baby nappies is low.

There is substantially greater potential for exposure with the use of Polymer in Reactint Red X64 in children's toys, because oral exposure could also occur. Exposure is likely to be high in children sucking or chewing foam toys containing bound Polymer in Reactint Red X64. Of particular concern are children in the age category 6 to 12 months, as they can hold objects and regularly place objects in their mouths for prolonged periods. However, oral exposure to children is reduced by a number of factors including limited mouthing times, due to sleep and attention spans and low saliva volumes.

The amount of Polymer in Reactint Red X64 that a child aged between 6 and 12 months will potentially be exposed to is 0.028 mg/kg bw/day assuming that the polymer is present in the foam at a maximum of 1%, the length of time that a toy would spend in a child's mouth is 3 hours and 1% of the colorant leaches from the foam per day (Appendix 1).

When comparing this to the LOAEL derived from repeated dose animal testing (150 mg/kg bw/day), a margin of exposure (MOE) greater than 5000 is observed (Appendix 1). The MOE is estimated by dividing the LOAEL by the estimated exposure. Therefore the potential for adverse health effects in children is considered to be low. The use of the LOAEL rather than the NOAEL is considered appropriate in this instance because only minimal findings were observed at the LOAEL of 150 mg/kg bw/day: occasional observations of noisy respiration and decreased respiratory rate in 3/10 and 1/10 animals respectively. In contrast, mortality and numerous signs of clinical toxicity were seen in animals intermittently throughout the study at 400 mg/kg bw/day. Thus, the effects seen qualitatively and quantitatively at 150 mg/kg bw/day indicate that the no effect level is likely to be very close to the LOAEL.

It should be noted that use in toys was not identified in the limited survey of Australian formulators, but is one of the international uses of Polymer in Reactint Red X64 and the polymer may be present in imported foam toys.

10.3 Environmental

It is estimated that the amount of Polymer in Reactint Red X64 released to the environment is low. Spills from transport or handling (< 10 kg per year) are disposed of to approved landfill or incinerated by licensed waste contractors after treatment. Washings from storage drums (10 kg per year) are discharged into a trade waste sewer. Polyurethane foams containing Polymer in Reactint Red X64 are expected to 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, high molecular weight and the polymeric nature of Polymer in Reactint Red X64.

The environmental hazard posed by the polymer is rated as negligible when manufactured into foam products (the major use), as the polymer will be incorporated into the foam matrix. Similarly use in a primer in industrial applications should not lead to release.

11. Discussion and Conclusions

Polymer in Reactint Red X64 is imported into Australia as a component (< 50%) of the mixture Reactint Red X64. Current and projected imports of Reactint Red X64 are < 1 tonne per year, equivalent to < 500 kg Polymer in Reactint Red X64 per year. The major use is as a colorant for polyurethane foams, for applications such as packaging, furniture, bedding, carpet underlay and novelty items such as foam toy balls and puzzles. During the assessment, use in a primer paint for engineering parts and machinery was also identified. Concentrations of Polymer in Reactint Red X64 up to 1% may be used, but in a recent survey ranged from approximately 0.005% to 0.5%.

Polymer in Reactint Red X64 has low acute oral toxicity in rats (LD50 is 4818 and 4203 mg/kg bw for males and females respectively). It is a slight eye irritant but is not a skin irritant or a skin sensitiser. In a 28-day repeat-dose testing of rats by gavage the NOAEL was identified as 15 mg/kg bw, based on slight clinical signs of toxicity at the LOAEL of 150 mg/kg bw. Polymer in Reactint Red X64 was negative in a reverse mutation assay in both *Salmonella typhimurium* and *Escherichia coli* and in a mouse micronucleus test. A chromosomal aberration test with Chinese hamster lung (CHL) cells was positive at the top dose only in the presence of metabolic activation. Overall the chemical is not considered genotoxic on the basis of these tests. However, as a positive result was seen in the in vitro chromosome aberration test in the presence of metabolic activation (albeit at the top dose only in the absence of a clear dose-response relationship), a second in vivo study in a different somatic cell would assist in further clarifying the clastogenicity observed in vitro.

Polymer in Reactint Red X64 does not meet the criteria for classification under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a). For comparison purposes only, the Globally Harmonised System for Hazard Classification and Labelling of Chemicals (GHS) classification for Polymer in Reactint Red X64 is attached in Appendix 2.

Exposure during occupational use of Polymer in Reactint Red X64 is likely to be low. As it does not have high volatility, the most relevant route of exposure is dermal, but absorption would be limited by the high molecular weight of the polymer. Once reacted into polyurethane the polymer is chemically bound, and accelerated extraction tests indicate that it remains predominantly bound. Workplace controls required for the manufacture of polyurethane foam with isocyanates would reduce exposure to other chemicals used in the process, such as Polymer in Reactint Red X64. Spray application of primer paint containing Polymer in Reactint Red X64 may lead to inhalational exposure of workers, however this would be limited by the low concentration of colorant in the product (approximately 0.025%). The risk of adverse effects from the occupational use of Polymer in Reactint Red X64 is expected to be low.

The importer of Polymer in Reactint Red X64 advised that, to the best of their knowledge, the marketed product Reactint Red X64 has not been the subject of any customer complaints regarding health, environmental or safety issues in Australia or internationally.

The public may have contact with a variety of products coloured with Polymer in Reactint Red X64 both imported and manufactured. The highest potential for risk of adverse effects is considered to be via oral exposure to children who may chew foam toys containing Polymer in Reactint Red X64. The potential exposure in this scenario is estimated to be 0.028 mg/kg bw/day and MOE is 5000 when compared to the LOAEL obtained from repeated-dose studies in rats. Therefore it is considered that use of Polymer in Reactint Red X64 in polyurethane foams presents a low risk to the public.

However it should be noted that there is some uncertainty in interpretation of the proprietary extraction test results used to estimate public exposure. The extraction test submitted used severe conditions, such as off-specification foams that may not bind Polymer in Reactint Red X64 to the same extent as under normal use, higher than normal levels of colorant, and extraction with solvent. From this test it is difficult to conclude the level of extraction of Reactint Red X64 from foam under normal conditions of use and for foams that meet commercial specifications. It is considered that the test results would give an overestimate of the extraction of Polymer in Reactint Red X64 from foams. However the test results have been used in a reasonable worst case estimate of risk, which is calculated as low.

The *Australian Standard for Children's toys (safety requirements) Part 3: Toxicological requirements (AS 1647.3 - 1995)*, (Standards Australia, 1995) outlines in Appendix F a standard test for extraction of colorants from children's toys. The basis of the extraction test specified in the standard is the transfer of the colorant to filter paper soaked in simulated perspiration or simulated saliva, when the filter paper is placed in intimate contact with the toy. It is considered that this test would give a more realistic indication of leaching of Polymer in Reactint Red X64. The standard is currently under review but the new draft contains similar provisions. Foam toys or foam produced for toy manufacture should at least meet the requirements of this standard extraction test.

Experimental data on the environmental effects of Polymer in Reactint Red X64 are not available. Reactint Red X64 was not biodegradable when tested to OECD TG 301C. However, it undergoes transformation and the transformation products have not been identified. Release of Polymer in Reactint Red X64 to the environment is expected to be low, and the risk to the environment similarly low. However, Polymer in Reactint Red X64 has properties indicative of bioaccumulation potential and there is no experimental ecotoxicity data available. Noting the lack of ecotoxicity data and the high water solubility, further review concentrating on the environmental effects would be required if Polymer in Reactint Red X64 was to be used in applications where it was not bound to matrix and release to water was possible.

12. Recommendations

Recommendation 1: Extraction from toys

It is recommended that foam toys and foam produced for toys and coloured with Polymer in Reactint Red X64 be tested for colorant extraction. One such test is contained in *Australian Standard (AS 1647.3-1995) Children's toys (safety requirements) Part 3: Toxicological requirements*. It is considered that this test would give a realistic indication of leaching of Polymer in Reactint Red X64 in normal use from foam used in toys, and the toys should at least meet this standard. Information on such testing requirements should be included in the technical sales literature for Reactint Red X64 to facilitate compliance with this recommendation.

Recommendation 2: Occupational controls

The risk of adverse health effects from occupational use of Polymer in Reactint Red X64 is low. This assessment supports the control measures recommended in the original new chemical assessment report NA/405. The control measures for Reactint Red X64 containing Polymer in Reactint Red X64 are:

- local exhaust ventilation during repackaging and transferral operations;
- avoidance of spillage and splashing of the chemical. Spillages should be cleaned up promptly and put into containers for disposal; and
- if engineering controls and safe work practices are insufficient to reduce exposure to a safe level, employers should ensure that personal protective equipment such as gloves, safety glasses and overalls are used by workers to minimise occupational exposure; Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Recommendation 3: Material Safety Data Sheets (MSDS)

The MSDS for the marketed product Reactint Red X64 containing Polymer in Reactint Red X64 was provided in a format consistent with NOHSC's *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994c). Information presented in this report should be used to update the MSDS, including the results of the additional toxicity studies and information on the additional use in primers. A copy of the MSDS should be easily accessible to employees.

Recommendation 4: Disposal

Any large spills of Reactint Red X64 containing Polymer in Reactint Red X64 should be bunded and cleaned up promptly with absorbants and put into containers for disposal. Disposal of any material containing Polymer in Reactint Red X64 should be to approved landfill or incineration.

13. Secondary Notification

Under Section 65 of the Act, the secondary notification of Polymer in Reactint Red X64 may be required where an applicant or other introducer (importer) or new manufacturer of Polymer in Reactint Red X64, becomes aware of any circumstances that may warrant a reassessment of its hazards and risks. Specific circumstances include:

- a. The function or use of Polymer in Reactint Red X64 has changed, or is likely to change, significantly. If the current use pattern and volumes change and environmental exposure is expected, aquatic toxicity data would be required to allow a more comprehensive assessment of environmental effects;
- b. The amount of Polymer in Reactint Red X64 introduced into Australia has increased, or is likely to increase significantly;
- c. Manufacture of Polymer in Reactint Red X64 has begun in Australia;
- d. Additional information has become available on the adverse health and/or environmental effects of Polymer in Reactint Red X64; or
- e. Additional information has become available on the amount of Polymer in Reactint Red X64 that may be leached from polyurethane foam children's toys under normal conditions of use.

The Director must be notified within 28 days of the introducer becoming aware of any of the above circumstances.

Appendix 1: Exposure calculations

Assumptions used in calculating the potential exposure a child aged between 6 and 12 months would receive from Polymer in Reactint Red X64 are listed below:

1. Toy is made of 20 g of foam;
2. Polymer in Reactint Red X64 is present in a toy at 1%;
3. One percent (1%) of Polymer in Reactint Red X64 will leach out of the toy over 24 hours;
4. The length of time the toy spends in a child's mouth is estimated at a maximum of 3 hours a day for a 6 to 12 month old child; and
5. The approximate body weight of a 6 to 12 month old child is 9 kg.

$$\text{Exposure (mg/kg bw/day)} = \frac{\text{Weight of the toy (mg)} \times \text{Percent of Polymer in foam} \times \text{Percent of the total Polymer expected to leach} \times \text{Proportion of day the foam spends in a child's mouth}}{\text{Bodyweight of the child (kg)}}$$

So the exposure equals:

$$= 20 \times \frac{1}{100} \times \frac{1}{100} \times \frac{3}{24} \times \frac{1}{9} \times 1\,000 = \text{mg/kg/day}$$

$$= 0.028 \text{ mg/kg/day}$$

Appendix 2: Classification under the Globally Harmonised System for Hazard Classification and Communication

In this report, Polymer in Reactint Red X64 has been classified against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999a). As a comparison only, the classification of Polymer in Reactint Red X64 using the Globally Harmonised System for Hazard Classification and Labelling of Chemicals (GHS) (OECD, 2002) is presented in Table 1. This system is not mandated in Australia and carries no legal status but is presented for information purposes. GHS classification and information documentation is available at

<http://www.unece.org/trans/main/dgdb/dgsubc4/c4age.html>

Table 1: GHS classification for Polymer in Reactint Red X64.

Hazards	Classification	Hazard communication
Acute toxicity	Category 5: (Oral LD ₅₀ between 2000 and 5000 mg/kg bw.)	Symbol: none Signal word: Warning Hazard Statement: May be harmful if swallowed

There are insufficient data available to fully categorise all areas of the GHS including physical, health and environment effects of Polymer in Reactint Red X64.

Appendix 3: Material Safety Data Sheet for Reactint Red X64

This MSDS was provided by Asia Pacific Speciality Chemicals Limited. It is reproduced here as a matter of public record. The format of this MSDS is acceptable under the NOHSC's *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994c). However the contents require updating as outlined in Recommendation 3. The accuracy of this information remains the responsibility of the applicant.

Material Safety Data Sheet



Reactint Red X64

Infosafe No. ACSCY **Issue Date** May 2001 **Status** ISSUED by APSSC

Not classified as hazardous according to criteria of NOHSC

COMPANY DETAILS

Company Name Asia Pacific Specialty Chemicals Limited (ABN 32000316138)
Address 15 Park Road SEVEN HILLS
NSW 2147
Emergency Tel. 1800 022 037 (24H)
Tel/Fax Tel: (02) 9839 4000 Fax: (02) 9674 6225
Other Information New Zealand: Asia Pacific Specialty Chemicals (NZ) Limited
119 Carbine Road
Mt Wellington, Auckland 6
Emergency Tel: 0800 243 622 (24H)
Telephone: (09) 276 4019
Fax: (09) 276 7231

IDENTIFICATION

Product Name Reactint Red X64
Proper Shipping Name None Allocated
Other Names None Listed
UN Number None Allocated
DG Class None Allocated
Packing Group None Allocated
Hazchem Code None Allocated
Poisons Schedule Not Scheduled

Physical Data

Appearance Liquid
Melting Point < 0°C
Boiling Point > 100°C @ 14.7 psia
Vapour Pressure n/a psia
Specific Gravity 1.1 (Water = 1)
Flash Point 213°C (> 415.4°F)
Flamm. Limit LEL N/A
Flamm. Limit UEL N/A
Solubility in Water Miscible

Other Properties

Volatile Component	< 0.5% % @ 100°C @ 14.7 psia
Autoignition Temp.	N/A
Vapour Density	> 1 (Air = 1)
Odour	Slight, sweet odor
Colour	Dark Red
Stability	This compound is stable at ambient conditions.
Haz. Polymerization	Hazardous polymerization will not occur.
Materials to Avoid	Avoid contact with strong oxidizing agents.

Ingredients

Ingredients	Name	CAS	Proportion
	POLYMERIC COLORANT BLEND	Proprietary	100 %

Other Information Nonionic Polymeric Colorant

HEALTH HAZARD INFORMATION

Health Effects

Acute - Swallowed	Essentially non-toxic.
Acute - Eye	May be slightly irritating. Not known to cause permanent injury to eye tissue.
Acute - Skin	This material is not a primary skin irritant. Prolonged or repeated skin contact may cause irritation.
Acute - Inhaled	No information regarding inhalation available. No hazards expected in normal industrial use.
Other Information	The health hazards of this product should be low under normal industrial and commercial uses. Prolonged or repeated contact may cause skin or eye irritation. This material is a concentrated colorant. Do not allow material to enter soil or surface water.

First Aid

Swallowed	If swallowed, immediately give 2 glasses of water. Never give anything by mouth to an unconscious person. Contact a physician.
Eye	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops or persists.
Skin	Wash affected area with large amounts of soap and water. Get medical attention if irritation develops or persists.
Inhaled	Although this product is not known to cause respiratory problems, if breathing is difficult, remove to fresh air and provide oxygen. Get medical attention if cough or other symptoms develop.
Other Information	Flammability: 1 Reactivity: 0 Personal protection Index: B

Advice to Doctor

Other Health Hazard Information

PRECAUTIONS FOR USE

Exposure Limits	No Information Available.
Eng. Controls	No special ventilation requirements.

Personal Protection

Respirator Type (AS 1716)	Under normal use conditions, with adequate ventilation, no special respiratory protective equipment is required.
Eye Protection	Wear safety glasses. Where contact with this material is likely, chemical goggles are recommended.
Clothing	Wear protective gloves to minimize skin contamination. For brief contact, normal work attire should be sufficient. When prolonged or frequently repeated contact could occur, use protective clothing impervious to this material.

Flammability

SAFE HANDLING INFORMATION

Storage and Transport

Storage Regulations	Protect containers from physical damage. Do not stack drums more than three pallets high.
Handling	HANDLING (PERSONNEL): Wash hands thoroughly after handling. Wash contaminated clothing before reuse. HANDLING (PHYSICAL ASPECTS): Avoid extreme temperatures. Keep container closed to avoid contamination.
Proper Shipping Name	None Allocated

Spills and Disposal

Spills & Disposal	SAFEGUARDS (PERSONNEL): Wear appropriate personal protective equipment. INITIAL CONTAINMENT: Do not allow material to enter soil or surface water. Absorb spills with inert material. All waste materials should be packaged, labeled, and transported in accordance with all national, state/provincial, and local requirements. LARGE SPILLS PROCEDURE: This material is a concentrated colorant. Contain spilled material. Large spillage should be dammed-off and pumped into containers. take up the remainder by absorbent material. Do not allow material to enter soil or surface water. All waste materials should be packaged, labeled, and transported in accordance with all national, state/provincial, and local requirements.
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SMALL SPILLS PROCEDURE:

Absorb spills with inert material. Do not attempt clean up with water. Avoid disposal into waste water treatment facilities. Floor may become slippery. All waste materials should be packaged, labeled, and transported in accordance with all national, state/provincial, and local requirements.

Disposal

Uncleaned empty containers should be disposed of in the same manner as the contents. This material is a concentrated colorant. Avoid washing material into sewer systems without proper treatment and authorization by the treatment facility management. All waste materials should be packaged, labeled; and transported in accordance with all national, state/provincial, and local requirements.

Fire/Explosion Hazard

Fire/Explos. Hazard No known unusual hazards in a fire/explosion situation.

Hazardous**Decomposition or****Byproducts**

Decomposition will not occur if handled and stored properly.

Fire Fighting**Precautions**

As in any fire, wear self-contained breathing apparatus pressure-demand MSHA/NIOSH (approved or equivalent) and full protective gear. Avoid breathing smoke, fumes, and decomposition products. Contain runoff water. Contaminated extinguishing water must be disposed of in accordance with applicable regulations.

Extinguishing Media

Water, carbon dioxide, foam or dry powder.

Hazchem Code

None Allocated

OTHER INFORMATION**Toxicology**

Confidential Ingredient - Not printed in Ingredient List

Test Code: Ames Assay

Description: This product was tested for mutagenic activity in the Salmonella-E. Coli/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay.

Species: Salmonella typhimurium and Escherichia coli

Results: The test article was found to be non-mutagenic under the test conditions.

Reference: HWA code: 16664-0-409R

Test Code: Acute Oral Toxicity Study

Species: Rat

Results: The estimated LD50 was determined to be 4,146 mg/kg (combined sexes).

Information on**Ecological Effects**

No information available.

Regulatory**Information**

HMIS Rating- Health: 1

This material or all of its components are listed on the Inventory of Existing Chemical Substances under the Toxic Substance Control Act (TSCA). This material or all of its components are listed (or considered as having been notified) on the European Inventory of existing Chemical Substances (EINECS).

WHMIS Hazard Symbols:

None

EEC Symbols and Indications of Danger:

None

Manufacturers Advice

The information contained in this Material Safety Data Sheet is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of Milliken Chemical. The data on this sheet are related only to the specific material designated herein. Milliken Chemical assumes no legal responsibility for use or reliance upon these data.

Other Information

1-800-424-9300 or 1-202-483-7616 (CHEMTREC)

Manufacturers Details: Milliken Chemical

P.O. Box 817

1440 Campton Road

Inman, SC 29349 USA

1-864-472-9041 (For questions and emergencies)

CONTACT POINT

Contact

Australia: Business Hours: Mr Paul Verren
Telephone: (02) 9839 4024
After Hours: 1800 022 037
New Zealand: Business Hours: Mr Lloyd Williams
Telephone: (09) 276 4019
Emergency Tel: 0800 243 622

IMPORTANT ADVICE:

This MSDS summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this MSDS and consider the information in the context of how the product will be handled and used in the workplace including its use in conjunction with other products. If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact Asia Pacific Speciality Chemicals. Our responsibility for products sold is subject to our standard terms and conditions, a copy of which is sent to our customers and is also available on request.

End of MSDS

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