File No: LTD/1317

May 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Liquitint® Red ST

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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Polymer in Liquitint® Red ST

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Walk Off Mats Asia Pacific Pty Ltd (ABN: 14 002 708 830)
U7/95 O'Sullivan Beach Rd,
Lonsdale, South Australia, 5160
and
Albright & Wilson (ABN: 36 004 234 137)
22 Davis Rd,
Wetherill Park, NSW, 2164

NOTIFICATION CATEGORY
Limited-small volume: Polymer with NAMW ≥ 1000 (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical Name, Other Names, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Polymer Constituents, Residual Monomers/Impurities, Use Details, Import Volume, and Site of Reformulation

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Absorption/Deabsorption

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Low Volume Chemical Permit

NOTIFICATION IN OTHER COUNTRIES
USA (PMN, 1995), Korea (1999), China (2002), New Zealand (1998), Brazil (1999)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Liquitint® Red ST

METHODS OF DETECTION AND DETERMINATION

METHOD	IR and UV Visible spectroscopy
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>97%

DEGRADATION PRODUCTS
The polymer is stable under normal conditions of use.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The residual monomers and impurities are expected to be of low volatility and as such loss during use is not expected.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a liquid (up to 30% notified polymer) by sea in 20 L high-density polyethylene pails or 210 L drums.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

USE
The notified polymer is used as a colourant in household and industrial soaps and detergents. The notified polymer is present in the consumer products at up to 0.1%, typically the notified polymer would be present at 0.0005–0.01%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
The product containing the notified polymer will be warehoused at site(s) located in Sydney New South Wales.

TRANSPORTATION AND PACKAGING
The imported liquid product Liquitint® Red ST (up to 30% notified polymer) will be imported in 20 L high density polyethylene pails or 210 L drums and transported by road to the warehouse(s) for storage until required. The end-use products (maximum 0.1% notified polymer) will be typically transported in by road in 1–2 L plastic containers to retail outlets and industrial users Australia-wide.

5.2. Operation description

The notified polymer is not manufactured in Australia. Blending or packaging of the product containing the notified polymer occurs in Australia. Retail and cleaning/laundry workers will handle the finished products containing the notified polymer.

Blending and packing
The 20 L pails or 210 L drums of liquid product containing the notified polymer (up to 30%) will be transported by forklift or manually as required from the warehouse to the production area. At the blending plant the imported liquid product containing the notified polymer is transferred manually from the pail or drum to a storage tank or directly to the blending tank. This is typically achieved by manually opening the pail or drum and measuring out the product containing the notified polymer. In some operations this may occur by largely automated means whereby by the drum is lanced and the contents automatically transferred by transfer lines to the blending tank. During the blending process, the product containing the notified polymer is pumped automatically through to the blending tank (closed system) to formulate a variety of cleaning products that contains the notified polymer (maximum 0.1%). The end-use products containing the notified polymer are characteristically packed by means of automated and enclosed filling systems into 1–2 L plastic containers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport	unknown	unknown	< once per week

Warehouse and Storage	5	0.5 hour	once per week
Reformulation (Blending)	10	8 hours per day	50 days per year
Maintenance and Cleaning	5	< 8 hours per day	< 50 days per year

Exposure Details
Transport and warehousing
Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the imported product containing the notified polymer (up to 30% notified polymer). The product will be handled in the warehouse by forklift handling of pails or drums or manual handling of individual packages. During transport and warehousing, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Blending and packing
The main routes of exposure to the notified polymer (up to 30% notified polymer) are dermal and accidental ocular exposure during manual measuring and transferring of the imported product to the blending tank.

It is possible that dermal and accidental ocular exposure may also occur if manual intervention is required during the automated blending and packaging operations and if the packaging is accidentally breached. Maintenance workers will have intermittent dermal and the potential for accidental ocular exposure to the notified polymer when performing maintenance/cleaning of the equipment in general.

All workers involved in handling the imported product and blended product will typically wear personal protective equipment (PPE) such as safety glasses, safety boots, PVC/latex gloves, protective clothing, if necessary. The blending operations typically occur in a closed system under local exhaust ventilation (LEV). All production operators are typically trained in the appropriate operational procedures and precautions. All workers have access to the MSDS.

Once the formulated cleaning products are packaged for distribution, no further worker exposure is expected except when packaging is accidentally breached.

End-use
While the notifier gives no details, it is estimated that a large number of retail and cleaning/laundry workers may potentially be exposed to the notified polymer (maximum of 0.1%) by means of end-use cleaning products. Dermal exposure is expected to be the main route of exposure but inhalation exposure to aerosols could occur if products include spray cleaning products. It is expected that use of the end-use products by cleaning/laundry workers would be similar (albeit more frequent) to the pattern of public exposure. The level of PPE used by cleaning workers is likely to vary and would include gloves in a number of cases.

Retail workers would only be exposed to the notified polymer (maximum of 0.1%) in the case of inadvertent breach of the packaging. In the event of an accident, spills will be removed in accordance with the manufacturers instructions.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported into Sydney and transported by road to a distributor in Sydney, NSW. From here, it is then transported to the reformulation site, again by road, also located in Sydney, NSW. During the transport and handling operations, only accidental release through mishap is expected. Any spilt notified polymer is expected to be physically contained, collected and subsequently disposed of to secure landfill.

At the reformulation site, the notified polymer is removed from the import containers and held in a storage tank. The import containers are then rinsed with water and the rinsate will also be emptied into the storage container. Rinsed import containers, with negligible residual notified polymer are then expected to be disposed of to secure landfill.

From the storage tank, the notified polymer is then fed into a closed mixer/blender and incorporated

with other ingredients. From here it is subsequently bottled using an automatic filling machine. Release to the environment may occur at this time from the unlikely event of spills and from the routine cleaning and maintenance operations. Large spills are expected to be contained by standard physical engineering means, and collected using absorbent pads, which would then be disposed of to secure landfill. Small spills and releases from equipment cleaning and maintenance operations are expected to be disposed of to sewer as trade waste.

RELEASE OF CHEMICAL FROM USE
The notified polymer is proposed to be used primarily as a colourant in household and industrial cleaners. As such, it is expected that apart from the very small quantity that is disposed of to landfill, as residual in containers or from major spills, effectively the entire quantity of imported notified polymer will be disposed of after use to sewer.

5.5. Disposal

The major route for disposal of the notified polymer will be to the sewer after use. A very small proportion of the total imported quantity is expected to be disposed of to landfill, as residual in containers.

5.6. Public exposure

The notified polymer will be incorporated into household cleaning/laundry products at up to 0.1% widespread public exposure is expected. There is the potential for low level albeit regular dermal and accidental ocular contact by the public with the notified polymer during use of cleaning products. Inhalation of aerosols could occur during use of spray cleaning/laundry polymers.

There could be incidental dermal exposure to detergent liquid itself through splashes or contamination of the outside of the packaging. Dermal exposure may also occur through inadvertent use of products to wash hands.

Accidental oral exposure of young children to cleaning products is also possible.

It is expected that some consumers would wear gloves for certain cleaning tasks while others would not. However, exposure to the notified polymer will be minimised by the low concentration (<0.1%) of the notified polymer in the consumer products.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is introduced as an aqueous solution at a concentration of up to 30% (Liquitint® Red ST).

Appearance at 20ºC and 101.3 kPa	Dark red liquid with sweet odour (Liquitint® Red ST)
Boiling Point	100ºC (Liquitint® Red ST)
Remarks	Datum obtained from MSDS.
Freezing Point	-2ºC (Liquitint® Red ST)
Remarks	Datum obtained from MSDS.
Density	1048 kg/m^3 (temperature not specified)
Remarks	Datum obtained from MSDS.
Vapour Pressure	Not determined
Remarks	This has not been measured for the notified polymer, but it is expected to be very low due to the polymer's relatively high molecular weight.
Water Solubility	The polymer is completely soluble in water.
Remarks	No test result has been provided, but the notified polymer (up to 30% notified

polymer) is introduced as an aqueous solution.

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ days*
4	20	>365
7	20	>365
9	20	>365

Remarks As the notified polymer showed less than 10% hydrolysis at 50°C for 6 days, hydrolysis is not expected to occur within ambient environmental conditions (pH 4-9).

TEST FACILITY Bruhnke, John D (1997a)

Partition Coefficient (n-octanol/water) log K_{OW} = 2.763 at 20°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).

Remarks HPLC Method. The notified polymer eluted midway of five the reference substances.

TEST FACILITY Bruhnke, John D (1997b)

Adsorption/Desorption log K_{OC} = 7.747

METHOD QSAR - PCKOCWIN

Remarks The QSAR program warned that the K_{OC} of the tested structure may be sensitive to pH. The estimated K_{OC} represents a best-fit to the majority of experimental values.

TEST FACILITY PCKOCWIN Program (v1.66)

Dissociation Constant Not determined

Remarks The notified polymer does not contain dissociable functionality. While the notified polymer contains a potentially cationic functionality, previous notifications for closely related polymers indicate this will not occur in the environmental pH range of 4-9.

Particle Size Not applicable

Remarks Test not conducted. The notified polymer is introduced in liquid.

Flash Point >100°C (Liquitint® Red ST)

METHOD Determined using Cleveland Open Cup apparatus.

Remarks Datum obtained from MSDS.

Flammability Limits Not determined.

Remarks Test not conducted. The notified polymer is imported only as an aqueous solution. Based on the flash point, the notified polymer as introduced is not considered to be a flammable liquid.

Autoignition Temperature Not determined

Remarks Test not conducted. The notified polymer is imported only as an aqueous solution.

Explosive Properties

Remarks Test not conducted. The notified polymer contains functional groups which may infer explosive properties, however, polymers containing similar structural units

have not been found to be explosive.

Reactivity

Remarks The notified polymer is stable under normal conditions of use

7. TOXICOLOGICAL INVESTIGATIONS

No toxicological data is available for the notified polymer. The following toxicological data for an analogue polymer was provided. The analogue is considered acceptable as the notified polymer differs only in the polymeric chain.

Endpoint	*Result and Assessment Conclusion*
1. Rat, acute oral (males)	LD50 = 4818 mg/kg bw
2. Rat, acute oral (females)	LD50 = 4203 mg/kg bw
3. Rabbit, skin irritation	non-irritating
4. Rabbit, eye irritation	slightly irritating
5. Skin sensitisation - non-adjuvant test	no evidence of sensitisation.
6. Rat, <gavage> repeat dose toxicity - 28 days.	NOAEL 15 mg/kg bw
7. Genotoxicity - bacterial reverse mutation	non mutagenic
8. Genotoxicity – in vitro <chromosome aberration>	genotoxic
9. Genotoxicity – in vivo <micronucleus assay>	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 401 Acute Oral Toxicity.
Species/Strain Rat/Sprague-Dawley
Vehicle
Remarks - Method

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	2000	0/10
II	5/sex	4000	0/5 males 3/5 females
III	5/sex	5000	3/5 males 3/5 females

LD50 For males > 4818 mg/kg bw
For females > 4203 mg/kg bw

Signs of Toxicity 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. No deaths of clinical signs of toxicity occurred in group I. 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.

Effects in Organs At necropsy, red or pink staining of connective tissue was observed throughout the body at 4000 mg/kg bw and above.

Remarks - Results None.

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY Corning Hazleton Inc. (1995a)

7.2. Irritation – skin

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3/sex
- Vehicle: Neat, undiluted product
- Observation Period: 48 hours
- Type of Dressing: Occlusive
- Remarks - Method: Deviations from the standard protocol
  1. Skin reactions were noted 30 minutes and 48 hours after patch removal.
  2. Exposure period 24 hours
  3. Skin abraded

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	1	< 48 hours	0
Oedema	0	0	-	0

*Calculated on the basis of the scores at 48 hours for ALL animals.

Remarks - Results: 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. No skin reactions were observed at the intact site at either observation.

CONCLUSION The test substance is non-irritating to the skin.

TEST FACILITY Corning Hazelton Inc. (1995b)

7.3. Irritation – eye

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 6
- Observation Period: 7 days
- Remarks - Method: None.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.9	2	>72 hours <7 days	0
Conjunctiva: chemosis	0.4	2	>72 hours <7 days	0
Conjunctiva: discharge	0	0	-	-
Corneal opacity	0	0	-	-
Iridial inflammation	0	1	<24 hours	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results: 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.

CONCLUSION — The test substance is slightly irritating to the eye.

TEST FACILITY — Corning Hazelton (1995c)

7.4. Skin sensitisation

TEST SUBSTANCE — Analogue polymer (50% concentration)

METHOD — Skin Sensitisation - <closed-patch test>.

Species/Strain — Guinea pig/Dunkin-Hartley

MAIN STUDY

Number of Animals — Test Group: 10 Control Group: 10

INDUCTION PHASE — Induction Concentration:
intradermal: Not applicable
topical: 100%

Signs of Irritation — At induction, skin reactions of very faint to faint erythema were observed in all test animals.

CHALLENGE PHASE

1st challenge — intradermal: Not applicable
topical: 100% test substance

2nd challenge — topical: 75% test substance

Remarks - Method — At induction, 0.4 mL undiluted test substance (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 test substance 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 undiluted test substance was performed 1 week after the initial challenge.
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 as a positive control, a "strong" sensitiser, instead of one of the recommended "mild/moderate" sensitisers.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100% test substance (1st) 75% test substance (2nd)	9/10	6/10	0/10	0/10
Control Group	0	8/10	6/10	0/10	0/10

Remarks - Results — 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%.

CONCLUSION — There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.

TEST FACILITY Corning Hazelton (1995d)

7.5. Repeat dose toxicity

TEST SUBSTANCE Analogue polymer

METHOD Repeated Dose Oral Toxicity Study in Rodents – Dose Range Finding Study
- Species/Strain: Rat/Sprague-Dawley
- Route of Administration: Oral – gavage
- Exposure Information: Total exposure days: 14 days; Dose regimen: 7 days per week; Post-exposure observation period: 0 days
- Vehicle: Distilled water
- Remarks - Method: In a dose ranging study 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 test substance in distilled water for up to 14 consecutive days.

RESULTS

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 test substance treated animals due to the colorant nature of the test material was not considered a toxicologically significant finding.

TEST FACILITY Safepharm (1997a)

7.6. Repeat dose toxicity

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
- Species/Strain: Rat/Sprague-Dawley
- Route of Administration: Oral – gavage
- Exposure Information: Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days
- Vehicle: Distilled water
- Remarks - Method: None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	15	0/10
III (mid dose)	5/sex	150	0/10
IV (high dose)	5/sex	400	2/5 males 0/5 females
V (control recovery)	5/sex	0	0/10
VI (high dose recovery)	5/sex	400	0/10

Mortality and Time to Death

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. In the recovery group (400 mg/kg bw/day), no deaths were observed. All other animals survived until scheduled necropsy.

Clinical Observations

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.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

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 ≥ 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.

Effects in Organs

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.

Remarks – Results

In the recovery group (400 mg/kg bw/day) 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 increases (25-60%) in biochemical parameters are 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.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 15 mg/kg bw/day in this study, based on the effects seen at 400 and 150 mg/kg bw/day. The LOAEL for these effects, occasional observations of noisy respiration and decreased respiratory rate in a few animals, is 150 mg/kg bw/day.

TEST FACILITY Safepharm (1997a)

7.7. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, *E. coli*: WP2uvrA,
Metabolic Activation System	Rat liver S9
Concentration Range in Main Test	a) With metabolic activation: 6.7 - 5000 µg/plate b) Without metabolic activation: 6.7 - 5000 µg/plate
RESULTS	
Remarks - Results	No increase in the number of revertants was seen in any of the tested cultures. Positive controls confirmed the validity of this test.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Corning Hazelton (1995e)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE	Analogue polymer (50% concentration)
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Chinese hamster lung cells
Remarks - Method	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 of test substance 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 the test substance in the absence of metabolic activation until harvesting at 24 and 48 hours. Both experiments scored 200 metaphases per group.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	5-30	6	18
Test 2	1.25-30	24	24
Test 3	1.25-30	48	48
Present			
Test 1	2.5-60	6	18

*Cultures selected for metaphase analysis.

RESULTS	
Remarks - Results	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.

CONCLUSION — The notified chemical was clastogenic to Chinese Hamster lung cells treated in vitro under the conditions of the test.

TEST FACILITY — Safepharm (1997b)

7.9. Genotoxicity – in vivo

TEST SUBSTANCE — Analogue polymer (50% concentration)

METHOD — OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain — Mice/CD-1
Route of Administration — Intraperitoneal injection

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours*
I (vehicle control)	5/sex/sacrifice time	0	24,48,72
II (low dose)	5/sex/sacrifice time	20	24,48,72
III (mid dose)	5/sex/sacrifice time	40	24,48,72
IV (high dose)	5/sex/sacrifice time	80	24,48,72
V (positive control, CP)	5/sex	CP	72

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity — Two males and one female died in the 72-hour sampling group at 80 mg/kg bw/day.
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

Genotoxic Effects — No increase in the incidence of micronuclei was observed following treatment with the test substance, but the positive control, cyclophosphamide, gave a statistically significant increase in micronuclei.

Remarks - Results — 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 test substance was bioavailable to the bone marrow following intraperitoneal (ip) administration.

CONCLUSION — The test substance was not clastogenic in this in vivo micronucleus assay under the conditions of the test.

TEST FACILITY — Safepharm (1997c)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer.
METHOD	Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphians. Standard Methods for the Examination of Water and Wastewater
Species	Fathead Minnow (*Pimephales promelas*)
Exposure Period	96 h
Auxiliary Solvent	Nil
Water Hardness	130-142 mg $CaCO_3$/L
Analytical Monitoring	Temperature, Dissolved Oxygen, pH
Remarks – Method	The notified polymer was analysed as one of a batch of twelve polymers. A range-finding test was conducted to determine the concentration range for the definitive study.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0		10	0	0	0	0
32		10	0	0	0	0
56		10	0	0	0	0
100		10	0	0	0	0
180		10	0	0	0	0
320		10	0	0	0	5
560		10	10	10	10	10
1000		10	10	10	10	10

LC50	320 mg/L at 96 hours (95 CI: 180-560 mg/L)
NOEC	32 mg/L at 96 hours.
Remarks – Results	The abnormal effects of surfacing, loss of equilibrium, quiescence, and/or fish on bottom of the test chamber were noted in the 56, 100, 180, and 320 mg/L concentrations during the test. Analysis of the test concentrations was not performed, and the results are based, therefore, on the nominal concentrations only. Test solutions were described as a dark red liquid.
CONCLUSION	The notified polymer is not harmful to fish.
TEST FACILITY	ABC Labs (1996)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be imported into Sydney, where it will be reformulated with other ingredients to form household and industrial cleaners, of which the notified polymer is a colourant. Nearly all of the notified polymer will be disposed of to sewer after use, with only small quantities, including that proportion remaining as residual in containers and from major spills, being disposed of to landfill.

In sewer, some of the notified polymer is expected to associate with suspended particles and sediment. In landfill, the notified polymer is not expected to be mobile and should adsorb to sediment, where over time it should slowly degrade through biotic and abiotic processes to simple carbon and nitrogen based compounds.

Based on the worst-case scenario of 100% notified polymer being released to the aquatic environment via the sewer, with nil removal, a predicted environmental concentrations (PECs) of the notified polymer have been calculated:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.67	µg/L
PEC - Ocean:	0.07	µg/L

The potential for the notified polymer to bioaccumulate is low due to its high level of water solubility and will be limited due to the diffused release to sewer Australia wide.

9.1.2. Environment – effects assessment

The PNEC has been calculated based on the single fish end point, as shown below, using a conservative assessment factor of 1000.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	320.00	mg/L
Assessment Factor	1,000.00	
Mitigation Factor	1.00	
PNEC:	320.00	µg/L

9.1.3. Environment – risk characterisation

The Risk quotient (RQ) values, where RQ = PEC/PNEC, for freshwater and marine receiving environments have been calculated for the "worst case" scenario, as shown in the table below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.67	320	0.002
Q - Ocean:	0.07	320	0.000

As the RQ for both river and marine receiving waters are below 1.0, the proposed diffuse use of the notified polymer, at current expected import volumes, is unlikely to pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Skin contact will be the main route of exposure although eye contact by means of inadvertent splashes is also possible. Due to the colourant nature of this polymer, exposure is likely to be evident to exposed persons and this may assist in minimising dermal exposure.

Transport, Warehouse and Storage

Worker exposure during transport and storage is unlikely except in the events of accidents.

Blending and packaging
The imported product contains up to 30% of the notified polymer. Dermal and possibly ocular exposure to the notified polymer could occur during the transfer of the product to the blending vessel and equipment cleaning and maintenance. The level of exposure would vary from site to site depending on the level of automation of the formulation process.

The estimated dermal exposure is 126 mg/day, based on an EASE model using reasonable worst case defaults for the exposure scenario 'manual addition of liquids' (European Commission, 2003) and assuming the notified polymer is present at a concentration of 30%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 1.8 mg/kg bw/day. Worker exposure would be further limited by the use of fully automated/enclosed processes and PPE.

Following formulation of the end use products containing 0.1% of the notified polymer, worker exposure is unlikely due to the automated and enclosed filling and packaging system, except in the event of accidental spills and leakages.

End use
Workers may be exposed to the notified polymer during final application of the formulated cleaning products containing 0.1% of the notified polymer. The estimated dermal exposure is 9 – 27 mg/day, based on the EASE model using following inputs: direct handling, extensive contact, wide dispersive use, and assuming an average exposed surface areas of 1800 cm^2 for forearms and hands. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 0.13 – 0.39 mg/kg bw/day.

Using the typical product concentrations of 0.0005-0.01%, the estimated systemic exposure would be 0.0006 - 0.04 mg/kg bw/day

Professional cleaners may use PPE at workplaces which would reduce the levels of exposure.

9.2.2. Public health – exposure assessment

Since the notified polymer will be in products sold to the general public, widespread public exposure to the notified polymer at a concentration of 0.1% is expected.

Based on exposure estimation to a range of household products in Europe (SDA, 2005), maximum single product use dermal exposure is expected for the household products in the table below. Assuming a bodyweight of 60 kg, a 100% dermal absorption factor, a concentration of 0.1% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe, exposure to the notified polymer in these products is as follows:

Product Type	Maximum Single Product Use Exposure (mg/kg bw/day)
Household laundry products	
Laundry detergents indirect: liquid	0.00364
Fabric conditioners indirect: liquid regular	0.00222
Fabric conditioners indirect: liquid concentrate	0.00143
Handwashing: liquid laundry and fabric conditioners	0.00003
Pre-treatment liquid neat	0.00097
Household cleaning products	
APC liquid	0.0001
APC spray (neat) diluted	0.00001
APC gel (neat) diluted	0.00004
APC spray (neat) undiluted	0.00229
APC gel (neat) undiluted	0.00458

APC: All Purpose Cleaner

In addition, since products containing the notified polymer are stored and used in a domestic environment, there are possibilities of accidental ingestion, especially by young children.

9.2.3. Human health – effects assessment

No toxicological data were available for the notified polymer. The notified polymer contains a substructure, which has health concerns relating to mutagenicity and adverse liver and thyroid effects.

Toxicological data on an analogue polymer was considered acceptable, as only slight differences in the polymer chain exist. Hence, structurally similar metabolised products would be expected.

Metabolism
The azo linkage is the most labile portion of an azo dye molecule, and it is readily enzymatically metabolised in mammals, including man (SCCNFP, 2002). Liver azo reductase enzymes reductively cleave the molecule into component amines. Some metabolism may also occur in the cells of the bladder wall, and during percutaneous absorption. Anaerobic intestinal bacteria are also capable of catalysing reductive cleavage of the azo bond. Bacterial skin microflora have been reported to be able to break down azo dyes into smaller amine species through azo reduction, and these may be readily absorbed (SCCNFP, 2002).

Acute toxicity.
The analogue is of low acute toxicity by the oral route and it is assumed that the notified polymer would also be of low acute oral toxicity. Acute dermal toxicity has not been established. Given the molecular weight range of the notified polymer (MW > 500), absorption through intact skin is not expected to be significant although it cannot be discounted given the partition coefficient (log Pow = 2.76) and high water solubility of the notified polymer. Log P values between 2 and 3 are optimal for dermal absorption particularly when water solubility is high. Hence the possibility of harmful effects by the dermal route cannot be ruled out. Acute inhalation toxicity has not been established but the notified polymer is a non-volatile polymeric liquid consequently this is not considered to be a relevant route of exposure except during spray application of end use products which the notified polymer is present at low concentrations in (maximum of 0.1% notified chemical) and will typically be contained in high viscosity household cleaning products (that limit potential inhalation exposure).

Irritation and Sensitisation
In a skin irritation study the analogue was not a skin irritant and it is expected that the notified polymer would not be a skin irritant. The analogue was shown to be a slight eye irritant and it is expected that the analogue polymer may also be an eye irritant.

The analogue was shown not to be a skin sensitiser and therefore it is expected that the notified polymer would not be a skin sensitiser.

Repeated Dose Toxicity
A NOAEL of 15 mg/kg bw/day was established for the analogue polymer in a 28-day study based on the dose-dependent increase for mortality and clinical signs of toxicity at 400 and 150 mg/kg bw/day and it is expected that the notified polymer would also produce similar effects.

Mutagenicity
Azo dyes as a class are a concern for their potential induction of mutagenicity and carcinogenicity. Reductive cleavage or degradation into component aromatic amines is perhaps the most important mechanism leading to the genotoxicity of azo dyes. The notified polymer is not to expected to be reductively cleaved to release any of the restricted aromatic amines specified in either the Appendix to EC Directive 76/769/EEC (EC, 2004) or the annexes of EU SCCNFP/0495/01 (SCCNFP, 2002). However the notified polymer may breakdown to an amine which has shown to be mutagenic *in vitro*.

A reverse mutation test in *Salmonella typhimurium* and *Escherichia coli* indicated the analogue was not mutagenic to bacteria with and without metabolic activation. A chromosomal aberration tests in V79 Chinese Hamster Lung Cells (*in vitro*) showed the analogue polymer was

clastogenic to CHL cells treated *in vitro* under the conditions of the test. The analogue polymer was not clastogenic, however, in an *in vivo* mouse micronucleus assay under the conditions of the test. The analogue polymer is therefore not considered to be genotoxic *in vivo* and based on this the notified polymer is also not expected to be genotoxic *in vivo*.

Hazard classification for health effects
Based on the available data, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Based on a NOAEL of 15 mg/kg bw/day, derived from a 28-day rat oral study and the reasonable worst-case worker exposure estimation during formulation and end uses, the margin of exposure (MOE) is calculated as follows:

	Concentration of Notified Polymer	Systemic Exposure (mg/kg bw/day)	MOE
Blending (manual handling of liquids)	30%	1.8 mg/kg bw/day	8.3
End use	0.1 % (maximum)	0.13 – 0.39 mg/kg bw/day	116-39
End use	0.0005-0.01 % (typical)	0.0006 - 0.04 mg/kg bw/day	23000 – 389

MOEs greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data may not be acceptable for workers involved in the manual transfer of the imported liquid product However, certain levels of uncertainties exist in the estimation of the systemic exposure including not taking workplace control measures into consideration in the EASE modelling for worker exposure estimation and a number of assumptions, for example, 100% dermal absorption for the notified polymer. Therefore, this estimate is likely to be an overestimate. Use of PPE (as described) and mechanic controls, such as automated processes, will limit the risk.

Although the MOE for end use workers may be less than 100 (indicating the risk of systemic effects may not be acceptable) given the conservative nature of this estimate (conservative model, total surface area of hands and forearms used in estimate, 100% dermal absorption and maximum rather than typical concentration of the notified polymer in the end-use products) the risk of adverse systemic effects in end use workers is considered to be low. The use of PPE would reduce the risk.

9.2.5. Public health – risk characterisation

Based on the NOAEL of 15 mg/kg bw/day, MOEs for a number of likely consumer product categories (0.1% maximum notified polymer in domestic products) are calculated and presented in the table below. The concentrations that can yield a MOE of 100 for all the listed products are also calculated.

Product Type	Estimated Exposure*	MOE
Household laundry products		
Laundry detergents: liquid	0.00364	4120
Fabric conditioners: liquid regular	0.00222	6760
Fabric conditioners: liquid concentrate	0.000143	10490

Handwashing: liquid laundry and fabric conditioners	0.00003	500000
Pre-treatment liquid neat	0.00097	15460
Household cleaning products		
APC liquid	0.0001	150000
APC spray (neat) diluted	0.00001	1500000
APC gel (neat) diluted	0.00004	375000
APC spray (neat) undiluted	0.00229	6550
APC gel (neat) undiluted	0.00458	3280

*SDA (2005
APC = All Purpose Cleaner

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. As the all the calculated MOEs are ≥ 100, the risk to public health is considered to be low.

There is a very slight chance of ingestion of the notified polymer due to accidental ingestion of household cleaning products. As a worst-case scenario, a 10 kg child ingesting 5 mL of a liquid formulation containing 0.1% v/v notified polymer would receive a dose of approximately no more than 0.05 mg/kg bw which is significantly below the expected lethal dose (LD_{50} > 2000 mg/kg). Given the low concentration of the notified polymer in the formulated products, the risk of lethal effects as a result of accidental ingestion is considered to be low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Acute oral toxicity	5	May be harmful if swallowed

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the polymer is not considered to pose a risk to the environment based on its reported use pattern and volume.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Moderate Concern to occupational health and safety under the conditions of the occupational settings described for manual handling of the imported product. The concern would be mitigated by the use of PPE and engineering controls.

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the products containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to products containing the product containing the notified polymer as introduced during blending:
  - Automation of formulation processes, especially when transferring the product containing the notified polymer
  - Appropriate controls to avoid spillages

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the product containing the notified polymer as introduced during blending and end uses by workers:
  - Avoid direct skin and eye contact during end uses
  - Appropriate workplace training in handling of chemicals

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the product containing the notified polymer as introduced:
  - protective clothing
  - gloves
  - eye protection

- Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by incineration or to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if

- the importation volume exceeds one tonne per annum notified polymer; or
- the polymer has a number-average molecular weight of less than 1000; or
- if the concentration of notified polymer exceeds 0.1% in end-use products; or
- any personal care products (including baby care products) containing the notified polymer are to be introduced to Australia.
- any additional toxicity studies becomes available on the notified polymer or analogue used for other health endpoints in this assessment; or

or

(2) Under Section 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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