

File No: STD/1100

23 May 2005

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Cashew, nutshell liq., polymer with formaldehyde, oxidized linseed oil and phenol

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Cashew, nutshell liq., polymer with formaldehyde, oxidized linseed oil and phenol**1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

FMP Group (Aust) Pty Ltd (ABN 14 004 332 496) of Elizabeth St, Ballarat, VIC, 3350

and

Huntsman Chemical Company Australia Pty Ltd (48 004 146 338) of Somerville Road, Brooklyn, VIC, 3012

NOTIFICATION CATEGORY

Standard: Polymer with NAMW < 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Molecular weight

% of polymer constituents

Particle size details

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Vapour pressure

Hydrolysis as a function of pH

Partition Coefficient

Adsorption/Desorption

Dissociation Constant

Flash Point

Flammability Limits

Autoignition temperature

Explosive Properties

Toxicological data

Ecotoxicological data

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

Cashew, nutshell liq., polymer with formaldehyde, oxidized linseed oil and phenol

OTHER NAME(S)

Resinox MG1946 Resin intermediate.

MARKETING NAME(S)

The notified polymer is supplied as a component (approximately 90%) of the resin Resinox RM72.

CAS NUMBER

148373-03-9

MOLECULAR FORMULA

(C₆H₆O).(CH₂O).(unspecified).(unspecified).

The molecular formula for the UVCB parts of the polymer Cashew nutshell liquid and oxidised linseed oil cannot be specified.

STRUCTURAL FORMULA

Due to the UVCB parts of the polymer, the structure of the notified polymer has not been defined. The structure of the polymer formed from the cashew nutshell liquid, phenol and formaldehyde is believed to be typical of phenolic novalacs. The structure and the mechanism of the inclusion of the linseed oil, polymerised, oxidised into the polymer is not known.

MOLECULAR WEIGHT (NAMW)

Number Average Molecular Weight (NAMW) <1000

SPECTRAL DATA

METHOD Infrared Spectroscopy, ¹H NMR and ¹³CNMR
 Remarks Spectra provided.

3. COMPOSITION

DEGREE OF PURITY

~84% (Based on residual monomer content)

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

<i>Chemical Name</i>	Cashew, nutshell liquid purified		
<i>CAS No.</i>	8007-24-7	<i>Weight %</i>	5%
<i>Hazardous Properties</i>	<u>Classification</u> R38 Irritating to skin R41 Risk of serious eye damage R43 May cause sensitisation by skin contact <u>Concentration cut-off</u> Conc ≥20%: Xi; R38; R41; R43 ≥10%Conc<20%: Xi; R41, R43 ≥5%Conc<10%: Xi; R36, R43 ≥ 1%Conc<5%: Xi; R43		
<i>Chemical Name</i>	Phenol		
<i>CAS No.</i>	108-95-2	<i>Weight %</i>	6%*
<i>Hazardous Properties</i>	<u>Classification</u> (NOHSC 2003a) R24/25 Toxic in contact with skin and if swallowed R34 Causes burns <u>Concentration cut-off</u> Conc ≥5%: T; R24/25; R34 ≥1%Conc<5%: Xn; R21/22; R36/38		

* based on measured levels in Resinox RM72

<i>Chemical Name</i>	Formaldehyde
<i>CAS No.</i>	50-00-0
<i>Weight %</i>	0.01%*
<i>Hazardous Properties</i>	<u>Classification</u> (NOHSC 2003a) R40 Limited Evidence of a carcinogenic effect R23/24/25 Toxic by inhalation and if swallowed R34 Causes burns R43 May cause sensitisation by skin contact
	<u>Concentration cut-off</u> Conc \geq 25%: T; R40; R23/24/25; R34; R43 \geq 5%Conc<25%: Xn; R40; R20/21/22; R36/37/38; R43 \geq 1%Conc<5%: Xn; R40; R43 \geq 0.2%Conc<1%: Xi; R43

* based on measured levels in Resinox RM72

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

<i>Chemical Name</i>	Linseed oil, polymd., oxidised
<i>CAS No.</i>	66071-03-2
<i>Weight %</i>	5%

ADDITIVES/ADJUVANTS
None

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
Cashew, nutshell liquid purified	8007-24-7	Confidential	5
Phenol	108-95-2	Confidential	6*
Formaldehyde	50-00-0	Confidential	0.01*
Linseed oil, polymd., oxidised	66071-03-2	Confidential	5

* based on measured levels in Resinox RM72

DEGRADATION PRODUCTS

Based on its chemical similarity to phenol-formaldehyde polymers, cured Resinox RM72 is expected to be chemically stable in the environment and thermally stable up to approximately 300°C. Products of combustion can include toxic gases such as carbon monoxide, formaldehyde and nitrogen oxides.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Trace amounts of formaldehyde (<0.01%) may be released during heat curing of Resinox RM72 and phenol (<6%) may slowly leach from the uncured resin compound in soil. Once cured the monomers are fully reacted to form a heat and chemically resistant phenolic plastic. There should be no loss of monomers during handling and use of the friction products. However, during use the friction material slowly wears to dust and thermal degradation products.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be manufactured at Huntsman Chemical Company plant at Brooklyn, VIC.

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

The following amount is proposed to be manufactured in Australia:

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	50-100	50-100	50-100	50-100	50-100

Of this the following amount is proposed to be exported:

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	20-50	20-50	20-50	20-50	20-50

USE

Resinox RM72 Resin Compound containing the notified polymer is used as a raw material in combination with other ingredients to manufacture friction materials for disc brake pads.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Not applicable

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer will be manufactured at the Huntsman Chemical Company plant at Brooklyn where it will also be combined with other ingredients to form Resinox RM72 Resin Compound.

The friction material mix formulation and manufacture of the brake disc occurs at FMP Group, Ballarat, VIC.

TRANSPORTATION AND PACKAGING

Resinox RM72 Resin Compound is transported in sealed 15 kg polyethylene lined paper bags or 800 kg bulk bags. It will be transported from the manufacturing facility by truck in shipments of up to 500-800 kg at a time.

5.2. Operation description

Polymer manufacture and Resinox RM72 Resin Compound formulation

Once the notified polymer has been manufactured in the reactor kettle it is heated to 150°C and sampled for property testing. When in specification, the notified polymer is dropped molten through a hatch onto the cooling floor. The notified polymer spreads over the floor to a depth of 4-6 inches. The cooling floor is cleared prior to the notified polymer being dropped, apart from the reactor kettle operator who initiates the automated process. Once the dropping process is initiated the reactor kettle operator also vacates the area for a period of 20 minutes. Over a period of 12 – 20 hours depending on the ambient conditions, the notified polymer cools and solidifies. Once the notified polymer has cooled, cooling floor operators break the resin using sledgehammers and crowbars. The notified polymer is then manually lifted onto a conveyor belt, where it is crushed into golf ball sized lumps. The lumps are discharged into open head drums and stored until they are required for grinding.

The notified polymer is mixed with hexamine by ground resin operators and charged via a chute with a grill to the grinder. After grinding the formulated resin containing approximately 90% notified polymer is discharged via a chute into multiwalled polyethylene lined bags. Once the required amount is discharged, the bag is sewn automatically and packed onto a pallet.

Friction material formulation

The formulated resin containing the notified polymer is transported by forklift to the pre-weigh and mixing area. An operator places an unopened bag on to the debag station using a vacuum operated bag lifter. The machine then cuts the bag open, removes the content through vacuum and disposes of the bag automatically. The formulated resin containing the notified polymer is conveyed to the mixer using a closed vacuum conveyor directly from the debagging machine via the silos and mixed with the remainder of fibres and fillers used to form the completed friction material mix. The friction material mix containing < 10% notified polymer is released into plastic buckets which have been automatically placed below the mixer. Once the transfer to the bucket is complete a lid is placed on the bucket while it is still under extraction.

Brake disc manufacture

The friction material mix (containing < 10% notified polymer) is hand weighed and moulded at the

presses in to the brake discs at a temperature of 150°C. The completed pads undergo further automated grooving and grinding in an enclosed system.

End Use

Brake pads will mainly be installed by professional mechanics although installation by car owners is possible.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hrs/day)</i>	<i>Exposure Frequency (days/year)</i>
Polymer/Resinox RM72 manufacture			
Reactor operator	5	12	6
Cooling floor operator	5	12	6
Ground Resin operator	5	12	6
Foreman	1	1	14
Technical Leader	1	0.5	14
Maintenance fitter	3	1	5
Laboratory Chemist/Technician	5	1	6
Friction material mix formulation			
Warehousing personnel	Up to 10	7	230
Initial weigh	10	7	230
Initial mix	10	7	230
Brake disc manufacture			
Hand weigh/mould	200	7	230
Grooving and grinding	50	7	230

Exposure Details

Polymer manufacture and Resinox RM72 Resin Compound formulation

Laboratory staff may be exposed to the notified polymer (100%) during sampling and testing. As the majority of workers are cleared prior to the resin being dropped, only the one reactor operator who initiates the drop of the resin is considered to have potential for inhalation exposure of resin fumes. The dropping of the resin takes place in a well-ventilated area. If operators are required to enter the kettle floor within 20 minutes of the resin drop then respiratory protection is required. Exposure to the notified polymer could occur during the break up and transfer of the notified polymer to the grinder. The resin is completely solid at this stage, with little or no dust generation and hence dermal exposure is expected to be the main route. Workers wear masks as a precaution.

Grinding of the notified polymer occurs in a closed system and hence worker exposure is not expected during this process. Similarly, due to the automated nature of bagging process worker exposure is not expected except in the event of a machine malfunction. However, inhalation exposure to atmospheric dust and dermal exposure to residues on the outside of the bag could occur. Dust from the grinder and pack out areas is extracted and collected. Operators routinely wear dust masks for all resin pack-out

Friction material formulation

Due to the automated nature of the debagging, mixing and filling operations, worker exposure to the notified polymer is not expected except in the event of a machine malfunction. Operators are protected from dust/fibres and fumes by an integral plant-wide dust and fume extraction system.

Brake disc manufacture

Exposure to the notified polymer during transfer to the press is not expected due to the use of lids. Dermal and possibly inhalation exposure to the notified polymer at a concentration of <10% could occur during the hand weighing of the friction material formulation. Workers are protected from dust/fibres and fumes by an integral plant-wide dust and fume extraction system. In addition workers wear overalls, safety boots, and protective eyewear and are encouraged to wear protective gloves when manually handling the materials.

Once the brake disc is pressed and cured at 150 °C, the notified polymer will be bound within an inert

matrix and hence dermal exposure is not expected. Inhalation exposure to dust during grooving and grinding is not expected due to the enclosed and automated nature and the use of extraction systems.

End use

Worker exposure to the notified polymer during brake disc installation is not expected as the polymer is bound within an inert matrix and hence is not expected to be bioavailable.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer is reacted in the kettle and then dropped molten through a hatch onto the cooling floor. At this stage the resin is completely solid. The resin blocks are manually lifted onto a conveyor belt where it is crushed into lumps and stored in drums until they are required for grinding. The lump resin is ground with hexamine via a chute. Once the resin and hexamine goes into the chute, the remainder of the grinding takes place in a closed system. Thus there is little environmental release associated with these processes. Packaging of the resin containing the notified polymer in plastic bags further minimises the potential for release during transport.

The notified polymer is conveyed to the mixer using a closed vacuum conveyor directly from the debagging machine via the silos. Once the mixer has completed its cycle, the mix is weighed into the buckets under full extraction. The vacuumed material from the extraction at both mix and raw material weigh-out is transferred into a sealed baghouse from which the contents are transferred to a machine that solidifies the dust and sent to landfill. Residues collected and not suitable for recycling will be heat cured to immobilise any free monomer and consigned to landfill. This is estimated to be 1% of the resin usage. The residual polymer in the bag is estimated to be <0.01%. The bags are returned for refilling and will be taken to landfill at the end of its useful life by a third party (SITA).

Any waste generated during manufacture is disposed of as in the baghousing process above. The bucket contains very little residual mix and is removed by vacuum to the sealed bag house and the bucket is reused for subsequent mixes. The notifier indicates that the effect of wastes generated from cleaning of the equipment are minimal as there is no need for routine cleaning of these items and any waste would be dealt with through the sealed bag-house. However, the notifier also indicates that aqueous waste from the resin manufacturing process is collected and treated in the plants biological effluent treatment plant before discharge to the sewage system, though content of the notified polymer will be very low.

RELEASE OF CHEMICAL FROM USE

The notified polymer is fully cured during the fabrication (by heat-based pressing) into brake linings. Once cured, the notified polymer will be bound within an inert matrix. The cured polymer present in the friction products should not pose an exposure risk. Most of the notified polymer will be released to the environment in the form of dust particles generated during use of the brake pads. This dust would be widely dispersed onto roads and ultimately become part of the soil complex, though a portion may be washed into stormwater drains following rain. Unconsumed portions of the brake pads would be consigned to landfill.

5.5. Disposal

Resin waste would be cured and disposed in an approved landfill or be incinerated.

5.6. Public exposure

The notified polymer is not supplied directly to the public. Exposure to car owners during the installation of the brake pads is not expected as the polymer is bound within an inert matrix and hence is not expected to be bioavailable.

During braking, the disc pad friction material is likely to wear off and be widely dispersed on the roads. As such there is potential for the public to be exposed to the notified polymer through inhalation of the brake pad debris.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Brown lumps with slight phenolic odour (notified polymer)

Melting Point/Freezing Point 75 °C (notified polymer)

METHOD Bar Melting Point Method
The bar melting point is the temperature at which a portion of a test sample just adheres to the surface of a heated bar. The copper bar is heated by means of a heating element inside the bar and the temperature is determined by thermocouples connected along the length of the bar.

Ground test substance is placed on the surface of a copper bar at a position relating to its anticipated melting point. After exactly 10 seconds a natural fibre brush is used to brush the sample from the bar. If no powder adheres to the brush, the melting point has not been reached and a new sample is placed at another point along the bar that has been set at a higher temperature. The bar melting point is the temperature at which a portion of the sample just adheres to the bar.
Remarks Data supplied by notifier. Test Report not provided.

Density 1190 kg/m³ at 25°C (notified polymer)

METHOD The specific gravity was determined by comparing the dry weight of a piece of resin to its weight in water.

Remarks Data supplied by notifier. Test Report not provided.

Vapour Pressure Not determined

Remarks The notified polymer is not expected to exert any significant vapour pressure at ambient temperatures on the basis of the low vapour pressure of the constituents of the notified polymer.

Limited vapour pressure information was available for the polymer constituents at high temperatures. The vapour pressure of phenol at 160°C is 53.3 kPa.

Water Solubility <1.233 x 10⁻³ g/L at 20°C (Resinox RM72)

METHOD OECD TG 105 Water Solubility – Preliminary test
Remarks Flask Method. The notified polymer was diluted a total of three times and left for a period of 3 days, 2 days and 1 day after each dilution respectively. At the end of each observation period, the notified polymer did not appear to have dissolved totally. The result reflects the concentration of the most dilute solution tested.

TEST FACILITY Data supplied by notifier. Full Study Report not provided.

Hydrolysis as a Function of pH Not determined

Remarks As the notified polymer is highly insoluble in water, hydrolysis test is not able to be performed. Further, there are no hydrolysable groups present in the polymer.

Partition Coefficient (n-octanol/water) Not determined

Remarks Based on the low water solubility of the notified polymer, it is likely to be partitioned to the octanol layer.

Adsorption/Desorption Not determined

Remarks Due to the low water solubility and the hydrophobic chains present in the notified polymer, it is likely that the notified polymer would be adsorbed to soil.

Dissociation Constant

Not determined

Remarks Based on its chemical similarity to phenol-formaldehyde polymers, the notified polymer is not expected to dissociate under use conditions. In addition, the notified polymer is practically insoluble in water.

TEST FACILITY

Particle Size

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.
Remarks Based on information provided for Resinox RM72 and other ground phenolic resins it is expected that the majority (>90%) of the notified polymer will be in the inhalable size range (<100 µm) with a significant proportion of particles (20-30 %) in the respirable size range (<10 µm)

Flash Point

Not determined

Remarks The notified polymer is used in processes up to a temperature of 150°C. The notified polymer does not flash in this temperature range.

TEST FACILITY

Flammability Limits

Not determined

Remarks The notified polymer is not expected to be flammable under normal conditions of use.

Autoignition Temperature

Not determined

Remarks The notified polymer is used in processes up to a temperature of 150°C. There is no evidence of self-ignition in this temperature range.

Explosive Properties

Not determined

Remarks In common with other phenolic resin powders, the notified polymer is a combustible powder and has the potential to generate explosive dust clouds.

Reactivity

Remarks The notified polymer is unreactive under normal storage conditions. There are no known hazardous incompatibilities with other substances. Resinox RM72 designed to cure at elevated temperatures.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicity data has been provided for the notified polymer. The toxicology profile of the notified polymer (as introduced) is predicted to be dictated by the residual polymer constituents present. Toxicity data for the constituents Cashew, nutshell liquid and Linseed oil, polymerised, oxidised is summarised below. Extensive toxicological data is available for phenol and formaldehyde and as such these constituents have not been included in this section. Their hazard classification and impact on the potential health effects of the notified polymer has been covered elsewhere in this report.

<i>Endpoint and Result</i>	<i>Test Substance</i>	<i>Assessment Conclusion</i>
Rat, acute oral	Cashew, nutshell liquid	toxicity LD50 >5000 mg/kg bw
Rat, acute oral	Linseed oil, polyimd., oxidised	toxicity LD50 >4986 mg/kg bw
Rat, acute dermal	-	not determined
Rat, acute inhalation	-	not determined
Rabbit, skin irritation	Cashew, nutshell liquid	irritating
Rabbit, eye irritation	Cashew, nutshell liquid	severely irritating
Guinea pig, skin sensitisation – adjuvant test	Cashew, nutshell liquid	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	Cashew, nutshell liquid	NOEL 200 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	Cashew, nutshell liquid	non mutagenic
Genotoxicity – in vitro chromosome aberration test	Cashew, nutshell liquid	non genotoxic
Genotoxicity – in vitro cell gene mutation test	Cashew, nutshell liquid	non genotoxic
Genotoxicity – in vivo	-	not determined

7.1 Acute toxicity – oral

TEST SUBSTANCE	Cashew, nutshell liquid (grade unspecified)
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat
Vehicle	Test substance administered undiluted.
Remarks - Method	2 male and 2 female animals from each dose group were sacrificed on day 3.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	7 per sex	2000	0
II	7 per sex	3200	1 male and 2 female
III	7 per sex	5000	2 female

LD50	>5000 mg/kg bw
Signs of Toxicity	Only non specific signs of toxicity. Surviving animals had recovered between day 4 (low dose) and day 11 (high dose)
Effects in Organs	No details were provided
Remarks - Results	Other than the information above, no detailed results were provided. Test data has not been reviewed.

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

TEST FACILITY European Chemical Bureau (2000)

TEST SUBSTANCE Linseed oil, polymd., oxidised

METHOD OECD TG 401 Acute Oral Toxicity

Species/Strain Rat/Wistar CrI.: (WI) BR

Vehicle Test substance administered undiluted.

Remarks - Method No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5 per sex	4986	0

LD50 >4986 mg/kg bw

Signs of Toxicity There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.

Effects in Organs There were no remarkable necropsy findings.

Remarks - Results

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY IBR (1988)

7.2. Acute toxicity – dermal

No acute dermal toxicity data was provided for the polymer constituents Cashew, nutshell liquid and Linseed oil, polymerised, oxidised.

7.3. Acute toxicity – inhalation

No acute inhalation toxicity data was provided for the polymer constituents Cashew, nutshell liquid and Linseed oil, polymerised, oxidised.

7.4 Irritation – skin

TEST SUBSTANCE Cashew, nutshell liquid (grade unspecified)

METHOD EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain Rabbit

Remarks - Method No other details on the method were provided. Test data has not been reviewed.

RESULTS

Remarks - Results The test substance was reported to be highly irritating with an EC classification 'irritating to skin'. No detailed results were provided. Test data has not been reviewed.

CONCLUSION The test substance is irritating to the skin.

TEST FACILITY European Chemical Bureau (2000)

7.5. Irritation – eye

TEST SUBSTANCE Cashew, nutshell liquid (grade unspecified)

METHOD EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit
Remarks - Method	No other details on the method were provided. Test data has not been reviewed.

RESULTS

Remarks - Results	The test substance was reported to be highly irritating with an EC classification 'risk of serious damage to eyes. No detailed results were provided. Test data has not been reviewed.
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CONCLUSION	The test substance is severely irritating to the eye.
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TEST FACILITY	European Chemical Bureau (2000)
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7.6. Skin sensitisation

No sensitisation study was provided for the polymer constituent Linseed oil, polymerised, oxidised.

TEST SUBSTANCE	Cardolite NC-700 (Cashew, nutshell liquid, distilled)
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METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test
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Species/Strain	Guinea pig
PRELIMINARY STUDY	Not reported

MAIN STUDY

Number of Animals	Test Group: 20	Control Group: 10
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INDUCTION PHASE

Induction Concentration:

intradermal: 1% w/v in liquid paraffin BP

topical: 25% v/v in liquid paraffin BP

Signs of Irritation

After intradermal injection: well-defined erythema was commonly noted at the 24-hour observation. Incidents of moderate to severe erythema were also noted at this time. Well-defined erythema persisted at all intradermal injection sites at the 48-hour observation.

After topical injection: Very slight or well-defined erythema with or without very slight oedema, was commonly noted at the topical induction sites at the 1-hour observation.

CHALLENGE PHASE

1st challenge

topical: 5% and 2% v/v in liquid paraffin BP

Remarks - Method

Only a summary of the study was provided. Limited method details were available. Details of the application of two different challenge concentrations was not provided.

The study also included poison ivy as a test substance but these results are not considered relevant to this assessment and have not been included

RESULTS

Animal	Challenge Concentration	Number of animals showing skin reactions after:			
		1 st challenge		2 nd challenge	
		24 h	48 h	24 h	48 h
Test Group	5%	11	14	-	-
	2%	6	5*	-	-
Control Group	5%	Not provided	Not provided	-	-
	2%	Not provided	Not provided	-	-
		provided	provided		

* No skin reactions were noted at the challenge sites of two of these animals at the 24-hour observation.

Remarks - Results	<p>Only a summary of the study was provided.</p> <p>Challenge at 5%: Very slight to well-defined erythema was noted in eleven animals at the 24-hour observation. Very slight oedema was also noted at five of these sites at this observation. Very slight erythema was noted in 14 animals at the 48-hour observation, with very slight oedema at two of these sites. Desquamation was seen in seven animals. No evidence of erythema or oedema was seen at the 72-hour observation. No details of control group reactions were included.</p> <p>Challenge at 2%: Very slight or well-defined erythema was noted in six animals at the 24-hour observation. Very slight oedema was also noted at one of these sites at this observation. Very slight erythema was noted in five animals at the 48-hour observation. Very slight erythema persisted in one animal at the 72-hour observation. Desquamation was noted in one animal at the 48-hour observation and 3 animals at the 72-hour observation. No details of control group reactions were included.</p> <p>All animals were reported to show an expected gain in bodyweight over the study period. No signs of ill-health were noted in any animal.</p>
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	Safepharm Laboratories (1996), EPA (2002)

7.7. Repeat dose toxicity

No repeat dose toxicity study was provided for the polymer constituent Linseed oil, polymerised, oxidised.

TEST SUBSTANCE	Cashew Nutshell Liquid (Grade unspecified)
METHOD	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: None
Vehicle	Corn oil
Remarks - Method	Only a summary of the study was reviewed. Other than information provided above, no details of the method used was provided.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals*</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
I (control)	10 per sex	0	not recorded
II (low dose)	10 per sex	40	not recorded
III (mid dose)	10 per sex	200	not recorded
IV (high dose)	10 per sex	1000	4

*assumed from remarks in the summary

Mortality and Time to Death

Four female rats from the top dose groups died during the dosing period.

Clinical Observations

Top dose group males were recorded to show reduced bodyweight gain, food consumption and food conversion efficiency.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

Raised alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase levels were noted for top dose group animals. Top dose group males were also recorded to show reduced globulin levels.

Haematology

A marginal elevation of erythrocyte count and haemoglobin concentration was recorded for top dose group males and higher neutrophil and platelet counts were recorded in top dose group females.

Urinalysis

Urinalysis was recorded to show reduced pH only.

Effects in Organs

Increased absolute and relative liver weights were reported in top dose females.

It was noted that no treatment related macroscopic finding were seen and histopathological review of 32 tissues revealed only indication of local stomach irritation.

Remarks – Results

Laboratory findings were determined after 3 weeks treatment. Other than the information above, no detailed results were provided. The statistical significance if any findings/observations noted has not been recorded. Test data has not been reviewed.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day in this study, based on the lack of treatment related effects noted at this and lower dose levels.

TEST FACILITY

European Chemical Bureau (2000)

7.8. Genotoxicity – bacteria

No bacterial mutation study was provided for the polymer constituent Linseed oil, polymerised, oxidised.

TEST SUBSTANCE

Cardolite NC 511 (Cashew, nutshell liquid, distilled)

METHOD

OECD TG 471 Bacterial Reverse Mutation Test.
 Plate incorporation or Pre incubation procedure not specified
S. typhimurium: TA1538, TA1535, TA1537, TA98, TA100
 S9 fraction from Aroclor induced rat liver.
 a) With metabolic activation: 50-5000 µg/plate
 b) Without metabolic activation: 50-5000 µg/plate
 Vehicle: Acetone
 Remarks - Method: Only a summary of the study was provided. The full study has not been reviewed.

Deviations from standard protocol
 Strains used did not include either *E.coli* WP2 strains or *S. typhimurium* TA102 as recommended in the protocol for the detection of certain mutagens.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent	not reported			
Test 1		>5000	1500	negative
Test 2		>5000	1500	negative
Present	not reported			
Test 1		>5000	1500	negative
Test 2		>5000	1500	negative

Remarks - Results	<p>No significant increase in the frequency of revertant colonies was recorded for any of the bacterial strains with any dose of the test material, either with or without metabolic activation.</p> <p>A precipitate was observed at and above 1500 µg/plate, however this did not interfere with the scoring of revertant colonies.</p> <p>Although only a summary of the study was provided, individual results were included in this summary.</p>
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	EPA (2002)

7.9.1 Genotoxicity – in vitro Chromosomal Aberration Test

TEST SUBSTANCE	Cardolite NC 511 (Cashew, nutshell liquid, distilled)
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Cell Type	Human Lymphocytes
Metabolic Activation System	S9 fraction from Aroclor induced rat liver.
Vehicle	Dimethylsulfoxide
Remarks - Method	Only a summary of the study was provided. Limited method details were available.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	6.25*, 12.5*, 25*	not specified	20 hours
Test 2a	12.5*, 25*, 37.5*	not specified	20 hours
Test 2b	25*	not specified	44 hours
<i>Present</i>			
Test 1	1.56*, 3.125*, 6.25*	not specified	20 hours
Test 2	0.78*, 1.56*, 3.125*	not specified	20 hours
Test 2b	3.125*	not specified	44 hours

*Cultures selected for metaphase analysis.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>	not reported			
Test 1		>25	not reported	negative
Test 2a		37.5	not reported	negative
Test 2b			not reported	negative
<i>Present</i>	not reported			
Test 1		12.5	not reported	negative
Test 2a		6.25	not reported	negative
Test 2b			not reported	negative

Remarks - Results	<p>Although only a summary of the study was provided, individual results were included in this summary.</p> <p>The test material did not induce a significant increase in the frequency of cells with chromosome aberrations or polyploid cells in either the presence or absence of activation.</p>
CONCLUSION	The notified chemical was not clastogenic to human lymphocytes treated

in vitro under the conditions of the test.

TEST FACILITY EPA (2002)

7.9.2 Genotoxicity – in vitro Mammalian Cell Gene Mutation Test.

TEST SUBSTANCE

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
 Species/Strain Chinese Hamster
 Cell Type/Cell Line Ovary (CHO)/KI BH4
 Metabolic Activation System S9 fraction from Aroclor induced rat liver.
 Vehicle Dimethylsulfoxide
 Remarks - Method Only a summary of the study was provided. Limited method details were available. Test reported to be conducted to OECD test guidelines.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Expression Time</i>	<i>Selection Time</i>
<i>Absent</i>				
Test 1	0.75*, 1.5*, 3*, 6*, 12*	not specified	not specified	not specified
Test 2	0.75*, 1.5*, 3*, 6*, 9*	not specified	not specified	not specified
<i>Present</i>				
Test 1	1.5*, 3*, 6*, 12*, 18*	not specified	not specified	not specified
Test 2	3*, 6*, 12*, 18*, 24	not specified	not specified	not specified

*Cultures selected for metaphase analysis.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>	not reported			
Test 1		47.19*	not reported	negative
Test 2		47.19*	not reported	negative
<i>Present</i>	not reported			
Test 1		47.19*	not reported	negative
Test 2		47.19*	not reported	negative

* Stated in summary report. Could not be determined from other data provided.

Remarks - Results The test material did not induce significant or dose-related increases in mutant frequency per survivor in either the presence or absence of metabolic activation in either of the two experiments.

CONCLUSION The notified chemical was not clastogenic to CHO cells at the HGRPT locus treated in vitro under the conditions of the test.

TEST FACILITY EPA (2002)

7.10. Genotoxicity – in vivo

No *in vivo* genotoxicity data was provided for the polymer constituents Cashew, nutshell liquid and Linseed oil, polymerised, oxidised

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted for the notified polymer. However, fate and ecotoxicity data were provided for the components of the notified polymer.

8.1.1. Ready biodegradability

TEST SUBSTANCE	Linseed oil, polymd., oxidised
METHOD	According to EEC document XI/400/64 rev. 2
Inoculum	Activated sludge from domestic sewage treatment plant
Exposure Period	42 days
Auxiliary Solvent	None
Analytical Monitoring	COD and DOC
Remarks - Method	The Repetitive Die Away Test was used to evaluate the biodegradability of the poorly soluble test substance. It is performed in an aerobic aquatic environment after single or repetitive additions of the test substance. The biodegradability is followed by oxygen uptake and for soluble compounds by dissolved organic carbon (DOC) analysis. A low result does not necessarily mean that the test substance is not biodegradable under environmental conditions but rather that more work is required to establish this.
	A defined medium was inoculated with activated sludge and spiked with the test substance. Three repetitive weekly additions were conducted. Measurements were made weekly up to two weeks after the last addition. The tests were carried out in triplicate. The oxygen uptake was calculated and the biodegradation was expressed as the % oxidation (BOD/COD). Sodium acetate was used as the reference for the validation of the test.

RESULTS

<i>Test substance</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	35	7	75
14	48	14	77
21	32	21	74
28	24	28	76
35	25	35	77
42	30	42	79

Remarks - Results	The % degradation for the test substance was 35% after one week and increasing to 40% during the second week. Repetitive additions indicate that biodegradation in this type of testing approximates 30% after one week. It is apparent that % degradation in the test did not reach 60% after 28 days. This may indicate that more tests are required to establish the ready biodegradability of the test substance. Degradation in the reference reached 75% after 7 days thus validating the test criteria.
CONCLUSION	The test substance is considered not readily biodegradable based on the above test.
TEST FACILITY	Akzo Research (1988)

8.1.2. Bioaccumulation

As the notified polymer is highly insoluble in water, there is a potential for bioaccumulation to occur. However, based on its proposed use pattern and its limited direct discharge to water, the potential bioaccumulation to aquatic organisms is expected to be low.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Linseed oil, polymd., oxidised
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static
Species	Zebra-fish – <i>Brachydanio rerio</i>
Exposure Period	96 h
Auxiliary Solvent	none
Water Hardness	The sum of calcium and magnesium ions was 2.5 mmol/L
Analytical Monitoring	
Remarks – Method	10 fish were used for each of the treatment concentrations of 1000, 625, 391, 244, 153 and 100 mg/L and for the control. The contents of each glass tank were mixed thoroughly for 2 h to facilitate the dissolving and/or dispersing of the solid test sample. It is not clear whether the solution after stirring remained clear. At 0, 1, 24, 48, 72 and 96 h after the start of the test, the fish were inspected for symptoms of disorders of the swimming behaviour, visible peculiarities of the respiratory function and changes of the outward appearance. Dissolved oxygen concentration, pH and temperatures were within the acceptable limits throughout the test.

RESULTS

Concentration mg/L <i>Nominal</i>	Number of Fish	Mortality			
		24h	48h	72h	96h
1000	10	10	10	10	10
625	10	0	0	0	10
391	10	0	0	0	2
244	10	0	0	0	0
153	10	0	0	0	0
100	10	0	0	0	0
Control	10	0	0	0	0

LC50	390 mg/L at 96 hours (nominal)
NOEC (or LOEC)	244 mg/L at 96 hours.
Remarks – Results	The water solubility of the linseed oil, polymd., oxidised is unclear. It is expected that linseed oil, polymd., oxidised would be insoluble in water due to its hydrophobicity. Consequently, it is possible that the toxic effects observed could be a physical effect from the undissolved oil. Therefore, this result should be treated with caution.

CONCLUSION	The test substance is considered to be practically non-toxic to fish.
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TEST FACILITY	NATEC Institut (1988)
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The notifier has also provided a literature report which indicates that phenolic compounds separated from crude cashew nutshell liquid have exhibited molluscicidal activity with 48 h LC50 of 0.35 –1.4 mg/L. However, commercial cashew nutshell liquid (cardanol) did not exhibit molluscicidal activity with a NOEC of 5 mg/L (Sullivan 1982). The notifier has also provided toxicity data for phenol on the aquatic organisms such as fish, aquatic invertebrates and alga (Verschuere 1996). These results are summarised in Table 1. It should be noted that although residual levels of the polymer constituents are present, the relevance of these results is uncertain and therefore they should be viewed with caution.

Table 1: Acute toxicity of the notified polymer-related monomers to aquatic organisms

Compounds (reference)	Species	96 h LC50 (mg/L)	IC10 (mg/L)	48 h EC50 (mg/L)
Phenol (Verschuere 1996)	Fish (Blue gill)*	5.7	28	
Blown linseed oil (NATEC Institut 1988; see report above)	Zebra fish	390		
Components of cashew nutshell liquid (Sullivan 1982)	Freshwater snail (<i>Biomphalaria glabrata</i>)			0.35 – 1.4
Phenol (Verschuere 1996)	Green alga		28	
Phenol (WHO 1994)	<i>Daphnia magna</i>			7 – 100 (5 results)

* Results for 20 species are available

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer is insoluble in water and is not expected to be readily biodegradable. Residues collected from the manufacturing process will be heat cured prior to landfill and are estimated to be 1% of the resin usage. Any waste generated during manufacture is disposed of as in the baghousing process. Although aqueous waste from the manufacturing process will eventually be discharged to sewage, it is considered to be low. It is expected that the notified polymer will be adsorbed to sludge during the waste water treatment process. Approximately <0.01% of the residues will remain in the bags which will be taken to landfill after its useful life.

Most of the environmental release will occur on the road as a result of the release of dust particles from the brake pad from friction, where it may be washed off with rain into stormwater drains. It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified polymer released into the aquatic environment via stormwater drains. However, a worst case PEC might be estimated if it is assumed that 20% of notified polymer used in Australia (i.e. 16000 kg (assuming 100 tonnes manufactured with only 20 tonnes exported)) is washed into the stormwater drains in a single metropolitan area with a geographical footprint of 500 square kilometres and an average annual rainfall of 50 cm. With a maximum annual release into this localised stormwater system of 16000 kg and the annual volume of water drained from this region estimated to be approximately $250 \times 10^6 \text{ m}^3$, the resultant PEC is approximately 64 µg/L. It should be stressed that this result is very much a worst case scenario.

9.1.2. Environment – effects assessment

It is not possible to determine a predicted no effect concentration (PNEC) for aquatic ecosystems in order to assess the risk to aquatic organisms as no ecotoxicity data were provided for the notified polymer. Although there are ecotoxicity data available for the monomeric constituents of the notified polymer, it is inappropriate to use any of these for the risk assessment.

9.1.3. Environment – risk characterisation

The use pattern of the notified polymer could result in widespread exposure to the aquatic environment throughout Australia through the washing off roads into the stormwater system. The worst case PEC is 64 µg/L but no PNEC can be established. However, the notified polymer is non-ionic, which are generally acceptable as being not of concern if the NAMW is >1000. While this is <1000 there were difficulties with its measurement and the evidence is that it is considerably larger than measured. It is unlikely that the toxicity will be close to the order of the worst case PEC of 64 µg/L. Further, the low water solubility of the polymer and its potential to become associated with the sediments can expect to reduce the possibility of sufficient amounts to remain in solution to cause acute toxicity in the aquatic environment. While it can be assumed that the notified chemical will not degrade readily, it is likely to undergo slow biodegradation under environmental conditions.

Overall, the environmental risk from the proposed use of the notified polymer is expected to be low. However, the potential exists for physical fouling of aquatic organisms by undissolved material in the advent of a sizeable release to waterways. For this reason and the uncertainty of toxic effects to other aquatic organisms the bulk notified polymer should be prevented from entering waterways.

As the notified polymer has low water solubility, degradation in or leaching of the cured waste from landfill sites is not expected. Incineration of the notified polymer is expected to produce oxides of carbon.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Polymer manufacture and Resinox RM72 Resin Compound formulation

Laboratory Staff

Due to the temperature of the notified polymer as sampled (150°C), dermal exposure to the notified polymer during sampling and testing is not expected. Although inhalation exposure to resin fumes may occur, minimal exposure is expected due to the small quantities involved.

Reactor Operator

The reactor operator who initiates the drop to the floor process has the potential to be exposed to fumes from the notified polymer. However, in a personal atmospheric monitoring study conducted by Huntsman during the manufacture of another phenol-formaldehyde resin, the level of phenol detected during the 'drop to the floor process' was below the limit of detection (Huntsman, 2003). Based on vapour pressures of the polymer constituents, the atmospheric concentration of phenol for a typical phenol-formaldehyde resin is considered to represent the likely atmospheric concentration of fumes from the notified polymer. Therefore, based on the results of this study and the relatively short exposure time, inhalation exposure is expected to be low. Exposure to notified polymer fumes on return to the cooling floor area is not expected as the area is well ventilated and any fumes generated are expected to have been dispersed.

Cooling floor operator

Dermal exposure to the notified polymer could occur during break up of the resin and transfer to the grinding machine. Although dermal contact with the notified polymer will be frequent, contact time for each exposure is expected to be short. Inhalation exposure during these processes is expected to be negligible as little or no dust is reported to be generated and workers wear masks to limit any potential exposure.

Ground resin operator

Exposure to the notified polymer during the grinding process is not expected as the grinding takes place in an enclosed system. Inhalation exposure to atmospheric dust and dermal exposure to residues on the outside of the bag could occur in the packing area. The majority (>90%) of the notified polymer will be in the inhalable size range (<100 µm) with a significant proportion of particles (20-30 %) in the respirable size range (<10 µm). The average full shift atmospheric concentration of dust during packout of the 800kg bags was calculated to be 4.3 mg/m³ based on personal dust monitoring carried out during the packing of another phenol-formaldehyde resin (Huntsman, 1998). Therefore for a 70 kg worker, assuming an inhalation rate of 1.3 m³/hour, 12-hour exposure time, 100% bioavailability and that the notified polymer is present at concentration of 90%, inhalation exposure is estimated to be 0.9 mg/kg bw/day. Exposure would be reduced by the use of face masks.

Friction material formulation

Due to the automated nature of the debagging, mixing and filling processes, the main route of exposure is expected to be from atmospheric dust. FMP carry out regular monitoring of the pre-weigh and mixing areas. Levels of dust are reported not to exceed the NOHSC recommended exposure standard for inspirable dust of 10 mg/m³ (NOHSC 1995). Therefore for a 70 kg worker, assuming an inhalation rate of 1.3 m³/hour, 7-hour exposure time, 100% bioavailability and that the notified polymer is present at concentration of 90%, inhalation exposure is estimated not to exceed 1.2 mg/kg bw/day.

Brake disc manufacture

The estimated dermal exposure during the hand weighing of the friction material formulation to the moulds is 0.01-0.1 mg/cm²/day, based on EASE model (EASE) using the following input parameters: non-dispersive use, direct handling and intermittent contact and assuming the notified chemical is present at concentration of 10%. Therefore, for a 70 kg worker with surface area for hands and forearms at 1960 cm² and a worst case 100% dermal absorption factor, systemic exposure is estimated to be 0.28-2.8 mg/kg bw/day. This is expected to be an overestimate of exposure due to the presence of dust extraction systems. The wearing of PPE will further reduce the exposure.

Inhalation exposure to the notified polymer during weighing, curing and grooving and grinding process is expected to be low due to the use of extraction systems and the enclosed nature of the process.

End use

Worker exposure to the notified polymer during brake disc installation is expected to be negligible as the notified polymer is bound within an inert matrix and hence is not expected to be bioavailable.

9.2.2. Public health – exposure assessment

The notified polymer is not supplied directly to the public. Exposure to the notified polymer through contact with brake pads manufactured using the notified polymer is not expected as the notified polymer will be bound within an inert matrix. Although, there is the potential for inhalation exposure of brake wear debris containing the notified polymer, exposure by this route is expected to be low due to the disperse nature of the release and the concentration (<10%) of the notified polymer in the brake pad.

9.2.3. Human health – effects assessment

No toxicity data has been provided for the notified polymer. The toxicology profile of the notified polymer (as manufactured) is predicted to be dictated by the residual polymer constituents present.

Toxicokinetics, metabolism and distribution

Due to the presence of low molecular weight species, absorption of the notified polymer cannot be discounted.

Acute toxicity

The polymer constituents cashew, nutshell liquid and linseed oil, polymerised, oxidised were of low acute oral toxicity in rats. No dermal or inhalation toxicity data was available for these polymer constituents. Phenol is classified in the NOHSC Designated List of Hazardous Substances (NOHSC 2003a) as toxic in contact with skin and if swallowed, with a cut off concentration for this classification of 5%. Formaldehyde is classified (NOHSC 2003a) as toxic by inhalation, in contact with skin and if swallowed, with a cut off concentration for any classification for acute toxicity of 5%.

Based on this information and the level of residual polymer constituents, the notified polymer as manufactured is expected to be toxic in contact with skin and if swallowed due to the residual phenol content.

Irritation and Sensitisation.

Based on the available data, cashew, nutshell liquid is considered to be irritating to skin and severely irritating to the eye. No irritancy toxicity data was available for linseed oil, polymerised, oxidised, however, the suppliers MSDS states that this polymer constituent is non-irritating to skin and eyes. In addition, linseed oil polymerised, oxidised is not included on the NOHSC list of designated substances (NOHSC 2003a). Phenol is classified (NOHSC 2003a) as 'causes burns' with a cut-off concentration for this classification of 5%. Formaldehyde is classified (NOHSC 2003a) as 'causes burns' with a cut-off classification for any irritant classification of 5%.

Based on this information and the level of residual polymer constituents, the notified polymer as manufactured is expected to be corrosive/severely irritating due to the residual phenol.

In a skin sensitisation adjuvant test in guinea-pigs with cashew, nutshell liquid, there was evidence of reactions indicative of skin sensitisation when challenged at a concentration of 5% and 2%. Formaldehyde is classified (NOHSC 2003a) as 'may cause sensitisation by skin contact' with a cut-off concentration for this classification of 0.2%.

Based on this information and the level of residual polymer constituents, the notified polymer is considered to have the potential to cause skin sensitisation due to the residual cashew, nutshell liquid. Although no data was available, the potential for respiratory sensitisation cannot be discounted.

Repeated Dose Toxicity

In a 28 repeat dose oral study in rats with cashew, nutshell liquid, treatment related effects for animals dosed at 1000 mg/kg bw/day included raised alkaline phosphatase, alanine aminotransferase and aspartate transferase levels, a marginal elevation of erythrocyte count and haemoglobin concentration in males and higher neutrophil and platelet counts in females and increased absolute and relative liver weights in females. The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day in this study.

Mutagenicity

Cashew, nutshell liquid was negative in an Ames test and was considered to be non-clastogenic in both an *in vitro* chromosome aberration test and an *in vitro* gene cell mutation test.

Carcinogenicity

Formaldehyde is classified (NOHSC 2003a) as a category 3 carcinogenic substance with a concentration cut-off of 1%. Given the low level of residual formaldehyde (0.01%), the notified polymer as manufactured is not considered to be a potential carcinogen.

Exposure limits

Relevant exposure standards for atmospheric contaminants in the occupational environment (NOHSC, 1995) are:

Formaldehyde 1.2 mg/m³ (TWA) and 2.5 mg/m³ (STEL)

Phenol 4 mg/m³ (TWA)

Hazard classification for health effects.

No toxicological data have been provided for the notified polymer and therefore the substance cannot be classified in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances. (NOHSC 2004).

However, based on the presence of residual polymer constituents and the cut-off concentrations for classification (NOHSC 2003a, NOHSC 2004), the classification and labelling details for the notified polymer as manufactured are:

R24/25 Toxic in contact with skin and if swallowed

R34 Causes burns

R43 May cause sensitisation by skin contact

The formulated friction material contains <10% notified polymer, based on the corresponding concentrations of the polymer constituents, the notified polymer would not contribute to the hazard classification of the formulated friction material.

9.2.4. Occupational health and safety – risk characterisation

The toxicology profile of the notified polymer (as manufactured) is predicted to be dictated by the residual polymer constituents present (particularly phenol and cashew, nutshell liquid) and as such the notified polymer as manufactured is considered to be toxic in contact with skin and if swallowed, corrosive and a skin and potential respiratory sensitiser. However, these hazardous properties are only considered to be relevant when the polymer constituents are available i.e. in fumes generated when the notified polymer is heated and in dust.

Polymer manufacture and Resinox RM72 Resin Compound formulation

Laboratory Staff

The risk to laboratory workers is considered to be low due to the minimal exposure expected.

Reactor Operator

The worker who initiates the 'drop to the floor' process has the greatest potential for the risk of adverse health effects. However, due to current workplace practices in place for other phenol-formaldehyde resins, exposure to notified polymer fumes is considered to be low and as such the risk to this worker is also considered to be low. However, as the polymer constituent 'cashew, nutshell liquid' is a potential respiratory sensitiser the risk of sensitisation cannot be discounted.

Cooling floor operator

Although dermal exposure to the notified polymer could occur during break up of the resin and transfer to the grinding machine, the residual monomers which are predicted to drive the toxicity of the notified polymer are not considered to be available in this form and as such the risk of an adverse health effect as a result of this process is considered to be low. Although the inhalation of dust has the potential to lead to adverse health effects, due to the use of masks this is not considered to be a significant source of exposure.

Ground resin operator

Inhalation exposure to atmospheric dust and dermal exposure to residues on the outside of the bag could occur in the packing area. Inhalation exposure is estimated to be 0.9 mg/kg bw/day. No repeat dose toxicity study for the notified polymer itself and hence no NOAEL is available and as such a margin of exposure cannot be established. However, based on other ingredients, the resin Resinox RM-72 is classified as R42: May cause sensitisation by inhalation. Therefore, control measures in place to maintain exposure levels to as low as possible i.e. use of respiratory protection would also reduce exposure to notified polymer dust and reduce the risk of adverse health effects. Due to the potential risk of irritation and sensitisation, overalls and impermeable gloves should be worn to prevent skin contact with dust residues on the outside of the bags.

Friction material formulation

Due to the automated nature of the debugging, mixing and filling processes, the main route of exposure is expected to be from atmospheric dust. Inhalation exposure is estimated not to exceed 1.2 mg/kg bw/day. No repeat dose toxicity study for the notified polymer itself and hence no NOAEL is available and as such a margin of exposure cannot be established. However, based on other ingredients, the resin Resinox RM-72 is classified as R42: May cause sensitisation by inhalation. Therefore, control measures in place to maintain exposure levels to as low as possible would also reduce exposure to notified polymer dust and reduce the risk of adverse health effects. The site is reported to have monthly fibre and dust monitoring regime that ensures that the extraction systems are working efficiently. Based on these control measures, the risk of adverse health effects is considered to be low, although sensitisation cannot be discounted.

Brake disc manufacture

The estimated dermal exposure during the hand weighing of the friction material formulation to the moulds 0.28-2.8 mg/kg bw/day. This is expected to be an overestimate of exposure due to the presence of dust extraction systems. No repeat dose toxicity study for the notified polymer itself and hence no NOAEL is available and as such a margin of exposure cannot be established. However, the risk of adverse systemic effects for workers is expected to be low due to the concentration of the notified polymer and the expected low toxicity at this concentration. Nevertheless, as sensitisation from skin contact cannot be fully discounted, overalls and impermeable gloves should be worn.

Inhalation exposure to dust and fumes is reduced by the presence of extraction systems. The site is reported to have monthly fibre and dust monitoring regime that ensures that the extraction systems are working efficiently. In addition, the level of free formaldehyde and ammonia (an expected air contaminant based on other ingredients) were below the level of detection when personal and static monitoring was conducted during the brake disc curing process (Zurich 2003, Huntsman 2004). Based on these control measures and the expected low toxicity at the concentration levels present, the risk of adverse health effects is considered to be low, although sensitisation cannot be discounted.

End use

Worker exposure to the notified polymer during brake disc installation is expected to be negligible and as such the risk to these workers is also considered to be negligible.

9.2.5. Public health – risk characterisation

Due to the minimal levels of exposure expected, the risk to public health from the proposed use of the notified polymer is considered to be low.

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

10.1. Hazard classification

No toxicological data have been provided for the notified polymer and therefore the substance cannot be classified in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances. (NOHSC 2004).

However, based on the presence of residual polymer constituents and the cut-off concentrations for classification (NOHSC 2003a, NOHSC 2004). The classification and labelling details for the notified polymer as manufactured are:

R24/25 Toxic in contact with skin and if swallowed
R34 Causes burns
R43 May cause sensitisation by skin contact

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern

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 due to the potential risk of respiratory sensitisation.

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 notified polymer and products containing the notified polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003b). They are 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 notified chemical and products containing the notified chemical) provided by the notifier were 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- Based on the presence of residual polymer constituents the notifier should give the

notified polymer as manufactured the following health hazard classification:

- R24/25 Toxic in contact with skin and if swallowed
- R34 Causes burns
- R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified polymer:
 - Conc >80%: R24/25; R34; R43
 - 10%>Conc <80%: R21/22; R36/38; R43

Health Surveillance

- As the potential for skin and respiratory sensitisation exists, the notifier's MSDS should be provided to the authorised medical practitioner responsible for health surveillance in the workplace. Employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of adverse health effects. Sensitised persons should be transferred to another workplace.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as manufactured and during use:
 - Local Exhaust ventilation should be implemented where there is a likelihood of exposure to dust and fumes.
- Employees should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as manufactured and during use:
 - Minimise dust generation
 - Do not breathe dust and fumes
 - Avoid contact with skin and eyes
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as manufactured and as a component of Resinox RM72, where there is a likelihood of exposure to dust and fumes.
 - Protective eyewear, chemical resistant industrial clothing, impermeable gloves and respiratory protection.

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

- Atmospheric monitoring should continue to be conducted by both notifiers to ensure that control measures are working efficiently and that workplace exposures to dust and fumes from the manufacture and handling of the notified polymer are considered to be as low as reasonably possible.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical 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 cured prior to landfill or be incinerated.

Emergency procedures

- Vacuum or sweep up spills and collect in drum for re-use or 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 residual polymer constituent content of the notified polymer has changed or is likely to change, in a way that may result in an increased risk of an adverse effect of the polymer on occupational health and safety.

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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