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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

EFKA-8530

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:

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Director
NICNAS

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EKFA-8530

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Limited (ABN 97 005 061 469)
235 Settlement Road,
Thomastown, VIC 3074

Multichem Pty Ltd (ABN 47 006 115 886)
Suite 6, 400 High Street,
Kew, VIC 3101

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:
Import volumes
Chemical name
CAS number
Molecular and structural formulae
Molecular weight
Spectral data
Percentage of notified polymer in final products
End use customers

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

Physical and Chemical Properties:

Melting point
Boiling point
Vapour pressure
Water solubility
Hydrolysis as a function of pH
Partition Coefficient
Adsorption/Desorption
Dissociation constant
Particle size
Flash Point
Flammability limits
Autoignition temperature

Toxicological data:
Acute dermal
Acute inhalation
Skin and eye irritation
Repeat dose toxicity
Genotoxicity

Ecotoxicity data
Biodegradability

Bioaccumulation
Acute toxicity to fish
Acute/chronic toxicity to aquatic invertebrates
Algal growth inhibition tests
Inhibition of microbial activity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EFKA 8530 (NSN 11888)
Canada: NSN Schedule VI review completed (August 2003)
A schedule VII will be required before eligible for DSL listing

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
EKFA 8530

SPECTRAL DATA

METHOD	Infrared Spectrum
Remarks	A reference spectrum was supplied.

METHODS OF DETECTION AND DETERMINATION

METHOD	Gel Permeation chromatography
Remarks	Solvent used was tetrahydrofuran, calibration using polystyrene.
TEST FACILITY	Polysis (2004)

3. COMPOSITION

DEGREE OF PURITY
> 95%

IMPURITIES/RESIDUAL MONOMERS
Information was supplied on hazardous and non-hazardous impurities.

ADDITIVES/ADJUVANTS
None.

DEGRADATION PRODUCTS
No dangerous decomposition products known.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The residual monomers may be lost to the environment when the polymer or product containing it is in the liquid state. However, once the paint product are cured, the monomers will be trapped in the solid matrix.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. It will be imported in steel pails (25 kg) net weight or steel drums of approximately (200 kg) net weight. The product will be formulated into paints as an additive for pigment dispersion. The notified polymer will be present in formulated paint at less than 5%.

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

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

USE
Paint additive in the automotive industry.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be transported from dockside by road to the notifier's warehouse for storage and then supplied to paint manufacturers for formulation into a range of paints. The finished paints will be packed in 1 L, 4 L and 10 L steel paint cans and pails and 200 L drums for distribution to numerous automotive companies within Australia.

5.2. Operation description

Pails of the notified polymer (EFKA 8530) will be transported by road from the wharf to the Multichem warehouse and then as needed to the customer's warehouses. Three incoming goods receiving personnel will unload the containers of EFKA 8530 and store them in designated storage areas.

The liquid polymer will be formulated into paint products at the customer's paint manufacturing site. Formulation of the notified polymer into paint products will involve transfer of notified polymer by metered dosing to mixing vessel and mixing the notified polymer and other ingredients in a sealed vessel fitted with a high-speed mixer and local ventilation system. Each batch is to be quality checked and adjustments made as required. The resultant paint is filtered prior to being dispensed into 1 L, 4 L and 10 L steel paint cans and pails and 200 L drums using automated filling machine. The resultant paint contains less than 5% of the notified polymer. Paint products containing the notified polymer will be warehoused at the paint manufacturer's site prior to distribution to end-users.

The finished paint products will be supplied to automotive industry for topcoats (OEM and refinish). The tinted base paint contains less than 5% of the notified polymer. At the end user sites the paint will be stirred and then placed in a spray gun. The object to be primed with the paint will be sprayed then heat cured, resulting in the painted article.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transportation and Storage			
Transporting from dock to notifier's site for warehousing (loading/unloading trucks)	3	2-3 hours/day	10-15 days/year
Transporting to formulation site for storage prior to use	3	2-3 hours/day	10-15 days/year
Paint manufacture			
Workers involved in weighing, mixing and bead milling operations.	6	30 min to 6 hrs/day	4 days/week 4 weeks/year
Workers involved in filling cans of coating	4	3 hrs/day	4 days/week for 4 week working period
Quality control/chemists and technical service	4-8	1 hr/day	4 days/week for 4 week working period

Cleaning operations	2	30 min/day	4-days/week for 4 week working period
Paint application			
Automotive Industry	>1000	8 hrs/day	5 days/week

Exposure Details
Transport and Storage: Waterfront, transport and warehouse workers are not expected to be exposed to the notified polymer except in the case of an accident involving spillage from the pails of EFKA-8530. Spills are cleaned up by absorbing with liquid-binding material (sand, diatomite, acid binders, universal binders or sawdust) and recovered into containers for disposal in accordance with local government regulations. No controls are required. Gloves, coveralls and goggles are available if required.

Paint formulation:
Paint make up – Workers may be exposed to the polymer via dermal and ocular exposure due to drips, spills and splashes during charging of mixer and blending. Workers will wear coveralls, goggles and impervious gloves. Aerosols may be released during blending, but inhalation exposure is low due to enclosed mixing and exhaust ventilation system.

QC testing: Dermal and ocular exposure is possible from drips, spills and splashes during batch adjustment and when taking and testing samples. Workers wear coveralls, goggles and impervious gloves to minimise exposure.

Filling into drums: Dermal exposure may be possible due to drips and spills when connecting filling lines. The paint is filled into drums under local exhaust ventilation and workers wear overalls, goggles and impervious gloves. Therefore exposure is minimal.

Maintenance workers: There is possible of skin contact during equipment maintenance. Workers wear coveralls, goggles and gloves.

End use: Workers exposed to the reformulated product will mostly consist of professional spray painters applying the special paint coatings to surfaces. Spray painting will be conducted in ventilated spray booths which are equipped with recirculating systems. In such cases inhalation, dermal and ocular exposure is expected to be minimal. The spray operators will also wear anti-static flame retardant overalls, anti-static footwear and cartridge type respirators, in addition to the PPE mentioned.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer will not be manufactured in Australia. Local operations will include transport and storage, paint formulation, filling and packaging and application by end-users using spray gun.

During storage and paint manufacture the notified polymer will be released in the following ways:

- Spills - up to 1%, up to 30 kg annually to landfill
- Import container residue - less than 2%, up to 60 kg annually to landfill
- Equipment cleaning (paint formulation) - up to 1%, up to 30 kg generally to next batch

During the paint formulation operations, it is anticipated that there will be minimal release of the notified polymer during manual transfer from the storage containers to the mixers and during filling of paint into containers or during blending since it is undertaken in enclosed systems under exhaust ventilation and in a bunded area. Spills will be within bunded areas and collected with inert absorbent material (eg sand) and placed in a sealable container ready for disposal. The process equipment, blending tanks and mixers, will be cleaned with suitable solvent which is collected and used in the next batch, if possible, otherwise it will be disposed off-site via licensed contractors.

Import containers will not be rinsed prior to disposal.

RELEASE OF CHEMICAL FROM USE

Release of the notified polymer to the environment as a result of its use in the automotive industry is expected to be minimal due to the controlled nature of the industry, unless an accidental spillage occurs, and include:

- Spills - up to 1%, up to 30 kg annually to landfill
- Container residue - up to 2.5 %, up to 75 kg annually to landfill
- Overspray - up to 30%, up to 900 kg annually to landfill
- Equipment cleaning - up to 5%, up to 150 kg annually to waste contractor

All spills will be contained, collected with inert absorbent material (eg sand) and placed in a sealable container ready for disposal. Since the modern HVLP spray guns have a 70% spray efficiency while the older high pressure guns have an efficiency of only 30%, the former are used more frequently and have been used in the above overspray release estimation. As the paint will be applied within a specialised spray booth, all overspray will be contained and collected for disposal in the spray booth filters.

Any paint residue in empty paint containers will be allowed to dry and then disposed of with the container.

Painting equipment will generally be cleaned with solvent. This effluent will be collected and reused if possible otherwise it will be disposed of off-site.

5.5. Disposal

The import containers, 25 kg pails and 200 kg steel drums, and steel end-user paint cans, containing any residual notified polymer (up to 135 kg annually), will be disposed to landfill as industrial waste. At the paint manufacturing plants effluent generated during equipment cleaning (up to 30 kg of waste notified polymer annually), will be collected and disposed of to a liquid waste facility by a licensed contractor (eg for solvent recovery) or possibly reused on-site. Generally there will be no release to sewer.

Any spilt material (containing up to 60 kg annually of the notified polymer) will be disposed of to landfill. The spray booth filters are replaced every 2 to 4 months and the used filters (containing up to 900 kg of notified polymer annually) will be disposed of to landfill. Any effluent from wet scrubbers, if used, will go to licensed liquid water facilities.

5.6. Public exposure

There is little potential for exposure of the public to notified polymer, as it will not be sold to the public. The only likely exposure of the public would occur in the event of an accident during transportation of the EFKA 8530 or formulated paint product containing the notified polymer. Although the public will make contact with car surfaces containing the notified polymer, there is little potential for exposure since the polymer is trapped within the paint matrix.

6. PHYSICAL AND CHEMICAL PROPERTIES

The data presented in this section is not for the notified polymer. It represents either the product containing the polymer or results from estimation modelling for the acid form. Obtaining results for some properties, eg log P_{ow} and adsorption/desorption, is difficult due to the surface active nature of the notified polymer.

Appearance at 20°C and 101.3 kPa	Clear yellowish liquid
Boiling Point	180°C at 101.3 kPa

Remarks Estimated from one fragment of the molecule.

Density 1045 kg/m^3, temperature not specified

Remarks Method not specified, nor whether test carried out on notified polymer or marketed product.

Vapour Pressure Not determined. It is expected to be relatively low due to the potentially anionic form.

Water Solubility The product containing the notified polymer was determined to be miscible with water.

Remarks Preliminary testing only was carried out, with total organic carbon content analysis. At pH 2 the sample dispersed in water forming a translucent solution. At pH 7 and pH 9 the sample totally dissolved to form a clear solution. The amount of notified polymer used was not stated (but see hydrolysis below).

Use of the ACD Estimation model gave a water solubility estimate of 44 mg/L using an uncharged molecule.

EPIWIN (v3.10) modelling based on the most hydrophobic estimates, estimated a water solubility of 4.47 mg/L (shortest chain) to 0.44 mg/L (longest chain).

The notified polymer is expected to have surfactant properties, which make the determination and interpretation of water solubility difficult.

TEST FACILITY Polysis Lab (2004)

Hydrolysis as a Function of pH Some hydrolysis observed.

Remarks The stability of the notified polymer in acidic and basic conditions was tested. The product containing the notified polymer was mixed with buffered water to give a concentration of 4000 mg/L and pHs of 1.2, 4, 7 and 9 and then shaken in 40ºC. The pH 1.2 solution was shaken for 1 day while the others were shaken for 14 days. After shaking the solutions analysed with GPC, FT-IR and ^{1}H NMR. The findings were;

- GPC analysis showed that the molecular weight decreased under acidic and basic conditions
- FT-IR analysis showed a change in the IR adsorption peak intensity of the key group
- ^{1}H NMR analysis showed that some hydrolysis had occurred.

EPIWIN (v3.10) modelling carried out by DEH indicated a half-life of 17.3 days at pH 8 and 173 days at pH 7.

Partition Coefficient (n-octanol/water) log Pow = 4.08 (estimation)

METHOD ACD Estimation Model

log Pow = 4.08 (shortest chain) to 5.56 (longest chain)

METHOD EPIWIN (v3.10) Model
Remarks This modelling, carried out by DEH, is expected to represent the most hydrophobic estimates.

Adsorption/Desorption log K_{oc} = 3.6 (estimation)

METHOD ACD Estimation Model

log K_{oc} = 1.44 (shortest chain) to 1.97 (longest chain)

METHOD EPIWIN (v3.10) Model
Remarks Expected to represent the most hydrophobic estimates.

Dissociation Constant Not determined

Remarks	Expected to have a pKa of 3-4 based on the structure (typical acidity).

Flash Point Not determined

Flammability Limits Not determined.

Autoignition Temperature Not determined

Explosive Properties Not determined.

Reactivity

Remarks	Under normal conditions the polymer will not degrade or depolymerise. No dangerous reactions known.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicological data on the notified polymer were supplied for acute oral toxicity and skin sensitisation (LLNA). The toxicological profile was also estimated from studies on a chemical that forms one component of the molecule, and from data supplied on an analogue. The component is expected to be a metabolite of the notified chemical in biological systems and has a common functional group that may be sensitising. The analogue contains a side-chain of similar length and some of the same functional groups as the notified chemical.

Endpoint and Result	Test substance	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	Notified chemical	low toxicity
Rat, acute oral LD50 > 2000 mg/kg bw	Analogue 22% solution	low toxicity
Rat acute oral LD50 708 mg/kg bw	Chemical component	harmful
Mouse acute oral LD50 2400 mg/kg bw		low toxicity
Rat, acute dermal LD50 >1000 mg/kg bw in rabbit 1560 mg/kg bw in guinea pig	Chemical component	harmful
Rat, acute inhalation LC50 0.72 mg/L/4 hour	Chemical component	Level of toxicity not determined
Rabbit, skin irritation	Analogue 22% solution	slightly irritating
Rabbit and human skin irritation testing	Chemical component	irritating or severely irritating
Rabbit, eye irritation	Analogue 22% solution	irritating
Rabbit, eye irritation	Chemical component	irritating or severely irritating
Guinea pig, skin sensitisation – adjuvant test	Analogue 22% solution	no evidence of sensitisation
Guinea pig, skin sensitisation – adjuvant test	Chemical component	evidence of sensitisation
Skin sensitisation – Mouse local lymph node assay (LLNA)	Notified chemical	evidence of sensitisation
Skin sensitisation - Mouse local lymph node assay (LLNA)	Chemical component	evidence of sensitisation
Rat, repeat dose toxicity – oral 28 days and subcutaneous injection 53days	Chemical component	Insufficient data to set a NOAEL
Genotoxicity – bacterial reverse mutation	Analogue 22% solution	non mutagenic
Genotoxicity – bacterial reverse mutation	Chemical component	non-mutagenic
Genotoxicity – in vitro DNA synthesis inhibition tests	Chemical component	inhibited DNA synthesis
Genotoxicity – in vitro cytogenetic assay	Chemical component	non genotoxic
Carcinogenicity	Chemical component	no evidence of carcinogenicity

7.1 a) Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (Batch 21531 FE6)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/HanRcc:WIST (SPF)

Vehicle	Purified water
Remarks - Method	A limit test at 2000 mg/kg bw was carried out on 6 female rats (2 groups of 3)

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	2000	0/3
2	3F	2000	1/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	Slight to moderately ruffled fur was noted in all animals until Day 2, and persisted in two animals until Day 3 and one animal until Day 4. All group 2 animals had hunched posture until the 5-hour reading and slight sedation was noted in 2 animals of this group at the 2-hour and 5-hour readings. The animal killed in extremis showed slight to moderate ruffled fur and hunched posture from days 11 to 13, laboured respiration from days 8 to 13 and cyanosis on day 13. The body weight of all animals was within normal ranges, except for a 1.8% drop in one animal in the last week of the study.
Effects in Organs	Not collapsed lungs and the digestive tract (stomach, duodenum, jejunum, ileum, caecum, colon and rectum) distended with gas were noted at the necropsy of the animal killed in extremis. No macroscopic findings were noted at the necropsies of the other animals.
Remarks - Results	One animal was killed in extremis on Day 13. Using Annex 2d) of the OECD test method 423, the estimated acute oral toxicity of the notified chemical would be 2000-5000 mg/kg bw.

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

TEST FACILITY RCC (2007a)

7.1 b) Acute toxicity – oral

TEST SUBSTANCE Analogue chemical 22% aqueous solution

METHOD OECD TG 401 Acute Oral Toxicity.

Species/Strain	Rat/Sprague Dawley
Vehicle	Arachis oil BP
Remarks - Method	A single dose was administered by gavage

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M, 5F	2000	None

LD50	> 2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	Observation period was 14 days.

CONCLUSION The analogue chemical at 22% is of low toxicity via the oral route.

TEST FACILITY Safepharm (1996)

7.1 c) Acute toxicity – oral

TEST SUBSTANCE	Component of notified chemical
METHOD	Not specified
Species/Strain	Rat and mouse
Remarks - Method	Full study report not reviewed.
RESULTS	
LD50	708 mg/kg bw rat 2400 mg/kg bw mouse
Remarks - Results	Detailed results not provided
CONCLUSION	The notified chemical is harmful in the rat and of low toxicity in the mouse via the oral route.
TEST FACILITY	European Chemicals Bureau (2000)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Component of notified chemical
Remarks - Method	Acute dermal toxicity data was provided for two animals. No details of the methods used were provided.

RESULTS

Species	*Results*
Rabbit	LD50 = 1560 mg/kg bw
Guinea pig	LD50 > 1000 mg/kg bw

Remarks - Results	No details of signs of toxicity or effects in organs were provided
CONCLUSION	The test substance is harmful via the dermal route.
TEST FACILITY	European Chemicals Bureau (2000)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	Component of notified chemical
METHOD	
Species/Strain	Rat
Exposure Period	1 hour
Remarks - Method	The summary of one acute inhalation toxicity study was provided. Other than the exposure period no details of the method used was provided.
RESULTS	
LC50	> 0.72 mg/L/hour
Remarks - Results	No details of signs of toxicity or effects in organs were provided
CONCLUSION	Due to the low dose and exposure time it is not possible to classify the toxicity of the test substance via inhalation.
TEST FACILITY	European Chemicals Bureau (2000)

7.4 a). Irritation – skin

TEST SUBSTANCE	Analogue 22% aqueous solution
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/Himalayan
Number of Animals	3 males
Vehicle	None
Observation Period	Up to 4 days
Type of Dressing	Not stated

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0.66	0.66	1	3 days	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	1 h scores not recorded.
CONCLUSION	The analogue chemical is slightly irritating to the skin at 22%.
TEST FACILITY	Laboratory of Pharmacology and Toxicology (1995a)

7.4. b) Irritation – skin

TEST SUBSTANCE	Component of notified chemical
METHOD	Results of two rabbit studies and two human studies were very briefly reported.
CONCLUSION	The component chemical was reported to be severely irritating or irritating to the skin.
TEST FACILITY	European Chemicals Bureau (2000)

7.5.a) Irritation – eye

TEST SUBSTANCE	Analogue, 22% aqueous solution
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 female
Observation Period	Up to 11 days

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1	1	1	1	< 11 days	0
Conjunctiva: chemosis	0	1	1	1	< 10 days	0
Conjunctiva: discharge	3	3	3	3	< 11 days	0
Corneal opacity	0	1	1	1	< 11 days	0
Iridial inflammation	0	1	1	1	10 days	0

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

Remarks - Results

CONCLUSION	The analogue chemical is irritating to the eye at 22% but would not be classified based on these results
TEST FACILITY	Laboratory of Pharmacology and Toxicology (1995b)

7.5. b) Irritation – eye

TEST SUBSTANCE	Component of notified chemical
METHOD	Not specified
Species/Strain	Rabbit
Remarks - Method	Results of four rabbit studies were very briefly reported. Test conditions varied.
CONCLUSION	The component chemical was reported to be severely irritating or irritating to the eye.
TEST FACILITY	European Chemicals Bureau (2000)

7.6.1 a) Skin sensitisation – Guinea pig maximisation test

TEST SUBSTANCE	Analogue, 22% aqueous solution
METHOD	OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test.
Species/Strain	Guinea pig/Dunkin Hartley
MAIN STUDY	
Number of Animals	Test Group: 10 M Control Group: 5 M
INDUCTION PHASE	Induction Concentration: intradermal: 0.01% topical: undiluted
Signs of Irritation	No comment provided.
CHALLENGE PHASE	
1st challenge	intradermal: none topical: 0.01%
2nd challenge	Not performed
Remarks - Method	No report on the preliminary study provided. Vehicle for dermal challenge was 0.8% hydroxypropylmethyl cellulose.

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	0.01%	0/10	0/10	-	-
Control Group	-	0/5	0/5	-	-

Remarks - Results

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Laboratory of Pharmacology and Toxicology (1995c)

7.6.1 b) Skin sensitisation – Guinea pig maximisation test

TEST SUBSTANCE	Component of notified chemical
METHOD	OECD TG 406 Skin Sensitisation – maximisation test EC Directive 96/54/EC B.6 Skin Sensitisation - maximisation test.
Species/Strain	Guinea pig
PRELIMINARY STUDY	Conducted but no details provided
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 1% in physiological saline topical: 35% in deionised water
Signs of Irritation	Both the control and test group animals had severe erythema and/or oedema after the topical induction stage. These effects were attributed to the adjuvant.
CHALLENGE PHASE	
1st challenge	topical: 25% in deionised water
2nd challenge	topical: 1% in deionised water
Remarks - Method	Full study report not reviewed.

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	25%	10/10	Not provided	N/A	N/A
	1%	N/A	N/A	3/10	3/10
Control Group	25%	5/5	Not provided	N/A	N/A
	1%	N/A	N/A	0/5	0/5

Remarks - Results	After the first challenge both control and test group animals showed severe erythema and/or oedema accompanied by eschar. All skin reactions were regarded as mainly irritative. Following the second challenge 3/10 test animals had severe erythema and/or oedema 24 and 48 hours after exposure. No adverse skin reactions were observed in control animals.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	European Chemicals Bureau (2004)

7.12T. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical (Batch 21531 FE6)
METHOD	OECD TG 429: Skin sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Acetone/Olive Oil 4:1
Remarks - Method	The study on the positive control α-hexylcinnamaldehyde was performed prior to the main study.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	888.1	-
25	12910-7	14.54
50	14293.1	16.09
100	14864.7	16.74
Positive Control		
0(vehicle control)	492.5	-
5	1005.4	2.04
10	3108.1	6.31
25	6130.7	12.45

Remarks - Results: The lymph nodes (8) of all animals in a group were pooled before measurement, therefore the median result could not be reported. No EC3 value was assigned, as stimulation indices at all tested concentrations were > 3. The positive control demonstrated the sensitivity of the assay.

CONCLUSION: There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical..

TEST FACILITY: RCC (2007b)

7.6.2 Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Component of notified chemical

METHOD

Species/Strain: Mouse
Vehicle: N,N-Dimethylformamide
Remarks - Method: Full study report not reviewed.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	Not provided	Not provided
1	Not provided	11.2
2.5	Not provided	22.
5	Not provided	31.5
Positive Control		
25% hexyl cinnamic aldehyde in acetone:olive oil (4:1)	Not provided	14.6

Remarks - Results: Moderate erythema was observed in all high dose (5%) group animals on day 2 and in a few animals in all test groups on day 3. Statistically significant difference of the mean ear thickness in the mid hand high dose test animals compared to the negative control group confirmed these effects.

As the positive result (SI> 3) in the low dose test animals was not accompanied by increased ear thickness and excessive local irritation, false positive results can be excluded.

CONCLUSION: There was evidence of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.

TEST FACILITY European Chemicals Bureau (2004)

7.7.1 28 day Repeat dose oral toxicity (rat)

TEST SUBSTANCE Component of notified chemical

METHOD

Species/Strain	Rat
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: None
Vehicle	Feed
Remarks - Method	Only a summary of the study was reviewed. Other than information provided above, no details of the method used was provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration ppm*		*Mortality*
		Nominal	*Actual*	
I (control)	Not provided	0	0	Not recorded
II (low dose)	Not provided	300	Not provided	Not recorded
III (mid dose)	Not provided	1000	Not provided	Not recorded
IV (high dose)	Not provided	3250	Not provided	1

Mortality and Time to Death
One rat died in the highest dose groups on day 8; cause of death was not determined.

Clinical Observations
Slight reduced weight gain (unspecified) in high dose animals was recorded.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No details provided.

Effects in Organs
There was a statistically significant difference (unspecified) in relative adrenal weight in all dose groups compared to the control group. There was no difference in relative liver, kidney and testes weight.

Remarks – Results
Other than the information above, no detailed results were provided. Test data has not been reviewed.

CONCLUSION
Due to insufficient information, it is not possible to establish a No Observed Adverse Effect Level (NOAEL) in this study.

TEST FACILITY European Chemicals Bureau (2000)

7.7.2 53 day Repeat dose oral toxicity (rat)

TEST SUBSTANCE Component of notified chemical

METHOD

Species/Strain	Rat

Route of Administration	subcutaneous injection
Exposure Information	Total exposure days: up to 53 days; Dose regimen: 7 days per week; Post-exposure observation period: None
Vehicle	Sesame Oil
Remarks - Method	Each rat was started at the age of 7 days. The dose was increased from 0.1 to 2.0 mg/day/rat. Only a summary of the study was reviewed. Other than information provided above, no details of the method used was provided

RESULTS

Remarks – Results

The average weight, length and rate of development of the injected rats showed no significant variations compared to the control.

Other than the information above, no detailed results were provided. Test data has not been reviewed.

CONCLUSION

Due to insufficient information it is not possible to establish a No Observed Adverse Effect Level (NOAEL) in this study.

TEST FACILITY European Chemicals Bureau (2000)

7.8.a) Genotoxicity – bacteria

TEST SUBSTANCE Analogue 22% solution

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100,
Metabolic Activation System	
Concentration Range in Main Test	a) With metabolic activation: 312 - 5000 µg/plate b) Without metabolic activation: 312 - 5000 µg/plate
Remarks - Method	Details of method not provided..

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	-	-	> 5000
Present				
Test 1	-	-	-	> 5000

Remarks - Results It was not stated whether cytotoxicity or precipitation occurred.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Safepharm (1994)

7.8.b) Genotoxicity – bacteria

TEST SUBSTANCE Component of notified chemical

METHOD & RESULTS

Remarks - Method: The following information was provided for five bacterial mutation assays, four of which were described as Ames tests. Only a summary of these studies was reviewed. Other than information provided below, no details of the method used was provided

Method	*Species/Strain*	*Metabolic activation*	*Result*
not provided	not provided	with and without	negative
not provided	*Salmonella typhimurium* TA 100	no data	negative
not provided, described as a bacterial gene mutation assay	*Escherichia coli* Sd-4-73	no data	negative
Not provided	*Salmonella typhimurium* TA1535, TA1537, TA1538, TA98, TA100	with and without	negative
preincubation method	*Salmonella typhimurium* TA97, TA98, TA100, TA102, TA104	with and without	negative

Remarks - Results: Other than the information above, no detailed results were provided. Test data has not been reviewed.

CONCLUSION: The test substance was not mutagenic to bacteria under the conditions of these tests.

TEST FACILITY: European Chemicals Bureau (2000)

7.9.1 Genotoxicity – in vitro DNA synthesis inhibition test

TEST SUBSTANCE: Component of notified chemical

METHOD: Not specified in detail.

Cell Type/Cell Line: Human fibroblasts
Remarks - Method: Tested with and without metabolic activation.

CONCLUSION: The notified polymer inhibited DNA synthesis human fibroblasts treated in vitro under the conditions of the test.

TEST FACILITY: European Chemicals Bureau (2000)

7.9.2 Genotoxicity – in vitro Vicia root tip micronucleus assay

TEST SUBSTANCE: Component of notified chemical

METHOD & RESULTS

Remarks - Method: The following information was provided for the following in vitro genotoxicity study

Method	*System of testing*	*Metabolic activation*	*Result*
vicia root tip micronucleus assay for clastogenicity	primary root tips of Vicia faba	no data	negative

Remarks - Results	Other than the information above, no detailed results were provided. Test data has not been reviewed.
CONCLUSION	The test substance was not clastogenic to vicia root tip cells treated in vitro under the conditions of the test.
TEST FACILITY	European Chemicals Bureau (2000)

7.10. Genotoxicity – in vivo

No data submitted.

7.11 Chronic toxicity/carcinogenicity 2 year study (rat)

TEST SUBSTANCE	Component of notified chemical
METHOD	
Species/Strain	Rat
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 2 years; Dose regimen: 7 days per week;
Vehicle	Feed
Remarks - Method	Only a summary of the study was reviewed. Other than information provided above, no details of the method used was provided

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration*		*Mortality (at 2 years)*
		Nominal (%)	*Actual (approx) mg/kg bw*	
I (control)	12 male	0	0	6/12
II (low dose)	12 male	0.5	250	10/12
III (mid dose)	12 male	1.0	500	10/12
IV (high dose)	12 male	1.5	750	12/12

Mortality and Time to Death

Most of the deaths occurred during the second year of the experiment. At eighteen months the mortality rate in the mid and high dose animals had increased (unspecified) but not significantly. At two years the test chemical had increased the mortality rate significantly.

Clinical Observations

Bodyweight gain in the first 52 weeks of the study were significantly reduced in the mid ($P < 0.05$) and high ($P < 0.001$) dose group animals by approximately 20 and 40% respectively, compared to controls. No significant differences in feed consumption were noted.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No details provided.

Effects in Organs – General

Enlarged and irregularly shaped epithelial cells in small to moderate numbers of renal tubules (generally in the proximal convoluted tubules), were seen in Group III (3 of 12) and Group IV (4 of 12) rats.

Increased (unspecified) atrophy of the liver and testis and less focal calcification in large arteries was reported in Group IV rats.

Effects in Organs – Tumours

No tumorigenesis was reported

Remarks – Results
Other than the information above, no detailed results were provided. Test data has not been reviewed.

The dose administered to Group II, III and IV animals was approximately 5%, 70% and 94% respectively of the reported oral LD50 value for the test chemical of 708 mg/kg bw (European Chemicals Bureau, 2000)

CONCLUSION
There was no evidence of carginogenicity. Due to excess mortality observed in all dose groups it is not possible to establish a No Observed Adverse Effect Level (NOAEL) in this study. The NOAEL in male rats would be < 250mg/kg bw.

TEST FACILITY European Chemicals Bureau (2000), Fitzhugh (date not disclosed)

8. ENVIRONMENT

Data for a number of purported analogues were provided for environmental fate and ecotoxicological investigations, however, most were not accepted due to significant differences in structure.

8.1. Environmental fate

Data for an acceptable analogue has been provided and presented in this section.

8.1.1. Ready biodegradability

TEST SUBSTANCE Acceptable analogue

METHOD OECD TG 301 E Ready Biodegradability: Modified OECD Screening Test, modified in accordance with Appendix 1 of the German "Tensidverirdnung".
Inoculum: Secondary effluent form waste water treatment plant at Wiesbaden.
Exposure Period: 19 days
Auxiliary Solvent: None
Analytical Monitoring: Determination of bismuth-active substances (BiAS) according to DIN 38409, part 23.
Remarks - Method: Initial concentration of test substance – 0.51 g/L
Initial BiAS level – 270 mg/L

RESULTS

Day	*BiAS level in test solution*	*BiAS level in control*	*%BiAS removal*
0	270	<1	0
5	136	<1	50
14	118	<1	56
19	12	<1	96

The BiAS level measures the amount of surfactants containing polyethylene oxide (Holt 1992). In this method the parent compound is broken down, and not necessarily reduced to basic elemental units.

CONCLUSION The report concludes that since on day 19 the BiAS removal was 96%, exceeded the 80% required in the "Tensidverordnung", the test substance may be classified as readily biodegradable.

TEST FACILITY Institut Fresenius (1992)

8.1.2. Bioaccumulation

Not determined. However, it is unlikely to bioaccumulate due to its high water solubility and biodegradability (Connell 1989).

8.2. Ecotoxicological investigations

Data for an acceptable analogue have been provided and presented in this section.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Accepted analogue
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static conditions. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - semi-static conditions.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	The preliminary range finding test indicated that the definitive study should use the following concentrations: 10, 18, 32, 56 and 100 mg/L. Measured amounts of the stock solution, 3 g/L, which was prepared by the ultrasonic disruption of a measured amount of the test material in 1 L of dechlorinated tap water, were dispersed in water to give the desired test concentrations. The concentrations and homogeneity of the test solutions were not determined. The test vessels were covered, maintained at 14°C, had a photoperiod of 16 hours of light and 8 hours of darkness and the vessels were aerated throughout the study period. The test solution was renewed daily. Observations were made at 3, 6, 42,48, 72 and 96 hours. Environmental parameters were maintained at acceptable levels.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*					
Nominal	*Actual*		*3 h*	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	10	0	0	0	0	0	0
10	-	10	0	0	0	0	0	0
18	-	10	0	0	10	10	10	10
32	-	10	0	6	10	10	10	10
56	-	10	10	10	10	10	10	10
100	-	10	10	10	10	10	10	10

LC50	13 mg/L at 96 hours.
NOEC	10 mg/L at 96 hours.
Remarks – Results	The LC50 was determined by Thompson's moving average method (1947). Loss of equilibrium and moribund fish were observed at the test concentration 32 mg/L at 3 and 6 hours respectively with all fish dead at 24 hours.
CONCLUSION	Under the study conditions the test substance is harmful to aquatic life (United Nations, 2003).
TEST FACILITY	Safepharm (1996b)

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Accepted analogue
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static conditions.
Species	Ide (*Leuciscus idus melantus*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	None
Remarks – Method	The preliminary range finding test indicated that the definitive study should use the following concentrations: 1, 2, 3 and 4 mg/L. Stock solution (1 g/L) was prepared by dilution with drinking water. The test vessels were maintained at 20°C. The environmental parameters pH (7.77–8.31), dissolved oxygen (7.39–8.54) and water temperature (19-20°C) were maintained at acceptable levels. No observations on the test solution (eg clear or no undissolved material) were given.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality %*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
1	-	10	0	0	0	0
2	-	10	0	10	20	40
3	-	10	0	0	20	30
4	-	10	60	100	-	-

LC50	3 mg/L at 96 hours.
NOEC	1 mg/L at 96 hours.
Remarks – Results	The LC50 was determined by probit analysis. No sublethal effects indicated.
CONCLUSION	Under the study conditions the test substance is toxic to aquatic life (United Nations, 2003).
TEST FACILITY	Institut Fresenius (1991a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Accepted analogue
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – static conditions.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	None
Remarks - Method	The preliminary range finding test indicated that the definitive study should use the following concentrations: 1, 2, 4, 8, 16, 32, 64 and 128 mg/L. A stock solution (1 g/L) was prepared by dilution with reconstituted water according to DIN 38412, part 30. Each test concentration was done in quadruplicate. Again there were no observations on the test solution (eg clear or no undissolved material) given. The environmental parameters of pH (6.97-7.66), temperature 918.5-20.6) and dissolved oxygen (7.42-8.25) were measured at the beginning

and end of the study, and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of D. magna*	*Percentage Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
1	-	20	0	0
2	-	20	0	0
4	-	20	0	0
8	-	20	10	65
16	-	20	80	100
32	-	20	100	100
64	-	20	100	100
128	-	20	100	100

LC50	8 mg/L at 48 hours
NOEC	4 mg/L at 48 hours
Remarks – Results	The 48 hour LC50 was determined by the calculation of the geometric mean.

CONCLUSION Under the conditions of the study the test substance is toxic to aquatic life (United Nations, 2003).

TEST FACILITY Institut Fresenius (1991b)

8.2.3. Algal growth inhibition test

Algal studies not undertaken and no acceptable analogue data were provided.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Exposure will only occur due to use of the notified polymer as it will not be manufactured in Australia. It will be reformulated into paints that will be used across Australia by professional trades people in the automotive industries, ie will not be available for general consumer use. The proposed use pattern and waste management indicate a low potential for environmental release of the notified polymer. Solid wastes (containing up to 1095 kg annually of the notified polymer) resulting from the paint manufacture and paint use will be collected and sent to landfill or incineration. The majority of the waste notified polymer will be contained within an inert paint matrix before reaching landfill. In landfill the notified polymer is likely to adsorb to soil organics material and therefore will not be mobile. Since it is likely to be readily biodegradable it will breakdown relatively quickly.

Liquid effluents (containing up to up to 180 kg) produced from paint formulation and use will be sent to liquid waste plants, including solvent recovery, where it is likely that the notified polymer will end up in any resultant sludge which will be disposed of to landfill. A small amount of the notified polymer may be present in final effluent discharged to sewer, which is expected to undergo further treatment prior to eventual discharge to the aquatic environment.

The majority of the notified polymer will be contained within the paint matrix formed by the interaction of the other paint components, thus forming a very high molecular weight and stable paint film. As the coating degrades over time, any fragments, chips and flakes of the lacquer will be of little concern as they are expected to be inert. The surfaces coated with the polymer are likely to be either recycled for metal reclamation or be placed into landfill at the end of their useful life (5-20 years). When recycled the polymer would be destroyed in furnaces and

converted to water vapour and oxides of carbon and nitrogen.

The polymer is not expected to bioaccumulate, due to its expected biodegradability and expected low environmental release.

9.1.2. Environment – effects assessment

Only ecotoxicological data on an accepted analogue were provided in the notification dossier. This analogue data indicates that the notified polymer may by toxic to aquatic invertebrates and fish. However, under normal usage, the polymer is not expected to enter the aquatic compartment and pose a threat to aquatic organisms.

Further modelling using ECOSAR (v 0.99), indicates that the ecotoxicity of the notified polymer lies in the range of harmful to highly toxic to aquatic life (United Nations, 2003). The results of the modelling of the shortest and longest carbon chain versions of the notified polymer, using the modelled log P_{ow} values (see section 6) are:

ECOSAR Class	Organism	Shortest chain	Longest chain
Neutral Organic SAR	Fish	14 d LC50 2.192	14 d LC50 0.335
Acrylates	Fish	96 h LC50 1.498	-
	Daphnid	48 h LC50 1.339	-
	GreenAlgae	96 h LC50 0.157	-
Acrylates-acid	Fish	-	96 h LC50 10.882
	Daphnid	-	48 h LC50 4.605
	GreenAlgae	-	96 h LC50 0.566

Based on environmental grounds the notified polymer would have GHS classification of Acute category 2 (based on analogue data).

9.1.3. Environment – risk characterisation

The polymer is unlikely to present a risk to the environment when it is incorporated into the paint and applied to motor vehicles. The automobiles will be recycled or consigned to landfill at the end of their useful life and the paint containing the notified substance will share the fate of the motor vehicle.

The main environmental exposure arises from landfill disposal (up to 1095 kg of notified polymer). The notified polymer will be contained by any available paint component that will cross-link to form an inert paint matrix and bind to soil and remain immobile in the environment. Under normal usage there will be no release into the aquatic environment.

The environmental assessment was undertaken on the premise that the notified polymer would solely be used by automotive professionals with little release to the aquatic compartment. If the notified polymer is to be used in ways where there is a more significant release to water, for example in paint that will be used for architectural or DIY purposes, then the risk will have to be reassessed and may require the provision of full environmental data (including fate, bioaccumulation and ecotoxicity) on the notified polymer considering the expected toxicity.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, worker exposure to the notified polymer or to products containing it, is expected to be very low, and would only occur if accidental spillage of the materials occurred.

During processing of the notified polymer into paint formulations there is potential for dermal/ocular exposure of workers. However standard engineering controls for formulation, eg enclosure and local exhaust ventilation, would limit this to incidental exposure. Exposure at this stage could occur to the notified polymer as imported, or to paint formulations containing < 5% of the notified polymer.

Potential for exposure occurs at the end-use stage, when paint formulations containing < 5% of the notified polymer are prepared for application and sprayed onto automotive components.

Dermal/ocular exposure is likely during cleaning of the equipment and during the small-scale preparation for spraying, which may involve stirring the paint, and transfer to the spray gun. During the spraying process itself, inhalation and possibly ingestion exposure is possible, because aerosols containing the notified polymer would be formed during atomisation of the paint. The extent of dermal/ocular and inhalation exposure will depend on the controls in place, including isolation and engineering measures. It is estimated that > 1000 workers will carry out spray painting using formulations containing the notified polymer. Some of this will occur at large facilities manufacturing new automotive components. Some will occur as refinishing at crash repairer shops, that may vary in the type and effectiveness of spray booths or other equipment. While much of the spray painting may be carried out with a high level of controls, the possibility of less effective control measures and therefore higher worker exposure cannot be ruled out.

It should be noted that worker exposure to the notified polymer in paint would leave obvious staining, and would therefore be avoided by workers wherever possible.

Worker exposure to the notified polymer in dried paints is likely to be minimal, as the polymer will be encapsulated as part of the cured paint film.

9.2.2. Public health – exposure assessment

Once the paint containing the notified polymer is applied to the substrate in the automotive industry, the notified polymer is bound in an insoluble polymeric matrix and is not bioavailable. Therefore no significant dermal or inhalation exposure to the public is expected.

9.2.3. Human health – effects assessment

No pharmacokinetic or toxicological information was supplied for the notified polymer. The polymer is of relatively low molecular weight and skin absorption is possible.

Studies on the notified polymer were provided for acute oral toxicity and skin sensitisation (LLNA). The likely profile of human health effects was also estimated on the basis of two analogue chemicals. One chemical is a structural component of the notified polymer, and is expected to be a metabolite in biological systems. The second chemical is an analogue containing a side-chain of similar length and some of the same functional groups as the notified polymer. Full studies were not available for the toxicological tests on the analogues.

Based on the study on the notified chemical itself, the polymer is of low acute toxicity by the oral route. There was substantial variation in the acute oral toxicity results carried out on the analogue and component chemicals, however the polymer itself is considered the most relevant test material. . Acute inhalation toxicity was tested only at a low concentration for one hour only, and the likely toxicity for this route cannot be determined.

Short summaries of varied animal and human testing of the two analogues indicate that the notified polymer is likely to be irritating or severely irritating to skin and eyes. The analogue chemical was slightly irritating to skin as a 22% solution in a test to OECD protocols. In one of two rabbit studies the component chemical was stated to be classified as irritating. In two human studies it was described as a severe skin irritant at 100% and irritating to vulvar skin at 20%. In five rabbit studies that used varying protocols, the component chemical was described as irritating or highly irritating to eyes. These results are consistent with the classification status of the component chemical and the acidic functionality of the notified polymer. The notified polymer is classified as irritating to skin and eyes on the basis of the analogue data.

The notified polymer was a sensitiser in a mouse LLNA study. The component chemical was a skin sensitiser in both a guinea pig study and a mouse LLNA. Although a guinea pig test on the analogue was negative, it is considered a poor measure of this endpoint because it was carried out on a dilution of the chemical (22%), and the challenge concentration used in the study was extremely low (0.01%). Other factors likely to affect the sensitisation potential of the notified polymer are that a derivative of the component chemical is reported to be a strong sensitiser and the notified polymer itself shows a structural alert for sensitisation. Based on the study on the

notified polymer and analogue data the notified polymer is classified as a skin sensitiser. The notified polymer contains a significant level of a residual monomer that is a skin sensitiser.

Insufficient information was available to set a NOAEL from two repeat dose studies on the component chemical (an oral 28 day feeding study and application by subcutaneous injection for 53 days). Low mortality was noted, with the only death occurring in the highest test group of 750 mg/kg bw day in the oral study. In this study the high dose group also showed slightly reduced weight gain, and all groups showed a statistically significant variation in relative adrenal weight. No adverse effects were noted in rats dosed subcutaneously for up to 53 days with up to 2000 mg/kg bw/day.

Excess mortality was noted in all dose groups (250, 500 and 750 mg/kg bw/day) in a two-year carcinogenicity study in male rats on the component chemical. Adverse effects on the kidney and reduced weight gain were noted in the two higher dose groups, and increased atrophy of the liver and testis and less focal calcification in large arteries occurred at the highest dose.

Bacterial mutagenicity tests on both analogues were all negative. The component chemical was negative in an in vitro Vicio root tip micronucleus test. It caused reduced DNA synthesis in an in vitro study in human lymphocytes, an effect considered by the study authors to indicate DNA damage.

No evidence of carcinogenicity was found in a two year feeding study in male rats on the component chemical.

No information on the reproductive effects of the notified polymer or its analogues was available.

Hazard classification for health effects.
Based on the available data on analogues, the notified polymer is classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) with risk phrases:

R36/38: Irritating to eyes and skin
R43 May cause sensitisation by skin contact

9.2.4. Occupational health and safety – risk characterisation

Absorption of the notified polymer into the body may occur because of its relatively low molecular weight. Based on analogue data it is expected that it will have irritating effects on skin and eyes. Based on an LLNA study, the notified polymer is a skin sensitiser. It also contains a significant level of a residual monomer that is a skin sensitiser. The level of this monomer present is lower than the cut-off concentration for classification under the *List of Designated Hazardous Substances* (NOHSC, 1999a).

The notified polymer will be imported in 25 kg pails and 200 kg drums. It will be used as an ingredient in industrial automotive paints for spray application, in both original equipment manufacture (OEM) and refinishing applications.

Dermal/ocular exposure to the notified polymer may occur during paint manufacture and paint application by spray painting. In addition inhalation and possibly ingestion exposure may also occur during spray painting.

During formulation exposure would be reduced by engineering controls such as enclosed tanks, but some risk of skin sensitisation remains through incidental skin contact with the notified polymer or paint it at up to 5%. This risk would be further reduced by use of protective clothing including gloves.

In spray painting both engineering controls such as spray booths and full personal protective

equipment are needed to reduce the exposure and the risk of skin sensitisation to acceptable levels. The risk would be further reduced by spray painting being carried out according to the *National Guidance Material for Spray Painting* (NOHSC, 1999).

Once the final paint mix has hardened, the notified polymer is bound within the matrix and unavailable for exposure. Therefore, should exposure occur, the risk of health effects from the polymer is low.

Overall the health risk to workers is considered low, if appropriate engineering controls are in place to prevent exposure.

9.2.5. Public health – risk characterisation

Once the paint containing the notified polymer is applied to the substrate in the automotive industry, the notified polymer is bound in an insoluble polymeric matrix and is not bioavailable. Therefore no significant exposure or risk to the public is expected.

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

10.1. Hazard classification

Based on the available analogue data and studies on the notified polymer, it is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). The classification and labelling details are:

R36/38: Irritating to eyes and skin
R43 May cause sensitisation by skin contact

And

Classification of the notified chemical suing the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) was not carried out, as most available data referred to analogues of the notified chemical. The GHS system is not mandated in Australia.

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 Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a component of automotive paints.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the *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 notified chemical provided by the notifier was in accordance with the *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 test and analogue data, the notifier should apply the following health hazard classification for the notified polymer:
  - Xi: R36/38 Irritating to eyes and skin
  - Xi: R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - 20% ≥ R36/38, R43
  - 1% ≥ conc < 20%, R43

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer:
  - Closed tanks and lines for formulation and filling of paint containing the notified polymer;
  - Use of engineering controls in spray painting to minimise exposure of workers.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer;
  - Avoid splashing, spills and generation of aerosols during formulation and filling processes;
  - Spray application of paint containing the notified polymer should be in accordance with the *National Guidance Material for Spray Painting* (NOHSC, 1999b)
  - Workers using spray products containing the notified polymer should be instructed in their proper handling and use, including information about the additional risks posed by spray application.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Protective gloves
  - Safety glasses or goggles
  - Industrial clothing
  - Respiratory protection during spray painting, or if aerosols are formed
  - Full body protection during spray painting

  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.

- As potential for skin sensitisation exists, the notifier's MSDS should be provided to the authorised medical practitioner responsible for health surveillance in the workplace.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by paint manufactures and warehouse sites to minimise environmental exposure during paint formulation and storage of the notified chemical:
  - All process equipment and storage areas should be bunded.

Disposal

- The notified chemical should be disposed of to landfill for solids and to licensed waste contractors for liquids.

Emergency procedures

- Spills/release of the notified polymer should be handled by collecting spillage, where practicable , using absorbent material and place into labelled containers for disposal.
- Do not allow to enter drains, groundwater, watercourses or soil.

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
- there are any changes to the use pattern which significantly increase the potential for aquatic exposure eg use in paint for architectural or home handyman use;
- the notified polymer is used at > 5%;
- import volume of the notified polymer exceeds 3 tonnes per year; or
- adverse skin sensitisation effects during use are reported.

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.

13. BIBLIOGRAPHY

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