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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Dabco FE1034

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 9577 8888.
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Air Products Australia Pty Ltd (ABN 81 000 754 638)
2/20 Hunter Street
Parramatta NSW 2124

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Identity of chemical
Composition
Introduction and use information

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Manufacturing process
Partition coefficient
Absorption/desorption
Particle size
Oxidising properties
Acute inhalation study
Bioaccumulation study

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Netherlands (1992)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
XFE 1034

MARKETING NAME(S)
Dabco FE1034

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component of a formulated resin preparation at >50% concentration. The resin preparation will be mixed with other ingredients to form an intermediate resin product containing <1% notified chemical, for use in the manufacture of polyurethane parts.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	<10	<10	<10	<10

USE
The notified chemical is to be used in the manufacture of polyurethane parts.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated

IDENTITY OF RECIPIENTS
Air Products Australia Pty Ltd
2/20 Hunter Street
Parramatta NSW 2124

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in ethylene glycol at >50% notified chemical in 205 L steel drums. It will be transported from the wharf by road to the notifier's warehouse prior to distribution to a customer in Victoria for reformulation into an intermediate resin product. The intermediate resin product (containing <1% notified chemical) is subsequently manufactured into polyurethane parts.

5.2. Operation Description

Formulation of intermediate resin
The imported product containing the notified chemical is transferred by pump into a 7500 L mix tank. A mixture of glycol and other additives are added separately into the mixing tank, and the mixture blended and agitated to form the intermediate resin. The mixture is automatically discharged into resin product drums.

Manufacture of polyurethane parts
The raw materials including the intermediate resin are loaded by pump into a day tank, which feeds the polyurethane part machine moulds. The notifier states that the polyurethane parts are made in machines and that moulding operations are automated and enclosed.

5.3. Occupational exposure

Formulation of intermediate resin
Two workers are expected to be potentially exposed by dermal contact to the notified chemical during formulation of intermediate resin. These workers are responsible for operating the transfer pumps and mixing tank. Another worker is assigned to the drumming station, in charge of drumming the intermediate resin. A laboratory quality assurance staff could be exposed by dermal contact to the notified chemical when taking samples and preparing small batches for testing.

Dermal exposure may also occur when cleaning blending vessels and if drips and spills occur during the blending operation.

Manufacture of polyurethane parts
No detailed information on the manufacture of polyurethane parts was provided. The notifier states that

only one worker will be involved in filling day tanks with the intermediate resin and will be potentially exposed to the notified chemical. Polyurethane manufacture is carried out in enclosed and automated polyurethane part machine moulds. However, skin and eye exposure may occur during discharge of the viscous foam through a pouring tube into the mould, particularly if splashing occurs.

Transport and storage workers will handle sealed drums of products containing the notified chemical.

5.4. Release

RELEASE OF CHEMICAL AT SITE

There will be very little release from the production of the intermediate resin. Very small amounts may be lost due to spills but it is likely that the material will be contained and reused, if possible. Generally, the process equipment is not cleaned between batches. If for some reason there is a wash down, the resultant effluent will firstly go to an on-site effluent treatment plant and then discharged into the sewer. The import drums are drained, so that less than 0.5% (less than 12.5 kg) is left in the drum when it is sent to a licensed drum recycling plant. At the recycling plant, the drum will be cleaned generally by incineration, thus producing water and oxides of carbon and nitrogen. Any out of specification resin will be reprocessed.

RELEASE OF CHEMICAL FROM USE

At this stage no user sites have been identified. However, generally the process equipment at a plant producing polyurethane articles is dedicated solely to that job so there is no cleaning between batches. As with the production of the resin, if the equipment is cleaned any effluent generated will go to an effluent treatment plant and then to sewer. Ultimately, it is unlikely that a significant amount of the notified chemical would reach the sewer.

Small amounts of 'off-cuts' may be produced and these may go to landfill.

5.5. Disposal

Only a small amount of the notified chemical will be disposed of to landfill and therefore, it is unlikely that the notified chemical will reach the aquatic environment when used as specified.

5.6. Public exposure

It is expected that during transport, storage, reformulation and polyurethane manufacture, exposure of the general public to the notified chemical will be low, except in the event of an accidental spill.

Public exposure to the notified chemical will occur from dermal contact with finished polyurethane articles, such as work, casual, and athletic shoe soles and automotive skin parts including arm rests, steering wheels, and sun visors.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Light yellow viscous liquid, partly crystallysed
Melting Point/Freezing Point	Not determined
METHOD	OECD TG 102 Melting Point/Melting Range.
Remarks	The viscosity of the notified chemical increased with decreasing temperature until it solidified.
TEST FACILITY	RCC Notox (1991a)
Boiling Point	>250°C at 101.3 kPa
METHOD	OECD TG 103 Boiling Point.
TEST FACILITY	RCC Notox (1991b)
Density	1070 kg/m^3 at 25°C

METHOD OECD TG 109 Density of Liquids and Solids.
TEST FACILITY RCC Notox (1991c)

Vapour Pressure 33×10^{-3} kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
Remarks The behaviour of the test substance during the study was not ideal. A large decline in the vapour pressure, which was likely to be due to the presence of volatiles and/or absorbed air, was observed during the study. Therefore, the vapour pressure readings were extrapolated to give an estimation of the initial measurement in each series. The vapour pressure of the pure substance was estimated to be less than 6 Pa at 25°C.
TEST FACILITY RCC Notox (1991d)

Water Solubility >1000 g/L at 20°C

METHOD OECD TG 105 Water Solubility (Column elution –flask method).
Remarks In the preliminary test, 25.1 g of the test substance was added to 25 mL of double distilled water in a flask. It was stirred and maintained at 30°C for 5 mins, after which it was allowed to cool for 23 hours. Throughout the study, the resulting solution was clear without any visual phase separation. The notified chemical was readily soluble.
TEST FACILITY RCC Notox (1991e)

Hydrolysis as a Function of pH

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*t= 0 days, 50.0±0.5 °C*	*t= 5 days, 50.0±0.5 °C*
4	4.00	3.97
7	6.97	7.01
9	9.02	9.00

Remarks The test substance consists of 2 components (a cationic part and an anionic part). During the study the cationic component remained present. However, the amount of the anionic component decreased as pH decreased, presumably due to protonation and removal during the test and/or during sample pretreatment.
TEST FACILITY RCC Notox (1991f)

Partition Coefficient (n-octanol/water) log Pow at 20°C: -4.0 to 2.9

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks N-(2-hydroxypropyl)-triethylene diaminium, log P_{ow}=-4.01
2-ethylhexanoic acid, log P_{ow}=2.96
2-ethylhexanoate, sodium salt, log P_{ow}=-0.85

Calculated using an atom/fragment contribution method.
TEST FACILITY Safepharm Laboratories Limited (2000)

Adsorption/Desorption Not determined.

Remarks The test was not conducted since the substance is an ammonium salt.

Dissociation Constant pKa = 4.72

METHOD OECD TG 112 Dissociation Constants in Water. (Titration method).
Remarks The titration method using 0.01M hydrochloric acid was undertaken. The dissociation constant was determined three times, at a temperature of 20±1°C.
TEST FACILITY RCC Notox (1992)

Particle Size Not determined.

Remarks The notified chemical is a viscous liquid.

Flash Point 135°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
TEST FACILITY RCC Notox (1991g)

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
TEST FACILITY RCC Notox (1991h)

Autoignition Temperature 275°C

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY RCC Notox (1991i)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY RCC Notox (1991j)

Reactivity

Remarks The notified chemical is predicted not to have oxidising properties.

ADDITIONAL TESTS

Fat Solubility 18±6 mg/100 g in standard fat HB 307 at 37.0±0.5°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks The notified chemical is not very fat soluble.
TEST FACILITY RCC Notox (1991k)

Surface Tension 69.0 mN/m on a 1g/L solution at 20°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.

Remarks Concentration: 1 g/L
The notified chemical is not surface active.
TEST FACILITY RCC Notox (1991l)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD_{50} (males) >5000 mg/kg bw	low toxicity
Rat, acute oral LD_{50} (females) 4770 to 5660 mg/kg bw	low toxicity
Rat, acute oral LD_{50} (combined) >5000 mg/kg bw	low toxicity
Rat, acute dermal LD_{50} >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation - adjuvant test/non-adjuvant test.	evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL = 50 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chromosome Aberration Test	genotoxic
Genotoxicity – in vivo Micronucleus Test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 401 Acute Oral Toxicity and EC Directive 84/449/EEC B.1 Acute Toxicity (Oral).

Species/Strain — Rat/Wistar
Vehicle — Propylene glycol
Remarks - Method — A limit study at a dose level of 4770 mg/kg bw was conducted. Due to a calculation error, the limit dose of 5000 mg/kg bw was not obtained. Therefore, the study is repeated at a dose level of approximately 5660 mg/kg bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	4770	1/10 (female)
2	5/sex	5660	4/10 (females)

LD50 — Male: >5000 mg/kg bw
Female: 4770 to 5660 mg/kg bw
Combined: >5000 mg/kg bw

Signs of Toxicity — Lethargy, ataxia, piloerection were observed at both doses, as well as dyspnoea, absence of reaction to external stimuli and coma at 4770 mg/kg bw.

Effects in Organs — Red appearance of the lungs was reported at 4770 mg/kg bw dose. Clear liquid stomach contents, dark appearance of the glandular stomach and/or the lungs was reported at 5660 mg/kg bw dose. Changes were not accompanied by microscopic changes.

Remarks - Results — One female died at 4770 mg/kg bw dose and another 4 females died at 5660 mg/kg bw dose. Deaths occurred within 24 hours of dosing. All surviving animals had recovered from systemic toxicity by day 4 and did not show any abnormalities at termination.

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

TEST FACILITY — RCC Notox (1991p)

7.2. Acute toxicity - dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity and EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Wistar
Vehicle	Propylene glycol
Type of dressing	Semi-occlusive
Remarks - Method	A limit study at a dose level of 1810 mg/kg bw was conducted. Due to a calculation error, the limit dose of 2000 mg/kg bw was not obtained. Therefore, the study is repeated at a dose level of 2000 mg/kg bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	1800	0/10
2	5/sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No signs of irritation were observed.
Signs of Toxicity - Systemic	Lethargy was observed in animals dosed at 1810 mg/kg bw only. All animals recovered by day 3. All animals showed either body weight gain or body weight loss over the first week of treatment.
Effects in Organs	No macroscopic abnormalities were seen at necropsy.
Remarks - Results	
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	RCC Notox (1991q)

7.3. Acute toxicity - inhalation

The acute inhalation toxicity test was not conducted.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion and EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

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	0.3	0	1	24 hrs	0
Oedema	0	0	0	1	40 min	0

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

Remarks - Results: Slight erythema and oedema were observed in all animals. All animals appeared normal and individual Draize scores were zero within 48 hours. No staining and corrosive effects on treated skin were observed.

CONCLUSION: The notified chemical is slightly irritating to skin.

TEST FACILITY: RCC Notox (1991r)

7.5. Irritation - eye

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion and EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 females
Observation Period: 14 days
Remarks - Method: Fluorescein staining to examine the potential for corneal injury was repeated after day 7 and day 14 observations in one animal.

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	2.7	2	3	3	7 days	0
Conjunctiva: chemosis	1.7	1.3	1.3	3	7 days	0
Conjunctiva: discharge	0.67	0.67	0.3	1	72 hours	0
Corneal opacity	1.7	0	0.3	2	72 hours	0
Iridial inflammation	0.3	0	0.3	1	24 hours	0

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

Remarks - Results: All animals showed corneal and conjunctival irritation characterised by slight corneal opacity, diffuse redness, and swelling including nictating membrane of the conjunctiva, which were reversible within 14 days in all animals. One animal had slight iridial inflammation, which persisted for 24 hours.
Corneal epithelial damage was observed in all animals after 24 hours of fluorescein treatment, which persisted up to 7 days for one animal.

No evidence of ocular corrosion was observed.

CONCLUSION: The notified chemical is irritating to the eye.

TEST FACILITY: RCC Notox (1991s)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test and EC Directive 96/54/EC B.6 Skin Sensitization – Maximisation Test.
Species/Strain	Guinea pig/Himalayan
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 2% topical: 50%
MAIN STUDY	
Number of Animals	Test Group: 20 females Control Group: 10 females
induction phase	Induction Concentration: intradermal injection 2% in propylene glycol topical application 50% in propylene glycol
Signs of Irritation	All animals showed slight erythema after occluded topical induction exposure for 48 hours.
CHALLENGE PHASE	
1st challenge	topical application: 50% in propylene glycol topical application: 25% in propylene glycol topical application: 10% in propylene glycol
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 hours	*48 hours*
Test Group			
A	50%	16/20	12/20
B	25%	7/20	11/20
C	10%	7/20	6/20
Control Group			
A	50%	0/20	1/20
B	25%	0/20	0/20
C	10%	0/20	0/20

Remarks - Results	No signs of systemic toxicity were observed during the primary irritation experiment; however, 3/5 animals showed body weight loss. The skin reactions observed after the challenge were characterised by spotted to intense redness, swelling, crusts and scaliness.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	RCC Notox (1991t)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: none
Vehicle	Propylene glycol
Remarks - Method	Warming the test substance prior to dosing resulted in variable specific gravity. Therefore, the specific gravity of the vehicle and the exact dosages administered were adjusted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	50	0/10
III (mid dose)	5/sex	200	0/10
IV (high dose)	5/sex	1000	0/10

Mortality and Time to Death

There were no unscheduled deaths during the study. However, three animals died during blood sampling, probably as a result of overexposure to anaesthetic (ether) on the day of termination.

Clinical Observations

Excessive salivation was observed in the majority of the high dose group animals during weeks 2 to 4. One mid-dose group female showed rales on day 28.

There were no dose-related differences noted in body weight between the groups, except for a non-statistical reduction of body weight in male animals in the high dose group. Body weight gain were similar to the control groups, except for a statistically significant reduction on body weight gain in high dosed males when compared with the control group from week 3 until the end of the study. Food consumption in all treated groups were comparable to the control group.

No abnormalities were found upon ophthalmoscopical examination of animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No significant differences were observed in the haematology and clinical chemistry parameters apart from minor non-dose related changes. The sporadic changes in haematology parameters include decreased in mean haematocrit in males and females, decreased in mean platelets in males, decreased in mean erythrocyte count, haemoglobin and platelets in females, and increased mean corpuscular haemoglobin concentration in males. Similarly, the minor changes in clinical chemistry parameters include decreased in mean gamma glutamyl transferase, glucose and total protein in males and decreased in mean aspartate aminotransferase in females.

Effects in Organs

Macroscopic observations at the end of the study revealed no treatment related findings. Absolute organ weights for all treated groups were similar to controls. Statistically significant increase in liver weights was confined to mid dosed females. Mid and high dosed males showed higher kidney: body weight ratios compared with controls. Kidney: body weight ratios in low dose females were comparable to control group.

In high dosed males an increase in the incidence of eosinophilic inclusion bodies in the proximal convoluted tubules of the kidneys was observed. This finding was not increased when compared with the low and mid dose control groups.

Remarks – Results

The salivation observed in high dosed males could be due to an irritant effect or the bad taste of the test substance and considered not to be of toxicological significance. The rales observed in one female mid dose group were incidental, and not considered to be treatment related.

Body weight and body weight gain were mostly comparable with the control group. The effects on haematology and clinical chemistry parameters were either not statistically significant, lacked a dose-response, or isolated occurrences. There were no changes in ophthalmoscopy in any treated group.

The increase in liver weight found in low dose females was not considered to be of toxicological importance, in the absence of a dose response.

The statistically significant increased kidney:body weight ratios in mid and high dosed males were considered to be related to the increase in eosinophilic inclusion bodies observed microscopically in the kidneys of high dose males.

CONCLUSION

The No Observed Effect Level was established as 50 mg/kg bw/day in this study, based on the minimal changes in the kidney seen at mid and high dose males, and the microscopic changes in the kidney of high dose males.

TEST FACILITY	RCC Notox (1991u)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test and EC Directive 2000/32/EC B.14 Other Effects-Mutagenicity –Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System	Rat liver S9 fraction from animals pretreated with Aroclor 1254 in corn oil.
Concentration Range in Main Test	a) With metabolic activation: 100 - 5000 µg/plate. b) Without metabolic activation: 100 – 5000 µg/plate.
Vehicle	Saline (-S9); Dimethylsulfoxide (+S9)
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	No substantial increase in the number of revertant colonies was seen in any strain either in the presence or absence of metabolic activation. Appropriate positive and negative control values were within the background historical ranges, indicating that the test conditions were optimal and that the test system responded appropriately.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC Notox (1990)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test and EC Directive 92/69/EEC B.10 Mutagenicity (in vitro mammalian cytogenic test.
Cell Type/Cell Line	Human lymphocyte
Metabolic Activation System	Rat liver S9 fraction from animals pretreated with phenobarbitone and β-naphthoflavone
Vehicle	None
Remarks - Method	A preliminary test was performed on cell cultures using a 4-hour exposure time in the absence and presence of metabolic activation (S9) followed by a 20-hour recovery period, and a continuous exposure of 24 hours in the absence of S9. There were no scorable metaphases present on the 24-hour continuous exposure in the absence of S9 at the highest dose level (3140 µg/mL). Therefore, the maximum dose selected for metaphase analysis was 1570 µg/mL for the 24-hour continuous exposure in the absence of S9.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 98.13, 196.25, 392.5, 785*, 1570*, 3140*	4 hours	20 hours
Test 2	0*, 98.13, 196.25, 392.5, 588.75*, 785*, 1570*	24-hour continuous exposure	-
Present			
Test 1	0*, 98.13, 196.25, 392.5, 785*, 1570*, 3140*	4 hours	20 hours
Test 2	0*, 98.13, 196.25, 392.5, 785*, 1570*, 3140*		

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results

Test 1
A dose related inhibition of mitotic index was observed and 32% mitotic inhibition was achieved at a dose level of 3140 µg/mL (maximum dose tested) in the absence of S9.

No marked reduction in mitotic index was observed at any dose level in the presence of S9.

No statistically significant increases in the frequency of cells with aberrations and the numbers of polyploid cells were observed either in the absence or presence of S9.

Test 2
A dose-related inhibition of mitotic index was observed and a >50% mitotic inhibition was achieved at and above 785 µg/mL dose level in the absence of S9. Also, the test material induced a statistically significant dose-related increase in the frequency of cells with chromosome aberrations in the absence of S9. The aberrations were predominantly of the chromatid and chromosome break with only one exchange.

No marked inhibition or mitotic index was observed in the presence of S9.

No statistically significant increases in the numbers of polyploid cells were observed either in the absence or presence of S9.

CONCLUSION — The notified chemical was clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY — Safepharm Laboratories Limited (2002)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 474 Mammalian Erythrocyte Micronucleus Test and EC Directive 2000/32/EC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.

Species/Strain — Mouse/Swiss CD-1 SPF

Route of Administration — Oral – intubation.

Vehicle — Water

Remarks - Method — Preliminary tests were conducted in 4 doses (3/sex/group) ranging from 2000 to 5000 mg/kg. At 5000 mg/kg dose, 5 animals were found dead on day 1. Animals dosed at 4000 mg/kg initially showed symptoms of lethargy, ataxia, piloerection, bradypnoea and/or absence of reaction, and 2 animals died on day 2. All animals dosed at 3000 and 2000 mg/kg initially showed lethargy and ataxia, and also piloerection at 3000 mg/kg. The animals dosed at 3000 and 2000 mg/kg recovered within 20 hours and 3 hours, respectively. The dose selected for the micronucleus test was 3000 mg/kg based on the result of the preliminary study. Extra test animals were dosed in the micronucleus test to allow sufficient animals per treatment group to be analysed.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I – Vehicle control	5/sex	0	24
II	5/sex	0	48
III	5/sex	0	72
IV	5/se	3000	24
V	5/sex	3000	48
VI	5/sex	3000	72
VII – Positive control CP	5/sex	50	48

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity — >3000 mg/kg

Genotoxic Effects — During the micronucleus test, 3 male and 10 female dosed animals died. Therefore, the number of animals differed per treatment group. There were at least 4 animals/treatment group; therefore the number of animals was sufficient for the analysis of the incidence of micronuclei.

The mean body weights of all treated animals were comparable with the control groups.

Remarks - Results — No increase in the frequency of micronuclei was observed in all dosed groups at any sampling time.

Appropriate positive controls induced significant increase in micronuclei, indicating that the test system responded appropriately.

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

TEST FACILITY — RCC Notox (1991v)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: XFE-1034

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. (Modified Sturm Test)

Inoculum	Activated sludge from a municipal sewage treatment plant.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The amount of CO_2 generated was determined by titration of the remaining barium hydroxide in the third absorber bottle with 0.05 N standardised hydrochloric acid.
Remarks - Method	Two test concentrations (10 mg/L (low) and 20 mg/L (high)) along with a positive control (20 mg/L sodium acetate and inoculum) and a blank control (containing inoculum but no test material or positive control substance) were used. Four bottles, one for each treatment, were made up to 3 L with Milli-Q water and then each was attached to 3 CO_2-absorber bottles containing 80 mL 0.025 N $Ba(OH)_2$. Titrations were done on every other day for the first 10 days and then every 5 days.

RESULTS

Test substance 10 mg/L		*Test substance 20 mg/L*		*Sodium acetate*	
Day	*% degradation*	*Day*	*% degradation*	*Day*	*% degradation*
2	0.0	2	0.1	2	0.0
5	2.4	5	7.9	5	16.3
7	6.5	7	15.6	7	31.4
9	11.0	9	21.0	9	38.2
12	17.0	12	26.0	12	45.0
16	23.0	16	29.6	16	54.8
21	29.1	21	33.5	21	70.7
28	32.8	28	34.5	28	75.0
28	32.8	28	34.8	28	75.2
28	32.8	28	37.1	28	75.2

Remarks - Results: The control substance (sodium acetate) degraded by more than 60% within 17 days and reached 75% degradation in the 28 days, thus indicating the study was valid.

CONCLUSION: Under the specified conditions of the modified Sturm test the test material is not readily biodegradable since less than 60% degraded in the 10 days after reaching 10% degradation.. However, it can be seen that a portion of the material did degrade in the 28 days.

TEST FACILITY: RCC Notox (1991w)

8.1.2. Bioaccumulation

CONCLUSION: This study was not conducted. Due to its low partition coefficient (log P_{ow}), it is unlikely that the notified chemical will bioaccumulate.

8.2. Environmental effects

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	XFE-1034
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – static.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	2.4 mmol/L.
Analytical Monitoring	HPLC
Remarks – Method	Five test concentrations (100, 180, 320, 560 and 1000 mg/L, along with blank controls were studied. Ten (10) fish were added to each treatment. A 16 hour photoperiod was maintained throughout the study. Observations on mortality and sublethal effects were taken at 4, 24, 48, 72 and 96 hours. Dissolved oxygen, pH and temperature were monitored daily.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	1	10	0	0	0	0	0
100	100	10	0	0	0	0	0
180	180	10	0	0	0	1	0
320	320	10	0	0	0	0	0
560	513	10	0	0	0	0	1
1000	935	10	0	0	1	0	0

LC50	>1000 mg/L at 96 hours.
NOEC (or LOEC)	<180 mg/L at 96 hours.
Remarks – Results	Dead fish were observed in 180, 560 and 1000 mg/L concentrations, with sublethal effects being observed in the concentrations of 180 mg/L and above. The temperature ranged from 14 to 16.5ºC, pH varied from 8.3 to 8.6, while the dissolved oxygen was greater than 5 mg/L.
CONCLUSION	The material appears to have an effect on the rainbow trout (eg discolouration and abnormal swimming) but since the LC_{50} is greater than 1000 mg/L it is practically non-toxic to fish.
TEST FACILITY	RCC Notox (1991x)

8.2.2. Acute/chronic toxicity to aquatic invertebrates.

TEST SUBSTANCE	XFE-1034
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	210 mg $CaCO_3$/L.
Analytical Monitoring	None
Remarks - Method	Five test concentrations (100, 180, 320, 560 and 1000 mg/L, along with blank controls were studied. Ten (10) daphnia were added to each treatment. A 16-hour photoperiod was maintained throughout the study. Observations on mobility and mortality were taken at 24 and 48 hours. Dissolved oxygen, pH and temperature were also monitored. The study

was conducted in duplicate.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
0		20	0	0
56		20	0	0
100		20	0	0
180		20	0	1
320		20	0	1
560		20	1	5
1000		20	4	15

LC50	736 mg/L at 48 hours (95% C.I. 612-954 mg/L)
NOEC (or LOEC)	320 mg/L at 48 hours
Remarks - Results	After 24 hours, there was 5% and 20% immobilisation at 560 and 1000 mg/L respectively and none at 320 mg/L and lower. However, at 48 hours immobilisation occurred at 180 mg/L and higher, with immobilisation increasing to 25% and 75% in 560 and 1000 mg/L respectively. No immobilisation occurred in the control. The temperature ranged from 18.5 to 21°C, pH varied from 8.3 to 8.4, while the dissolved oxygen was greater than 5 mg/L.
CONCLUSION	The material is very slightly toxic to Daphnia.
TEST FACILITY	RCC Notox (1991y)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	XFE1034
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Green alga Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range Nominal	6.25, 12.5, 25, 50 and 100 mg/L
Concentration Range Actual	95 – 107% of nominal concentrations
Remarks - Method	Algae (nominal cell density 10^4 cells per mL) were exposed to the test substance at the nominal concentrations of 6.25, 12.5, 25, 50 and 100 mg/L for 72 h at 24˚C under constant illumination and shaking. Analysis of the test substance concentrations at 72 hours indicated a 95 to 107% variation in actual concentration.

RESULTS

Biomass	*Growth*	*LOEC*
E_bC_{50}	*E_rC_{50}*	*mg/L at 72 h*
Mg/L at 72 h	*mg/L at 72 h*	
28 (95% C.I. 24-33 mg/L)	53	6.25

Remarks – Results	The nominal concentrations were used to determine the results. No abnormalities were observed during the study. After 72 hours, at the concentrations of 6.25, 12.5 and 25 mg/L the cultures were observed to be bright green while at 50 and 100 mg/L they were pale green.

CONCLUSION	The results indicate that the notified substance is slightly toxic to algae.
TEST FACILITY	Safepharm Laboratories Limited (2001a)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	XFE 1034
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Mixed population Activated Sewage Sludge
Exposure Period	3 hours
Concentration Range Nominal	1000 mg/L
Remarks – Method	For the preparation of the stock solution, the test material was dispersed directly into water via ultrasonic disruption. 250 mL of the stock solution was then mixed with synthetic sewage, activated sludge and water to give the required concentration (1000 mg/L). 3,5-dichlorophenol was used as a reference material. It was treated in a similar way to give concentrations of 3.2 and 32 mg/L. At each 30 minutes the BOD of an aliquot of solution from the test vessels was determined. The temperature through out the study was 21°C.
RESULTS	
30 minute EC_{50}	>1000 mg/L
30 minute NOEC	>1000 mg/L
Remarks – Results	The 30 minute EC_{50} for 3,5-dichlorophenol was determined to be 10 and 19 mg/L, which is acceptable (ie between 5-30 mg/L). No undissolved material was observed in the test vessels during the study.
CONCLUSION	The results indicate that the notified substance does not inhibit microbial activity.
TEST FACILITY	Safepharm Laboratories Limited (2001b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The main environmental hazard would arise from release of the notified chemical during storage or transport. The use of bunded containment minimises the risk of release at storage sites. Less than 1% (<100 kg notified chemical) may be released to the environment annually via spills and production waste. This release is expected to be distributed across several sites, thus minimising the degree of risk to the environment at any given time.

The notified chemical will ultimately suffer the same fate as the finished article at the end of its useful life, ie be disposed of to landfill. Since it will be incorporated into the inert matrix of the polyurethane it will pose minimum risk to the environment. The notified chemical is not readily biodegradable, has a low partition coefficient and a high water solubility, all indicating that any material released would eventually partition to water. However, given its cationic nature it is expected to rapidly associate with soil and sediments.

9.1.2. Environment – effects assessment

The notified chemical is practically non-toxic to fish and daphnia, and slightly toxic to algae. In addition, bioaccumulation is not expected due its high water solubility, which suggests that it is

unlikely to cross biological membranes (Connell, 1990).

The PNEC can be calculated by dividing the toxicity value for the most sensitive organism (in this case algae, EC_{50} = 28 mg/L) by 100, thus giving a PNEC of 0.28 mg/L.

9.1.3. Environment – risk characterisation

The majority of the notified chemical will be incorporated into the matrix of the intermediate resin. Once this has been used to form the solidified polyurethane article, the notified chemical will pose little risk to the environment. It is non-toxic to fish and only slightly toxic to daphnia and algae and there will be limited aquatic exposure with less than 1% likely to reach waterways, which is likely to be lower than the PNEC.

The above considerations indicate minimal risk to the environment when the notified chemical is used as specified.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Formulation of intermediate resin

Since the manufacture of the intermediate resin is largely enclosed and automated, limited dermal exposure to the notified chemical may occur when connecting and disconnecting pump lines, drumming off resin product and during maintenance of equipment. Drips and spills during blending will be collected into drums before being disposed of by licensed disposal contractors. Mandatory personal protective equipment (PPE) includes overalls, impermeable gloves, safety glasses and hardhat. Extraction systems are located at discharge points and local exhaust ventilation is in place during the manufacturing process.

Exposure to laboratory staff is limited because of the small amount of notified chemical handled, the use of laboratory fume hood extraction and protective equipment, such as laboratory coat, gloves and eye protection.

Manufacture of polyurethane parts

The manufacture of polyurethane parts is fully automated. Exposure to the notified chemical is limited to dermal contact when connecting and disconnecting the transfer lines to the foam machine. After curing, the notified chemical will be largely trapped within the foam matrix, thereby reducing exposure. Similar PPE applies to that recommended in the manufacture of resin intermediate. Local exhaust ventilation is in place during the manufacturing process.

Transport and storage workers are unlikely to be exposed to the notified chemical except in the event of an accident.

9.2.2. Public health – exposure assessment

It is expected that during transport, storage, reformulation and polyurethane manufacture, exposure of the general public to the notified chemical will be low, except in the event of an accidental spill.

Public exposure to the notified chemical will occur from dermal contact with finished polyurethane articles, such as work, casual, and athletic shoe soles and automotive skin parts including arm rests, steering wheels, and sun visors. Finished polyurethane articles will contain <1% of the notified chemical.

Clean-up personnel should wear self-contained breathing apparatus and butyl rubber protective clothing. Spills should not be allowed to enter water courses should be contained and absorbed with non-reactive absorbent material (eg. sand) and transferred by suction into appropriate chemical waste containers. The area should be flushed with water spray. Large spills should be recovered with a vacuum truck. Waste should be disposed of in accordance with local, State and Federal regulations.

9.2.3. Human health - effects assessment

The notified chemical has low acute oral and dermal toxicity. It is a slight skin irritant, moderate

eye irritant and demonstrated evidence of skin sensitisation. In a 28-day oral repeat dose study, differences in the haematology and clinical chemistry parameters, body weight and absolute organ weights were observed; however, a dose response was not demonstrated. Increased kidney weight in relation to the body weight was observed and inclusion bodies were seen microscopically in the kidneys, and were confined to mid and high dose males. Given the effects observed in the kidney, the NOEL is set at 50 mg/kg bw/day (the lowest dose tested).

The notified chemical showed a positive result in the in vitro mammalian test, but was negative in the in vitro bacterial mutagenicity test. The in vivo mutagenicity test (micronucleus assay) was negative, which suggest that the notified chemical is not genotoxic in vivo.

On the basis of the data supplied, the notified chemical, DABCO FE1034, would be classified as an irritant (Xi) substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) and warrants the risk phrases: R36 - Irritating to eyes and R43 - May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

Overall, the risk of adverse effects arising from exposure to the notified chemical is low due to largely enclosed and automated operations, in the manufacture of intermediate resin and polyurethane parts. However, due to the eye irritation and skin sensitisation potential of the notified chemical, dermal and ocular exposure should be avoided, when connecting and disconnecting hoses and maintenance operations.

The low concentration of the notified chemical in the intermediate resin (<1%), the limited contact to the notified chemical during intermediate resin formulation and polyurethane manufacture, the presence of adequate ventilation in the workplace and the use of recommended PPE would ensure that occupational risk posed by the notified chemical is low when used as specified in the notification.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical will arise from dermal contact with finished polyurethane articles, such as work, casual, and athletic shoe soles and automotive skin parts including arm rests, steering wheels, and sun visors. It will react into the final polyurethane chemical matrix, therefore unlikely to be bioavailable. Consequently the risk from public exposure to the notified chemical throughout all phases of its life-cycle is considered to be low.

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

10.1. Hazard classification

Based on the available data, the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R36 – Irritating to eyes

R43 - May cause sensitisation by skin contact.

10.2. Environmental risk assessment

On the basis of the available information, the overall environmental hazard of the notified chemical is expected to be low.

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 an ingredient in the production of polyurethane parts.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). 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 NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R36: Irritating to eyes
  - R43: May cause sensitisation by skin contact
  - S36/37: Wear suitable protective clothing and gloves

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥20% concentration: Irritating to eyes
  - ≥1% concentration: May cause sensitisation by skin contact

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Exhaust ventilation during mixing, drumming off resin intermediate and transfer of polyurethane into moulding machines
  - Enclosed and automated manufacture of intermediate resin and polyurethane parts

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - During transfer operations and cleaning of equipment, avoid spills and splashing

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Chemical resistant gloves
  - Protective clothing which protects the body, arms and legs
  - Safety glasses
  - Hard hat

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

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

- If products and mixtures containing the notified 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 chemical should be disposed of into landfill.

Emergency procedures

- Spills/release of the notified chemical should be contained as described in the MSDS (ie. Contain with absorbent material and transfer to a sealable waste container) and the resulting waste disposed of in landfill.

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(2) of the Act:
  – if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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