a

File No: STD/1060

5 May 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

KAT

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 Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

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

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

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

KAT

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Toyota Tsusho (Australasia) Pty Ltd
231-233 Boundary Rd
Laverton North VIC 3026

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:
Chemical identity
Purity and impurities
Import volume
Details of use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a function of pH
Absorption/desorption
Dissociation constant
Explosive and oxidising properties
Acute inhalation study
Induction of germ cell damage assay
Daphnia reproduction study
Biodegradation study
Bioaccumulation study.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU (1999, 2001)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
KAT

SPECTRAL DATA

METHOD	UV/visible, IR, X-ray diffraction
Remarks	Spectra provided.
TEST FACILITY	DKKK (2000a, 2000b)

METHODS OF DETECTION AND DETERMINATION

METHOD	Potentiometric titration, flame emission spectrophotometry, inductively coupled plasma (ICP) spectrophotometry.

TEST FACILITY DKKK (2000c)

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of brazing flux.

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

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

USE
Brazing flux.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Australian Automotive Air P/L
453 Dorset Road
Croydon VIC 3136.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by sea as a component (30-55%) of pastes or slurries. These would typically be supplied in 5 kg plastic bottles. In some products the brazing flux formulation is incorporated as a core within the metal wire used for brazing, and this wire is supplied as 4.5 kg bobbins. The plastic bottles and wire/flux assemblies are transported and stored in cardboard outer packs to the warehouse of the enduser.

5.2. Operation description

The products containing the notified chemical will be used at one site in Australia, as an aid to metal-metal fusion in a brazing process.

Use of flux as paste/slurry
The 5 kg bottles are stored in the warehouse area until moved to the production area for use. After stirring, enough paste or slurry flux for a day's use is decanted into small reservoirs at the workstations (for hand-brazing or semi-automatic brazing). The flux is applied to the metal component to be brazed by brush, or in some cases the brazing wire is dipped in the flux. The metal parts and the brazing wire used for the join are heated to the melting point of the brazing wire and the joints are made. The metal assembly is cooled and washed by water shower.

Use of flux as core-filled wire
The bobbins of wire are moved to the production area from the warehouse as needed, to the brazing machine or to individual workstations for hand brazing. The flux-filled wire is heated to the melting temperature of the brazing wire, and applied to the metal components to be joined. The metal assembly is cooled and washed by water shower.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Task*	*Number*	*Exposure Duration*	*Exposure Frequency*
Factory worker	Transfer of formulation	Up to 15	1 hour per day	Daily
Brazer	Application of flux and brazing	Up to15	8 hours per day	Daily
Cleaning staff	Cleaning of equipment	Up to 5	1 hour per day	Weekly

Exposure Details

Use of flux as paste/slurry

Dermal exposure to notified chemical (at a concentration up to 55%) could occur during transfer of the flux slurry to the workstations. Dermal and potentially inhalation exposure to the notified chemical could occur during application of the flux to the metal component. Exhaust ventilation is present at each workstation. All workers will wear safety glasses with some workers wearing latex gloves.

During brazing, inhalation is considered to be the most likely route of exposure. Exposure to the notified chemical following brazing is not expected as the notified chemical will either be trapped between the brazed metals or removed in the washing/cooling water.

Use of flux as core-filled wire

As the flux is incorporated within the metal wire, no transfer or application of the flux is required. As such inhalation exposure during brazing is considered to be the most likely route of exposure. Exposure to the notified chemical following brazing is not expected as the notified chemical will either be trapped between the brazed metals or removed in the washing/cooling water.

Cleaning

Dermal and inhalation exposure to residues of flux could occur from waste dust and during the cleaning of equipment. The potential for exposure is considered to be greater when the paste/slurry form of the flux has been used as less wastage is expected when using the core-filled wire.

5.4. Release

RELEASE OF CHEMICAL AT SITE

There will be no release due to manufacture or reformulation in Australia as the notified chemical will not be made or reformulated in Australia.

RELEASE OF CHEMICAL FROM USE

At the site, the notified chemical will be used in two forms – paste and as a core in brazing wire.

In the paste form, a surplus amount is initially applied to the metal and then washed off during the washing/cooling stage. The amount of surplus paste cannot be determined, so it is conservatively estimated that annually approximately 2% (up to 60 kg) of the notified chemical would be released via this source. There may be minor spills during the filling of the daily working reservoir, this would represent less than 0.5% (up to 15 kg) annually of the notified chemical. A residue of paste will remain in the empty plastic container, as the paste is fairly thick this may be up to 2% of the contents, ie 2% (up to 60 kg) annually of the imported notified chemical.

In the wire core form there will be minimal release of the notified chemical. There is no surplus material being applied, so that during the washing/cooling stage only trace amounts will be washed off.

The washing/cooling water is collected in a sump under each booth.

5.5. Disposal

The washings sump is emptied out as needed by a licensed liquid waste contractor. Thus up to 60 kg per annum of the notified chemical will go to a licensed treatment plant with treated effluent going to sewer and sludge to landfill. The empty containers and their contents are disposed of via licensed waste contractors to a prescribed landfill. Thus up to 75 kg will go to landfill annually.

5.6. Public exposure

The brazing flux containing the notified chemical is not supplied to the general public. Although members of the public may come into contact with metal parts which have been brazed using the notified chemical, the notified chemical will either be trapped between the brazed metals or removed during processing.

6. PHYSICAL AND CHEMICAL PROPERTIES

All physico-chemical studies were done using 99.5% pure (technical grade) material.

Appearance at 20°C and 101.3 kPa White, amorphous powder

Melting Point/Freezing Point Decomposition occurred above 240°C, prior to melting.

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Differential Scanning Calorimetry method. A sample of 99.5% purity was tested. During the heating process, the test material demonstrated an endothermic effect between 126°C and 218°C and lost 4% of its mass. When the test was repeated on the same sample, this effect did not re-occur. An exothermic effect was noted at higher temperatures, above 240-288°C. No melting was observed at temperatures up to 375°C. The study authors commented that the initial endothermic effect seemed to be a non-reversible change, as it did not occur on re-testing of the same sample. They suggested that the compound or part of it may decompose at temperatures > 126°C, with evaporation of the lighter fraction of the compound. The authors stated that the exothermic reaction above 240°C is likely to be caused by reaction or decomposition of the test substance.
TEST FACILITY	Notox (1998a)

Density 3860 kg/m^3 at 20°C

METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Air comparison pycnometer method used. The test substance was dried at room temperature with silica gel before testing.
TEST FACILITY	Notox (1998b)

Vapour Pressure 2.3x10^{-5} kPa at 20°C

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	The method used (static method) is not recommended for determination of vapour pressure below 1x10^{-3} kPa. However, a correction for thermal transpiration was made because of the low vapour pressure. Measurements were made at three different temperatures and plotted graphically to calculate the vapour pressure at 20°C.
TEST FACILITY	Notox (1998c)

Water Solubility 12 g/L at 20°C

METHOD	OECD TG 105 Water Solubility (Flask Method). EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method was used, on the basis of preliminary trials.

Two test reports were submitted, for two separate studies. The first study determined water solubility to be 16 g/L. However, in this study the concentration of notified chemical in the water phase decreased as a function of stirring time, up to 72 hours (which was the last time point tested). In the second study, further time points were measured, up to 240 hours stirring time. It was found that equilibrium was reached at 72 hours, so only measurements from 72 hours onwards were used to calculate mean concentration and solubility. This resulted in a lower determination of 12 g/L.

The water solubility was determined using inductively coupled plasma atomic emission spectrometry (ICP-AES).

No explanation was suggested for the decrease in water solubility over time.

TEST FACILITY Notox (1999a), Notox (1999b).

Hydrolysis as a Function of pH Not determined.

Remarks The notified chemical is not expected to undergo hydrolysis as there are no hydrolysable functional groups.

Partition Coefficient (n-octanol/water) log P_{ow} ≤-4.5.at 20°C ($p_{ow} \leq 3.2x10^{-5}$)

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks Estimation from water solubility and n-octanol solubility.

Two sets of studies were conducted. In both, the n-octanol solubility was calculated to be ≤0.38 mg/L after 7 days of stirring. From above, the water solubility was found to be 16 and 12 g/L in the two studies. Thus the respective partition coefficients (P_{ow}) determined as a quotient of the n-octanol solubility and the water solubility, are ≤ $2.4x10^{-5}$ at 19.0±1.0°C and ≤ $3.2x10^{-5}$ at 20.0±2.0°C.

TEST FACILITY Notox (1999c), Notox (1999d)

Adsorption/Desorption Not determined.

Remarks Since the notified chemical is inorganic, the adsorption/desorption cannot be determined. Due to its ready water solubility the notified chemical is expected to be mobile in soil and sediments.

Dissociation Constant Not determined

Remarks There is no mode of chemical dissociation for the notified chemical.

Particle Size

METHOD OECD TG 110 Particle Size Distribution.

Range (μm)	*Mass (%)*
< 5 μm	2.0%
5-10 μm	20.8%
10-20 μm	31.6%
20-50 μm	40.5%
> 50 μm	5.1%

Remarks OECD Guideline states that this method is only applicable to water insoluble substances, defined as $<10^{-6}$ g/L water solubility. The two water solubility tests submitted for this notification give results of 12 and 16 g/L. The particle size test report states that data submitted by the sponsor showed water solubility of 600 mg/L. The notified chemical also dissolved up to 100 mg/L in ethanol, but did not

dissolve in cyclohexane (tested at 30 and 100 mg/L); therefore cyclohexane was used as the suspending liquid for the test. Particle size distribution was measured by laser diffraction.

TEST FACILITY Notox (1998d)

Flammability Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks The notified chemical could not be ignited with a flame. The test material coloured black and emitted sparks and black smoke upon contact with the ignition source.

TEST FACILITY Notox (1998e)

Not likely to react or produce flammable gas on contact with water

METHOD Statement based on structure of chemical.

Remarks The notified chemical does not contain groups that may lead to evolution of highly flammable gases in dangerous quantities. Experience in handling demonstrated that the notified chemical does not react with water.

TEST FACILITY Notox (1998f)

Not pyrophoric

METHOD Statement based on structure of chemical.

Remarks The notified chemical does not contain any chemical group that may lead to spontaneous ignition a short time after coming into contact with air at room temperature. Experience in handling demonstrated that the notified chemical does not ignite upon contact with air.

TEST FACILITY Notox (1998g)

Autoignition Temperature > 400ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks The test substance was heated from room temperature to 400ºC.
No endothermic or exothermic reaction was noted during the test.

TEST FACILITY Notox (1998h)

Explosive Properties Not explosive

METHOD Statement based on structure of chemical.

Remarks The notified chemical does not contain any chemically unstable or highly energetic groups that might lead to an explosion.

TEST FACILITY Notox (1998i)

Oxidizing Properties Not oxidising

METHOD Statement based on structure of chemical.

Remarks The notified chemical does not contain any group that might act as an oxidising agent.

TEST FACILITY Notox (1998j)

Reactivity Not highly reactive

Remarks The notifier states that the notified chemical is considered to be stable. It is combustible, and will produce noxious fumes in a fire. However, there is no experimental evidence to demonstrate anticipated combustion products.

Surface Tension 72.9 mN/m at 20ºC

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions. EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	Concentration: 1.108 g/L A ring tensiometer was used. From the result the notified chemical is not considered to be surface active.
TEST FACILITY	Notox (1998r)

72.5 mN/m at 20ºC

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions. EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	Concentration: 1.0 g/L A ring tensiometer was used. From the result the notified chemical is not considered to be surface active.
TEST FACILITY	Notox (1999k)

6.1 Comments on physico-chemical properties

The melting temperature test (Notox 1998a) showed that the notified chemical undergoes an exothermic reaction above 240ºC but did not clarify what occurs at this temperature. The study authors suggested that the effect is likely to result from reaction or decomposition.

The notifier has stated that the substance does not volatilise, decompose or react at elevated temperatures, but that water is driven off, regenerating the powder form of the chemical.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	low toxicity LD50 > 2000 mg/kg bw
Rat, acute dermal	low toxicity LD50 > 2000 mg/kg bw
Rat, acute inhalation	not performed
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 30 mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration	genotoxic
Genotoxicity – in vivo mouse micronucleus	non genotoxic
Pharmacokinetic/Toxicokinetic studies	not performed
Developmental and reproductive effects	not performed
Carcinogenicity	not performed

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical 99.5%
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/Wistar Cr1 (WI) BR Charles River
Vehicle	1% aqueous carboxymethylcellulose
Remarks - Method	Acute Toxic Class method not followed strictly, as only one dose level was tested, analogous to the Limit Test. Three animals of each sex were tested, rather than 3 animals of one sex as suggested in the test guideline. Microscopic examinations were not carried out on necropsy.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	One female was found dead on day 2, and one male was found dead on day 4. Tremors and abnormal gait were noted in the non-surviving male on day 3. Lethargy, hunched posture and piloerection were noted in the surviving animals between days 1 and 8. Body weight gain by surviving animals was similar to that expected for untreated animals.
Effects in Organs	Red discolouration of the glandular mucosa of the stomach, reduction in size of the spleen and haemorrhages in the thymus were noted on post-mortem examination of the animals that died during the study. Thickening of the limiting ridge of the stomach and a flaccid appearance of the right testes was found in one surviving male.
Remarks - Results	While testing was not carried out according to the protocol of the Acute Toxic Class method, the mortality rate at 2000 mg/kg bw suggests that the LD_{50} is > 2000 mg/kg bw.

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

TEST FACILITY Notox (1998k)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical 99.5%

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Wistar strain Cr1: (WI) BR Charles River
Vehicle	1% aqueous carboxymethylcellulose
Type of dressing	Occlusive.
Remarks - Method	After the 24 h exposure period, residual test substance was removed with a tissue moistened with tap water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	2000	0/5
2	5 F	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Erythema, necrosis, scabs and/or scales were seen in the treated skin-area of two males and all females during the 14-day observation period. Scars had developed on four animals on termination.
Signs of Toxicity - Systemic	Two females exhibited red staining of the head, periorbital area and/or neck between days 1 and 5. No further signs of systemic toxicity were noted in any animals. Reduced body weight gain or body weight loss was seen in all animals during the first week post-treatment. During the second week one female continued to lose weight but the remaining animals gained weight.
Effects in Organs	No macroscopic abnormalities were seen at necropsy.
Remarks - Results	The body weight disturbances may result from the burden of the dermal

application and the severe local skin effects.

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

TEST FACILITY Notox (1998l)

7.3. Acute toxicity – inhalation

Not performed.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical 99.5%

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M.
Vehicle	None, however the powder was moistened with water immediately before application in order to obtain close contact with the skin.
Observation Period	72 h.
Type of Dressing	Semi-occlusive.
Remarks - Method	After the 4 h exposure period, the test substance was removed from the skin using a tissue moistened with tap water, and then with a dry tissue.

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	0	0	-	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 There was no evidence of irritating or corrosive effects on the skin and no staining of the skin by the test substance. No systemic effects were observed.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Notox (1998m)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical 99.5%

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	1 M
Observation Period	21 days
Remarks - Method	The substance was tested on one animal initially, in line with the sequential testing strategy recommended in the guidelines. A single sample of 97.8 mg of the notified chemical (powder) was instilled into the eye of the rabbit. Immediately after the 24 h observation, both eyes were instilled with 2% fluorescein at pH 7, to determine corneal epithelial damage. The treated eye was then rinsed with approximately 50 mL tepid tap water to remove

residual test substance, using a velocity of flow that did not affect the eye. The untreated eye was rinsed in similar manner. This process did not completely remove residual test substance, which was still visible in the eye on day 2.

RESULTS

Lesion	*Mean Score* Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1			
Conjunctiva: redness	2.7	3	>21 days	3
Conjunctiva: chemosis	3.3	4	> 21 days	1
Conjunctiva: discharge	2.3	3	> 21 days	1
Corneal opacity	1.0**	2	> 21 days	1
Iridial inflammation	1.0	1	< 14 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours.
**Corneal epithelial damage was also noted.

Remarks - Results

Vocalisation was noted immediately after instillation, indicating pain.
The test substance caused marked effects on the cornea, iris and conjunctivae.
The cornea showed opacity, and epithelial damage covering a maximum of 75% of the corneal area at 24 h, reducing to 25% at 21 days. Pannus (neovascularisation of the cornea) occurred as a result of the injury, from day 7 onwards.
Slight iridial inflammation had resolved by 14 days.
Redness, chemosis and discharge of the conjunctivae were noted. Reduced elasticity of the eyelids was noted at 14 and 21 days after instillation. Signs of necrosis on the eyelids and nictitating membranes were apparent from 7 d to termination. Corneal damage, pannus and irritation of the conjunctivae also persisted to termination.

CONCLUSION

The notified chemical is severely irritating to the eye.

TEST FACILITY

Notox (1998n)

7.6. Skin sensitisation

TEST SUBSTANCE

Notified chemical 99.5%

METHOD

OECD TG 406 Skin Sensitisation – Maximisation Test method.
EC Directive 96/54/EC B.6 Skin Sensitisation – Guinea-Pig Maximisation Test (GPMT).

Species/Strain

Guinea pig/Albino, Himalayan strain.

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
intradermal: 0.02%*
topical: 50%**
*This was the lowest of several concentrations tested, and still produced grade 3 erythema after 24 h and grade 2 after 48 h.
** No irritation was noted after dermal application at this concentration, the highest that could technically be applied.

MAIN STUDY

Number of Animals

Test Group: 10 F Control Group: 5 F

INDUCTION PHASE

Induction Concentration:
intradermal: 0.02%
topical: 50%

Signs of Irritation	After topical application, no irritation was noted, except for small scabs in 3/10 test animals and 1/5 controls. There was no erythema or oedema. After intradermal injections of Freunds Complete Adjuvant (FCA) and water, well-defined to severe erythema was noted in both test and controls groups, in the presence and absence of the test substance. One control animal showed signs of necrosis at the injection site. After intradermal injection of the test substance in the vehicle, there was slight erythema in 8/10 test animals, but no irritation where only the vehicle was injected.
CHALLENGE PHASE	
1st challenge	topical: 50%
2nd challenge	topical: Not conducted
Remarks - Method	The vehicle was 1% carboxymethylcellulose. As dermal application produced no irritation in the preliminary test, the skin of test and control animals was pre-treated with 10% sodium dodecyl sulfate in Vaseline 24 h before epidermal induction exposure in the the main test .

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	50%	0/10	0/10	N/A	N/A
Control Group	50%	0/5	0/5	N/A	N/A

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	Notox (1998o)

7.7. 28-day repeat dose oral toxicity

TEST SUBSTANCE	Notified chemical 99.5%.
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 strain Cr1: (WI) BR Charles River
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: None
Vehicle	1% aqueous carboxymethylcellulose
Physical Form	Homogeneous suspension.
Particle Size	It is likely that the notified chemical was partially dissolved in the suspension, as it is moderately soluble in water (1.2% w/v). Particle size determination on the solid (Notox 1998d) showed that it was mainly 5 – 50 μm.
Remarks - Method	No significant protocol variations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*

I (control)	5 M / 5 F	0	0
II (low dose)	5 M / 5 F	30	0
III (mid dose)	5 M / 5 F	150	0
IV (high dose)	5 M / 5 F	845 (nominal 750)	4 M, 4 F

Mortality and Time to Death

High dose animals (4 M, 3 F) died between days 15 and 29. An additional female died during blood sampling on day 29. No deaths were seen in other groups.

Clinical Observations

Hunched posture and piloerection were seen in high dose animals from days 8-10, mostly persisting until death or the end of the study. Brown or red staining of the fur and red staining of the periorbital region also occurred from days 8-10 but in most animals had cleared in 2-9 days. At later stages of treatment, the majority of the female high-dose animals had a pale appearance and showed hypersensitivity to touch. Emaciation was seen in two females shortly before their deaths on days 16 and 22, and one male showed lethargy, tremors, diarrhoea, hunched posture and piloerection on day 28, the day before it was found dead. Salivation observed on several occasions in high dose males and females may have been test substance-related as it was not seen in the other groups. However it may also have been due to the taste and the higher dose level.

Symptoms in the low and mid dose groups comprised mainly brown or red staining of fur in some animals and piloerection or swelling of the throat region in individual animals. In these dose groups the symptoms were mainly temporary and disappeared 2-4 days after appearance. However one mid dose female showed piloerection for 14 days continuously.

Alopecia in a control female and 4/5 low dose females and isolated skin effects in one male of each of the test groups were not considered treatment related, because of low incidence and absence of a dose response relationship.

Using a computerised motor activity monitoring system, a dose dependent decrease in motor activity was noted, although no statistical analysis was performed, and two low dose animals (1 male, 1 female) showed extremely increased motor activity. The increased activity may have occurred by chance and may not have toxicological significance. No effects were observed in other functional observation tests.

A statistically significant reduction in body weight was noted in high dose males and females (weight loss or reduced body weight gain). No effect was noted in other dose groups or controls. Food consumption was reduced in high dose animals over the first two weeks of the study. After correction for body weight, the changes were evident in week 2 only. Interpretation of data on high dose group food consumption in the second half of the study was difficult because of mortality, however indications were that there were no marked differences between high dose animals and controls. No differences in food consumption were noted in other dose groups compared to control animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Mean corpuscular volume (MCV) was decreased and red cell distribution width (RDW) was increased in the three surviving high dose animals (2F, 1M). In this group there was also a marked increase in the differential count for neutrophils (SEG), consequent to a marked increase in absolute numbers of neutrophils. This effect was also reflected in a slight increase in total white blood cells. A minor statistically significant decrease in MCV in mid dose animals was found, however this was due to higher than average readings in the control animals. Minor statistically significant differences in low dose animals were considered to have occurred by chance, as their distribution did not show a trend by treatment group or sex.

High dose animals showed changes in aspartate aminotransferase, creatinine, urea and inorganic phosphate (increased values) and albumin and potassium (decreased values). These changes were statistically significant in the two surviving females, and consistent with effects in the surviving male. Total protein and albumin were decreased to statistically significant levels in mid dose females, but not males. A statistically significant variation in the alanine aminotransferase (ALAT) in mid dose females was considered to have arisen by chance and not of biological significance. Significant changes were not seen in the low dose group.

Effects in Organs

Organ weight

Organ weights could not be evaluated for the high dose group because of the high number of deaths that occurred before scheduled necropsy. Statistically significant increases in kidney and spleen weight were noted in mid dose females, however the organ/body weight ratios were within the range of the controls. Statistically significant increases in heart weight and hearth/body weight ratio in low dose males were not considered treatment related, in the absence of a dose response relationship.

Gross Pathology

The main macroscopic changes noted at necropsy were in the stomach and spleen in high dose animals, and stomach only in mid and low dose animals. The changes comprised haemorrhages in or red discoloration of the glandular mucosa, irregular surface of the forestomach, thickness or discolouration of the limiting ridge in the stomach, and reduced size of the spleen. The effects to the stomach showed a dose related pattern. Other findings in the high dose group were reduced size, enlargement or haemorrhage of the thymus (both sexes), reduced size of the prostate, testes and seminal vesicles (males), and haemorrhagic contents of the duodenum and jejeunum, black discolouration of the mesenteric lymph nodes and reduced size of the caecum (females).

Histopathology

The macroscopic changes noted in stomach and spleen were reflected in the microscopic examination. A dose related granulocytic inflammation of the glandular mucosa, with foveolar apoptosis, was found in all dose groups. Mucosal erosion in males and increased severity of forestomach inflammation in females were also seen in the high dose animals. Reduced splenic haemopoiesis and lymphoid atrophy were seen in the high dose group.

Other microscopic changes in high dose animals only were an increase in the incidence and severity of cardiac myofibre degeneration/necrosis, tubular atrophy of the testes in two males, and sinusoidal macrophages in mesenteric and mandibular lymph nodes. Tubular regeneration in kidneys was seen, predominately in males, in mid and high dose groups. Urothelial hyperplasia occurred in some rats of each sex in the mid dose group.

Remarks – Results

The severity of the lesions in the stomach were considered to have contributed to the early deaths of several high dose animals, and were indicative of the irritating properties of the test substance. Uraemia and reduced haemopoiesis in the spleen were also identified as major adverse effects. Changes in clinical appearance, motor activity and body weights were considered secondary to the stomach, splenic and renal lesions, and to reflect a poor condition of the animals. Additional macroscopic and/or microscopic changes in the heart, testes and lymph nodes suggest that there is no single target organ for the test substance.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 30 mg/kg bw/day in this study, based on effects at 150 mg/kg/day on the stomach and kidneys and spleen. The clinical signs noted at 30 mg/kg/day were transient. The minor effects in the stomach at 30 mg/kg/day were considered adaptive changes to the irritant substance as they were not accompanied by organ dysfunction and are commonly seen in gavage dosing.

TEST FACILITY	Notox (1999i)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical 99.5%
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100*, *E. coli*: WP2uvrA,* * Used in Test 2 only.
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in	a) With metabolic activation: 5000 µg/plate.

Main Test	b) Without metabolic activation: 5000 µg/plate.
Vehicle	Dimethylsulfoxide
Remarks - Method	Two independent tests were carried out, based on a single preliminary test using TA100 and WP2uvrA.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	WP2uvrA: > 5000 TA100: slight reduction in revertants at 5000	> 5000, except for slight reduction in revertants in TA100	3300*	negative
Test 2	N/A	> 5000	3300*	negative
Present				
Test 1	WP2uvrA: > 5000 TA100: 5000	> 5000	3300*	negative
Test 2	N/A	> 5000	3300*	negative

* Precipitate was noted in the top agar and on the plates at the beginning of the incubation period at 3300 and 5000 µg / plate, but was not evident at the end of the incubation period.

Remarks - Results	Cytotoxicity was not induced at the concentrations tested. No mutagenic effects were observed.

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

TEST FACILITY Notox (1998p).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical 99.5%

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Cultured peripheral human lymphocytes
Metabolic Activation System	1.8% v/v S9 fraction from Aroclor 1254 induced rat liver
Vehicle	Dimethylsulfoxide
Remarks - Method	An upper concentration of 333 µg/mL was chosen in the range finding study, on the basis of precipitation. The concentrations used in the main test did not cause cytotoxicity. The main tests were carried out in duplicate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	33*, 100*, 333*	3 h	24 h
Test 2a	33*, 100*, 333*	24 h	24 h
Test 2b	33*, 100*, 333*	48 h	48 h
Present			
Test 1	33*, 100*, 333*	3 h	24 h
Test 2	33*, 100*, 333*	3 h	48 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 333*	> 333	333	negative
Test 2a	N/A	> 333	333	positive
Test 2b	N/A	> 333	333	positive
Present				
Test 1	> 333	> 333	333	negative
Test 2	N/A	> 333	333	negative

* Slight toxicity only was seen at 100 and 333μg/mL with 48 h treatment and fixation time.

Remarks - Results

Statistically significant positive results were seen at the highest dose tested without metabolic activation, after 24 and 48 h exposure periods. The number of cells with aberrations was elevated, with and without gaps.
A 3 h exposure period without metabolic activation and the tests with metabolic activation were negative. Significant cytotoxicity could not be obtained under the conditions of the test.

CONCLUSION

The notified chemical was clastogenic to cultured peripheral human lymphocytes treated in vitro when tested without metabolic activation for extended exposure periods (24 h and 48 h).

TEST FACILITY

Notox (1998q)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE

Notified chemical ≥ 99%

METHOD

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

Species/Strain: Mouse NMRI BR (SPF)
Route of Administration: Oral – gavage
Vehicle: Suspension in 1% carboxymethylcellulose
Particle Size: The particle size of the material suspended was not reported. It is likely that the notified chemical was partially dissolved in the suspension, as it is moderately soluble in water (1.2% w/v). Particle size determination on the solid (Notox 1998d) showed that it was mainly 5 – 50 μm.
Remarks - Method: The dosage for the main test was chosen on the basis of a range-finding study of 3 days using single doses of 2000, 1000 and 750 mg/kg. In this study all animals treated with 2000 mg/kg died or were humanely killed on day 2. Clinical signs of toxicity were evident in the 1000 mg/kg group and in 1/3 animals in the 750 mg/kg group.
Single doses were used for the main test. Vehicle controls were not used, as historical data showed the vehicle to cause no deleterious or mutagenic effects.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
II(low dose)	5 + 5 M, 5 + 5 F	250	24 & 48
III (mid dose)	5 + 5 M, 5 + 5 F	500	24 & 48
IV (high dose)	5 + 5 M, 5 + 5 F	1000	24 & 48
V (positive control CP)	5 M, 5 F	50	48

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	Clinical signs of toxicity at 1000 mg/kg included rough coat, hunched posture and lethargy. No mortality occurred and recovery occurred within 42 h of dosing. No effects were noted in 250 or 500 mg/kg dose groups. In general there was no reduction in the ratio of polychromatic to normochromatic erythrocytes in the test groups compared to the historical control data, which was in the region of 1. This suggests that the test compound or the positive control did not have a toxic effect on erythropoiesis. Although the ratios were below 1 for males in both 1000 mg/kg groups (0.75 ± 0.21 and 0.93 ± 0.19), these values were not identified by the study authors as being statistically significant. As the ratio for most other groups was above one, the reliance on historical controls in this study may have reduced the sensitivity of the evaluation of toxicity.
Genotoxic Effects	No increase in the frequency of micronucleated polychromatic erythrocytes was observed in the polychromatic erythrocytes of the bone marrow of any of the test groups. The positive control cyclophosphamide showed a statistically significant increase, indicating that the test conditions were adequate.
Remarks - Results	The highest dose tested produced clinical signs of toxicity, indicating that systemic absorption occurred. Because no toxicity was seen to erythropoiesis, it is not clear whether the substance reached the target organ.

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

TEST FACILITY Notox (1999j)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

The notified chemical is inorganic and thus does not contain any organic carbon required for biodegradation to occur.

8.1.2. Bioaccumulation

Not determined. It is expected not to bioaccumulate due to its high water solubility.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static.
Species	Carp (*Cyprinus carpio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Inductively coupled plasma emission spectroscopy.
Remarks – Method	Test medium used - ISO-medium

In the range finding test conducted with three concentrations (0.1, 10 and 100 mg/L) precipitation of white material was noticed at 100 mg/L after 24 hours. However, no toxic effects or mortality was observed in any of the test concentrations.

The final test consisted of a control blank and 100 mg/L. A 16 hour photoperiod was maintained throughout the study and dissolved oxygen and pH were measured daily in all vessels, while temperature was measured daily but only in the control vessel. No aeration at commencement for 48 h.

A reference study was conduct to validate the test conditions, using pentachlorophenol at 0.06, 0.1, 0.15, 0.22 and 0.32 mg/L.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0 (Blank control)		7	0	0	0	0	0
100		7	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	= 100 mg/L at 96 hours.
Remarks – Results	Analysis showed that initially there was 73% of the expected element present in the test concentration (100 mg/L). After 96 hours this decreased by more than 20%. During this time precipitation was observed, probably due to the formation of low soluble salts. Average exposure concentrations were calculated by using the geometric mean (40.1 mg/L).

The dissolved oxygen started at 9.7 and dropped to 6.2 on day 2, where upon aeration was recommenced and the DO rose to 8.9 by day 4. In the control the pH range from 7.3 to 8.2 while in 100 mg/L it ranged from 6.7

to 7.6. The temperature remained around 20.0ºC. The variations in DO and pH are acceptable.

The LC_{50} of the reference substance (pentachlorophenol) was 0.13 mg/L (95% fiducial limits 0.12–0.17 mg/L). This result validates the study conditions.

CONCLUSION Under the conditions of the study the test substance was very slightly toxic to fish (Mensink et al 1995).

TEST FACILITY Notox (1999e)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

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	250 mg $CaCO_3$/L
Analytical Monitoring	Inductively coupled plasma emission spectroscopy.
Remarks - Method	From initial range-finding test (0.1, 1, 10 and 100 mg/L) it was determined that the final test concentrations should range from 5.6 to 100 mg/L increasing by a factor if 1.8. The test concentrations were done in duplicate. Analysis samples were taken from controls, 5.06, 18 and 100 mg/L at the beginning and end of the study. Dissolved oxygen (DO) and pH were measured at the beginning and end of the study in all concentrations, while temperature was measured daily in a control. Reference substance – potassium dichromate at 0.1, 0.18, 0.32, 0.56, 1.0 and 1.8 mg/L.

RESULTS

Concentration mg/L			*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*			*24 h*	*48 h*
	Element	Substance			
0.0	-	-	20	0	0
5.6	0.27	2.9	20	0	0
10	0.44	4.7	20	0	
18	086	9.0	20	0	0
32	2.1	22	20	0	0
56	3.9	41	20	8	19
100	7.3	77	20	10	20

LC50	31 mg/L at 48 hours (95% fiducial limits 29-35 mg/L)
NOEC (or LOEC)	22.3 mg/L at 48 hours
Remarks - Results	Analysis showed that initially there was 67%, 73% and 110% of the expected element present in 5.6, 18 and 100 mg/L respectively. After 48 hours these had decreased to 39%, 35% and 54% for 5.6, 18 and 100

mg/L respectively – decrease of greater than 20%. During this time precipitation was observed, probably due to the formation of low soluble salts. At concentrations the two highest concentrations after 24 hours there was also a thin layer at the surface. Average exposure concentrations were calculated by using the geometric mean.

The DO started at 9.6 and dropped to 9.0 by the end of the study. The pH initially ranged from 6.9 to 7.9 with the final range being 7.3 to 7.7. The temperature remained at 20.5ºC.

The 48 h EC_{50} for the reference substance was 0.52 mg/L (95% fiducial limits 0.46-0.65 mg/L). This validated the study conditions.

CONCLUSION Under the conditions of the study the test substance was slightly toxic to daphnia (Mensink, 1996). The toxic effect may be physical due to the precipitated material.

TEST FACILITY Notox (1999f)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Selenastrum capricornutum*	
Exposure Period	72 hours	
Concentration Range	Nominal concentration of substance:	4.5, 10, 22, 45 and 100 mg/L
	Nominal element concentration:	0.43, -, 2.1, - and 9.5 mg/L
	Actual element concentration start:	0.5, -, 1.8, - and 8.2 mg/L
	Actual element concentration end:	0.28, -, 1.4, - and 6.4 mg/L
Auxiliary Solvent	None	
Water Hardness	24 mg $CaCO_3$/L	
Analytical Monitoring	Inductively coupled plasma emission spectroscopy.	
Remarks - Method	The pH was measured at the beginning and end of the study, while temperature was recorded daily in the control. Cell density was counted be microscope at the every 24 hours. Reference Substance – potassium dichromate at 0.18, 0.32, 0.56, 1.0, 1.8 and 3.2 mg/L.	

RESULTS

These results are for the whole complex.

Biomass		*Growth*	
E_BC_{50} *mg/L at 0-72 h*	NOEC *mg/L*	E_RC_{50} *mg/L at 0-72 h*	NOEC *mg/L*
18 (95% C.I. 9.3–35 mg/L)	8.0	31 (95% C.I. 18–53 mg/L)	8.0

Remarks - Results Average exposure concentrations were calculated by using the geometric mean.

The E_BC_{50} (0-72 h) for the reference substance was 1.1 mg/L and the E_RC_{50} was 1.4 mg/L. This result validates the study conditions.

CONCLUSION Under the study conditions, the test substance is slightly toxic to algae (Mensink, 1996).

TEST FACILITY Notox (1999g)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Micro-organisms in activated sludge
Exposure Period	30 mins
Concentration Range	Nominal: 50, 100 and 200 mg/L
Remarks – Method	Reference substance – 3,5-dichlorophenol at 3.2, 10 and 32 mg/L. Aeration was continuous during the contact time, then the mixture was transferred to a 300 mL oxygen bottle and sealed. Oxygen was measured for 10 minutes while there was no aeration. There were 3 controls and duplicates of the 100 mg/L test concentration.
RESULTS	
IC50	>100 mg/L
NOEC	=100 mg/L
Remarks – Results	There was a slight inhibition of respiration (11 and 14%) at 100 mg/L, while at 50 and 200 mg/L there was no inhibition. The temperature remained at 20^{o}C during the study. The mean respiration rate between the 3 controls was less than 15% and the EC_{50} of the reference substance was 11 mg/L. These findings validate the study conditions.
CONCLUSION	Under the conditions of the study the test substance is very slightly toxic to activated sludge micro-organisms (Mensink, 1996). The exposure time was very short usually it is 3 hours. Over the 30 mins there was some toxic effects, however this may be more significant over the full 3 hours.
TEST FACILITY	Notox (1999h)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

When the notified chemical is used as the core of the brazing wire, its the release will be minimal. It will only be released in the wash water but at much lower levels than when it is used as a paste. Therefore the following risk assessment is based on the use of the paste flux.

Spilt paste will be wiped up with rags, which will then be disposed of to prescribed landfill along with the empty paste container and any residues. This represents up to 2.5% of the imported notified chemical, which equates to up to 75 kg annually going to landfill in a worst case scenario. In landfill, due to its water solubility the notified chemical will be mobile. However, since the waste material is going to a prescribed landfill any leachate will be contained and monitored.

The surplus waste will be washed off the brazed article with the resultant washwater being retained onsite until removal by a licensed liquid waste contractor. The contractor is likely to treat the effluent and then dispose of the liquid to sewer and the sludge to prescribed landfill. Since the notified chemical is readily soluble and has a low P_{ow}, it is likely to remain in the water column.

The predicted environmental concentration (PEC) in the aquatic environment of the notified chemical can be estimated using the available information and taking into account that the effluent in the sewer will be treated at the Western Treatment Plant, Werribee:

Amount released to sewer	60 kg
Daily Influent volume to STP	500 ML
Number of days used	350
PEC_{sewer}	1.71 µg/L
PEC_{ocean} (dilution factor 10)	0.171 µg/L

The available data indicate that when the chemical is released into the aqueous phase of a STP it will partition into the water compartment and that there is no removal. Therefore the PEC in Port Phillip Bay remains 0.171 µg/L. However, the pre-treatment of the effluent before it is released to sewer may entail the use of coagulant in which case the amount of the notified chemical being released to sewer will be less and subsequently the PEC values will be less.

9.1.2. Environment – effects assessment

The results of the acute aquatic toxicity tests provided are listed below.

Organism	*Duration*	*End Point*	*mg/L*
Fish	96 h	LC_{50}	>100
Daphnia	48 h	EC_{50}	31
Algae	96 h	E_BC_{50}	18
Microbial activity	30 min	EC_{50}	>100

Using the lowest EC_{50} of 18 mg/L for algae and a safety factor of 100 (OECD), since there are toxicity data for three trophic levels, a predicted no effect concentration (PNEC) for aquatic ecosystems of 0.18 mg/L has been estimated (EC_{50}/100).

9.1.3. Environment – risk characterisation

The risk of the release of 60 kg of the imported notified chemical can be estimated by determining the aquatic risk quotient (RQ = PEC/PNEC), using the PEC_{ocean} = 0.171 µg/L and PNEC = 180 µg/L. Therefore the RQ is 0.001. The RQ value is less than 1, therefore the proposed use does not represent a risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Use of flux as paste/slurry

Exposure to the notified chemical could occur during the transfer of the flux to the workstation, the application of the flux to the metal parts and the brazing process. The brazer (who undertakes both the application of the flux and the brazing process) is considered to be the worker with the greatest potential for exposure and as such their exposure is discussed in more detail below:

Ocular Exposure

Ocular exposure to the notified chemical would be minimised by the use of safety glasses.

Dermal Exposure

The estimated dermal exposure during flux application is 0.055-0.55 mg/cm^2/day, based on EASE model (EASE) and assuming the notified chemical is present at concentration of 55%. Therefore, for a 70 kg worker with surface area for hands at 820 cm^2 and a worst case 100% dermal absorption factor, systemic exposure is estimated to be 0.6-6.4 mg/kg bw/day. Due to the relatively small amounts of the flux applied in semi-automated and manual brazing, the lower limit (0.6 mg/kg bw/day) should be used as the exposure value. The wearing of gloves would limit the exposure.

Inhalation Exposure

Task	*Dust levels[1] (mg/m^3)*	*Atmospheric conc. of notified chemical[2] (mg/m^3)*	*Inhalation exposure[3] (mg/kg bw/day)*
Flux Application	1.5	0.825	0.12
Hand Brazing	0.2	0.11	0.02
Auto Brazing	0.1	0.055	0.008

1) Data from atmospheric monitoring study at Australia Automotive Air P/L (EHS, 2004)
2) Assuming the worst case that all the dust is flux and notified chemical is present at a concentration of 55%
3) For a 70 kg worker, assuming an inhalation rate of 1.3 m^3/hour, a 8 hour exposure time and 100% bioavailability

Use of flux as core-filled wire

Inhalation exposure to the notified chemical during brazing is considered to be the most likely route of exposure. This is estimated to be 0.02 mg/kg bw/day for hand-brazing and 0.008 mg/kg bw/day for semi-automatic brazing.

Cleaning

Dermal and inhalation exposure to residues of flux could occur during the cleaning of equipment. Exposure to the notified chemical is expected to be low relative to other workers due to the nature of the work and the lower frequency and duration of exposure and if dust generation is avoided.

9.2.2. Public health – exposure assessment

The public is not expected to come into contact with the notified chemical and as such public exposure is expected to be negligible.

9.2.3. Human health – effects assessment

No information was supplied on toxicokinetics, metabolism and distribution. The notified chemical is of low acute toxicity by the oral and dermal routes. It is non-irritating to skin and no potential for skin sensitisation was shown in a guinea pig maximisation test.
The notified chemical was a severe eye irritant in a single rabbit tested by the OECD method. Effects on the cornea and conjunctivae persisted to the end of the 21-day observation period, as did signs of necrosis on the eyelids and nictitating membranes.

A NOAEL of 30 mg/kg/day was determined for repeated dose toxicity in a 28-day oral gavage study in rats. Mortality occurred at the highest dose tested of 845 mg/kg/day, with severe effects

on the stomach and spleen. Effects on kidneys, heart, testes and lymph nodes also occurred, suggesting that there is no single target organ.

Genotoxicity test results were mixed, with a negative result in a bacterial reverse mutation test and in an in vivo mouse micronucleus study. The notified chemical gave positive results at the highest dose tested without activation in an in vitro chromosome aberration study. While the highest concentrations technically feasible were tested in the negative assays, it should be noted that the optimum conditions were not reached in the mutagenicity study because cytotoxicity was not induced. Similarly, in the mouse micronucleus test systemic absorption was demonstrated, but no confirmation through reduced erythropoiesis that that the target organ had been reached. On the basis of the test results the chemical is not classified for genotoxicity.

No tests for reproductive effects or carcinogenicity were available. However reproductive organs were among those examined during the 28-day repeat dose study.

The notified chemical is already in use in Japan and the EU. The notifier advised that they are not aware of information on effects in use, either from specific incidents or epidemiological data.

The notified chemical contains fluorine atoms and may have the potential for similar effects as inorganic fluoride compounds. Adverse effects of fluoride exposure in animals include effects on the skeleton, clastogenicity, possible carcinogenicity and reproductive effects. (IPCS 2002).

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002). It is classified as having a risk of serious damage to eyes (X_i R41) on the basis of the persistence of the ocular lesions. It is also classified as having a danger of serious damage to health by prolonged exposure (X_n R48) on the basis of stomach lesions and renal changes in rats dosed at 150 mg/kg/day in a 28-day oral study. On the available information, no classification is made for other endpoints.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is a severe eye irritant and repeated exposure could have an adverse effect on health including effects on the kidney, spleen and stomach.

Ocular exposure to the notified chemical would be minimised by the use of safety glasses and as such the risk of severe eye irritation is considered to be low.

The highest level of exposure is expected for brazers who both apply the flux in paste/slurry form and carry out the brazing by hand. Overall exposure (dermal and inhalation) for this type of worker is estimated to be 0.74 mg/kg bw/day. Based on a NOAEL of 30 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 40.5. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Although a MOE of 100 has not been established in this case, the exposure estimated by EASE is likely to be an over estimate as it does not take into account the presence of exhaust ventilation. In addition, as dermal exposure is the main contributor to this exposure estimate, the wearing of gloves would limit the exposure and hence reduce the risk of adverse health effects. As dermal exposure is also the main route of exposure for workers involved in the transfer of flux to the workstation, the wearing of gloves is also considered appropriate for these workers in order to reduce the risk of adverse health effects.

The maximum estimated exposure for brazers using the flux as core-filled wire is 0.02 mg/kg bw/day. Based on a NOAEL of 30 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 1500. Therefore, the risk of systemic effects using modelled worker data is acceptable for workers using the flux as core-filled wire.

The risk to workers involved in cleaning is considered to be low due to the anticipated lower levels of exposure, however, as a precaution workers involved with cleaning should avoid contact with the skin, wear safety glasses and carry out damp cleaning to minimise dust generation.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical is expected to be negligible and as such the risk to public health is also expected to be negligible.

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:

X_i R41 with risk phrase "Risk of serious damage to eyes".

X_n R48/22 with risk phrase "Harmful: danger of serious damage to health by prolonged exposure if swallowed".

and

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

	Hazard category	***Hazard statement***
Acute toxicity	5	May be harmful if swallowed (oral)
Serious eye damage/eye irritation	1	Causes serious eye damage
Target organ systemic toxicity following repeat exposure	2	May cause damage to organs through prolonged or repeated exposure
Acute hazards to the aquatic environment	3	Harmful to aquatic life
Chronic hazards to the aquatic environment	3	Harmful to aquatic life with long lasting effects

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Moderate Concern to occupational health and safety under the conditions of the occupational settings described based on the hazardous nature of the notified chemical and the manual handling of the flux containing it.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety*

Data Sheets (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - Xi: R41 Risk of serious damage to eyes
  - Xn: R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc $\geq$ 10%: R41, 48/22

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Use under local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure to the notified chemical as introduced:
  - Avoid skin and eye contact
  - Hygiene measures to avoid both the build up of dust and generation of airborne dust during cleaning

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Safety glasses
  - Impervious gloves

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

- Personal atmospheric monitoring should be conducted to measure workplace concentrations during use of the notified chemical if changes to processes have the potential to lead to increased exposure.

- 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.

Environment

- The following control measures should be implemented by users of the flux to minimise

environmental exposure during its use of the notified chemical:
- Bunding around the process area should be well maintained and only process drains should be within the area.

Disposal

- The notified chemical should be disposed of by licensed waste contractor to prescribed landfill or licensed liquid treatment plant.

Emergency procedures

- Spills/release of the notified chemical should be handled by manual collection and is contaminated then storage in labelled container and then disposal to 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(1) of the Act; if
- the importation volume exceeds three tonne per annum notified chemical; or

or

(2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY

DKKK (2000a) IR Analysis of notified chemical (4 December 2000) Osaka, Japan, Daichi Kigenso Kagaku Kogyo Co. Ltd.

DKKK (2000b) X-ray diffraction analysis of notified chemical (22 December 2000) Osaka, Japan, Daichi Kigenso Kagaku Kogyo Co. Ltd.

Estimation and Assessment of Substance Exposure (EASE). The EASE system was developed by the UK Health and Safety Executive in conjunction with the Artificial Intelligence Applications Institute. For a further description see: Marquart et al., Evaluation of Methods of Exposure Assessment for Premarket Notifications, TNO Report V 94.229 TNO Nutrition and Food Research (Zeist), 1994.

EHS (2004) Atmospheric Monitoring for Airborne Workplace Contaminants at Australian Automotive Air Pty Ltd Dorset Road Croydon April 1998 (Document No. 980414LD, 25 August 2004). Environmental Health Services (Australia) Pty Ltd. (Unpublished report provided by notifier)

European Commission (2003) Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances - Parts II and III.

IPCS (2002) Fluorides. Environmental Health Criteria 227. International Programme on Chemical Safety. World Health Organisation, Geneva. Accessed 10/11/04 at http://www.inchem.org/pages/ehc.html

Mensink et al (1995). Mensink, B J W G, Montforts, M, Wijkhuizen-Maslankiewicz L, Tibosch H & Linders J B H J. "Manual for summarising and evaluating the environmental aspects of pesticides. National Institute of Public Health and Environmental Protection. Bilthoven, The Netherlands.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2002) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Notox (1998a) Determination of the melting temperature of Notox Substance 81027. Project 239107. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998b) Determination of the density of Notox Substance 81027. Project 239129. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998c) Determination of the vapour pressure of Notox Substance 81027. Project 239131. Final report 19/10/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998d) Determination of the particle size of Notox Substance 81027. Project 239232. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998e) Determination of the flammability of Notox Substance 81027. Project 239175. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998f) Statement on the flammability (contact with water) of Notox Substance 81027. Project 239186. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998g) Statement on the pyrophoric properties of Notox Substance 81027. Project 239197. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998h) Determination of the relative self-ignition temperature of Notox Substance 81027. Project 239219. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998i) Statement on the explosive properties of Notox Substance 81027. Project 239208. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer)

Notox (1998j) Statement on the oxidising properties of Notox Substance 81027. Project 239221. Final report 17/11/98. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1998k) Assessment of Acute Oral Toxicity with Notox Substance 81027 in the Rat (Acute Toxic Class Method). Final report 28/9/98 NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1998l) Assessment of Acute Dermal Toxicity with Notox Substance 81027 in the Rat. Final report 28/9/98 NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1998m) Primary Skin Irritation/Corrosion Study with Notox Substance 81027 in the Rabbit. Final report 28/9/98 NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1998n) Acute Eye Irritation/Corrosion Study with Notox Substance 81027 in the Rabbit. Final report 28/9/98 NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1998o) Assessment of Contact Hypersensitivity to Notox Substance 81027 in the Albino Guinea Pig (Maximisation-Test). Final report 28/9/98 NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1998p) Evaluation of the mutagenic activity of Notox substance 81027 in the *Salmonella typhimurium* reverse mutation assay and the *Escherichia coli* reverse mutation assay (with independent repeat) Final report 28/8/98 NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1998q) Evaluation of the ability of Notox substance 81027 to induce chromosome aberrations in cultured peripheral human lymphocytes Final report 16/11/98 NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1998r) Determination of the surface tension of an aqueous solution of Notox substance 81027. Project 239142. Final report 17/11/98 NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999a) Determination of the Water Solubility of Notox Substance 81027. Project 239153. Final report 8/1/99. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999b) Determination of the Water Solubility of Notox Substance 81027. Project 278448. Final report 8/12/99. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999c) Determination of the partition coefficient (n-octanol/water) of Notox Substance 81027. Project 239164. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999d) Report Amendment Number 2. Determination of the partition coefficient (n-octanol/water) of Notox Substance 81027. Project 239164. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999e) 96 hour Acute Toxicity Study in Carp with Notox Substance 81027 (Static). Notox project 239333. Safety and Environmental Research B.V., 5203 DL 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999f) Acute Toxicity Study in *Daphnia magna* with Notox Substance 81027 (Static). Notox project 239344. Safety and Environmental Research B.V., 5203 DL 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999g) Freshwater Algal Growth Inhibition Test with Notox Substance 81027. Notox project 239355. Safety and Environmental Research B.V., 5203 DL 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999h) Activated Sludge Respiration Inhibition Test with Notox Substance 81027. Notox project 239366. Safety and Environmental Research B.V., 5203 DL 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999i) Subacute 28-day oral toxicity with Notox substance 81027. Notox project 239309. Final report 18/2/99. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999j) Micronucleus test in bone marrow cells of the mouse with Notox substance 81027. Notox project 239404. Final report 30/11/99. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

Notox (1999k) Determination of the surface tension of an aqueous solutuion of Notox substance 81027. Notox project 278459. Final report 1/12/99. NOTOX B.V., 's-Hertogenbosch, The Netherlands. (Unpublished report provided by notifer).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.