File No: STD/1148

May 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

CGL 777 MPA D

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

CGL 777 MPA D

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN 005 061 459)
235 Settlement Road
Thomastown VIC 3074

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 Name
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Detailed Composition
Detailed Import Quantity
Identity of Sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Italy 01-05-0415-01, 12 December 1991

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
CGL 210
TKA 40252
CGL 777 D
FAT 40'810/A

MARKETING NAME(S)
CGL 777 MPA D

SPECTRAL DATA

METHOD	UV/Visible, Infrared, Nuclear Magnetic Resonance and Mass Spectrometry
Remarks	Reference spectra were provided.
TEST FACILITY	Ciba (2001)

METHODS OF DETECTION AND DETERMINATION

METHOD High Performance Liquid Chromatography and Gas Chromatography
TEST FACILITY Ciba, Schweizerhalle, Switzerland

3. COMPOSITION

DEGREE OF PURITY
>94%

HAZARDOUS IMPURITIES
The notified chemical contains 4 known hazardous impurities, which are each present at typically <0.1% (0.5% max).

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as an 80% solution in 2-methoxy-1-methylethyl acetate, for reformulation into industrial products.

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

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

USE
The notified chemical is a UV absorber that will be used in specialised solvent-based lacquers, at a concentration of 2%, to stabilise and extend the life of the cured film.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
To be received at the notifier's facilities.

TRANSPORTATION AND PACKAGING
Imported by sea (by air rarely) in 20 kg plastic pails. Transported by road to blenders of specialised coatings and lacquers.

5.2. Operation description

Repacking
Any repacking of imported solution would take place at the notifier's warehouse in purpose-designed facilities.

Blending Operations
The imported solution will be weighed out to a decanting vessel and added to the blending vessel, or pumped to the blending vessel from a drum on scales. The blending vessel will also contain lacquer solvents, binder/s, pigment/s, fillers and additives.

Packing Blended Products
The blended products will be transferred in a closed system for automated packing into sealed end-use

cans.

Application of End Use Products
Blended products will be used as long-life lacquers for timber products at industrial sites. Following application to articles by painting or spraying, the lacquer will be dried at room temperature or elevated temperatures. This process causes the drying and curing of the notified chemical.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (per day)*	*Exposure Frequency (days/year)*
Re-packing	2	15-20 minutes	5
Warehousing	2	10-15 minutes	60-120
Weighing and blending	2	30-60 minutes	60-120
Laboratory testing	2	15-30 minutes	60-120
Transferring and packing-off	2	4-8 hours	60-120
Application of end use products	1-5/site	Unknown	Unknown

Exposure Details
Transport, Warehousing & Repacking
Exposure during transport and warehousing will only occur in the event of a major spill involving breach of import containers. Emergency procedures in the MSDS recommend personal protective equipment (PPE) including gloves, goggles and protective clothing.

Dermal exposure may occur during repacking of imported solutions. Ocular and inhalation exposure may also occur in the event of accidental splashes or spills. To limit exposure, facilities for the safe handling of chemicals will be used. Down-flow booths are used in which air flow is away from the operator and particulates are captured.

Weighing & Blending
Workers may be exposed while weighing out the imported solution and adding it to the blending vessel. Dermal exposure is the most likely route, with ocular exposure possible in the event of accidental splashes or spills. Exposure will be limited by local exhaust ventilation (LEV) and PPE including gloves, goggles and protective clothing.

Transferring and packing-off
Exposure during transfer of blended products for packing is expected to be very low, as transfer is in a closed system and packing-off is automated, into sealed end-use containers.

Application of End Use Products
Dermal, ocular and inhalation exposure may occur while using blended products, containing 2% notified chemical, as long-life lacquers for timber products at industrial sites. Blended lacquer products will be used in purpose designed equipment. Dermal exposure may occur during handling of end use products; dermal and ocular exposure may occur as a result of accidental splashes or spills; and inhalation exposure may occur as a result of overspray (mist) during application of the product. Exposure will be limited by the use of closed systems, or a combination of LEV and PPE including gloves, goggles and protective clothing.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. Local operations will include transport, storage and reformulation. Release to the environment may occur in the unlikely event of an accident during transport or if the packaging is damaged during handling and storage. Spilt notified chemical should be physically contained and collected, and will be disposed of by thermal decomposition in high temperature incinerators or sent to secure landfill. This represents a loss of less than 1% (maximum of 50 kg of notified chemical per annum).

During reformulation and filling there is the potential for release to the environment through spills. However, this should be contained by standard physical engineering means, and recycled if not contaminated, disposed of by thermal decomposition in high temperature incinerators or sent to secure landfill. Routine cleaning and maintenance of equipment used in the formulation and filling processes is expected to account for less than 1% of the total imported quantity of notified chemical (a maximum of 50 kg of notified chemical per annum).

The imported plastic containers are expected to contain 1% residual notified chemical (a maximum of 50 kg of notified chemical per annum), and are expected to be disposed of to secure landfill.

RELEASE OF CHEMICAL FROM USE

Of the total reformulated products containing the notified chemical, it is estimated that 30% will be supplied to industrial users in 200 L steel drums be applied to exterior timber doors, mainly by rollers, but also by spray. It is expected that minimal waste will be produced during the roller application process and this should not exceed 1% of the total import volume, i.e. a maximum of 50 kg per annum of notified chemical. Significantly more waste is expected to be produced by spray application, but this should not exceed 30% and is expected to be fully contained and disposed of to secure landfill as industrial waste. Some release could occur due to accidents resulting in damage to the containers during transport to the application facilities, but this is an unlikely scenario. In such cases, any spill would be contained, collected and after allowing to harden, be disposed of by incineration or to secure landfill.

The 200 L drums will be triple rinsed with solvent, with rinsings being retained for reuse, and very little (<0.02% or up to 1 kg) notified chemical remaining in the drum. The drums are sent to drum reconditioners where the residual notified chemical would be removed and thermally decomposed in a high temperature incinerator. Due to the very low solubility of the notified chemical, and the purported industrial use patterns, no release to the sewer is anticipated.

The major proportion (70%) of total reformulated product(s) containing the notified chemical will be supplied to the DIY market, in the form of high-performance exterior clear timber coatings in small containers. It is expected that this will be applied by brush mainly to timber exterior doors and window frames. Applicator equipment will be cleaned using solvents (most likely mineral turpentine), and after hardening will be disposed of to landfill. It is expected that a large proportion of the notified chemical will remain in the end-use containers, and after hardening over time will be disposed of to landfill. Due to its oil-based formulation, negligible quantities of notified chemical are expected to enter the sewer. Some release could occur due to an accident resulting in damage to the containers during transport or storage, however this is an unlikely scenario. In such cases, any spill would generally be contained, collected and after allowing for hardening, be disposed of to landfill.

5.5. Disposal

Residual notified chemical in the import containers will be disposed of to landfill. The main release during application will be through spray, which will be contained and disposed of to landfill. The majority of the imported chemical will be bound to timber, which will eventually be disposed of to landfill, recycled or incinerated. Residual chemical in the end-use product 200 L drums will be thermally decomposed in a high-temperature incinerator. Residual chemical in the small DIY containers will be disposed of to landfill.

5.6. Public exposure

Exposure during transport can only occur in the event of a major accident involving breach of import containers. Exposure during blending and application operations is only likely in the event of a major spill. Emergency procedures specified in the MSDS will substantially limit public exposure in such an event.

The notified chemical will be available to the public as a cured coating on finished timber products. The notified chemical will not be biologically accessible in this form, as it will be fixed in a cured polymer matrix. Thus no exposure is expected from coated finished articles.

It is estimated that 70% of the notified chemical will be available to the public in high performance exterior clear timber lacquers for DIY end use. It is expected that this will be applied, mainly by brush, to timber exterior doors and window frames. It is unlikely that personal protective equipment

(PPE) will be worn. Dermal exposure is likely, with occasional ocular exposure also possible, from drips and splashes during application. Dermal exposure is also likely, with possible ocular exposure, during cleaning of brushes. In this case, the hazard will be principally associated with the solvent used for cleaning.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Orange liquid

Melting Point/Freezing Point -20ºC

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Combination of visual test and thermal analysis.
TEST FACILITY RCC (2002a)

Boiling Point >300ºC at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Thermal analysis method.
Decomposition occurred before boiling, from 300ºC.
TEST FACILITY RCC (2002b)

Density 1081 kg/m^3 at 70ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Oscillating densitometer method.
TEST FACILITY RCC (2002c)

Vapour Pressure 1.8 x 10^{-16} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Calculated using the calculated boiling point (Meissner's method) of 860ºC (modified Watson Correlation), because the vapour pressure was expected to be below the measurement range of an experimental determination.
TEST FACILITY RCC (2002d)

Water Solubility <6 x 10^{-4} g/L at 20ºC and pH 6.5

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Shake Flask Method. Analytical method: High Performance Liquid Chromatography (HPLC) with UV detection.

A preliminary test using a simplified flask method with abbreviated equilibration times determined solubility as <0.6 mg/L. In the main test, the water solubility was determined to be below the limit of detection.
TEST FACILITY RCC (2002e)

Fat Solubility 8450 mg/100 g ± 70 mg/100 g HB 307 at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances; and
Directive 84/449 EEC, A.7
Remarks Analytical Method: HPLC.

In a preliminary test the miscibility of the test item and the fat was tested. Since the test item was not miscible with the standard fat in a 1:1 ratio, the main test was performed.

The fat solubility was not corrected for the purity of the test item.

TEST FACILITY RCC (2002l)

Hydrolysis as a Function of pH Not determined

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

Remarks According to EEC directive, the procedure C7 can only be used on water-soluble compounds. As the substance has no significant solubility in the different solvent systems available even with the use of different solubilisers (including acetone, DMSO and THF), testing could not be carried out.

TEST FACILITY RCC (2002f)

Partition Coefficient (n-octanol/water) log Pow = 11.4 at 20ºC (Tris-isomer)
log Pow = 15.3 at 20ºC (Tetra-isomer)

METHOD OECD TG 107 and 117 Partition Coefficient (n-octanol/water – P_{OW} Calculations Methods part).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks Due to the physico-chemical properties of the notified chemical, the HPLC method and flask shaking method were not applicable. Therefore the partition coefficient was calculated using the individual solubility in n-octanol and in water resulting in a log P_{OW} >> 6. Additionally, an estimation was performed using a model calculation based on the theoretical fragmentation of the molecule into substructures.

TEST FACILITY RCC (2002g)

Surface Tension 67 mN/m at 20ºC ± 0.1ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.

Remarks Concentration: 90% of saturation. The tensiometer method was used. Based on the criteria outlined in the OECD Guideline, the notified chemical is not a surface active substance.

TEST FACILITY RCC (2002m)

Adsorption/Desorption – screening test
log K_{oc} = 4.7 at 29°C (1st peak)
log K_{oc} = 6.5 at 29°C (2nd peak)
log K_{oc} = 7.3 at 29°C (3rd peak)
log K_{oc} = 7.8 at 29°C (4th peak)
log K_{oc} = 8.2 at 29°C (5th peak)

METHOD OECD TG 121 – Estimation of the Adsorption Coefficient KOC on Soil and Sewage Sludge using HPLC
EC Directive 2001/59 C.19 Estimation of the Adsorption Coefficient KOC on Soil and Sewage Sludge using HPLC

Remarks These results indicate that the notified chemical is immobile and remains preferably in soil. The retention time for one peak was greater than the most strongly absorbed reference, DDT.

This conclusion is supported by an estimation using a regression equation based on the water solubility, and relating the K_{OC} with the water solubility.

$$\log K_{OC} = -0.55 \log S + 3.64$$

This resulted in an estimated K_{OC} of >5729.

This is further supported by an addition estimation using a regression equation based on the octanol/water partition coefficient, relating the K_{OC} with P_{OW}.

$$\log K_{OC} = 0.55 \log S + 1.377$$

This resulted in a K_{OC} value of 3.79 x 10^7, confirming that the notified chemical is immobile in soils.

TEST FACILITY RCC (2002h)

Dissociation Constant

METHOD Hammett equation.
Remarks The notified chemical is not dissociated or protonated in the environmentally relevant pH range (5 to 8). The hydroxyl group of the phenol is dissociated in the basic range of pH.
TEST FACILITY RCC (2002i)

Particle Size Not applicable to a liquid.

Flash Point 177°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Pensky-Martens closed cup method.
TEST FACILITY RCC (2001a)

Flammability Limits Not determined

Autoignition Temperature 420°C

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks None
TEST FACILITY RCC (2002j)

Explosive Properties Not explosive

METHOD Estimation based on UN Recommendations on the Transport of Dangerous Goods (Manual of Tests and Criteria, Annex 6, Orange Book, 3rd edition, 1999).
Remarks Appraisal of molecular structure indicates no risk of rapid decomposition. No groups associated with explosive properties were present.

The oxygen balance was estimated to be < -200.

Using Differential Scanning Calorimetry, the total decomposition energy was found to be approximately 57 J/g, far below the UN limit of 500 J/g. The onset of the exothermic peak was above 300°C.
TEST FACILITY RCC (2002k)

Oxidising Properties Non oxidising

METHOD Oxidising properties screened based on UN Recommendations on the Transport of Dangerous Goods (Manual of Tests and Criteria, Annex 6, Orange Book, 3rd edition, 1999).
Remarks The classification procedure using experimental testing was not applied, as the notified chemical is an organic compound that contains oxygen chemically bonded only to carbon and hydrogen.

	Using the UN criteria, the notified chemical was judged to be non-oxidising.
TEST FACILITY	RCC (2002n)

Reactivity

Remarks	The notified chemical is does not demonstrate explosive or oxidising properties, and is expected to be stable at normal operating temperatures.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 > 2000 mg/kg bw Low toxicity
Rat, acute dermal	LD50 > 2000 mg/kg bw Low toxicity
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Predicted to be non irritating
Mouse, skin sensitisation – LLNA	No evidence
Rat, repeat dose oral toxicity – 28 days.	NO(A)EL 800 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro chromosome aberration	Non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

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/HanBrl: WIST (SPF)
Vehicle	Polyethylene glycol (PEG) 300
Remarks - Method	None.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity	Slightly ruffled fur in 2 females on the first test day.
Effects in Organs	No adverse macroscopic observations at necropsy.
Remarks - Results	None.

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

TEST FACILITY — RCC (2001b)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical.

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

Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	Corn oil.
Type of dressing	Semi-occlusive.
Remarks - Method	None.

RESULTS

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

1	5/sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Slight erythema was observed in 1 female and 3 males on test day 2, and in an additional female on days 2 and 3.
Signs of Toxicity - Systemic	None.
Effects in Organs	No adverse macroscopic observations at necropsy.
Remarks - Results	None.

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

TEST FACILITY RCC (2002o)

7.3. Irritation – skin

TEST SUBSTANCE Notified chemical.

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
Vehicle	None.
Observation Period	14 days.
Type of Dressing	Semi-occlusive.
Remarks - Method	0.5 g notified chemical was used, as the dose specified in test guidelines for very viscous test material.

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	1.33	0.67	0.67	2	96 hours	1
Oedema	0	0	0	0	-	0

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

Remarks - Results	Residue of test material strongly adhered to the test site and was evident on the skin of all animals throughout the 14 day observation period.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY RCC (2002p)

7.4. Irritation – eye

Not determined.

Remarks	The notified chemical is highly viscous and could not be applied to the rabbit eye using any method in the relevant test guidelines. No vehicle or solvent could be found that did not have irritating properties.

CONCLUSION Based on skin irritation results (RCC, 2002p), the notified chemical is not expected to present a significant hazard to eyes. However, the potential for inherent eye-irritating potential cannot be completely excluded.

TEST FACILITY Expert Statement, RCC (2002q)

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

TEST SUBSTANCE Notified chemical.

METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay.
Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	4:1 (v/v) acetone:olive oil
Remarks - Method	Positive control: alpha-hexylcinnamaldehyde. Positive controls were not conducted concurrent with this experiment; historical controls from several months previously were used to validate the assay.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	649	-
5	731	1.1
10	525	0.8
25	1287	2.0
Positive Control		
0	523	-
5	1316	2.5
10	1948	3.7
25	5082	9.7

Remarks - Results	A previous version of the notified chemical was initially classified as a sensitiser on the basis of a maximisation test in guinea pigs. However, after addition of an extra distillation step in production of the notified chemical in the form in which it will be introduced (CGL 777 MPA D), this study demonstrated that it could no longer be classified as a sensitiser. This is attributed to a reduction in the concentration of hazardous impurities, one of which is a known sensitiser.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	RCC (2003)

7.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EEC, Method B.7 Repeated Dose (28 Days) Toxicity (Oral)
Species/Strain	Rat/Wistar (SPF)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 Dose regimen: 7 days per week Post-exposure observation period: 14 days for recovery groups
Vehicle	Corn oil
Remarks - Method	A 5-day range-finding test (RCC, 2002r) was conducted prior to the 28-day oral toxicity study. In the range-finding study, dose levels of 200, 600 and 1000 mg notified chemical/kg body weight were administered daily for 5 days by oral gavage to SPF Wistar rats. 2 animals/sex received each dose. Controls received vehicle only (corn oil).

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	800	0/10
V (control recovery)	5/sex	0	0/10
VI (high dose recovery)	5/sex	800	0/10

Mortality and Time to Death
All animals survived until scheduled necropsy.

Clinical Observations
No treatment-related adverse clinical signs were observed during the study.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment-related adverse effects were observed in haematological, biochemical or urinalysis parameters after 28 days (non-recovery groups) or 42 days (recovery groups). Several incidences of statistically significant differences between treatment and control groups were not considered biologically significant due to the magnitude of the changes and the lack of any clear dose response relationship.

Effects in Organs
Macroscopic Findings
Low dose females had significantly heavier livers, while both low and high dose females had significantly higher relative liver weights, compared to vehicle controls. High dose females had significantly higher relative adrenal weights compared to controls. High dose recovery males had significantly higher relative heart weights compared to controls. In the absence of supporting histopathological results, or any indication of a dose response relationship, these were not considered to be treatment-related adverse effects.

No other treatment-related macroscopic effects were observed at necropsy.

Microscopic Findings
Differences in fatty changes (unspecified) were noted in the liver of high dose females and in the adrenals of mid and high dose males, compared to relevant controls. However, there was no dose response, and these observations were not considered to be adverse. No treatment-related changes were observed in either of the recovery groups.

Remarks – Results
In the 5-day range-finding test (RCC, 2002r), all animals survived to the end of the study. No clinical signs were evident at any dose level tested. Males treated with 600 or 1000 mg/kg bw/day had markedly lower absolute and relative thymus weights compared to controls, and males treated with 1000 mg/kg bw/day had slightly higher absolute and relative spleen weights compared with controls. It was not reported whether these findings were statistically significant. No other treatment-related macroscopic signs were reported. Dose levels for the 28-day study were based on these findings.

CONCLUSION
On the basis of this study a No Observed Effect Level (NOEL) could not be established. The No Observed (Adverse) Effect Level (NO(A)EL) was established as 800 mg/kg bw/day, based on the lack of a dose response or clear pathological indication for any of the effects observed in the treated groups.

TEST FACILITY RCC (2002s)

7.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

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 and Pre-incubation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbital/β-naphthoflavone-induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 33-5000 µg/plate b) Without metabolic activation: 33-5000 µg/plate
Vehicle	Dimethylsulfoxide
Remarks - Method	The first test was performed according to the plate incorporation procedure. The second test was performed according to the pre-incubation procedure.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		2500	1000	None observed
Test 2		None observed	1000	None observed
Present				
Test 1		1000	1000	None observed
Test 2		5000	1000	None observed

Remarks - Results	Positive control mutagens showed statistically significant increases in induced revertant colonies and negative controls were within historical limits.

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

TEST FACILITY RCC (2002t)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

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	Chinese Hamster V79 cells
Metabolic Activation System	Phenobarbital/β-naphthoflavone-induced rat liver S9 fraction.
Vehicle	Acetone
Remarks - Method	None.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hours)*	*Harvest Time (hours)*
Absent			
Test 1	10, 20*, 40*, 80*, 160, 320	4	18
Test 2	10, 20, 40*, 80*, 160*, 320	18	18
	40*, 80*, 160, 320	28	28
Present			
Test 1	10*, 20*, 40*, 80, 160, 320	4	18
Test 2	10, 20*, 40*, 80*, 160, 320	4	28

*Cultures selected for metaphase analysis.

RESULTS

Metabolic	*Test Substance Concentration (µg/mL) Resulting in:*

Activation	*Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None observed up	None observed	80	
Test 2	to 5000	None observed	80	40 and 80*
Present				
Test 1	None observed up	None observed	40	
Test 2	to 5000	None observed	80	

*Significant increases in aberrant cells were observed after 18 hours of treatment with 40 and 80 µg/mL notified chemical, in the absence of metabolic activation, compared to solvent control plates. However, these increases were within the historical control data range, and were therefore not considered biologically significant.

Remarks - Results	Positive control mutagens induced statistically and biologically significant increases in cells with structural chromosome aberrations and negative controls were with the historical range.
CONCLUSION	The notified chemical was not clastogenic to Chinese Hamster V79 cells treated in vitro under the conditions of the test.
TEST FACILITY	RCC (2002u)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.

Inoculum: Aerobic activated sludge from a wastewater treatment plant (ARA Ergolz II, Fűllinsdorf, Switzerland) treating predominantly domestic wastewater.

Exposure Period: 28 days

Auxiliary Solvent: None

Analytical Monitoring: Inorganic carbon concentration was analysed using a Shimadzu TOC-500 Analyser.

Remarks - Method: The percent biodegradation of the test item was calculated based on a total carbon content (TOC) of 0.67 mg C/mg test item.

The test was validated by referencing to several control tests. These included an abiotic control poisoned with 10 mg/L mercury dichloride, toxicity and procedure controls using the reference substance, sodium benzoate, an inoculum control, and an abiotic control blank poisoned with 10 mg/L mercury dichloride.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	-1.0	2	36.4
5	-1.7	5	50.0
7	-0.9	7	59.9
9	-0.9	9	64.2
12	0.0	12	65.6
14	7.5	14	70.2
19	0.8	19	75.1
23	2.6	23	76.6
27	2.3	27	75.6
28	3.7	28	78.6

Remarks - Results: Small amounts of CO_2 were found in the second absorber flask on day 14 and day 28. The CO_2 production of the test item in the test medium was within the range of the inoculum controls. Therefore, the amount of CO_2 in the second absorber flasks at the sampling dates between day 0 and day 14 and between day 14 and day 28 was extrapolated from the amount of CO_2 found in the second absorber flask on day 14 and day 28, respectively, assuming a linear increase from day 0 to day 14 and from day 14 to day 28. Consequently, the CO_2 production in mg C and the percentage degradation within these time periods were calculated by the sum of the amount of CO_2 found in the first absorber flasks and the extrapolated amount in the second absorber flasks.

As the reference sodium benzoate was biodegraded by 70% on day 14, the test was considered valid.

There was no inhibition effect on sludge micro-organisms.

CONCLUSION: The notified chemical was found to be not biodegradable under the test conditions within 28 days.

TEST FACILITY: RCC (2002v)

8.1.2. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 305 C - Bioconcentration: Flow-through Fish Test.
Species	Carp (*Cyprinus carpio*)
Exposure Period	Exposure: 28 days
Auxiliary Solvent	Polyoxyethylenesorbitanmonooleate (Tween 80) at 2 mg/L for high concentration and 0.2 mg/L for low concentration
Concentration Range	Nominal: 0.5 mg/L Actual: 0.05 mg/L
Analytical Monitoring	Not specified
Remarks - Method	Water hardness = 87 mg/L $CaCO_3$ pH 6.7 – 6.9 The calculations were made using the steady state method.
RESULTS	
Bioconcentration Factor	<= 11 whole body for "tris"
Remarks - Results	Full test report not available.

For other peaks:	High Conc.	Low Conc.
Bis	2 – 7	<14
Tris isomer deriv.	4 – 9	<37
Tris deriv.	3 – 11	<12
Tetra deriv. 3-7	<11	

CONCLUSION	Based on the details contained in the notifier's report, the notified chemical was found to not bioaccumulate under the test conditions within 28 days.
TEST FACILITY	Institute of Ecotoxicology Co. Ltd. Saitama

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – 96-Hour Semi-Static EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - 96-Hour Semi-Static.
Species	Zebra fish *(Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	A limit test was performed in accordance with the EU Commission Directive 92/69/EEC to demonstrate that the test item had no toxic effect on the Zebra fish up to the highest concentration that could be dissolved in the test water at a loading rate of 100 mg/L (Water Accommodated Fraction (WAF)). As the test concentration of the notified chemical in the test medium could not be analytically measured, the stability of the notified chemical in test water could not be confirmed. Therefore, a semi-static test procedure was chosen.

A supersaturated dispersion with a loading rate of 100 mg/L was prepared daily by dispersing the notified chemical in test water by intense stirring for seven days to dissolve a maximum concentration of the notified chemical in test water. Then, the dispersion of the notified chemical was filtered through a membrane filter (pore size 0.45 μm) and the undiluted filtrate was used as test medium. No remarkable observations were made concerning the appearance of the test medium, which was a clear solution throughout the whole test duration. All other test medium parameters, including pH and temperature remained within test guidelines.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
100	<0.01	10	0	0	0	0	0

96 hour LC50	>0.01 mg/L (measured WAF).
96 hour NOEC	=0.01 mg/L (measured WAF).
Remarks – Results	In the control and at the loading rate of 100 mg/L no mortality or visible abnormalities were determined during the test period of 96 hours. However, as the maximum concentration fish were exposed to was <0.01 mg/L, the results must be written in this form.

CONCLUSION The notified chemical had no acute toxic effects on zebra fish up to its solubility limit in test water under the test conditions.

TEST FACILITY RCC (2002w)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – 48-Hour Immobilization test, Static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - 48-Hour Immobilization test, Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	A limit test was performed in accordance with the EU Commission Directive 92/69/EEC to demonstrate that the test item had no toxic effect on *Daphnia magna* up to the highest concentration which could be dissolved in the test water at a loading rate of 100 mg/L (WAF). A supersaturated dispersion with a loading rate of 100 mg/L was prepared by dispersing the notified chemical in test water by intense stirring for 96 hours at room temperature in the dark to dissolve a maximum concentration of the notified chemical in test water. Then, the dispersion of the notified chemical was filtered through a membrane filter (pore size 0.45 μm) and the undiluted filtrate was used as test medium. No remarkable observations were made concerning the appearance of the test medium. The test medium was a clear solution throughout the whole test duration. No precipitate was observed throughout the whole test duration. The analytically measured test item concentration in the analysed test medium samples was below the limit of quantification of the analytical method at the start and the end of the test.

All other test medium factors, including pH and temperature remained within test guidelines.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
100	<0.010	20	0	0

48 hour LC50 >0.01 mg/L (measured Water Accommodated Fraction).
48 hour NOEC =0.01 mg/L (Water Accommodated Fraction).
Remarks - Results In the control and at the loading rate of 100 mg/L no immobilised test organisms were determined during the test period of 48 hours. However, as the maximum concentration Daphnids were exposed to was <0.01 mg/L the results must be written in this form.

CONCLUSION The notified chemical had no acute toxic effects on *Daphnia magna* up to its solubility limit in water under the test conditions.

TEST FACILITY RCC (2002x)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test and
EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species *Scenedesmus subspicatus*.
Exposure Period 72 hours
Concentration Range Nominal: 0.32, 1.0, 3.2, 10.0, 32.0, and 100 mg/L
Auxiliary Solvent None
Water Hardness 24 mg $CaCO_3$/L
Analytical Monitoring None
Remarks - Method Since the notified chemical was not soluble in water, six individual mixtures with loading rates of nominal 0.32, 1.0, 3.2, 10.0, 32.0, and 100 mg/L were prepared by dispersing the notified chemical in water by intense stirring for 96 hours at room temperature in the dark to dissolve a maximum concentration of the notified chemical in test water. Then, the dispersion of the notified chemical was filtered through a membrane filter (pore size 0.45 µm) and the undiluted filtrate was used as test medium.

The analytically measured notified chemical concentration in the analysed test medium with the loading rate of 100 mg/L was 15 µg/L at the start and the end of the test.

All other test medium factors, including pH and temperature remained within test guidelines.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at72 h	*NOE_bC mg/L at72 h*	*E_rC50 mg/L at 72 h*	*NOE_rC mg/L at 72 h*
>0.015	0.015	>0.015	0.015

Remarks - Results The mean algal cell densities in the test medium up to and including the highest loading rate of 100 mg/L (mean measured 15 µg/L) were at all counting dates identical with or even slightly higher than those in the

parallel control cultures. Thus, the notified chemical clearly had no inhibitory effect on the growth of *Scenedesmus subspicatus* during the exposure period of 72 hours at a loading rate of 100 mg/L WAF (mean measured concentration 15 µg/L). This loading rate was therefore determined as the 72-hour NOEC.

CONCLUSION The notified chemical has no toxic effect on algae up to its solubility limit in test water.

TEST FACILITY RCC (2002y)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test, and EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum Aerobic activated sludge from a wastewater treatment plant (ARA Ergolz II, Fűllinsdorf, Switzerland) treating predominantly domestic wastewater.

Exposure Period 3 hours

Concentration Range Nominal: 6.3, 12.5, 25, 50, and 100 mg/L

Remarks – Method According to the results of a pre-test, no stock solution could be prepared due to the low water solubility of the notified chemical. The notified chemical was mixed into tap water by ultrasonic treatment over 15 minutes and intense stirring over 24 hours at room temperature in the dark to dissolve the maximum amount of the test item and/or disperse it as homogeneously as possible. The reference substance 3,5-dichlorophenol was used to validate the test.

RESULTS

IC50 >100 mg/L

NOEC =100 mg/L

Remarks – Results Down to the lowest test concentration of 6.3 mg/L the notified chemical was not completely dissolved in the test medium. Thus, all test concentrations were clearly above the water solubility limit of the notified chemical under the present test conditions.

Up to and including the concentration of 100 mg/L (nominal) the notified chemical had no significant inhibitory effects (<15%) on the respiration rate of activated sludge after the incubation period of 3 hours.

The 3-hour EC50 of the reference item 3,5-dichlorophenol (positive control) was calculated to be 15 mg/L with 95% confidence limits from 11 to 20 mg/L. The 3-hour EC50 is within the guideline-recommended range, confirming the suitability of the activated sludge used and validating the test.

CONCLUSION The notified chemical does not significantly inhibit the respiration rate of activated sludge.

TEST FACILITY RCC (2002z)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported into Melbourne, then distributed to paint blenders. The notified chemical will be mixed with other ingredients to form clear coat paint. It is expected that 70% of the formulated product will enter the DIY market. The formulated product is expected to be applied to exterior timber doors and window frames by brush, where the notified chemical will be held in an inert film matrix bound to the substrate once cured by drying. Application equipment will be cleaned using mineral turpentine, which is expected to be disposed of to landfill. Residual formulated product containing the notified chemical in containers is also expected to be disposed of to landfill.

The remaining 30% of the formulated product is expected to enter the industrial market, and be applied to such products as manufactured exterior doors. It is possible in this case for spray or roller coating to be used. Waste generated from the industrial application process, in particular that arising from overspray, would be disposed of as industrial solid waste to secure landfill, where the notified chemical would remain locked in the cured coating particles.

Nearly all imported notified chemical will be contained in an inert film matrix bound to timber. Its fate will be linked to that of the treated timber, which will eventually be disposed of to landfill, where it is expected that the notified chemical will associate with soil and slowly degrade by biotic and abiotic processes to oxides of carbon and hydrogen.

As there is expected to be limited release to the aquatic compartment, a Predicted Environmental Concentration (PEC) cannot be derived.

Residual notified chemical remaining in containers will either be thermally decomposed in high-temperature incinerators, or disposed of to landfill. Potential for environmental exposure is very low due to the nature of the product and its expected use.

9.1.2. Environment – effects assessment

The results of the ecotoxicological studies indicate that the notified chemical is not expected to be acutely toxic to aquatic life up to the limit of its water solubility. All No Observed Effect Concentrations (NOECs) were determined to be <0.015 mg/L. A Predicted No Effect Concentration (PNEC) was not able to be derived

9.1.3. Environment – risk characterisation

Due to the limited release of the product to the aquatic compartment and the very low water solubility of the notified chemical, neither a PEC nor PNEC could be derived. However, the notified chemical is clearly not acutely toxic up to the limits of water solubility. Therefore, the environmental risk from the reported use pattern of the notified chemical is acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport, Warehousing

Occupational exposure to the notified chemical during transport and storage of imported solution containing 80% notified chemical is only likely in the event of accidental container spillage involving breach of import packaging. Exposure in these circumstances is expected to be infrequent and acute, and can be limited by use of appropriate personal protective equipment (PPE) during clean-up operations.

Repacking; Formulation

During repacking, and during weighing out and addition of imported solution to the blending vessel, dermal exposure is the most likely route. Ocular exposure may also occur as a result of accidental splashes or spills. Exposure will be minimal when limited by engineering controls including local exhaust ventilation (LEV) and PPE including gloves, goggles and protective clothing.

Dermal exposure during repacking, weighing out and addition of imported solution to the blending vessel was estimated using the EASE model (HSE, 1994). Assuming non-dispersive use and intermittent, direct handling, estimated exposure is 0-0.1 mg/cm^2/day. This equates to 0-0.08 mg/cm^2/day of the notified chemical. Therefore, for a 70 kg worker with surface area for hands at 820 cm^2 and forearms at 1140 cm^2, and assuming 100% absorption, systemic exposure is estimated to be 0-2.24 mg/kg bw/day of the notified chemical. This estimate would be reduced by the expected exposure duration: up to 20 minutes/day for repacking and up to 60 minutes/day for weighing and blending.

In the presence of controls such as LEV or PPE, estimated exposure is "very low".

During transfer of blended products for packing, exposure is expected to be very low, due to closed systems, automated packing-off into sealed end-use containers, and the low concentration (2%) of notified chemical in end use products.

Application of End Use Products

During application of end use lacquer products to timber articles, dermal exposure may occur during handling of end use products, and ocular exposure may occur as a result of accidental spills or splashes. However, exposure is expected to be low due to the low concentration (2%) of notified chemical in end use products, and use of PPE including gloves, goggles and protective clothing.

Inhalation exposure may occur during spraying of end use products onto timber articles, as a result of overspray or mist. Exposure will be limited by the use of LEV, personal respiratory protective equipment, and/or closed systems.

Using the EASE model, and assuming aerosols are produced and LEV is present, the estimated inhalation exposure during manual handling is 3983-7967 mg/m^3, which equates to 80-159 mg/m^3 notified chemical. In a closed system, estimated inhalation exposure is 0-4 mg/m^3, which equates to 0-0.08 mg/m^3 notified chemical. Therefore, for a 70 kg worker with an inhalation rate of 1.3 m^3/hour and 4 hours of exposure/day, systemic exposure is estimated to be 5.9-11.8 mg/kg bw/day if LEV is the only control measure used, or 0-0.006 mg/kg bw/day for a closed system.

9.2.2. Public health – exposure assessment

Exposure in the event of a major transport accident or industrial spill would be infrequent and acute, and limited by emergency procedures specified in the MSDS.

Exposure to the notified chemical in finished articles is expected to be negligible, as the notified chemical will be in a cured polymer matrix.

The major route of public exposure will be to DIY exterior timber lacquer products. Dermal exposure is likely, with ocular exposure possible, during application by brush and cleaning of brushes. It is not likely that PPE will be worn. However, exposure to the notified chemical will be limited by its low concentration (up to 2%) in end use products.

9.2.3. Human health – effects assessment

The notified chemical is of low acute oral and dermal toxicity in rats. Acute inhalation toxicity data were not provided.

The notified chemical is slightly irritating to rabbit skin. Eye irritation data were not provided. There was no evidence of sensitisation in a local lymph node assay (LLNA) in mice.

The notified chemical is not mutagenic in a bacteriological test and not clastogenic to Chinese Hamster V79 cells in vitro.

In a 28-day repeat dose toxicity study in rats, a NOEL could not be established. However, no adverse effects were found up to the highest dose tested, thus the NO(A)EL was established to be 800 mg/kg bw/day.

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

9.2.4. Occupational health and safety – risk characterisation

Repacking; Formulation

During repacking, weighing out and addition of imported solution to the blending vessel, dermal exposure was estimated to be 0-2.24 mg/kg bw/day for direct handling, and was too low to for a quantitative estimate in the presence of controls such as LEV or PPE. The margin of exposure (MOE) for chronic toxicity is based on a NOAEL of 800 mg/kg bw/day. MOE greater than or equal to 100 are considered to be acceptable to account for intra- and inter-species differences. For dermal exposure, the MOE is calculated to be >350 for direct handling. Therefore the risk of chronic systemic toxicity using modelled worker data is acceptable during repacking and formulation.

Application of End Use Products

During spray application of end use lacquer products to timber articles, inhalation exposure was estimated to be 5.9-11.8 mg/kg bw/day if LEV is the only control measure used, or 0-0.006 mg/kg bw/day for a closed system. Based on a NOAEL of 800 mg/kg bw day, the MOE is calculated to be 68-136 if LEV only is used, or >100,000 for closed systems. Therefore the risk of chronic systemic toxicity using modelled worker data is borderline unacceptable if LEV is the only measure used to control exposure from overspray, and acceptable for closed systems. Workers will require personal respiratory protection as well as LEV when applying lacquer products by spray in open systems.

9.2.5. Public health – risk characterisation

The likelihood of exposure of the public to DIY lacquer products containing the notified chemical is high. However, the available toxicological data indicate that no hazards have been determined for the notified chemical, and the concentration of notified chemical in end use products is low (up to 2%). Thus the overall risk to the public is expected 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 not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described, provided personal respiratory protection as well as LEV is used when applying lacquer products by spray in open systems.

10.3.2. Public health

There is No Significant Concern to public health when used as a component (2%) of lacquers sold for DIY use.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the imported solution containing 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 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the imported solution 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

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in lacquer products applied by spray:
  - Closed systems where possible.
  - LEV if open systems are used.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in lacquer products applied by spray:
  - Personal respiratory protection as well as LEV if open systems are used.

  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 by thermal decomposition in high temperature incinerators or to secure landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by containing and soaking up all residues in inert absorbent material. This should be scooped into marked containers for disposal as chemical waste.

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.

13. BIBLIOGRAPHY

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 (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.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

RCC (2001a) Determination of the Flash Point of TKA 40252 (CGL 210), Study Number 838800, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2001b) TKA 40252 (CGL 210): Acute Oral Toxicity Study in Rats, Study Number 838811, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002a) Determination of the Freezing Point/Freezing Range of TKA 40252 (CGL 210), Study Number 841541, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002b) Determination of the Boiling Point/Boiling Range of TKA 40252 (CGL 210), Study Number 841542, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002c) Determination of the Density of TKA 40252 (CGL 210), Study Number 841543, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002d) Determination of the Vapour Pressure of TKA 40252 (CGL 210), Study Number 841544, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002e) Determination of the Water Solubility of TKA 40252 (CGL 210), Study Number 841546, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002f) Hydrolysis Determination of TKA 40252 (CGL 210) at Different pH Values, Study Number 841568, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002g) Determination of the Partition Coefficient (n-Octanol/Water) of TKA 40252 (CGL 210), Study Number 841548, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002h) Estimation of the Adsorption Coefficient of TKA 40252 (CGL 210) on Soil Using High Performance Liquid Chromatography (HPLC), Study Number 844890, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002i) Calculation of the Dissociation Constant of TKA 40252 (CGL 210), Study Number 841552, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002j) Determination of the Auto-Ignition Temperature of TKA 40252 (CGL 210) According to EC Council Directive 92/69/EEC, Part.A.15. Project Number 844660, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002k) Expert Statement on the Explosive Properties of TKA 40252 (CGL 210), Study Number 841549, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002l) Determination of the Fat Solubility of TKA 40252 (CGL 210), Study Number 841547, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002m) Determination of the Surface Tension of an Aqueous Solution of TKA 40252 (CGL 210), Study Number 841545, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002n) Expert Statement on the Oxidizing Properties of TKA 40252 (CGL 210), Study Number 841551, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002o) TKA 40252 (CGL 210): Acute Dermal Toxicity Study in Rats, Study Number 841553, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002p) TKA 40252 (CGL 210): Primary Skin Irritation in Rabbits (4-Hour Semi-Occlusive Application), Study Number 841554, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002q) Expert Statement, TKA 40252 (CGL 210): Primary Eye Irritation Study in Rabbits, Study Number 841555, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002r) TKA 40252 (CGL 210): 5-Day Range-Finding Oral Toxicity (Gavage) Study in the Wistar Rat, Study Number 841558, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002s) TKA 40252 (CGL 210): 28-Day Oral Toxicity (Gavage) Study in the Wistar Rat, Study Number 841557, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002t) Salmonella typhimurium and Escherichia coli Reverse Mutation Assay with TKA 40252 (CGL 210), Study Number 841559, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2002u) *In Vitro* Chromosome Aberration Test in Chinese Hamster V79 Cells with TKA 40252 (CGL 210), Study Number 841560, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC Ltd (2002v) Ready Biodegradability of TKA 40252 (CGL 210) in a CO_2 Evolution (Modified Sturm) Test, Study Number 841567, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC Ltd (2002w) Acute toxicity of TKA 40252 (CGL 210) to Zebra Fish (*Brachydanio rerio*) in a 96-hour semi-static test, Study Number 841561, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC Ltd (2002x) Acute toxicity of TKA 40252 (CGL 210) to *Daphnia magna* in a 48-hour immobilization test, Study Number 841565, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC Ltd (2002y) Toxicity of TKA 40252 (CGL 210) to *Scenedesmus subspicatus* in a 72-hour algal growth inhibition test, Study Number 841565, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC Ltd (2002z) Toxicity of TKA 40252 (CGL 210) to activated sludge in a respiration inhibition test, Study Number 841672, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (2003) TKA 40252/3 (CGL 777 MPA): Local Lymph Node Assay (LLNA) in Mice (Identification of Contact Allergens), Study Number 848990, RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

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.