File No: STD/1175

January 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

TINUVIN®479

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
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

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
NICNAS

TABLE OF CONTENTS

TINUVIN®479

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)
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 Identity
Spectral Data
Purity and Identity of Impurities
Import volume
Identity of Recipients

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)
No.

NOTIFICATION IN OTHER COUNTRIES
Korea (KECI) – 2004

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
TINUVIN®479

METHODS OF DETECTION AND DETERMINATION

METHOD	Methods used for the quantitative determination of the notified chemical and impurities were High Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC). The identity of the notified chemical was determined using ^{1H}-Nuclear Magnetic Resonance (NMR), Mass Spectroscopy, Infrared Spectroscopy, UV-Visible Spectroscopy and Elemental Analysis.
Remarks	Spectral data provided by the notifier were consistent with the proposed structure..
TEST FACILITY	Ciba Specialty Chemicals (2003)

3. COMPOSITION

DEGREE OF PURITY
>90%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported in 20kg fibreboard cartons with polyethylene liners as neat chemical (powder).

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

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

USE
The notified chemical will be used as an additive ultra-violet (UV) light absorber (to counteract long term breakdown by UV light) at level of 1-3% in surface coatings for automotive use only.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne, VIC

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be used at up to 3 production sites in Australia for the preparation of surface clear coatings.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 20 kg fibreboard cartons with polyethylene inner liner. The product will be transported to the Ciba Speciality Chemicals warehouse at Thomastown and stored in a bunded area. No repackaging and dilution of the product is expected to occur at the notifier's site. The notified chemical will then be transported to end users (vehicle manufacturers) for reformulating and end use.

5.2. Operation description

The notified chemical is not manufactured in Australia. The notified chemical will be formulated into a clear surface coating product for use by vehicle manufacturers.

Reformulation
The end use product containing the notified chemical will be formulated in a batch process. The batch process operation involves weighing out the notified chemical and adding it to a 1000 L blender for mixing. The weighing out is conducted in a dispensary with local exhaust ventilation. The blending process is conducted under controlled conditions in systems for milling and screening. Mixing takes 30 minutes at room temperature and the coating formulation containing 1-3% notified chemical is then piped into 20L steel pails directly from the blending vessel via an automated process. The blender and pipelines are cleaned using solvent which will be fed back into the process where possible.

End use
The application of the coating formulation containing 1-3% notified chemical is by either manual or robot spray gun to automotive panels. These coated panels are then baked to cure the coating.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours.day)*	*Exposure Frequency (days/year)*
Storage and transport personnel	5-10	1-2	30-50
Reformulation	3-6	2-4	30-50
Paint tank operators	1-4	2	200
Spray paint operators	8-16	8	200
Spray paint cleaners	1-4	2	200
Robotic service operators	2-8	2	240

Exposure Details

Transport and storage
Transport and warehouse workers will be exposed to the notified chemical only in the event of a spill or if packaging is accidentally breached.

Reformulation
Dermal and possibly ocular and inhalation exposure to the notified chemical (100%) could occur during weighing and addition of the notified chemical to the blender. The weighing and loading operation will be carried out under exhaust ventilation. The MSDS recommends that overalls, gloves and eye protection be worn when handling the notified chemical.

Dermal and ocular exposure to the notified chemical at a concentration of 1-3% is possible from drips, spills and splashes during batch adjustment and when taking and testing samples for quality control purposes. Workers are likely to wear laboratory coats, gloves and eye protection.

Workers may also be exposed to the notified chemical at a concentration of 1-3% while connecting and disconnecting filling pipes and during cleaning. Workers may wear coveralls, gloves and eye protection when carrying out these activities.

End-use
Dermal and ocular exposure to the notified chemical (concentration 1-3%) is possible from direct contact with drips, spills and splashes during transfer of the coating formulation to both hand spraying equipment and the circulation tank of the robotic spraying system, applying the coating by hand spraying, and equipment cleaning and maintenance. Workers may also be exposed to the notified chemical by inhalation of coating aerosols containing the notified chemical during processes generating aerosols such as spraying, especially during manual spraying.

Manual touch-up is required after robotic spraying in around 10-20% of cases. Manual spraying will be done in a booth with exhaust/filter system. Workers in this area will be supplied with air-fed respirators and full protective equipment including imperative gloves, coveralls, anti-static footwear and eye protection, which will further reduce worker's exposure to the notified chemical.

Workers' exposure to the notified chemical after the coating is heated or baked is expected to be negligible as the coating containing the notified chemical is cured.

5.4. Release

RELEASE OF CHEMICAL AT SITE
During formulation annual environmental exposure of the product containing the notified chemical will result from the following pathways:

- ≤ 7 tonnes disposed of during coating application
- ≤ 0.1 tonnes generated from cleaning up minor spills and quality control testing
- 0.2 tonnes from manufacturing process
- 0.005 tonnes left in empty containers

RELEASE OF CHEMICAL FROM USE
The coating product containing 1 to 3% notified chemical would be applied by spray gun to automotive panels. Spraying is typically conducted in controlled environment in combination spray/oven boots. Excess spray is either collected by water curtains or a dry filter medium. The spray guns would typically be cleaned with solvent. It is estimated that waste from overspray will be up to 70%.

Once the coating has cured, as the notified chemical is encapsulated in inert matrix, the only possible opportunities for entering the environment would be as follows:

- Through the weathering of coatings, this is very gradual and diffuse and would result in negligible release of the notified chemical
- Through discard to waste of an article, where the article could be disposed to landfill or incinerated. The leachability to groundwater in landfill would be negligible and products of complete combustion to water and simpler compounds of carbon and nitrogen are not likely to cause problems because of the composition of the chemical.

5.5. Disposal

No aquatic release is anticipated during manufacture and end-use of the notified chemical. Waste produced during the manufacturing process would be collected by licensed waste contractors and be incinerated. It is expected that up to 70% of waste generated by the end-users will be disposed of in approved landfills as inert solid waste. In landfill, the solid waste should be contained in the inert matrix and not pose a significant risk to the environment.

5.6. Public exposure

The products containing the notified chemical will be for industrial use only and consequently no public exposure is anticipated except in the case of an accidental spill during transport. Although the public will make contact with car surfaces containing the notified polymer, there is little potential for exposure since the polymer is trapped within the paint matrix.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Slightly yellow powder, with no odour

Melting Point/Freezing Point 68.0 to 101.5 ºC

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Determined using the metal block method. Test conducted in compliance with the OECD principles of Good Laboratory Practice (GLP).
TEST FACILITY	Huntingdon Life Sciences (2003a)

Boiling Point > 288 ºC

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Examined by modified Siwoloboff method. Test conducted in compliance with the OECD principles of GLP. The samples were observed to darken significantly above 288ºC, indicating decomposition. No boiling was noted.
TEST FACILITY	Huntingdon Life Sciences (2003a)

Density 1140 kg/m^3 at 24ºC

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using a pycnometer; the reference liquid was heavy distallate of petroleum. Test conducted in compliance with the OECD principles of GLP.
TEST FACILITY	Huntingdon Life Sciences (2003a)

Vapour Pressure $\leq$ 1.1 x 10^{-7} kPa at 25ºC

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined using a vapour pressure balance. Test conducted in compliance with the OECD principles of GLP. Once degassing was complete, only slight deflections of the microbalance were obtained at the upper end of the temperature range investigated. Therefore, a maximum vapour pressure had to be quoted. To calculate a value for the vapour pressure at 25ºC, the regression line equation was extrapolated from 49.5ºC back to 25ºC.
TEST FACILITY	Huntingdon Life Sciences (2003a)

Water Solubility <0.00002 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Based on the results of a preliminary test the water solubility was determined using a column elution method with analysis by HPLC. Test conducted in compliance with the OECD principles of Good Laboratory Practice.

TEST FACILITY Huntingdon Life Sciences (2003a)

Fat Solubility 4000 mg/100 g of HB 307 Standard Fat at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.

Remarks Analysis done on a UV Spectrophotometer.
A definitive test (8 g of notified chemical/12 g of fat) was decided as only 1 out of 11 samples showed a clear single phase on a preliminary test. Also a test temperature of 37°C was selected as samples exposed to 30°C and 50°C were markedly different in appearance. Test conducted in compliance with the OECD principles of GLP.

TEST FACILITY Huntingdon Life Sciences Ltd (2003*a*)

Hydrolysis as a Function of pH Not determined

Remarks The hydrolysis of the notified chemical was not determined due to it low water solubility. The notified chemical contains a hydrolysable functional group but this is unlikely to occur in the environment with pH range of 4 to 9.

TEST FACILITY Huntingdon Life Sciences (2003*b*)

Partition Coefficient (n-octanol/water) log Pow > 6

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

Remarks Test conducted in compliance with the OECD principles of GLP.
HPLC Method:

- Column: Inertsil 5 μm C8
- Mobile Phase: Methanol:pH 7 phosphate buffer (3:1 v/v), ramped to 100% methanol at 27 minutes to elute the test substance.

Preliminary estimation was calculated using a LOGKOW computer program, giving an estimated log Pow of 10.7. Due to the high log Pow value obtained from the computer model a limited test only was performed. The notified chemical eluted after DDT (retention time 19 minutes), and only after the mobile phase was increased to 100% methanol.

TEST FACILITY Huntingdon Life Sciences (2003*a*)

Adsorption/Desorption log K_{oc} > 5.4
– screening test

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge Using High Performance Liquid Chromatography (HPLC)

EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge Using High Performance Liquid Chromatography (HPLC)

Remarks Test conducted in compliance with the OECD principles of GLP.
HPLC Method

- Column: Hypersil H5CPS, the stationary phase contains a moderate polar phase with lipophilic and polar moieties.
- Mobile Phase Acetonitrile:pH 4 phosphate buffer (55:45 v/v)

Methanol:pH 9 borate buffer (55:45 v/v)

The test was conducted at both pH 4 and pH 9. Analyses were performed identically, with the exception that the mobile phase employed was different for each pH. Again the test substance eluted after the highest reference standard DDT.

TEST FACILITY Huntingdon Life Sciences (2003*a*)

Dissociation Constant Not determined

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks It was not feasible to conduct this test due to low water solubility. The titrimetric method is only suitable for substances soluble above 0.1 g/L. The spectrophometric method was briefly investigated. It was found that a significant amount (50% v/v) of co-solvent was required to maintain the notified chemical in solution at such a concentration (10 mg/L) that a meaningful spectrum could be recorded. Spectra recorded at this concentration over a range of pH (2 to 12) have not significant differences, precluding this method for pKa determination.

There are not dissociable groups in the environmental pH range of 4 to 9.

TEST FACILITY Huntingdon Life Sciences (2003*a*)

Particle Size

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Mass (%)*
> 125	72.1
> 105	2.9
60.0-105	12.8
30.0-60.0	8.3
10.4-30.0	3.7
0.5-10.4	0.1

Remarks Following an initial sieve analysis, the particle size was examined by image analysis. Six replicate samples were analysed. Test conducted in compliance with the OECD principles of GLP.

Inhalable fraction: 3.9%
Respirable fraction: 0.1%

TEST FACILITY Huntingdon Life Sciences (2003*a*)

Flash Point Not determined

Remarks The notified chemical is a low volatility solid.

Flammability Not highly flammable

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

Remarks Test conducted in compliance with the OECD principles of GLP. The notified chemical melted, but failed to ignite

TEST FACILITY Huntingdon Life Sciences (2003c)

Autoignition Temperature > 400°C

METHOD Method described in BS 4056

Remarks Test method 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids not suitable as the notified chemical melts at 68 – 101.5°C.

The notified chemical was introduced in a flask containing air at 400°C and observed for five minutes. Test conducted in compliance with the OECD principles of GLP. No ignition was observed within five minutes.

TEST FACILITY Huntingdon Life Sciences (2003*a*)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Explosive potential of the notified chemical was studied under heating, mechanical shock and friction conditions. Test conducted in compliance with the OECD principles of GLP No explosion was recorded in any test.
TEST FACILITY Huntingdon Life Sciences (2003*a*)

Oxidising Properties Not oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Test conducted in compliance with the OECD principles of GLP. None of the test/substance cellulose mixtures burned to completion. The notified chemical did not show oxidising properties under this test condition.
TEST FACILITY Huntingdon Life Sciences (2003*a*)

Reactivity

Remarks The notified chemical is expected to be stable under normal conditions of use. The notified chemical decomposes at temperatures > 288°C.

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 determined
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non clastogenic
Genotoxicity – in vivo	not determined

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method – Limit Test EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Acute Toxic Class Method –Limit Test
Species/Strain	Rat/Crl:CD BR
Vehicle	1% w/v aqueous methylcellulose
Remarks - Method	No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	Piloerection was observed in all females on day 2, resolving completely by day 3. No clinical signs were observed in the males. There were no remarkable body weight changes during the study period.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	The LD50 cut-off estimated using the flow chart in Annex 2d of the OECD TG423 would be 5000 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Huntingdon Life Sciences (2003d)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Crl:CD BR
Vehicle	1% w/v aqueous methylcellulose
Type of dressing	Occlusive

Remarks - Method	No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Very slight to well-defined erythema and/or oedema was observed in three males and two females following removal of the dressings, resolving completely by Day 9. In addition, chemical burn (one male and one female), loss of elasticity (two females), skin damage at bandage removal (two males), yellow staining (all animals), dose residue (all animals), spots and/or scabbing (two male and two females) were noted resolving completely by day 11. The observed staining and dose residue did not impair assessment of erythema.
Signs of Toxicity - Systemic	There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.
Effects in Organs	Macroscopic examination revealed congestion of the liver in one male and white swellings on the kidney in another male. There were no remarkable necropsy findings in the other animals.

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

TEST FACILITY Huntingdon Life Sciences (2003e)

7.3. Acute toxicity – inhalation

Not determined.

7.4. 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	Test substance moistened with reverse osmosis water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP.

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	n/a	0
Oedema	0	0	0	0	n/a	0

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

Remarks - Results	There were no signs of toxicity or ill health in any rabbit during the observation period.

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

TEST FACILITY Huntingdon Life Sciences (2003f)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

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 3
Observation Period 8 days
Remarks - Method No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	1.3	0	2	3-7 days	0
Conjunctiva: chemosis	0	0	0	0	n/a	0
Conjunctiva: discharge	0	0	0	1	< 1 day	0
Corneal opacity	0	0	0	0	n/a	0
Iridial inflammation	0	0	0	0	n/a	0

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

Remarks - Results There were no signs of toxicity or ill health in any rabbit during the observation period. Instillation of the test substance gave rise to practically no or a slight initial pain response.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Huntingdon Life Sciences (2003g)

7.6. 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/Ca
Vehicle Acetone:olive oil (4:1 v/v)
Remarks - Method No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP.

The maximum practical dose was reported to be 50% w/v. Hexyl cinnamic aldehyde was used as the positive control.

RESULTS

Concentration (% w/v)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	236.4	
10	174.6	0.7
25	97.3	0.4
50	422.3	1.8
Positive Control		
25	1575.4	6.7

Remarks - Results	There were no deaths or signs of ill health or systemic toxicity observed during the study. Greasy fur was noted in all animals (treated and control). White particles on the ears were noted for three females treated with 25% notified chemical prior to dosing on Day 3. The following local effects were noted in animals treated with 50% notified chemical: hairloss (days 3-6), white particles on the ears on day 3-6 and reddening of the skin on the head (days 4-6). A stimulation index (SI) of 3 or more was not recorded for any of the concentrations tested. As higher concentrations of the notified chemical were not tested it is not possible to comment whether higher concentrations (> 50%) of the notified chemical would record an SI $\geq$3.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	Huntingdon Life Sciences (2003h)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Crl: CD (SD) IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	1% w/v methylcellulose in water
Remarks - Method	No significant protocol deviations although the bone marrow was not preserved and examined histopathologically. Test conducted in compliance with the OECD principles of GLP. Doses selected on the basis of a 7 day preliminary toxicity study, where at a dosage of 1000 mg/kg bw there were no deaths, no clinical signs associated with treatment, no remarkable changes in bodyweight or food consumption and no remarkable necropsy findings.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0
II (low dose)	5 per sex	15	0
III (mid dose)	5 per sex	150	0
IV (high dose)	5 per sex	1000	0
V (control recovery)	5 per sex	0	0
VI (high dose recovery)	5 per sex	1000	0

Mortality and Time to Death

No mortality was observed during either the treatment and recovery phase.

Clinical Observations

No treatment related clinical signs were observed. In the functional observations a statistically significant decrease in hindlimb grip strength was observed in group III (16%, $p < 0.05$) and IV (12%, $p < 0.05$) females. During the recovery phase, the mean hindlimb grip strength was comparable with controls.

There was no significant difference in body weight gain and food and water consumption in treated animals when compared to controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

A dose-related increase in mean phosphorus levels was observed in treated males when compared to controls with values reaching statistical significance in group IV (12%, $p<0.01$). A similar effect was not observed in females. At the end of the recovery period, phosphorus levels were similar to controls. All other statistically significant differences observed at the end of the treatment phase (increased calcium in all treated males, decreased calcium in group IV females, decreased alanine amino-transferase in group IV females and increased total protein in all treated females) are not considered to be treatment related as they are either not dose-related, slight (<10%), or the majority of individual values were within or similar to the concurrent control range.

Haematology

A dose-related decrease in mean platelet values was observed in treated males compared to controls with values reaching statistical significance in group III (17%, $p< 0.05$) and group IV (20%, $p<0.05$). In addition, group IV males showed slight but statistically significant higher mean haemocrit levels (5%, $p<0.05$) compared with controls. At the end of the recovery period, the Haemocrit and platelet values for group IV males were similar to controls.

Urinalysis

There were considered to be no treatment related effects to any of the urinalysis parameters tested.

Effects in Organs

Organ Weight

A statistically significant (but not dose-related) decrease in relative testes weight was observed in group III (15%, $p<0.01$) and group IV (7%, $p<0.01$) males. Absolute testes weight was similar to controls.

Macroscopic Findings

Minimal fluid distention of the uterus was noted in treated females (grp II 1/5, grp III and IV 2/5). At the end of the recovery period, this effect was only observed in 1/5 treated females.

Histopathology

Increased cellularity of the marginal zone in the spleen was noted in treated females (group II (4/5), group III (2/5 and group IV (3/5). An increased incidence in group IV females compared to controls was not observed at the end of the recovery period.

Luminal dilatation of the uterus was noted in treated females (grp II 1/5, grp III and IV 2/5). At the end of the recovery period, this effect was only observed in 1/5 treated females.

An increased incidence of oestrus was recorded in the vagina of group IV females (4/5) when compared to controls.

Remarks – Results

Clinical Observations

The observed decrease in hindlimb grip strength was considered to be incidental as there was no dose-response and individual values overlapped with control values especially at the high dose.

Clinical Chemistry

The increased phosphorus levels were not considered to be of toxicological importance as there was no similar response in females, there was no affect on the general condition of the animals and effects had reversed at the end of the recovery period.

Haematology

The increase in heamocrit levels were not considered to be attributable to treatment as there was no dose response, no associated effect on mean cell haemoglobin and mean cell volume and individual the majority of values were within the range of controls. The decreased platelet levels were considered to be of no toxicological importance as there were no affects on the clotting parameters and the effects reversed during the

recovery phase.

Effects in Organs
In the absence of a dose response and any test-substance related histopathological change the decrease in testes weight is considered to be of no toxicological relevance.

There was no dose relationship in the incidence of increased cellularity of the marginal zone in the spleen and this was not accompanied by a change in organ weight or effects in the haematological parameters. In addition, no effect was observed at the end of the recovery period and hence this is considered not to be an adverse effect.

The macroscopic and histopathological changes in the uterus were observed in the same animals. In the absence of other uterine changes and the reduced incidence at the end of the recovery period these effects are not considered to be adverse.

The relationship of the increased incidence of oestrus to treatment is uncertain given the small number of rats per group together with the expected variation in the stage of the oestrus cycle.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of toxicologically significant effects in the treated animals.

TEST FACILITY Huntingdon Life Sciences (2003i)

7.8. 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(Test 1) and Pre incubation procedure (Test 2)

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*:WP2uvrA (pKM101)
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	Test 1 a) With metabolic activation: 5-5000 µg/plate b) Without metabolic activation: 5-5000 µg/plate Test 2 a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Dimethylsulphoxide
Remarks - Method	No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	-			
Test 1		> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative
Present	-			
Test 1		> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative

Remarks - Results	No visible thinning of the background lawn or precipitation was observed in any test. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains, either in the presence or absence of activation in either test. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences (2003j)

7.9. 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.
Species/Cell Type	Human Lymphocytes
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP. Doses selected in order to include at least two precipitating dose levels in the concentration range.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	7.8, 15.6*, 31.3*, 62.5*, 125, 250, 500, 1000	3	20
Test 2	7.8, 15.6, 313.3, 62.5*, 125*, 250, 500*, 1000	3	20
Present			
Test 1	7.8, 15.6*, 31.3*, 62.5*, 125, 250, 500, 1000	3	20
Test 2	7.8, 15.6, 313.3, 62.5, 125, 250*, 500*, 1000*	3	20

*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	-	> 1000	31.3	negative
Test 2	-	> 1000a	125	negative
Present				
Test 1	-	> 1000	31.3	negative
Test 2	-	> 1000	125	negative

a) see remarks

Remarks - Results	In the absence of activation, the notified chemical caused a reduction in the mitotic index to 64% of the solvent control at 1000 µg/mL. However, a large amount of precipitate was observed at this dose level, obscuring metaphase cells. The quantitative analysis for polyploidy showed no statistically significant increase in the number of polyploid cells when compared to the solvent control. No statistically or biologically significant increases in the percentage of aberrant cells, above the vehicle control values, were recorded for any

	cultures treated with the test substance in either the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not clastogenic to Human Lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences (2003k)

7.10. Genotoxicity – in vivo

Not determined. The notified chemical was negative in a bacterial mutation assay and *in vitro* chromosomal aberration test.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD
- Inoculum: Activated sludge from Oakley Sewage Treatment Works
- Exposure Period: 29 days
- Analytical Monitoring: Hydrochloric Acid Titration
- Remarks - Method: The notified chemical was added to 2 x 5 litre vessels containing 3 litres of mineral salts medium inoculated with activated carbon (30 mg/L) to give a nominal test concentration equivalent to 10.5 mg Carbon/L. Two control vessels containing inoculated mineral salts medium alone and one contained mineral salts medium plus sodium benzoate (10 mg C/L). An additional mixture of sodium benzoate (10 mg C/L) and the notified chemical (10.5 mg C/L) was established in order to assess the potential inhibitory effects of the test substance on the activity of microbial inoculum.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	1	2	20
4	2	4	47
8	4	8	74
15	4	15	84
21	4	21	87
29	4	29	90

Remarks - Results

Mean cumulative CO_2 production by mixtures containing the notified chemical was negligible and had achieved 4% of the theoretical value (TCO_2, 115.6 mg CO_2) by the end of the test on day 28.

Air flow to all cultures ceased for approximately thirty minutes on day 3 and 10 minutes on day 4 of the test.

The carbon content of the notified chemical was calculated from information on the composition and empirical formula of constituents that was available at the time of study. Further information concerning the composition of the notified chemical was provided after the test was performed and as results of elemental analysis gave a definitive level of carbon, this was used to calculate the level of test substance (as carbon added to the test cultures). The recalculated value (equivalent to 10.5 mg as carbon/litre) differed slightly from the level originally determined and the intended concentration in the protocol, but was within acceptable range in accordance with the test guideline.

The biodegradation of the reference substance in a mixture containing the test and reference substance was calculated to confirm that the test substance was not inhibitory to the activity of the microbial inoculum. When the level of biodegradation of sodium benzoate achieved the pass level for ready biodegradation the treatment was terminated.

Cumulative CO_2 production in the controls was within the acceptable range for the assay system. The degradation of sodium benzoate was rapid and had achieved 64% of its TCO_2 after 6 days in the presence of the notified substance, which confirmed that the notified chemical was not inhibitory to the activity of microbial inoculum.

CONCLUSION	The notified chemical is not considered to be readily biodegradable.
TEST FACILITY	Huntingdon Life Sciences (2003l)

8.1.2. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 305 Bioconcentration: Flow-through Fish Test.
Species	*Cyprinus carpio*
Exposure Period	Exposure: 28 days Depuration: Not done
Auxiliary Solvent	
Concentration Range	Nominal: [1]High exposure level 0.1 mg/L [1]Low exposure level 0.01 mg/L Actual: [1]High exposure level 0.096 mg/L [1]Low exposure level 0.0098 mg/L [1] Notified chemical main component only
Analytical Monitoring	HPLC
Remarks - Method	
RESULTS	
Bioconcentration Factor	High exposure level: 1 – 5 (Notified chemical main component) 3 – 6 (Notified chemical minor component) Low exposure level: 12 (Notified chemical main component) 28 - 29 (Notified chemical minor component)
CT50	> 110 mg/L
Remarks - Results	The 96 hr-LC_{50} of TINUVIN 479 for zebra-fish (*Brachydanio rerio*) was greater than 110 mg/L. Two concentration levels were selected: 0.1 mg/L as a higher exposure level and 0.01 mg/L as a low exposure level. The experiment was set to 28 days based on the results of preliminary test. The test substance (notified chemical) was a reaction product and separated into multiple components by HPLC. In this study, bioconcentration factors (BCF) were determined for the main component (95.6%) and for the minor component (2.80%) in the test substance.
CONCLUSION	Bioconcentration factor in common carp (*Cyprinus carpio*) was determined to be low.
TEST FACILITY	Institute of Ecotoxicology (2003)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity for Fish – Semi-static conditions
Species	*Rainbow trout*
Exposure Period	96 Hours
Water Hardness	190 mg $CaCO_3$/L
Analytical Monitoring	Reverse Phase-HPLC-UV Analysis
Remarks – Method	The notified chemical is known to be sparingly soluble in water (<20 µg/L). The 100% water saturation was achieved by stirring the stock dispersion solution of 40 mg/L for 68 – 70 hours and then filtering through 0.45 µm cellulose nitrate membranes. The overall mean dissolved concentration was 12 µg/L. Concentrations of the notified chemical were measured on four occasions during the study and the overall mean calculated.

Accuracy and precision of the HPLC method were poor at the low analyte concentration (detection limit 0.03 µg/L).
The test media in the treatment and control groups were maintained at 13 – 14 ºC. However, on 4 of the 14 days the temperature of the stock vessel was recorded as 11 ºC.
The fish loading for the study was 0.59 g of wet fish per litre.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
[1]100%	[2]0.012	10	0	0	0	0	0
Control	[3]0.0005	10	0	0	0	0	0

[1]Assumed limit of aqueous solubility under test conditions, based on a stock concentration of 40 mg/L
[2] A mean value obtained from the duplicate samples taken at 0, 24, 72, and 96 hours
[3]The test material was detected in the controls samples

LC50	> 0.012 mg/L at 96 hours.
NOEC	0.012 mg/L at 96 hours.
Remarks – Results	At low analyte concentrations the accurate and precision of the method are consequently poor and therefore the actual concentration should be considered as an estimation of the dissolved concentration of the notified chemical. No mortality or adverse effects were observed following exposure of rainbow trout to notified chemical at its assumed limit of aqueous solubility under the test conditions. Neither, the NOEC nor the LC_{50} could be calculated. Therefore, the values were assumed.

CONCLUSION Results indicated that there was no toxic effect achieved at the maximum concentration of 100% saturation of the notified chemical.

TEST FACILITY Huntingdon Life Sciences (2003m)

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 Conditions

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Elendt M4 solution
Water Hardness	Not reported
Analytical Monitoring	Reverse Phase-HPLC-UV Analysis
Remarks - Method	The softened Elendt M4 solution was adjusted from description in the protocol to produce a media with the required hardness to fulfil test guideline requirements. The notified chemical is known to be sparingly soluble in water (<20 µg/L). The 100% water saturation was achieved by stirring the stock dispersion solution of 40 mg/L for 70 hours and then filtering through 0.45 µm cellulose nitrate membranes. The overall mean dissolved concentration was 3.5 µg/L. Levels of the notified chemical were measured at the start and end of the study and the overall geometric mean measured. Accuracy and precision of the HPLC method were poor at the low analyte concentration (detection limit 0.03 µg/L).

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*

[1]100%	[2]0.0035	10	0	0
Control	[3]0.0003	10	0	0

[1]Assumed limit of aqueous solubility under test conditions, based on a stock concentration of 40 mg/L
[2] A mean value obtained from the duplicate samples taken at 0 and 48 hours
[3]The test material was detected in 3 out of 4 controls samples

LC50	> 0.0035 mg/L at 48 hours
NOEC	0.0035 mg/L at 48 hours
Remarks - Results	The adult mortality recorded in the culture used for the study is slightly greater than the culture mortality recommended in the guidelines. However, the total number in the culture at that time was small, hence the death of two adults appear disproportional. At low analyte concentrations of interest the accurate and precision of the method are consequently poor and therefore the actual concentration should be considered as an estimation of the dissolved concentration of the notified chemical. No immobilisation in either the control or the test group was noted throughout the exposure period therefore neither, the NOEC nor the LC_{50} could be calculated. Therefore, the values were assumed.
CONCLUSION	There was no toxic effect observed at a maximum concentration of 100% saturation of the notified chemical.
TEST FACILITY	Huntingdon Life Sciences (2003n)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range	Nominal: 40 mg/L Actual: 0.00042 mg/L (100% Saturation)
Water Hardness	No reported
Analytical Monitoring	Reverse Phase-HPLC-UV Analysis Coulter Multisizer II particle counter
Remarks - Method	Algal cultures of six replicates, with an initial concentration of approximately $1x10^4$ cells/mL were exposed to the notified chemical to a 100% saturated solution. These cultures, together with one untreated control groups of six replicates, were incubated in a Gallenkamp illuminator orbital incubator unde continuous illumination at a temperature of 25 °C for 96 hours. Cells numbers were counted daily to monitor growth. The notified chemical is known to be sparingly soluble in water (<20 µg/L). The 100% water saturation was achieved by stirring the stock dispersion solution of 40 mg/L for 70 hours and then filtering through 0.45 µm cellulose nitrate membranes. The overall mean dissolved concentration was 0.42 µg/L. Concentrations of the notified chemical were measured at the start and end of the study and the overall geometric mean calculated. The pH of the control cultures was 8.2 at hours and from 9.2 to 9.6 at 96 hours. Accuracy and precision of the HPLC method were poor at the low analyte concentration (detection limit 0.03 µg/L).

RESULTS

Biomass		*Growth*	
E_bC50 (95% CL)	*NOEC*	*E_rC50 (95% CL)*	*NOEC*

mg/L (0-96 h)	*mg/L*	*mg/L (0-96 h)*	*mg/L*
> 0.00042	0.00042	> 0.00042	0.00042

Remarks - Results

At low analyte concentrations of interest the accuracy and precision of the method are consequently poor and therefore the actual concentration should be considered as an estimation of the dissolved concentration of the notified chemical.
The median effective concentration for inhibition of growth based on biomass and average growth rate could not be calculated because these values lay above that achieved in the saturated aqueous mixture of the notified chemical under the condition of this test. Therefore, the values were assumed.
The test was considered valid because cell concentrations in control cultures increases by a factor at least 16 with 96 hours.

CONCLUSION

There was not significant effect on *Selenastrum capricornutum* growth at the maximum concentration of 100% saturation of the notified chemical.

TEST FACILITY

Huntingdon Life Sciences (2003o)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum

Activated sludge from Oakley Sewage Treatment Work

Exposure Period

3 Hours

Concentration Range

Nominal: 1, 10, 100 mg/L

Remarks – Method

Sample of activated sludge (suspended solids 1.6 g/L) fed with synthetic sewage, were exposed to the test substance at 3 different nominal concentrations for 3 hours. Single mixtures were prepared for 1 and 10 mg/L and for the 100 mg/L prepared in triplicate. Their rate of O_2 consumption were determined and compared with those of control, containing activated sludge and synthetic sewer alone, which were established at the beginning and end of the culture series.
Solubility trials showed that the notified chemical was insufficiently soluble to allow the preparation of suitable aqueous stock solution. Therefore, appropriate weights samples were dissolved in dechlorinated tap water and sonicated for 10 minutes in order to form dispersions. The highest concentration employed in the study was approximately 1000 fold higher than the estimated limit of solubility of the compound. As undissolved particles of the test substance were observed on the surface of the liquor and attached to the walls of the beakers above the level of the cultures, mixtures were swirled periodically in order to ensure contact with the sludge.

RESULTS

IC50

> 100 mg/L

NOEC

100 mg/L

Remarks – Results

Sludge respiration rates were decreased, at most, by 7% of the mean control rate of 10 mg/L.
The EC_{50} of the test substance could not be calculated but is considered to be greater than 100 mg/L, the highest level tested.
Sludge respiration rates were progressively reduced in the presence of increasing concentration of the control (3,5-dichlorophenol). The specific respiration rate of the control culture established at the start and end of the test were 28.8 $mgO_2/g/h$. The 3 hours 50% effect concentration (EC_{50}) for 3,5-dichlorophenol was calculated to be 10.5 mg/L (95% confident limits 8.3 – 13.4 mg/L). These results show that the test was

	valid and that the sample of activated sludge employed was sensitive to inhibition.
CONCLUSION	The notified chemical has no inhibitory effect on the respiration rate of activated sludge at any of the concentrations employed in the test.
TEST FACILITY	Huntingdon Life Sciences (2003p)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is imported as slightly yellow powder to be used as a UV light absorber to be incorporated into surface coating in the automotive manufacture plants.

The end use product containing 1 to 3% of the notified chemical would be applied by spray gun to automotive panels. Spraying is typically conducted in controlled environment in combination spray/oven boots. Excess spray is either collected by water curtains or a dry filter medium. The spray guns would typically be cleaned with solvent.

Almost no environmental exposure is expected at end of the spraying process once the coating has been dried in an oven to form a cured paint matrix. The notified chemical in automotive paints is fully encapsulated in the coatings matrix and as such is not likely to be released to the environment. The only possible opportunities for entering the environment would be through the weathering of coatings, this is very gradual and diffuse and would result in negligible release of the notified chemical.

No aquatic release is anticipated during end-use of the notified chemical. Waste produced during this process (70% as overspray) will be disposed of in approved landfills as inert solid waste. In landfill, the solid waste should be contained in the inert matrix and accumulate (low water solubility, high Kow/Koc values and not biodegradable).

Used containers containing up to 10% of notified chemical are washed with a solvent system before the empty containers (containing 0.05% of notified chemical) are collected by licensed waste management to be incinerated, and the solvent and collected notified chemical are incorporated into the process again (recycled). Waste produced during manufacture processes (up to 2% of notified chemical) would be collected by licensed waste contractors for incineration.

A small amount of residual chemical (up to 200 kg or 1% per annum) from minor spills and quality control testing will be disposed of to sewage treatment plants. It is possible to calculate a predicted environmental concentration (PEC) based on the amount released to the sewer.

PEC = V/ P x W x D
= 200 x 10^6/20 x 10^6 x 200 x 365
= 0.14 μg/L

However, due to the low water solubility and high sorption to organic matter (high Kow/Koc values) the notified chemical would sorb to biosolids and likely to follow the wasted biosolids fate.

The majority of the notified chemical will be incorporated into coatings and is expected to remain bound within cured coatings at low levels on metal surfaces. Once the chemical is within a cured coating it is likely to share the fate of the substrate, which may involve recycling or landfill at the end of its useful lifetime.

9.1.2. Environment – effects assessment

The notified chemical is not toxic to fish, daphnia, algae and sewage micoorganisms up to the limit of its water solubility ranging between 0.42 to 12 μg/L. Therefore, it is not possible to derive a PNEC. Environmental release would manly be to landfills where the notified chemical should be contained in the inert matrix accumulate and likely to degrade over time to simpler compounds.

9.1.3. Environment – risk characterisation

A low potential for environmental release of the notified chemical is expected, with most wastes generated being either recycled, incinerated or landfilled. Once in the landfill environment, the notified chemical is likely to accumulate and degrade over time to simpler

compounds. In conclusion the risk is expected to be low if the chemical is used in the manner and levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage

Transport and warehouse exposure to the notified chemical is expected to be negligible except in the event of a spill or if packaging is accidentally breached.

Reformulation

The greatest potential for exposure is expected during weighing and addition of the notified chemical to the blender. The estimated dermal exposure is 84-840 mg/day, based on the EASE model (EASE) using the following inputs: non-dispersive use, direct handling (LEV not effective), intermittent contact (2-10 events per day) and assuming an exposed surface area of 840 cm^2 (hands only). Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and low log P_{ow}), systemic exposure is estimated to be 0.12 – 1.2 mg/kg bw/day. If local exhaust ventilation is effective dermal exposure is estimated by the EASE model to be very low. Exposure would be limited by the use of PPE.

The estimated atmospheric concentration of notified chemical due to dust is 5-50 mg/m^3, based on EASE model (EASE) using the following inputs: dry manipulation, non-fibrous and LEV absent. Therefore for a 70 kg worker, assuming an inhalation rate of 1.3 m^3/hour, 4 hour exposure time and 3.9% inhalable fraction, inhalation exposure is estimated to be 0.014-0.14 mg/kg bw/day. In the presence of effective local exhaust ventilation, inhalation exposure is estimated by the EASE model to be 0.006-0.014 mg/kg bw/day.

Quality control workers exposure to the notified chemical is expected to be low due to the low concentration of the notified chemical (1-3%), the expected small sample sizes involved and the use of PPE.

Due to the automated nature of the filling process, minimal exposure is expected. Where contact may occur during connecting and disconnecting filling pipes and during cleaning, exposure is expected to be low due to the low concentration of the notified chemical. Exposure would be further limited by the use of PPE.

End-use

Dermal exposure to the notified chemical at a concentration of 1-3% could occur from contact with coating during transfer and cleaning operations. However, exposure is expected to be low due to the use of PPE. The majority of the spray application is automatic (by robots) and hence exposure to the notified chemical is not expected. Although there is potential for inhalation exposure where manual spray coating occurs, this is considered to be negligible due to the use of engineering controls (spraybooth) and respiratory PPE (air-fed respirator).

Workers' exposure to the notified chemical after the coating is cured is expected to be negligible as the notified chemical will be bound within an inert matrix and hence unavailable for exposure.

9.2.2. Public health – exposure assessment

Public exposure to the notified polymer is expected to be negligible as the notified polymer will not be directly available to the public and although the public will come into contact with the exterior of car bodies painted with notified polymer, the notified polymer will be bound within an inert matrix and hence unavailable for exposure.

9.2.3. Human health – effects assessment

Toxicokinetics, metabolism and distribution.
No information is available regarding the toxicokinetics of the notified chemical. Based on the molecular weight and high log Pow, absorption is considered to be < 10% (European Commission, 2003).

Acute toxicity.
The notified chemical is considered to be of low acute toxicity via the oral and dermal routes. Although, acute inhalation toxicity has not been assessed this is not expected to be a major route of exposure due to the low percentage of respirable particles and the engineering controls used when the notified chemical is aerosolised.

Irritation and Sensitisation.
Based on the results of the irritation studies, the notified chemical is considered to be non-irritating to skin and slightly irritating to eyes. However, reactions observed in the dermal toxicity study indicate that prolonged contact with the notified chemical could cause skin irritation. There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical up to a concentration of 50%.

Repeated Dose Toxicity.
In a 28 day study in rats, the No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day based on the absence of adverse treatment related effects.

Mutagenicity.
The notified chemical was negative in an Ames test and an *in vitro* chromosome aberration test. The notified chemical is not considered to be a potential mutagen.

Hazard classification for health effects.
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

Worst-case exposure (dermal and inhalation) for workers involved in coating formulation is estimated to be 0.13 - 1.3mg/kg bw/day in the absence of LEV. Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 746 - 7462. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences and therefore the risk of systemic effects using modelled worker data is acceptable for formulation workers.

As prolonged contact (> 4 hours) with the notified chemical is not expected during weighing and transfer of the notified chemical, the risk of skin irritation is considered to be low. As the notified chemical is a slight eye irritant, workers should avoid eye contact and wear safety glasses as a precaution.

Following formulation, the risk to workers handling the coating (including application) is expected to be low due to the minimal predicted exposure and the likely low toxicity and low irritation potential of the notified chemical at this concentration.

9.2.5. Public health – risk characterisation

Exposure to the notified chemical is expected to be negligible and as such the risk to public health is considered 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 not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, 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***
Chronic hazards to the aquatic environment	4	May cause long lasting harmful effects to aquatic life

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

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

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Weighing and transfer of the notified chemical should be carried out under local exhaust ventilation.

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in the coating formulation:
  - Spray application should be carried out in a spray booth

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid prolonged skin contact and eye contact.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Eye protection

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

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the coating formulation:
  - Suitable respirators during manual spray application

  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 collected by licensed waste contractors to be incinerated or disposed of in approved landfills as inert solid waste.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled as described in the MSDS, collect up and place into market containers for disposal as chemical waste. Disposal of waste adsorbent or other wastes created in emergency is the same as for general waste management, that is, incineration or disposal to controlled landfill following negotiation with the relevant authority.

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

Ciba Speciality Chemicals (2003) Analytical Certificate (Study Number 14028152-1, 20 March 2003) Schweizerhalle, Switzerland, Ciba Speciality Chemicals Inc. (Unpublished report provided by notifier.)

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.

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 and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part I. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

Huntingdon Life Sciences (2003a) Physicochemical Properties (Study Number CBG845/032506, 11 April 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor; Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003*b*) Abiotic Degradation: Hydrolysis as a Function of pH (Preliminary Test) (Study Number CBG846/032503, 11 April 2003). Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003c) Flammability (Solids) (Study Number CBG861/024369, 4 March 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003d) Acute Oral Toxicity to the Rat (Acute Toxic Class Method) (Study Number CBG 847/024401/AC, 7 January 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003e) Acute Dermal Toxicity to the Rat (Study Number CBG 848/024400/AC, 7 January 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003f) Skin Irritation to the Rat (Study Number CBG 848/02656, 24 January 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003g) Eye Irritation to the Rat (Study Number CBG 848/032038, 26 March 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003h) Assessment of Skin Sensitisation Potential using the Local Lymph Node Assay in the Mouse (Study Number CBG 851/024396/LN, 27 March 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003i) Toxicity Study by Oral Administration to CD Rats for 4 Weeks Followed by a 2 Week Recovery Period (Study Number CBG 852/032420, 26 March 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003j) Bacterial Reverse Mutation Test (Study Number CBG 853/032002, 31 March 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003k) *In Vitro* Mammalian Chromosome Aberration Test in Human Lymphocytes (Study Number CBG 854/024604, 31 March 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor; Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences (2003l) Assessment of Ready Biodegradability – Modified Sturm Test (Study Number CBG859/024487, 16 May 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences Ltd (2003m) Acute toxicity to Fish (Study Number CBG855/032996, 14 August 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences Ltd (2003n) Acute toxicity to *Daphnia Magna* (Study Number CBG856/032997, 14 August 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences Ltd (2003o) Algal Growth Inhibition Assay (Study Number CBG857/032998, 15 August 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Huntingdon Life Sciences Ltd (2003p) Activated sludge - Respiration Inhibition Test (Study Number CBG858/024486, 4 April 2003) Huntingdon, England, Huntingdon Life Sciences Ltd. Sponsor: Ciba Specialty Chemicals Inc, Switzerland. (Unpublished report provided by notifier.)

Institute of Ecotoxicology Co., Ltd. (2003) Studies in Bioconcentration of TINUVIN 479 in Carp, *Cyprinus carpio* (Report No: E4-03026/C33/CP, 21 November 2003) Saitama, Japan, Institute of Ecotoxicology Co. Ltd. Sponsor: Ciba Specialty Chemicals K.K. Japan. (Unpublished report provided by notifier.)

NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1994b) 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 (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

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.