File No: STD/1221

January 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sumilizer GS

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Sumitomo Chemical Australia Pty Ltd (ABN: 21 081 096 255)
501 Victoria Avenue, Chatswood, NSW, 2067

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Spectral data
Degree of purity
Non-hazardous Impurities
Import volume
Use details
Identity of Recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a Function of pH
Adsorption/Desorption

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, PMN, 1995
EC Germany 2000, 2001
Japan, 1990
Korea, 1995

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
2-Propenoic acid, 2-[1-[3,5-bis(1,1-dimethylpropyl)-2-hydroxyphenyl]ethyl]-4,6-bis(1,1-dimethylpropyl)phenyl ester

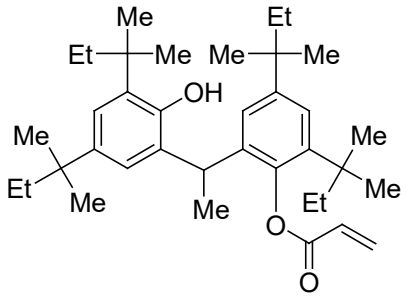
OTHER NAME(S)
2-(1-(2-Hydroxy-3,5-di-tert-pentylphenyl)ethyl)-4,6-di-tert-pentylphenyl acrylate
2,2'-Ethylidene bis (4,6-di-tert-amyl phenol) monacrylate
Sumilizer GS (F)

MARKETING NAME(S)
Sumilizer GS

CAS NUMBER
123968-25-2

MOLECULAR FORMULA
$C_{37}H_{56}O_3$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
549

METHODS OF DETECTION AND DETERMINATION

METHOD	UV-Visible and IR Spectroscopy, ^{13}C and ^{1}H NMR spectrometry, HPLC.
Remarks	Reference spectra were provided
TEST FACILITY	RCC NOTOX (1992), RCC NOTOX (1991)

3. COMPOSITION

DEGREE OF PURITY
>97%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia but will be imported by Wharf into Australia (cities not yet identified) at a concentration of 100%. It will be transported by road for storage at a warehouse until required for manufacturing.

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 is used as an additive (at a maximum of 1%) for plastics/resins. Final end use products may include plastic food packaging, plastic cassette wrappings and other consumer articles.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Substance will be imported by sea, the port of entry is not yet known.

IDENTITY OF MANUFACTURER/RECIPIENTS
None identified at this time.

TRANSPORTATION AND PACKAGING
The notified chemical (100% concentration) is transported by road in 20 kg paper bags lined with polyethylene from the port of entry to storage in a warehouse. The notified chemical is transported by road in its original packaging to the article manufacturing facility.

5.2. Operation description

The notified chemical is not manufactured in Australia. A typical operation description has been provided below as no end users have been identified at this time.

Manufacture of Pellets
The bags (20 kg) of pelleted product containing the notified chemical (100%) will be transported as required from the warehouse to the production area by forklift or manually. It is expected that all weighing, blending, and extrusion operations are undertaken under local exhaust ventilation. Alternatively, the notified chemical will be transferred manually from bags to the hopper directly where it is combined with other ingredients and mixed in a combination hopper that is fully enclosed. The resultant formulation is transferred automatically to an extruder, which is heated to the melting point of the components, and produces pelletised plastic containing the notified chemical at up to 1%. The pellets are automatically packaged into 20 kg plastic bags or 500 kg bulk bags or boxes.

Moulding
The 20kg bags or 500 kg bulk bags or boxes of reformulated pellets containing the notified chemical (at up to 1%) will be transported as required from the warehouse to the moulding plants. It is expected that the articles are made as required into pre-cast moulds injection moulding or a continuous piece by extrusion moulding. Typically, moulding processes are largely automated. Typically pellets containing the notified chemical are either weighed or added to a "loss-in weight" feeder by manually cutting open the bags or by manually scooping or pouring into a hopper. Material from the hopper is automatically fed into the moulding unit. Once molten the resultant mixture containing (up to 1% notified chemical) are moulded as required. Injection moulded products are then removed from moulds after cooling. Extrusion moulded products are typically carried along a conveyor, cooled and cut to the desired length. Moulded products are packaged by manual and/or automated means for transportation.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	2	1-7 min	
Process Workers – Blending and Extruding (includes maintenance and cleaning)	5	8 h	300 days/yr
Process Workers – Injection Moulding (includes maintenance and cleaning)	5	8 h	300 days/yr

Exposure Details
Transport and Warehousing
Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the imported product containing the notified chemical (up to 100%). During transport and warehousing, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Blending and Extrusion
The main routes of exposure to the notified chemical (up to 100%) are dermal and accidental ocular and inhalation exposure during weighing, and adding the notified chemical to the moulding/extrusion machine.

It is possible that dermal and accidental ocular and inhalation exposure may occur if manual intervention is required during the moulding process. Production operators and supervisors will have intermittent exposure to the notified chemical when cleaning the equipment in general. Quality control personnel will have intermittent exposure when sampling batches of the extrusion and/or final

products containing the notified chemical. Dermal and inhalation exposure may also occur during removal of products containing the notified chemical from moulds and conveyor, cutting and packaging operations.

Typically, workers involved in handling the imported chemical and products will wear personal protective equipment (PPE) such as safety glasses, gloves, protective clothing and dust masks, if necessary. Typically, weighing, batching, extruding and moulding operations occur under local exhaust ventilation (LEV).

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured within Australia. Therefore, there will be no release to the Australian environment at this stage.

RELEASE OF CHEMICAL FROM USE
The notified chemical is imported into Australia in Australia, either in concentrated form in 20 kg paper sacks, or in a formulated form in 20 kg resin bags. The imported products will be added to a hopper, and after mixing with other ingredients will be heated, polymerised and extruded and or moulded to form the final articles, thus entrapping the notified chemical within the resin. Uncontaminated spilt notified chemical will be returned to the hopper. Contaminated spilt notified chemical is expected to be collected and disposed of by incineration, along with any residual notified chemical within import containers. This is expected to account for up to 1% of the total annual import volume.

5.5. Disposal

Finished articles containing the notified chemical are expected to be disposed of to landfill at the end of the useful life. In landfill, the notified chemical is expected to remain within the moulded article, and thus be immobile. The notified chemical may eventually degrade via biotic and abiotic processes to form simple organic compounds.

Notified chemical that is disposed of by incineration is expected to be thermally degraded to form oxides of carbon and water.

5.6. Public exposure

No manufacture of the notified chemical will take place in Australia. The potential for exposure of the general public to the notified chemical during normal industrial storage, handling, transportation and manufacturing processes will be minimal. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of public exposure.

The notified chemical will be imported neat and will be used industrially for preparation of plastic articles containing the notified chemical (at up to 1%) for public use products. Widespread dermal exposure to a number of articles is expected, however the notified chemical is bound in the plastic and is not available for exposure under normal conditions of use.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White crystalline powder

Melting Point/Freezing Point 117.5-119.5ºC

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Determined by capillary tube in a liquid bath. Statement of GLP.
TEST FACILITY	RCC NOTOX (1990)

Boiling Point >250ºC at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks The notified chemical changed colour form white to yellow during the heating process indicating that decomposition, auto-oxidation and/or rearrangement may have occurred.
Statement of GLP.
TEST FACILITY RCC NOTOX (1991a)

Density 1010 kg/m^3 at 20.3-20.5ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined by gas comparison pycnometer.
Statement of GLP.
TEST FACILITY RCC NOTOX (1991b)

Vapour Pressure $4.5 \pm 1.0 \times 10^{-5}$ kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined by the static method.
Vapour pressure of the test substance was determined at 25, 35, 45, 55, 65, 70.07, 80.06, 90.06 and 100.05°C and the vapour pressure at 25°C determined by extrapolation.
Statement of GLP.
TEST FACILITY RCC NOTOX (1991c)

Surface Tension 75.3 mN/m at 20ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Test substance batch no. 6S-IR, Purity 99.3%
A saturated solution of test substance was used. A 1 mg/mL solution of test substance was stirred for approximately 19 hours then a sample was removed and centrifuged to give a clear supernatant on which the test was performed using as tensiometer.
Based on the criteria set in the EEC guideline (method A5), the test substance is not a surface active material.
TEST FACILITY RCC NOTOX (1991d)

Water Solubility $<5 \times 10^{-3}$ mg/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Column Elution Method
Analytical Method: HPLC
Test substance batch no. 6S-IR, Purity 99.3%
The water solubility is less than the limit of detection (5 X 10^{-6} g/L) for the analytical method.
TEST FACILITY RCC NOTOX (1991e)

Fat (or n-octanol) Solubility 50 ± 2 g/kg in standard fat HB 307 at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Test substance batch no. 6S-IR, Purity 99.3%
The concentration of test substance was determined by HPLC using the following conditions:
Column: LiChrospher PR-18
Mobile phase: Methanol : water 97:3 v/v
Flow rate: 1 mL/min

UV detection at 220 nm
TEST FACILITY RCC NOTOX (1991f)

Hydrolysis as a Function of pH Not determined

Remarks Test not conducted. This information is only required for water soluble chemicals. The water solubility of the notified chemical is <0.005 mg/L (LOD of the analytical method). The hydrolysis should be performed at half the saturated concentration level. Since this would also be below the level of detection of the analytical method, the measurement of hydrolysis as a function of pH is impractical. The notified chemical has an ester functionality which may hydrolyse under extreme conditions but is unlikely to in the environmental pH range of 4-9.

Partition Coefficient (n-octanol/water) log Pow ≥6.2 at 20°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks Analytical Method: HPLC
Column: LiChrospher RP-18, 125 x 4 mm (dp = 5 µm)
Mobile phase: Methano1:water 75:25 v/v
Flow: 1 mL/min
Detection: UV at 220nrn
Injection volume: 20 µL
The partition coefficients of the impurities of the test substance, detectable with the HPLC system used, were found to be 28 and 326 (log P_{OW} 1.45 and 2.51), but no major peak was able to be observed , even after a run of up to 4 hours (Rt of highest reference substance was 23 minutes).
TEST FACILITY RCC NOTOX B.V. (1991g)

Adsorption/Desorption Not determined
– screening test

Remarks Test not conducted. The high value of the octanol/water partition coefficient and the low water solubility suggests that the notified chemical would have a high affinity for the organic component of soils and sediments and therefore is not expected to be mobile in those media.

Dissociation Constant Not determined

Remarks Test not conducted. The test substance is a covalent, organic molecule that does not dissociate into ionic species. Therefore the measurement of dissociation constant is not applicable to this substance.

Particle Size Particle size distribution ranges from 106 µm to > 2000 µm

METHOD In-house

Range (µm)	*Mass (%)*
> 2000	0.3
1700-2000	5.9
1000-1700	64.9
500-1000	27.4
106-500	1.2
<106	0.3

Remarks No statement of GLP.
The dry sieving method is a recognised test method for determining particles size.
The notified polymer as imported is in pellet form.
TEST FACILITY Sumika Chemical Analysis Centre (1998)

Flammability Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical was ignited with a flame but extinguished without the presence of the ignition source.
Statement of GLP.
TEST FACILITY RCC NOTOX (1991h)

Autoignition Temperature No auto-ignition temperature (>119.5ºC).

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Test conducted up to 395ºC. No endothermic or exothermic reaction was observed up to 395ºC. No self-ignition observed up to the melting point of the test substance (119.5ºC).
Statement of GLP.
TEST FACILITY RCC NOTOX (1991i)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Explosive potential was studied under heating, mechanical shock or mechanical friction conditions. Mechanical stress caused by friction resulted in sparks (attributed to friction between the porcelain peg and plate) and decomposition of the notified chemical into a black and yellow residue. No explosion was recorded in any test.
Statement of GLP.
TEST FACILITY RCC NOTOX (1991j)

Oxidizing Properties Non oxidizing.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks In an initial test using a mixture of cellulose and test substance the mixture had a burning rate significantly faster than the fastest burning reference mixture. However, the burning behaviour of the tested cellulose/test substance mixtures was significantly different to the behaviour of the reference substances. A false positive was concluded from the initial test.
A second test was carried out using the fastest burning cellulose/test substance ratios (30/70 to 90/10) but the cellulose was replaced with a non-combustible agent (celite). This test showed that the celite/test substance mixtures burned more slowly than than the reference substance mixtures.
A further test was performed using the two fastest burning cellulose/test substance mixtures (as determined in the initial test) in an inert atmosphere. The cellulose/test substance mixtures could not sustain a burning reaction.
TEST FACILITY RCC NOTOX (1991k)

Reactivity

Remarks The notified chemical is considered to be non-oxidizing and is not capable of causing fire or enhancing the risk of fire when in contact with combustible material. No incompatible chemicals have been identified with the notified chemical. The product is not explosive when subjected to thermal sensitivity (flame) and mechanical impact (shock or friction). The product is considered to be stable under normal conditions of use. The chemical is designed to be reactive at high temperatures.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 … mg/kg bw	low toxicity

Rat, acute dermal LD50 … mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose <dermal> toxicity – 28 days.	NOEL ≥ 851 mg/kg bw/day
Rat, repeat dose <oral> toxicity – 90 days.	NOAEL 1360 mg/kg bw/day for males NOAEL 1430 mg/kg bw/day for females
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro <gene cell mutation>	non genotoxic
Genotoxicity – in vitro <chromosome aberration>	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD Analogous to OECD TG 401 Acute Oral Toxicity – Limit Test.

Species/Strain	Rat/Sprague Dawley.
Vehicle	0.5% methylcellulose aqueous solution
Remarks - Method	No statement of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	0	0/10
II	5/sex	2000	0/10
II	5/sex	5000	0/10

LD50	>5000 mg/kg bw
Signs of Toxicity	There were no treatment related deaths or remarkable body weight changes during the study period. Although the mean body weight gain at 2000 mg/kg in females was significantly lower than the control on days 7 and 14 this was not does dependent and not considered treatment related.
Effects in Organs	No macroscopic findings were recorded at necropsy.
Remarks - Results	None.

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

TEST FACILITY Sumitomo (1989a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD Analogous to OECD TG 402 Acute Dermal Toxicity – Limit Test.

Species/Strain	Rat/Sprague-Dawley
Vehicle	0.5% methylcellulose aqueous solution
Type of dressing	Semi-occlusive.
Remarks - Method	No statement of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	0	0/10
II	5/sex	2000	0/10

LD50 >2000 mg/kg bw

Signs of Toxicity - Local	No dermal irritation signs were elicited at the application site of the test substance.
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	No treatment related macroscopic findings were recorded at necropsy. The uterine horn was distended with fluid in one control females, however this has been observed occasionally within the testing laboratory.
Remarks - Results	None.

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

TEST FACILITY Sumitomo (1990a)

7.3. Acute toxicity – inhalation

REMARKS Not determined

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3/sex
Vehicle	Test material administered as supplied.
Observation Period	72 h
Type of Dressing	Occlusive
Remarks - Method	No statement of GLP.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	0	-	0
Oedema	0	0	-	0

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

Remarks - Results None.

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

TEST FACILITY Sumitomo (1989b)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3/sex
Observation Period	72 hours
Remarks - Method	No statement of GLP.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.83	1	< 48 hr	0
Conjunctiva: chemosis	1	2	< 48 hr	0
Conjunctiva: discharge	0.5	2	< 48 hr	0
Corneal opacity	0.5	1	< 48 hr	0
Iridial inflammation	0	0	-	-

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

Remarks - Results: The notified chemical induced slight redness and slight chemosis in conjunctiva in all rabbits 1 hour after application. Twenty-four hours after application, very slight opacity of cornea was also observed in 3 rabbits and slight to moderate discharge in conjunctiva in 2 rabbits. These reactions disappeared forty-eight hours after application.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Sumitomo (1989b)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: Analogous to OECD TG 406 Skin Sensitisation - <Magnusson and Kligman>.

Species/Strain: Guinea pig / Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 0.1-5% in corn oil and in 1:1 Freund's Complete Adjuvant:water
topical: 25% notified chemical in petrolatum

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 10

INDUCTION PHASE: notified chemical and in 1:1 Freund's Complete Adjuvant:water25% notified chemical in petrolatum

Signs of Irritation: Intradermal injection: The intradermal injections using Freund's Complete Adjuvant/water (1:1) (with and without notified chemical 5%) did not cause any irritation.
Topical Induction: The administration sites treated with only the notified chemical at 25% in petrolatum did not show any signs of irritation.

CHALLENGE PHASE

1st challenge: topical: 25% notified chemical in petrolatum

Remarks - Method: SDS pre-treatment before induction was performed as highest topical concentration in preliminary test did not produce irritation.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	25%	0	0
Control Group	25%	0	0

Remarks - Results: No dermal reactions were seen in either the control or the test groups at 24 or 48 hours after patch removal.

There were no deaths during the course of the study. There were no signs of systemic toxicity observed in the animals. No toxicologically significant changes in body weights were observed in the test animals.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Sumitomo (1990b)

7.7.1 Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 410 Repeated Dose Dermal Toxicity: 21/28-day Study.
Species/Strain	Mice / C3H/HeNHsd MTV$^-$
Route of Administration	Dermal –non-occluded
Exposure Information	Total exposure days: 28 days Dose regimen: 5/7 days per week Post-exposure observation period: None
Vehicle	Acetone
Remarks - Method	Statement of GLP. Deviations from OECD Protocol include: 1. No female animals were tested. 2. No post-observation period. 3. Functional observations not conducted. 4. Food consumption not measured. 5. No urinalysis parameters measured

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day**	*Mortality*
I (control)	10 males	0	0/10
II (low dose)	10 males	214	0/10
III (mid dose)	10 males	427	0/10
IV (high dose)	10 males	851	0/10

*calculated using the mean body weight (mean body weight = (sum of weekly mean body weights(kg) / number of weeks))

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

Clinical Observations
There were no clinical signs of toxicity were observed during the study period that were considered to be related to treatment. Other findings consisted of scabs and sores, which are commonly noted in rats of this age and strain, housed and treated under the conditions in this study. These findings were therefore considered of no toxicological significance.

Body Weight:
There were no treatment related changes to body weights. However the cumulative body weight gains for the low and mid dose groups were significantly (p value not stated) higher. This result was not considered to be toxicologically relevant, as this effect was not seen in the high dose group and not dose-dependant.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Urinalysis
Not performed

Haematology and Clinical Chemistry
There were no statistically significant or otherwise notable differences for clinical pathology results between the control and treated groups. One animal in the high dose group had several unusual values for clinical chemistry tests (e.g. total protein 42% decrease over mean value for high dose group; cholesterol 169% increase over mean value for high dose group) that were considered incidental because no other animal had

similar findings.

Effects in Organs
No organ weight variations or macroscopic or microscopic findings were observed. A significantly decreased mean right testis-to-body weight percentage for males in the mid dose group did not occur in a dose related manner. Macroscopic and microscopic observations noted in this study were random occurrences of findings occasionally seen in mice and were not considered to be carrier- or test material-related.

Remarks – Results
No deaths were noted through out the treatment period and no treatment related changes were noted in clinical signs, body weight, haematology, blood biochemistry, organ weight, macroscopic and microscopic observations.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 851 mg/kg bw/day for males based on the results of this study.

TEST FACILITY Corning Hazelton (1996)

7.7.2 Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD Analogous to OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.

Species/Strain	Rat / Sprague-Dawley (Crj; CD)
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 90 days; Dose regimen: 7 days per week; Post-exposure observation period: 4 weeks
Vehicle	base feed
Remarks – Method	Statement of GLP. Protocol deviations: 1. No functional behavioural observations, Grip Strength or Locomotor Activity 2. Interim sacrifice group (6 weeks) 3. No histopathology performed on the recovery group.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration mg/kg/day*		*Mortality*
		male	*female*	
I (control)	10 / sex	0	0	0/20
II (low dose)	10 / sex	13.2	14.2	0/20
III (mid dose)	10 / sex	132	144	0/20
IV (high dose)	10 / sex	1360	1430	0/20
V (control recovery)	10 / sex	0	0	0/20
VI (high dose recovery)	10 / sex	1360	1430	0/20

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

Clinical Observations
There were no treatment related clinical effects.

Food consumption
There were no differences in food consumption before or after allowance for body weight between treated and control animals.

Body Weights
There were no treatment related changes to body weights and body weight gain.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical Biochemistry
In the interim sacrifice group the total protein and albumin concentration for males in the high dose group was significantly decreased (5%, $p<0.01$ and 6%, $p<0.01$ respectively) although these results were within the historical control range.

In the 90 day treatment group significant decreases in the sodium concentration of the mid and high dose group were observed (1%, $p<0.056$ and 1%, $p<0.01$, respectively). The mean activity of triglycerides was decreased in males in the low dose group (32%, not significant) and the high dose group (16%, not significant) and in females of low, mid and high dose group (27%, not significant for all three treatment groups). The mean activity of aspartate aminotransferase in males in the mid and high dose group was increased (11%, not significant and 8%, not significant, respectively) and in females in the mid and high dose group (5%, not significant and 6%, not significant, respectively). The mean activity of alanine aminotransferase in females was increased in the low (23%, not significant), mid (30%, not significant) and high (20%, not significant) dose groups. These changes were reversible after the two weeks treatment free recovery period.

In the recovery group, additional findings not present in the treatment groups were a significant increase in alanine aminotransferase in high dose males (18%, $p<0.05$). The mean activity of triglycerides was also increased (35%, not significantly) in high dose males.

There were several other clinical biochemistry changes observed in the different treatment groups however these were not significant, nor dose-dependant and therefore not considered toxicologically relevant.

Haematology
In the interim sacrifice group the platelet count for males in the mid dose group was significantly decreased (10%, $p<0.05$). Haemoglobin concentration in females of the low (4%, $p<0.05$) and mid (5%, $p<0.01$) dose groups were significantly decreased. Haematocrit concentrations in females were significantly decreased in the low (4%, $p<0.05$) and mid (5%, $p<0.01$) dose groups. These findings were not dose-dependant and therefore not considered toxicologically relevant. There were several other haematological changes observed in the interim sacrifice group however these were not significant, nor dose-dependant and therefore not considered toxicologically relevant.

In the 90 day treatment group significant increases in the mean corpuscular haemoglobin of mid dose males was observed (3%, $p<0.01$). Haematocrit values were significantly increased in females of the mid dose group (4%, $p<0.05$). These findings were not dose-dependant and therefore not considered toxicologically relevant.

In the recovery group; significant decreases in neutrophil count for males in the high dose group were observed (20%, $p<0.05$). In females of the high dose group significant decreased were observed in leukocytes(19%, $p<0.05$), monocytes (36%, $p<0.05$) and lymphocytes (20%, $p<0.05$). These were not considered to be treatment related, since the changes were not dose-dependant nor observed in either the 90 day treatment group or the interim sacrifice group.

Urinalysis
There were no statistical significant differences in the parameters used for urinalysis in either sex.

Overall, there were no clinical signs of toxicity were observed during the study period that were considered to be treatment-related.

Effects in Organs
Organ weights
In the 90 day treatment group; significant decreases in absolute adrenal weight were noted in the low (11%, $p<0.05$) and high (17%, $p<0.01$) dose groups. However these findings were not observed in the relative organ to body weight values and were attributed to the low body weight values in the low and high dose group animals. Therefore these findings were not considered to be toxicological relevant. In the recovery group a significant increase in absolute organ weight of lungs (7%, $p<0.05$) and significant decrease in relative organ to body weight of thymus (17%, $p<0.05$) in males of the high dose group were observed. However neither change were not noted in the 90 day treatment group and therefore not considered to be treatment related. No

other test-item related changes in mean organ weights, organ to body weight ratios.

Macroscopic/Microscopic Findings
The major gross pathological findings observed in the 90 day treatment group included: yellowish-white points in the liver of some males in all dose groups and in four females of the high dose group only; and a malformation-like process in the liver of some males and females in all dose groups; and a white substance in the lumen of the urinary bladder in some males of all dose groups was observed; and brown points in some of the males in all dose groups; small red and soft findings were observed in the testis and in the epididymis of one male in the high dose group Various findings were observed in the liver, kidney, lung, thymus, pituitary, diaphragm, thyroid, uterus, ovary, skin, testis, thymic accessory lymph node, urinary bladder and auricle. All findings were considered to be spontaneous and/or incidental changes. Treatment-related gross pathological changes were not observed. There was no difference in the incidence or severity between the controls and treated groups with respect to the histopathological findings and were not considered treatment related.

Remarks – Results
No treatment related effects were noted in clinical observations, clinical biochemistry, haematology, urinalysis, effects in organ, macroscopic and microscopic changes.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1360 mg/kg bw/day for males and 1430 mg/kg bw/day for females based on the results of this study.

TEST FACILITY Sumitomo (1991b)

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. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, *E. coli*: WP2uvrA,
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with PCB
Concentration Range in Main Test	Test 1 a) With metabolic activation: Test 1: 156 - 5000 µg/plate b) Without metabolic activation: Test 1: 156 - 5000 µg/plate Test 2 a) With metabolic activation: Test 1: 156 - 5000 µg/plate b) Without metabolic activation: Test 1: 156 - 5000 µg/plate
Vehicle	Dimethyl sulfoxide

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	≥ 500	Negative
Test 2	> 5000	> 5000	≥ 625	Negative
Present				
Test 1	> 5000	> 5000	≥ 1500	Negative
Test 2	> 5000	> 5000	≥ 1250	Negative

Remarks - Results	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. 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	Sumitomo (1990c)

7.9.1 Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
Cell Type/Cell Line	V79 Chinese Hamster cells
Metabolic Activation System	S9 mix from Aroclor 1254-induced rat liver.
Vehicle	Ethanol
Remarks - Method	Statement of GLP. Protocol deviations include: 1. No historical control data provided.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	5, 10,25,50	2 h	7 days	7-10 days
Test 2	5, 10,25,50	2 h	7 days	7-10 days
Present				
Test 1	5, 10,25,50	2 h	7 days	7-10 days
Test 2	5, 10,25,50	2 h	7 days	7-10 days

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 50	> 50	≥ 50	Negative
Test 2		> 50	≥ 50	Negative
Present				
Test 1	> 50	> 50	≥ 50	Negative
Test 2		> 50	≥ 50	Negative

Remarks - Results	No statistically significant increases in mutant frequency for the test substance were observed in the absence or presence of metabolic activation. In all tests the positive control substances increased mutant frequencies significantly.
CONCLUSION	The notified chemical was not clastogenic to V79 Chinese Hamster cells treated in vitro under the conditions of the test.
TEST FACILITY	RCC NOTOX (1991l)

7.9.2 Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	Analogous to OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Chinese Hamster lung cells
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with PCB
Vehicle	1% Carboxymethylcellulose sodium salt
Remarks - Method	

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	20, 39, 78, 156, 313, 625, 1250*, 2500*, 5000*	24	24
Test 2	20, 39, 78, 156, 313, 625, 1250*, 2500*, 5000*	48	48
Test 3	20, 39, 78, 156, 313, 625, 1250*, 2500*, 5000*	6	24
Present			
Test 1	1250*, 2500*, 5000*	6	19
Test 2	20, 39, 78, 156, 313, 625, 1250*, 2500*, 5000*	6	24

*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	> 5000	> 5000	≥ 20	Negative
Test 2	> 5000	> 5000	≥ 20	Negative
Test 3	> 5000	> 5000	≥ 20	Negative
Present				
Test 1		> 5000	≥ 1250	Negative
Test 2	> 5000	> 5000	≥ 20	Negative

Remarks - Results

Cytotoxicity was not observed at any test concentration reported. No statistically or biologically significant increases in the percentage of aberrant cells above the vehicle control levels, were recorded for any cultures treated with the notified chemical 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 Chinese hamster lung cells treated in vitro under the conditions of the test.

TEST FACILITY

Sumitomo (1991a)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical with a purity of 99.3%
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Standard activated sludge, purchased from Chemicals Inspection and Testing Institute, Japan. The suspended solids content of the sludge was determined on the day of use to be 4450 mg/L.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Reverse phase HPLC, using a Lichrosorb RP-8 column and isocratic mobile phase (methanol : water 95:5 v/v) at a flow rate of 1 mL/min. UV detection at 285 nm
Remarks - Method	No deviations to protocol.

RESULTS

Test substance (100 mg/L)		*Aniline (100 mg/L)*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	74
14	1	14	97
21	0	21	99
28	0	28	99

Remarks - Results	During the incubation period, the oxygen consumption was measured automatically and continuously. On completion of the incubation phase (day 28), the residual amounts of test substance were determined by specific chemical analysis (HPLC). The biodegradation rate determined by BOD of the test material was 0% after 28 days. Primary degradation of test material was determined by HPLC and on complete of the test only 1% degradation was observed. The reference substance showed 74% biodegradation after 7 days and 100% after 14 days, thus demonstrating the suitability of the inoculum used in the test.
CONCLUSION	The test material cannot be classed as ready biodegradable.
TEST FACILITY	Sumitomo (1992).

8.1.2. Bioaccumulation

Compounds with log P_{OW} >3 are considered to have potential for bioaccumulation by aquatic organisms. However, in the log K_{OW} range above 6, the tendency to bioaccumulate decreases. Note, however, that the notified chemical could not be detected on the HPLC column, and it was surmised (probably correctly) that its logPow was $\geq$6.2, that of the most hydrophobic reference substance. This may be due to reduced membrane permeation kinetics, or reduced biotic lipid solubility for large molecules. In addition there is reduced bioavailability due to sorption to organic matter in the aqueous phase and uptake of these substances will thus not occur. For bioaccumulation to occur the test substance must be present in the aqueous phase in order for uptake to occur. Since there will be no direct release to the environment from the use of the manufactured product, there is no potential for bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical with a purity of 99.3%
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static conditions. EC Directive 84/449/EEC C.1 Acute Toxicity for Fish - static conditions.
Species	Carp (*Cyprinus carpio*)
Exposure Period	96 h
Auxiliary Solvent	Cremophor RH40 was used for dispersion of the test substance through the test medium.
Water Hardness	210 mg $CaCO_3$/L
Analytical Monitoring	There was no analysis performed because the solubility of the test substance in water was below 5 µg/L
Remarks – Method	Test Fish; mean length 2.3 ± 0.18 cm, mean weight 0.13 ± 0.036 g. Loading rate per vessel 0.43 g fish/litre. Since the test substance was highly hydrophobic (water solubility < 5 µg/L) Cremophor RH40 was used. A supersaturated solution of 1000 mg/L was prepared by dispersing 3 g of test substance mixed with Cremophor RH40 per 3 L. This resulted in incomplete dispersions with substance deposits. These solutions were stirred for 65 hours. The test fish were introduced immediately following the period of stirring. The final test was a limit test, based on there being no toxicity observed at 1000 mg/L in a range finding test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	NA	10	0	0	0	0	0
Cremophor[1]	NA	10	0	0	0	0	0
1000	NA	10	0	0	0	0	0

[1]Test medium containing 0.1 g/L Cremophor in water.

LC50	>1000 mg/L WAF at 96 hours.
NOEC	1000 mg/L WAF at 96 hours.
Remarks – Results	Exposure to a supersaturated solution of 1000 mg/L did not induce any effects. There was no mortality and the 96 hour LC50 was observed to be greater than the limit of water solubility. Due to the turbidity of the test solutions, effects other than mortality could be scored only at the end of the test when the fish were transferred to clear water. No effects were observed. The pH during the test ranged from 7.9 to 8.4. Oxygen concentration in the test media was > 5 mg/L and the temperature of the test medium ranged from 21 to 22°C. A reference test was performed using the positive control substance, pentachlorophenol at concentrations of 0.1, 0.18, 0.32, 0.56 and l.0 mg/L. The 96 h LC50 was 0.24 mg/L (95% CI of 0.19 and 0.34 mg/L) and was within the laboratory's historical range of 0.18 – 1.0 mg/L.
CONCLUSION	The notified chemical is non toxic at the limit of water solubility to *Cyprinus carpio*.
TEST FACILITY	RCC NOTOX (1991m)

8.2.2.1 Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical with a purity of 99.3%
METHOD	OECD 202. "Daphnia sp., acute immobilisation test and reproduction test", 1984 EEC Directive 841449, Method C-2: "Acute toxicity for daphnia", 1984
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Cremophor RH40 was used for dispersion of the test substance through the test medium.
Water Hardness	210 mg $CaCO_3$/L
Analytical Monitoring	Not performed
Remarks - Method	Test conditions: 18.5 to 20.5ºC, illumination of 16 h light, 8 h darkness, pH 8.0 to 8.5, Oxygen concentration the test media > 5mg/L (60% saturation). A supersaturated solution was prepared by adding a mixture of 1017.2 mg of test substance and 104.6 mg Cremophor RH40 to 1000 mL of test media. The resulting solution was stirred for 48 hours prior to use either filtered or unfiltered. Daphnia were exposed for 48 h to the supersaturated solution of 1000 mg/L, unfiltered in duplicate and filtered in duplicate. 10 daphnia were exposed per replicate. Control vessels were prepared, one with no test substance or other additives and one with the Cremophor RH40.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	NA	20	0	1
Cremophor Control	NA	20	0	0
1000 Filtered	NA	20	0	4
1000 Unfiltered	NA	20	0	2

LC50	>1000 mg/L at 48 hours.
NOEC	1000 mg/L at 48 hours.
Remarks - Results	After 24 hours of exposure no immobilization of daphnia was observed in either the saturated solution or its filtrate. After 48 hours of exposure 20% of the daphnia exposed to the filtrate were recorded immobile and 10% immobility was seen in the supersaturated solution. Under the conditions of the test, the 48 h EC50 of the test substance for immobilisation of Daphnia was greater than the water solubility in water (< 5 µg/L). Exposure to a supersaturated solution of nominally 1000 mg/L did not result in significant immobilisation of *Daphnia Magna* after 48 h of exposure. In the control vessels, <10% of the daphnids were immobilised (or trapped at the surface of the water). A reference test was performed using the positive control substance, potassium dichromate at concentrations of 0.0, 0.32, 0.56, 1.0, 1.8 and 3.2 mg/L. The 24 h EC50 was 2.26 mg/L, and the 48 h EC50 was 1.23 mg/L, both values were within the expected range.
CONCLUSION	The notified chemical shows some toxicity to *Daphnia magna* at the limit of water solubility in a saturated solution.
TEST FACILITY	RCC NOTOX (1991n)

8.2.2.2 Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical with a purity of 99.5% (batch no. 80417)
METHOD	OECD 211. Full Life Cycle Toxicity Test with Water Fleas, *Daphnia magna* Under Flow-Through Conditions.
Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	Dimethylformamide
Water Hardness	160-170 mg $CaCO_3$/L
Analytical Monitoring	Reverse phase HPLC analysis with UV detection. Limit of quantification (LOQ) was 0.0372 mg a.i./L. Exposure concentrations were analytically confirmed on days 0,7, 14, 15 and 21.
Remarks - Method	Test conditions: 19 to 22°C, illumination of 16 h light, 8 h darkness at 38 to 90 footcandles. Dilution water was fortified well water with specific conductivity of 480 to 500 µmhos/cm. pH of test vessels was in the range 7.7 to 8.1. Dissolved oxygen concentration of test vessels was 7.4 to 9.3 mg/L. A 20 mg a.i./mL primary stock solution of test substance in dimethylformamide was prepared weekly. The primary stock solution was subsequently diluted to give the remaining test concentrations. A solvent control was tested containing DMF at the same concentration as used in the test vessels. The highest concentration to achieve solubility was used, but there was no indication as to whether this was maintained over the 21 day test. Nominal test concentrations: 0.13, 0.25, 0.50, 1.0 and 2.0 mg a.i./L Mean measured concentrations: 0.15, 0.3, 0.51, 0.77 and 1.7 mg a.i./L
RESULTS	
EC50	>1.7 mg a.i./L at 21 days (immobilization and reproduction)
NOEC	1.7 mg a.i./L at 21 days (survival, growth and reproduction)
Remarks - Results	After 21 days of exposure, survival among the dilution water control and solvent control organisms averaged 90% and 95% respectively. Cumulative number of offspring released by each female offspring during the 21-day test was 120 and 129 respectively and the first brood of offspring was on day 7. At termination of the test, survival of daphnids was 90, 98, 92, 90 and 93% at concentrations of 0.15, 0.30, 0.51, 0.77 and 1.7 mg a.i./L respectively, and was not statistically significant different from the pooled control data. After 21 days of exposure, mean cumulative number of offspring released per female was 103, 97, 102, 121 and 125 at test concentrations of 0.15, 0.30, 0.51, 0.77 and 1.7 mg a.i./L respectively, and was not statistically significant different from the pooled control data. First brood release occurred on day 7 which was consistent with the pooled controls. There was no statistically significant difference in the mean total body length and mean dry weight at test termination in the pooled control and the 0.15, 0.30,0.51, 0.77 and 1.7 mg a.i./L test groups.
CONCLUSION	The test material is not chronically toxic to *Daphnia magna* at the highest concentration tested (1.7 mg/L).
TEST FACILITY	Springborn (2000)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical with a purity of 99.2%
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata (Selenastrurn capricornutumj*
Exposure Period	72 hours
Concentration Range	Nominal: 0.035, 0.063, 0.11, 0..20 and 0.35 mg/L Actual: 0.0342 to 0.349 mg/L
Auxiliary Solvent	DMSO
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Reverse phase HPLC analysis with UV detection. The measured concentrations at 72 h were significantly lower than those at the start of the test. Only in the highest concentration could the test material be detected after 72 h and the concentration was 24% of the initial concentration (assuming a starting concentration of 0.349 mg/L).
Remarks - Method	No significant protocol deviations. Test was conducted for 72 h under constant illumination (7000-8000 lux), at a temperature of 21.5 to 23ºC. pH of the media was in the range 8.0 to 8.3 for the duration of the test.

RESULTS

Biomass		*Growth*	
E_bC50 *mg/L at 72 h*	*NOEC* *mg/L*	*E_rC50* *mg/L at 72 h*	*NOEC* *mg/L*
>0.35[1]	0.035[1]	>0.35[1]	0.20[1]

[1]initial measured concentrations.

Remarks - Results	The results are based on the initial measured values due to high losses of test substance after 72 h. Statistically significant inhibition of cell growth was found at initial test concentrations $\geq$0.063 mg/L (P = 0.05), but at 0.35 mg/L only 25.9% inhibition was observed. Reduction of cell growth was only significant at the highest test concentration (0.35 mg/L). The 72 h ErC50 for the reference substance potassium dichromate was within the historical range at 1.32 mg/L,
CONCLUSION	The ErC50 of the notified chemical is >0.35 mg/L, where about 20% inhibition occurred.
TEST FACILITY	RCC NOTOX (1995a)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical with a purity of 99.2%
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 67/548/EEC, Part C. Activated Sludge Respiration Inhibition Test.
Inoculum	Micro-organisms in activated sludge
Exposure Period	0.5 hours
Concentration Range	Nominal: 100 mg/L limit test.
Remarks – Method	Activated sludge from a municipal sewage treatment plant was incubated with the test material. Due to the very low water solubility of the test material, Tween-80 (0.006% v/v) was used as an additive. Controls were prepared containing no test substance or Tween-80 and additive controls

	were prepared containing just the Tween-80. A reference substance, 3,5-dichlorophenol, was used at concentrations of 3.2, 10 and 32 mg/L
RESULTS	
IC50	>100 mg/L
NOEC	NA
Remarks – Results	No inhibition of the respiration rate was observed for the test substance at 100 mg/L. The mean respiration rate of the controls (1 & 2 and 3 & 4) were within 15% of each other. The mean respiration rate of additive controls 1 and 2 were outside the level required for the test to be valid (18%). However, since there was no significant inhibition in the test samples and the non-additive controls (3 and 4) were within 15% of each other, the test can be considered valid. The EC50 of 3,5-dichlorophenol was 15 mg/L, which was within the acceptable limit of 5-30 mg/L. The test was, therefore, valid.
CONCLUSION	The test substance was not toxic to activated sludge.
TEST FACILITY	RCC NOTOX (1995b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release of the notified chemical is expected to be limited to the landfill environment. It is anticipated that up to 1% of the total import volume, arising from contaminated spills and from residual within import containers, will be incinerated, thermally degrading to form oxides of carbon and water.

The remaining quantity of notified chemical is expected to be consumed in the moulding process, being either chemically or physically entrapped within the finished moulded article, which is expected to be disposed of to landfill at the end of its useful life. Within the landfill environment, the notified chemical is expected to remain entrapped, but over time it may eventually degrade via biotic and abiotic processes to form simple organic compounds.

Release to the aquatic environment is not anticipated at any time throughout the notified chemical life-cycle within Australia.

9.1.2. Environment – effects assessment

The notified chemical has been shown to be not harmful to fish up to the limit of its solubility in water ($<5 \times 10^{-3}$ mg/L at 20ºC - LOD), but there was some toxicity to daphnids in supersaturated solutions, and about 20% inhibition occurred to the growth rate of algae at 0.35 mg/L.

9.1.3. Environment – risk characterisation

A low potential for environmental release of the notified chemical is expected with most of the notified chemical being eventually released to landfill entrapped chemically or physically within the finished products. Therefore, based on the proposed import volumes and use pattern, the notified chemical is not expected to pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and Storage

Exposure to transport and warehouse workers is expected to be negligible, except in the event of an accidental spill.

Manufacture of Pellets

Dermal and possibly accidental ocular and inhalations exposure to the notified chemical may occur during the transfer from the bags to the blending vessel or hopper. Dermal exposure and from non-dusty solids is estimated to be negligible (European Commission, 2003).

Inhalation exposure is possible but is considered to be low as the as the notified chemical is introduced in pelletised form, is of low vapour pressure and does not contain particles in the inhalable range. Exposure would be further limited by the use of personal protective equipment (PPE) and engineering controls such as (Local Exhaust Ventilation).

Exposure during quality control, cleaning and maintenance processes is expected to be low due to the low concentration (up to 5%) and the expected use of PPE and engineering controls also.

Moulding

Dermal and possibly accidental ocular and inhalations exposure to the notified chemical may occur. However the moulding processes are largely automated and thus exposure is expected to be low. After curing the notified chemical is trapped within an inert matrix and is not bioavilable.

9.2.2. Public health – exposure assessment

As the notified chemical will be used as an additive in plastic for food contact packaging the potential migration of the notified chemical into food-simulating solvents was also determined

Covance (2005).

Mean (µg/in.2) of Notified Chemical				
Test Item	121°C for 2 hours	121°C for 2 hours, then 40°C for 22 hours	121°C for 2 hours, then 40°C for 94 hours	121°C for 2 hours, then 40°C for 238 hours
	10% Ethanol			
HIPS with 1% notified chemical	<0.100	<0.100	<0.100	<0.100
GPPS with 1% notified chemical	<0.100	<0.100	<0.100	<0.100
	50% Ethanol			
HIPS with 1% notified chemical	70.7	45.3	46.9	42.2
GPPS with 1% notified chemical	46.8	22.0	23.5	19.5

HIPS =High Impact Polystyrene, GPPS = General Purpose Polystyrene. Negative controls are not shown but confirmed the sensitivity of the test system.

The migration studies above show that migration of the notified chemical is possible from plastic, however the conditions under which the migration study was conducted are not expected to be typical end-use scenarios.

Given the wide application including use in food contact packaging products containing the notified chemical public exposure is possible, however exposure is expected to be low given the low concentration of notified chemical (1%) in end-use goods.

9.2.3. Human health – effects assessment

Acute toxicity
The notified chemical is considered to be of low acute toxicity when administered orally or when applied to the skin.

Irritation and Sensitisation
Rabbit studies of eye and skin irritation found that the notified chemical is slightly irritating to both eyes but non-irritating to skin.

The notified chemical is not considered to be a sensitiser at up to 25%w/v, based on the Guinea Pig Maximisation Test. The concentration of notified chemical used in the Guinea Pig Maximisation Test was 25%w/v, which is significantly lower than the concentration workers involved in manufacturing pellets, would be exposed to (up to 100%).

Repeated Dose Toxicity
Based on a 28-day subacute dermal toxicity study in rats, the No Observed Effect Level (NOEL) was established as 851 mg/kg bw/day based on the effects in the study. A 90 day subacute oral toxicity test determined a No Observed Adverse Effect Level (NOAEL) of 1360 mg/kg bw/day for males and 1430 mg/kg bw/day for females.

Mutagenicity
The notified chemical was found to be non-mutagenic in the Ames tests. The notified chemical was not clastogenic in an *in vitro* gene mutation test in cultured V79 Chinese Hamster cells and not clastogenic in an *in vitro* chromosomal aberration tests in cultured Chinese Hamster lung cells. The notified chemical is not considered mutagenic.

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

Manufacture of Pellets
Given the limited opportunity for exposure (limited to transfers of the imported notified

chemical to the blending vessel or hopper) the personal protective equipment (including eye protection) and engineering controls (local exhaust ventilation) in place there is low risk of adverse health effects to workers involved during the manufacture of pellets.

As the notified chemical is a slight eye irritant these control measures would also reduce the risk of adverse effects. There is low probability that nuisance dust levels could exceed the NOHSC exposure standard of 10 mg/m^3 (NOHSC, 1995).

Moulding
Following formation of pellets, the risk of adverse effects from exposure during moulding is expected to be low due to the low concentration of the notified chemical (up to 1%) and the incorporation of the notified chemical in an inert matrix.

The risk of systemic effects are not expected considering the low potential for repeated exposure. Overall, exposure to the notified chemical is expected to be low and therefore the risk to the workers is also expected to be low.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical is expected to be minimal and therefore the risk to public health is also 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*.

Based on the available data, the notified chemical does not meet the criteria for classification under the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) system.

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 Low Concern to public health when used under the public settings described.

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

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the 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 as introduced or where dust is generated:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid skin 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:
  - Gloves
  - Safety goggles
  - Coveralls
  - Dust masks

- 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 incineration or to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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