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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Pigment Yellow 382 E

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Director
NICNAS

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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
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Means of Identification
Molecular Weight
Spectral data
Methods of Detection and Determination
Purity
Impurities (Hazardous and Non-Hazardous)
Additives/Adjuvants
Import Volume
Use
Identity of Customers

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
None

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (PMN)
Europe (VIIA)
Japan (ISHL: 8–(2)-1928)
Canada (Schedule I)
Korea (KECI – 2003-3-2400)
China (IECSC) – 2004.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Chemical in Pigment Yellow 382 E
Cromophtal Yellow 382EOB (up to 80-100% notified chemical)
Microlen Yellow 382EOB-PG (up to 30-50% notified chemical)

METHODS OF DETECTION AND DETERMINATION

METHOD Liquid Chromatography
High Performance Liquid Chromatography, IR, UV-Visible, MS and ^{13}C NMR

spectroscopy.

Remarks Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>88-95% (confirm with notifier)

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be introduced in a ready to use pelleted (granulated) form (Microlen Yellow 382EOB-PG) or as a yellow powder (Cromophtal Yellow 382EOB).

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

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

USE
The notified chemical will be used as a colourant for a diverse range of plastics.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Ciba Specialty Chemicals Pty Ltd
235 Settlement Road
Thomastown VIC 3074

TRANSPORTATION AND PACKAGING
The notified chemical in Microlen Yellow 382EOB-PG will be imported in 20-kg polyethylene bags or 20-kg fibreboard cartons with polyethylene inner lining. The notified chemical in Cromophtal Yellow 382EOB will be imported in 10-kg polypropylene bags or 10-kg fibreboard cartons with polyethylene inner lining. The products containing the notified chemical will be transported by road to the warehouse for storage until required.

5.2. Operation description

Batching and Extruding
The bags (10 or 20 kg) or fibreboard cartons (10 or 20 kg) of product containing the notified chemical will be transported as required from the warehouse to the production area by forklift or manually. The notified chemical in the powder (80-100% notified chemical) or pelleted (granulated, up to 30-50% notified chemical) form is weighed manually before being added to a blending vessel for mixing with other components. The resulting powdered mixture is transferred by automated means to the feed hopper of an extruder from which molten strands are chopped into pellets and allowed to cool before being discharged via a closed transfer system for packaging by manual means into 15, 20 or 25 kg plastic bags for transport to customers' sites. During this process, the notified chemical (5–15% of the reformulated pellets) becomes encapsulated in the polymer matrix.

Moulding (typical customer scenario provided by the notifier)
At the customers' factories, the pellets containing the notified chemical is 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. The notified chemical (and possibly other additives) are mixed with polymer in a typical ratio

of around 1:10 reformulated pellets : polymer in the hopper. The resulted mixture is again melted and extruded under pressure through dies or mould of the appropriate shapes so as to produce the final plastic article. The final concentration of the notified polymer in the finished polymer products is estimated as being typically around 0.1–0.5%, although the range is likely to be close to 0.2–0.3%. The moulded plastic article or film can be moved manually or may be an automated production line.

Initially up to 5 customers' might use the reformulated pellets containing the notified chemical, although this may increase in the future. It is expected the polymer containing the notified chemical would be used in the manufacture of a diverse range of plastic products where coloration is important.

5.3. Occupational Exposure

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside workers	2 – 3	None expected	None expected
Transport and storage workers	4 – 8	1 hour/day	10 – 15 days/year
Process operators for masterbatch and injection moulding processes. (Weighing, loading, packing pellets and cleaning)	10 – 20	6 – 8 hours/day	50 - 100 days/year

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

Batching and Extruding
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 imported powdered product to the automated batching and pellet-extruding machine. The loading operation is carried out under a dust extractor and blending occurs in a closed extruder. Personal protective equipment (PPE) includes coveralls, dust mask, gloves and eye protection when carrying out the above activities. Much lower exposure would occur where the notified chemical is imported in pelleted form.

Moulding
The manufacture of plastic articles involves a highly automated process. The most likely route of exposure is dermal contact may occur when opening containers and manually charging the polymer masterbatch containing up to 15% of the notified polymer into an injection moulding machine. However, worker exposure is not anticipated since the notified chemical is encapsulated within the masterbatch and would not be available for exposure. Workers handling the masterbatch pellets containing the notified chemical will wear protective equipment including gloves, safety glasses and overalls. The injection moulding machines are enclosed and the process areas are fitted with local exhaust ventilation to capture fugitive emissions from the heated resin.

Handling of finished articles (which contain up to 0.5% of the notified polymer) made from resin granules would not result in exposure to the notified chemical for workers as it will be encapsulated in the polymer matrix and not available for exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported as a component of Microlen Yellow 382EOB-PG or Cromophtal Yellow 382EOB and will be used in masterbatch production to produce pellets for moulded or extruded plastic articles. There will be no environmental exposure associated with the manufacture of the notified chemical in Australia.

Small quantities of the chemical could be lost during preliminary mixing with polymer and other components prior to extrusion of the masterbatch, and all of this is likely to be placed into landfill.

Small spills of chemical would be swept up and either returned to the mix or disposed with other factory waste to landfill. It is expected the mixing and extrusion operations would be performed using local exhaust extraction/filtration so that any particulate matter released to the air during operations would be captured and retained on the filters, and all solid material retained on the filters would also be placed into landfill.

On occasions the extrusion equipment would be cleaned out and some solid scrap material removed from the equipment and also placed into landfill, as would any of the granulated masterbatch lost during packaging. Emptied bags of the chemical would be shaken into the masterbatch mix to remove residual material and then be placed into landfill.

Apart from spills no release of the chemical during dry mixing of the masterbatch compound with polymer, filler and other materials is expected during injection moulding of the final articles although it is possible that some scrap plastic may be produced during finishing of the final products. All such waste would be placed into landfill.

While no details of likely release of the notified chemical are available, large releases are not expected. If it is assumed that 2% is lost during masterbatch preparation and a further 3% lost as scrap and waste from injection moulding, then total losses associated with manufacturing activities are 5%. This equates to a maximum annual release of < 20 kg, all of which will be placed into landfill.

RELEASE OF CHEMICAL FROM USE
Once incorporated into plastic/polymer articles the notified chemical will be immobilised in the polymer matrix and little release is expected.

5.5. Disposal

Disposal via incineration in the presence of air, is the disposal route of choice. Spilled or reject material during manufacture of masterbatch or moulded articles will be collected and reused. Regranulated product unsuitable for reuse is bagged and disposed to secure landfill as normal industrial waste via a waste contractor. Packaging should be emptied as far as possible, and disposed to licensed waste landfill site.

5.6. Public exposure

During manufacture of formed plastic articles by injection and extrusion, any spillage will be contained within bunded areas. Public exposure during the injection and extrusion process is negligible.

The notified chemical in plastic articles is expected to be not biologically available. Public exposure through contact with articles containing the notified chemical is expected to be negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Yellow, crystalline powder with typical odour

Melting Point/Freezing Point >400°C

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Determined using differential scanning calorimetry (DSC). Melting of the chemical was not observed in the temperature range of 25°C – 400°C. There was some indication for a slow reaction or decomposition of the notified chemical starting at approximately 225°C. Statement of GLP.
TEST FACILITY	NOTOX B.V. (2001b)

Boiling Point >400°C

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Boiling of the chemical was not observed in the temperature range of 25°C – 400°C. There was some indication for a slow reaction or decomposition of the notified chemical starting at approximately 225°C. Statement of GLP.
TEST FACILITY	NOTOX B.V. (2001b)

Density 1830 kg/m^3 at 20°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density Determined by gas comparison pycnometer
Remarks	Statement of GLP.
TEST FACILITY	NOTOX B.V. (2001c)

Vapour Pressure $4.2 \times 10^{-4} \pm 0.02$ kPa at 20°C.

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined using static measurement. According to the guideline, the recommended range for the Static method is 10 up to 10^5 Pa. However, the Static method can even be used at below 10^{-1} Pa when using a suitable manometer. The vapour pressure of the notified chemical was measured at 24.30, 31.10 and 37.26°C. With respect to the environment, this is classified as very slightly volatile (Mensink *et al* (1995)). Statement of GLP.
TEST FACILITY	NOTOX B.V. (2001d)

Water Solubility < 0.2 mg/L at 19.5± 0.5°C

METHOD	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility. Column elution method Analytical method: HPLC with UV detection (378 nm)
Remarks	A blank column and two test columns were used in the study. The mean result for the two columns was 0.106 mg/L. The mean result obtained from the blank column was 0.105 mg/L. Hence, it is unclear whether the observed peak was for the test substance. However, the water solubility of the notified chemical was determined to be < 2 x 10^{-4} g/L (< 0.2 mg/L) at 19.5±0.5°C. Based on the results the notified chemical is very slightly soluble (Mensink *et al.* 1995). Statement of GLP.
TEST FACILITY	NOTOX B.V. (2001f)

Hydrolysis as a Function of pH Not determined.

Remarks	The notified chemical does not contain functional groups which are likely to undergo hydrolysis under the environmental pH range (4-9)

Partition Coefficient (n-octanol/water) log Pow at 20°C = -0.74

METHOD	Calculation method
Remarks	The Flask-shaking method (below detection in both solvents), the HPLC method and the estimation method proved not to be applicable for this compound. The partition coefficient was calculated using the Rekker calculation method.
TEST FACILITY	NOTOX B.V. (2001g)

Adsorption/Desorption log K_{oc} = 0.26

METHOD The adsorption/desorption of the notified chemical has been calculated using the method described in the Technical Guidance Document on Risk Assessment (1996).

Remarks The quoted value is the mean of the determination of log Koc using a quantitative structure activity relationship (QSAR) for hydrophobics (log Koc = -0.50) and amides (log Koc = 1.01).

TEST FACILITY NOTOX B.V. (2002a)

Dissociation Constant Not Determined

Remarks The notified chemical contains basic functionalities which would be expected to display typical basicity. Values for these groups were calculated during the partition coefficient study described above. The values for the pKa ranged between 5.06-7.32, indicating that the notified chemical will be protonated under the environmental pH range (4-9).

Particle Size Particle size distribution ranges from 0.2 µm to 5.4 µm

Range (µm)	*Mass (%)*
<0.191	10
<0.325	25
<0.752	50
<2.409	75
<5.399	90

METHOD Laser Diffraction Particle Size Analysis

Remarks A microscopic examination was also performed. The notified chemical appeared to be an agglomeration of amorphous small particles by microscopic visual estimation. The smallest particle size was approximately 3.2 µm. It was not possible to size the largest particles.
Mass median diameter (MMD) = 0.752 µm
Inhalable fraction <100 µm, 100%
Respirable fraction <10 µm, >90%
Statement of GLP.

The product chromophtal yellow containing 80–100% notified chemical possesses a particle size range of 4.5–879 µm.
Mass median diameter (MMD) = 17 µm
Inhalable fraction <100 µm, 73%
Respirable fraction <10 µm, 37%

TEST FACILITY Chilworth Technology (2002)

Flammability Not highly flammable

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

Remarks The notified chemical could be ignited, it burned with a yellow flame and turned black in contact with the ignition source. After removal of the ignition source, the flame extinguished immediately. No propagation throughout the test chemical pile was observed.
Statement of GLP.

TEST FACILITY NOTOX B.V. (2001h)

Flammability Limits (contact with water) Not highly flammable

Method EC Directive 92/69/EEC A.12 Flammability (contact with water)
Expert Statement.

Remarks The main component of the notified chemical does not contain functional groups that may lead to the evolution of highly flammable gases in dangerous quantities. Moreover, experience in handling the notified chemical does not react with water.

Statement of GLP.
TEST FACILITY NOTOX B.V. (2001i)

Flammability Limits (pyrophoric) Not pyrophoric

Method EC Directive 92/69/EEC A. Pyrophoric properties of solids and liquids
Expert Statement.
Remarks The main component of the notified chemical does not contain any chemical groups that may lead to the spontaneous ignition a short time after coming into contact with ait at room temperature. Furthermore, handling of the notified chemical supports this.
Statement of GLP.
TEST FACILITY NOTOX B.V. (2001m)

Autoignition Temperature >400ºC

Method 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks No endothermic or exothermic reaction was observed during the performance of the test up to 400ºC.
Statement of GLP.
TEST FACILITY NOTOX B.V. (2001k)

Explosive Properties Not predicted to be explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Expert Statement.
Remarks From the structural formula of the main components of the notified chemical, it can be concluded that the chemical is not explosive. The chemical does not contain any chemically unstable or highly energetic groups that might lead to an explosion.
Statement of GLP.
TEST FACILITY NOTOX B.V. (2001j)

Reactivity Not reactive.

Remarks Under normal conditions of use the notified chemical is stable. The notified chemical does not have oxidising properties and is not explosive

Surface Tension 73.6 mN/m at 20.0±0.5°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension of the notified chemical in water (90% saturation concentration) was determined using a ring tensiometer. Based on the criteria as outlined in the EEC guideline, the notified chemical is not a surface active material.
TEST FACILITY NOTOX B.V. (2001e)

Oxidising Properties Not predicted to be oxidizing.

METHOD EC Directive 92/69/EEC A.17 Oxidizing properties (solids).
Expert Statement.
Remarks The notified chemical is not considered to have oxidising properties based in the structure of the main component.
Statement of GLP.
TEST FACILITY NOTOX B.V. (2001l)

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
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL/NOAEL 1000 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro human lymphocyte	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 96/54, B.1 tris
Species/Strain	Rat/Wistar strain Crl (WI) BR
Vehicle	Water
Remarks – Method	No significant protocol deviations. Statement of GLP included.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	No adverse macroscopic observations at necropsy.
Remarks – Results	Hunched posture, uncoordinated movements and/or lethargy were shown by the females on days and/or 2, while piloerection was shown by one male on day 1. Additionally, one male and one female showed green faeces between days 3 and 7. No explanation could be given for this finding. These findings may be related to staining properties of the notified substance, as yellow staining observed among one female. There were no remarkable body weight changes during the study period.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	NOTOX B.V. (2001n)

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/Wistar strain Crl:(WI) BR
Vehicle	Water
Type of dressing	Semi-occlusive.
Remarks – Method	No significant protocol deviations. Statement of GLP included.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Two males showed ptosis, hunched posture and/or piloerection on days 1 and/or 2. Yellow staining of the treated skin and/or head, noted among all animals, was considered to be related to staining properties of the notified chemical. Other clinical signs noted during treatment among all animals consisted of chromodacryorrhoea, scales and/or scabs. The animals had recovered from the symptoms between days 7 and 15.
Signs of Toxicity - Systemic	There were no notified chemical-related systemic reactions.
Effects in Organs	No adverse macroscopic observations at necropsy.
Remarks – Results	There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period.

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

TEST FACILITY — NOTOX B.V. (2001o)

7.3. Irritation – skin

TEST SUBSTANCE — Notified chemical.

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

Species/Strain	Rabbit/New Zealand White Albino, SPF
Number of Animals	3 males
Vehicle	Moistened with water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks – Method	No significant protocol deviations. Statement of GLP included.

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	0.3	0	0.7	1	48 h	0
Oedema	0	0	0.3	1	24 h	0

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

Remarks – Results — Exposure to the notified chemical resulted in very slight erythema and no or very slight oedema in the treated skin areas of the rabbits, which had resolved within 24, 48 or 72 hours. Yellow staining of the treated skin by the notified chemical was observed between days 1 and 3 on all animals which did not hamper the scoring of skin reactions.

CONCLUSION — The notified chemical is slightly irritating to skin.

TEST FACILITY — NOTOX B.V. (2001p)

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 Albino, SPF
Number of Animals	3
Observation Period	72 hours
Remarks – Method	No significant protocol deviations. Statement of GLP included.

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	1	0.7	1	2	<72 hours	0
Conjunctiva: chemosis	0.3	0.3	0.3	2	<48 hours	0
Conjunctiva: discharge	0	0	0	1	<24 hours	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	1	<24 hours	0

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

Remarks – Results — Instillation of the notified chemical resulted in effects on the iris and conjunctivae. Iridial irritation was observed among all animals on day 1 and had resolved within 24 hours. Irritation of the conjunctivae was seen as redness, chemosis and discharge, which had completely resolved within 72 hours in all animals. No corneal opacity was observed, and treatment of the eyes with 2% fluorescein, 24 hours after notified chemical instillation revealed no corneal epithelial damage in any of the animals. Remnants of the notified chemical were present in the eyes of all animals on day 1. Yellow staining of the fur on the head and paws, caused by the notified chemical, was noted during the observation period.

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

TEST FACILITY — NOTOX B.V. (2001q)

7.6. Skin sensitisation

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 406 Skin Sensitisation - <Magnusson and Kligman>.
EC Directive 96/54/EC B.6 Skin Sensitisation - < Magnusson and Kligman >.

Species/Strain	Guinea pig/Dunkin Hartley strain, albino (SPF)
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 2% topical: 50%
MAIN STUDY	
Number of Animals	Test Group: 10 F Control Group: 5 F
Induction phase	Induction Concentration: intradermal injection 2% in water topical application 50% in water
Signs of Irritation	Intradermal: All animals showed well-defined to moderate erythema. Topical: All animals had small scabs.
CHALLENGE PHASE	
1st challenge	Topical application: 50% in water
2nd challenge	Topical application: 50% in water

Remarks – Method: Statement of GLP.
SDS pre-treatment before induction was performed as highest topical concentration in preliminary test did not produce irritation.
No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	50%	1/10	0/10	1/10	1/10
Control Group	50%	0/5	0/5	1/5	0/5

Remarks – Results: Yellow staining was observed at substance treated skin sites, 24 and 48 hours after first challenge and second challenge. This staining did not hamper the scoring of the skin reactions. The slight skin reaction, as observed in response to a 50% test substance concentration in one experimental animal after the first challenge phase also occurred in one control and one experimental animal in the second challenge. Since comparable skin reactions were observed in one control animal and based on the inconsistency in results, it was considered that all reactions observed were signs of non-specific irritation.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: NOTOX B.Y. (2001r)

7.7. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral)

Species/Strain: Rat/Wistar Crl:(WI) BR
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: 14 days
Vehicle: Water
Remarks – Method: Statement of GLP.
No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	50	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

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

Clinical Observations

There were no clinical signs of toxicity or behavioural changes during the study period that were considered to be related to treatment. All group 3 and 4 animals had produced yellow faeces from day 2 of the treatment phase onwards. This finding, which remained present up to day 3 of the recovery period in all high dose animals, was considered to be related to staining properties of the notified chemical. Other findings consisted of alopecia and scabs, 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. Clinical signs were absent among group 2 animals and control animals.

Functional Observations:

No changes were observed in hearing ability, pupillary reflex, static righting reflex and grip strength in the treated animals when compared to control animals. The variation in motor activity did not indicate a relation with treatment.

Food Consumption:

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

Body Weight:

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

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Biochemistry:

The mean concentration of bilirubin and chloride was significantly ($p<0.05$) increased in males treated with 1000 mg/kg/day values by 20% and 2% respectively but was reversed after the two weeks treatment free recovery period. In high dose males after the treatment free recovery period a significant ($p<0.05$) decrease (20%) in gamma-glutamyl transferase was observed and a significant ($p<0.01$) increase (5%) in inorganic phosphate concentrations. The mean concentration of urea was significantly ($p<0.05$) decreased in females treated with 1000 mg/kg/day values by 16%. The mean concentration of potassium was significantly ($p<0.05$) decreased in females treated with 50 mg/kg/day values by 10%. The mean concentration of chloride was significantly ($p<0.05$) increased in females treated with 150 mg/kg/day values by 2%. No dose-related response was observed for statistically significant changes occurring among female groups at the end of treatment. The changes in urea, potassium and chloride were reversed after the two weeks treatment free recovery period. The mean activity of aspartate aminotransferase was increased (not significantly) in groups II, III and IV by 6, 11 and 2% respectively at the end of the treatment period. In high dose females after the treatment free recovery period a significant ($p<0.05$) increase (12%) in aspartate aminotransferase was observed.

Creatinine values of treated males at the end of the treatment phase were slightly low in comparison to similar studies. No explanation could be given for this finding.

No other significant test item-related changes in parameters of clinical chemistry were noted.

Haematology:

The mean platelet value of high dose females was significantly increased (11%, $p<0.05$) but was reversed after the two weeks treatment free recovery period. The mean activity of mean corpuscular haemoglobin concentration was significantly ($p<0.05$) decreased in males and females treated with 50 mg/kg/day (2.5% and 2% respectively) and in males treated with 150 mg/kg/day (3.3%, $p<0.05$) and females treated with 150 mg/kg/day (3%, $p<0.01$). No dose-related response was observed for the decreased mean corpuscular values of group 2 and 3 animals at the end of treatment and was reversed after the two weeks treatment free recovery period. The incidence of alterations of individual white blood cell and neutrophil counts during the treatment period (not significant) were not within the stated historical control range but did not show a dose response and were therefore not considered to be of toxicological relevance.

Effects in Organs

Organ weights:

No test-item related changes in mean organ weights or organ to body weight ratios were observed.

Macroscopic Examination:

There were no test-item related macroscopic findings.

Yellowish discolouration of the cranial lobes of the lung of one high dose male was considered to be related to the presence of macrophages containing yellow-brown pigment (see Microscopic Examination). Gray-white discolouration of the cortex of the left kidney of one group 4 female correlated microscopically to a benign nephroblastoma. This lesion was considered to be within the stated historical background data. Other incidental findings among control or high dose animals included yellowish nodules on the epididymides, dark red discolouration of the lungs or mandibular lymph nodes, scab formation on the skin, gray-white foci on the right lateral lobe of the liver, an uterus containing fluid, and dark red foci on the thymus. These findings are occasionally seen among rats used in these types of studies according to the study report and at the incidence observed they were considered changes of no toxicological significance. Low and mid dose males were without macroscopic findings.

Microscopic Examination:
There were no test-item related microscopic findings.

Pigmented macrophages (containing brown-yellow pigment) in the lungs of one high dose animal male and female and in the oesophageal wall of one high dose male animal were noted. This pigment was considered likely to be the test compound and to be related to the gavage procedure, rather than being a toxicological event. Other microscopic findings were within the range of stated background pathology encountered in rats of this strain and age. These included minimal focal necrosis in the liver of two high dose group females and an early nephroblastoma in one high dose group female.

Remarks – Results
Clinical Chemistry
Changes observed at the end of the recovery period include significant increase in aspartate aminotransferase in high dose females and in high dose males a significant decrease in gamma-glutamyl transferase and a significant increase in inorganic phosphate concentrations. However no dose-related response was observed during the treatment period and the findings are therefore not considered toxicologically relevant.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) and No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day based on the results of this study.

TEST FACILITY	NOTOX B.V. (2001s)

7.8. Genotoxicity – *Bacterial Reverse Mutation*

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
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 uvrA.
Metabolic Activation System	Aroclor 1254 induced rat liver S9 – homogenate
Concentration Range in Main Test	<u>Test 1</u> a) With metabolic activation: Test 1: 10 - 5000 µg/plate b) Without metabolic activation: Test 1: 10 - 5000 µg/plate <u>Test 2</u> a) With metabolic activation: Test 1: 10 - 1000 µg/plate b) Without metabolic activation: Test 1: 10 - 1000 µg/plate
Vehicle	Dimethyl sulfoxide – suspension formed by ultrasonic agitation
Remarks – Method	No significant protocol deviations. Doses selected for Test 2 based on precipitation observed in combined preliminary Test 1.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	>5000	>5000	≥1000	Negative
Test 2	>1000	>1000	≥1000	Negative
Absent				
Test 1	>5000	>5000	≥1000	Negative
Test 2	>1000	>1000	≥1000	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: NOTOX B.V. (2001t)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical.

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

Cell Type/Cell Line: Cultured peripheral human lymphocyte
Metabolic Activation System: Aroclor 1254 induced rat liver S9-homogenate
Vehicle: Dimethyl sulfoxide
Remarks – Method: No significant protocol deviations.
Statement of GLP.
Doses selected based on precipitation observed at 3 µg/mL in preliminary test.
No historical control data provided.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	0.03, 0.1, 0.3*, 1*, 3*	3	24
Test 2		3	48
Absent			
Test 1	0.03, 0.1, 0.3*, 1*, 3*	3	24
Test 2	0.03, 0.1, 0.3*, 1*, 3*	24	24
Test 3	0.03, 0.1, 0.3*, 1*, 3*	48	48

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	>3	>3	3	Negative
Test 2	>3	>3	3	Negative
Absent				
Test 1	>3	>3	3	Negative
Test 2	>3	>3	3	Negative

Test 3	>3	>3	3	Negative

Remarks – Results	Cytotoxicity was not observed at any test concentration. 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. At the test-substance concentration of 3 µg/mL in the absence of metabolic activation, one polyploid cell was observed in each assay after 3 hour exposure and 24 hour harvest and after 48 hour exposure and harvest. No aneugenic potential was assumed.
CONCLUSION	The notified chemical has no clastogenic potential as it does not induce chromosome aberrations in cultured human peripheral blood lymphocytes.
TEST FACILITY	NOTOX B.V. (2001u)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD
- Inoculum: Activated sludge from a municipal sewage treatment plant
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring:
- Remarks - Method: Reference substance – Sodium Acetate
  Treatments - nutrient medium and inoculum
  - test substance (33.6 mg/L)
  - reference substance (40.3 mg/L)
  - toxicity control (test substance 33.6 mg/L and reference substance 40.5 mg/L).

  The notified chemical was tested in duplicate. A determination was done for the reference substance and toxicity control.

RESULTS

Test substance		*Sodium Acetate*		*Toxicity Control*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
2	0	2	0	2	3
5	1	5	20	5	11
7	2	7	33	7	24
14	5	14	59	14	30
23	10	23	81	23	51
29	14	29	92	29	55

Remarks - Results: The test substance was shown not to have an inhibitory effect on the microorganisms. All acceptability criteria were met with the exception that the positive control substance was just below 60% within 14 days. This slight deviation is not considered to influence the outcome of this study and the study is considered valid.

CONCLUSION: The notified chemical was found to be not readily biodegradable under the conditions of the test.

TEST FACILITY: NOTOX (2001u)

8.1.2. Bioaccumulation

No specific study is available for bioaccumulation. Other studies have shown that the notified chemical has a low $P_{OW} \leq -0.74$. Values of log P_{OW} below 3 indicate no bioaccumulation tendency. Aquatic exposure will also be limited.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified substance.

METHOD: OECD TG 203 Fish, Acute Toxicity Test – static.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish –static.

Species	Carp, *Cyprinus carpio*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	As a consequence of the poor solubility, a limit test was performed with carp exposed to a filtered (Schleicher and Schuell 604, ca. 5 µm) and an unfiltered supersaturated solution both prepared at nominal 100 mg/L without any additive. The supersaturated test solutions were stirred for three days in the dark prior to testing. Such a procedure ensured that maximum saturation was reached. Filtration removed the major part of the undissolved fraction of the notified chemical (> ca. 5 µm). The filtered solution was fluorescent yellow while the unfiltered solution was a yellow dispersion. The test vessels, each with 7 fish, were covered, exposed to a photoperiod of 16 dark/8 hours light and were aerated throughout the study. Water quality parameters of pH (7.4-8.0), temperature (21.2-22.2°C) and O_2 content (6.1- 9.1 mg/L) were within normal limits throughout study.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3½ h*	*24 h*	*48 h*	*72 h*	*96 h*
Blank (control)		7	0	0	0	0	0
100 (filtered)	15 – 0.85	7	0	0	0	0	0
100 (unfiltered)	60 – 69	7	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC (or LOEC)	>100 mg/L at 96 hours.
Remarks – Results	Analysis of samples taken from the unfiltered test solution showed that the concentration in the dispersion remained stable between 60 and 69 mg/L during the test period. The concentration in the filtered solution decreased during the test period from 14.8 mg/L at the start to 0.85 mg/L after 96 h. The test chemical induced no mortality at or below a nominal loading of 100 mg/L, the regulatory limit concentration. Owing to the poor solubility of the notified chemical in water, concentration levels toxic for carp could not be reached. Therefore, the 96 h-LC50 for carp exceeded the maximum solubility of the notified chemical in water.

CONCLUSION — The test substance was not toxic to fish up to the limit of its water solubility.

TEST FACILITY — NOTOX B.V. (2001v)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 202 Part I Daphnia sp. Acute Immobilisation Test
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia
ISO 6341 Water Quality –Determination of the inhibition of the mobility of *Daphnia magna* Straus – Acute Toxicity Test

Species	*Daphnia magna*

Exposure Period	48 hours
Auxiliary Solvent	None.
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	As a consequence of the poor solubility, a limit test was performed with carp exposed to a filtered (Schleicher and Schuell 604, ca. 5 µm) and an unfiltered supersaturated solution both prepared at nominal 100 mg/L without any additive. The supersaturated test solutions were stirred for three days in the dark prior to testing. Such a procedure ensured that maximum saturation was reached. Filtration removed the major part of the undissolved fraction of the notified chemical (> ca. 5 µm). The filtered solution was fluorescent yellow while the unfiltered solution was a yellow dispersion. The test vessels, each with 7 fish, were covered, exposed to a photoperiod of 16 dark/8 hours light and were aerated throughout the study. Water quality parameters of pH (7.8-8.0), temperature (20.7-21.8°C) and O_2 content (7.3-9.2 mg/L) were within normal limits throughout study.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Blank (control)		20	0	0
100 (filtered)	15 – 2.5	20	0	0
100 (unfiltered)	66 – 2.8	20	0	0

LC50	>100 mg/L at 48 hours
NOEC (or LOEC)	>100 mg/L at 48 hours
Remarks – Results	Analysis of samples taken from the unfiltered test solution showed that the concentration in the dispersion reduced from 66 to 2.8 mg/L during the test period. The concentration in the filtered solution also decreased during the test period from 15.0 mg/L at the start to 2.5 mg/L after 96 h. The notified chemical induced no immobility in Daphnia magna at or below a nominal loading of 100 mg/L, the NOEC. Owing to the poor solubility of the notified chemical in water, concentration levels toxic for crustaceans could not be reached. Therefore, the 48h-EC50 for *Daphnia magna* exceeded the maximum solubility of the notified chemical in water.

CONCLUSION — The test substance was not toxic to daphnia up to the limit of its water solubility.

TEST FACILITY — NOTOX B.V. (2001w)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE — Notified chemical.

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

Species	*Scenedesmus capricornutum*
Exposure Period	72 hours
Concentration Range	0.1, 1, 10, and 100 mg/L combined/limit range finding test
Nominal	10, 18, 32, 56 and 100 mg/L Final test
Concentration Range	1.9 , 7.67, 21.0 (Mean of three measurements at time 0, 24 and 72 h)

Actual	
Auxiliary Solvent	None.
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Due to the low solubility of new chemical and due to the composition of the test chemical containing several components of various solubility, water accommodated fractions in the range of 0.1 – 100 mg/L were prepared in the test medium and stirred for 3 days. Subsequently, test solutions were filtered through a paper filter (5 µm) to remove the fraction of non-dissolved chemical particles. The solutions tested in the combined limit/range-finding test were all prepared separately applying a three-day stirring period followed by filtration through a paper filter (Schleicher and Schuell 604, ca. 5 µm) to remove the fraction of non-dissolved chemical particles. Preparation of test solutions for the final test started with a stock solution containing a nominal loading of 100 mg/L. This solution was stirred for 3 days in the dark and subsequently treated with ultrasonic waves, which resulted in a homogeneous dispersion. This dispersion was then used for preparation of the lower test concentrations by subsequent dilutions in test medium. Subsequently, all test solutions were filtered through a paper filter (Schleicher and Schuell 604, ca. 5 µm) to remove the fraction of non-dissolved particles. Final test solutions ranged from very slightly yellow to yellow. After preparation, volumes of 50 mL were added to each replicate of the respective test concentration. Subsequently, adequate volumes of an algal suspension were added to each replicate providing a cell density of 10^4 cells/ml.

RESULTS

Biomass		*Growth*	
E_bC50 *mg/L at 72 h*	*NOEC* *mg/L*	*E_rC50* *mg/L at 72 h*	*NOEC* *mg/L*
47 (95% CI: 24-92 mg/L)	1.9	> 100	1.9

Remarks – Results	The measured concentrations ranged between 31-48% of nominal at the start of the study and fell to 5-14% of nominal at the conclusion of the study. Results are based on nominal concentrations. The NOEC for both cell growth inhibition and growth rate reduction was at nominally 10 mg/L, corresponding with an average exposure concentration of 1.9 mg/L.
CONCLUSION	The test substance is slightly toxic to algae (Mensink *et al. 1995*)
TEST FACILITY	NOTOX B.V. (2001x)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Aerobic activated sludge
Exposure Period	0.5 hours
Concentration Range Nominal	50 mg/L
Remarks – Method	Activated sludge samples from a sewage plant were incubated with the

	test material, together with two controls containing no test compounds. The test substance was run in duplicate at a single concentration and the reference compound in triplicate. Vessels were aerated during the tests, and O_2 consumption rates were monitored. Temperature was maintained at 21.8°C. Duplicate controls were run in parallel. Reference substance – 3,5-dichlorophenol Rate of respiration was determined after 30 minutes and 3 hours contact.
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
Remarks – Results	The respiration rates of the controls were within 15% of each other. Therefore, the test was considered to be valid. The IC50 for the reference substance was 8 mg/L which is in the accepted range of 5-30 mg/L.
CONCLUSION	There was no significant inhibitory effect on the respiration rate of activated sludge after 30 minutes.
TEST FACILITY	NOTOX B.V. (2001y)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

As no manufacturing or formulation/reprocessing will be undertaken in Australia, the only opportunities for release relate to preparation of masterbatches and use of the masterbatches. The material will be used in a small number (up to 3) of metropolitan masterbatch manufacturers in Australia. The generation of waste is limited to traces remaining from the cleanup of any spill, trace residues in empty packaging and materials used to clean equipment between campaigns and for maintenance. Accidental loss of containment at warehouse, at masterbatch manufacturer or in transit and incompletely emptied containers are disposed to landfill. It is estimated that only 0.05% of the residues will be left in empty bags. The notifier indicates that the notified chemical would not leave the masterbatch manufacturers' factory and would not reach a sewage treatment plant. The production floors of masterbatch factories are completely dry and no water is used for cleaning. Spills are swept or vacuumed up so that no solids can reach the effluent system. The equipment is purged with neutral resin and the waste is recycled into another product or sold for use in non-demanding products such as sleepers, garbage bags, outdoor furniture etc.

It is estimated that 10-25 article forming facilities may ultimately use masterbatches containing the notified chemical. In the usage of the compounded notified chemical in the form of the masterbatch, it is expected that the notified chemical will be encapsulated in the polymer matrix. The fate of the notified chemical will be the fate of the article which is likely to be recycled, incinerated or be buried in landfill. Losses during end-use are expected to be very low.

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

9.1.2. Environment – effects assessment

The results of the ecotoxicological studies indicate that the notified chemical is not expected to be acutely toxic to fish or aquatic invertebrates up to the limit of its water solubility. However the notified chemical was found to be slightly toxic to algae, with a 72 h E_bC50 of 47 mg/L based on nominal concentrations. A predicted No Effect Concentration was calculated to be 470 µg/L using a safety factor of 100.

9.1.3. Environment – risk characterisation

Due to the limited release of the notified chemical to the aquatic compartment and its very low water solubility, a PEC could not be derived, and therefore, a Risk quotient was not calculated. However, the notified chemical is only slightly toxic to algae, and is clearly not toxic to fish or aquatic invertebrates up to the limits of water solubility. Therefore, the environmental risk from the reported use pattern of the notified chemical is expected to be low.

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.

Batching and Extruding

The highest potential for worker exposure will occur when the notified chemical in powder form is used to produce masterbatches. Dermal and possibly ocular and inhalation exposure to the notified chemical may occur during the transfer of the notified chemical in powder form from the containers to the blending vessel. The estimated typical case dermal exposure is 3000 mg and 900 mg respectively using measured data for the exposure scenario 'dumping of powders in a formulation facility' (European Commission, 2003). Therefore, for a 70 kg worker and a 100% dermal absorption factor, reasonable worst-case and typical case dermal exposure is estimated to be 43 mg/kg bw/day and 13 mg/kg bw/day, respectively. Much lower exposure would occur when masterbatch is produced using the notified chemical in pelleted form.

The estimated atmospheric concentration of notified chemical due to dust is 5-50 mg/m^3, based on EASE model (EASE) using reasonable worst-case defaults (European Commission, 2003). Therefore for a 70 kg worker, assuming an inhalation rate of 1.3 m^3/hour, 8 hour exposure time and 73% inhalable fraction, inhalation exposure is estimated to be 0.6-5.4 mg/kg bw/day

The use of appropriate PPE such as gloves, safety goggles and dust masks and engineering controls such as local exhaust ventilation will limit exposure by these routes.

Once the powder has been added to the mixing vessel, it is in a closed system and exposure should be precluded. In addition, the notified chemical is encapsulated within a matrix and should not be bioavailabe. Therefore, exposure during subsequent moulding operations can be precluded.

9.2.2. Public health – exposure assessment

Public exposure may occur if accidental release of the chemical during transport occurs. Under normal circumstances the public should only contact the notified chemical when it is incorporated in an inert solid matrix. Given the wide range of plastic articles containing the notified chemical public exposure is likely. However, overall public exposure is expected to be low.

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. Information on acute inhalation toxicity was not available.

Irritation and Sensitisation

Rabbit studies of eye and skin irritation found that the notified chemical is slightly irritating to both eyes and skin. Staining of the skin was evident in all three animals at the 24 hour observation period but this was reversed by 48 hours.

The notified chemical is not considered to be a sensitiser at up to 50%w/v, based on the guinea pig maximisation skin sensitisation assay results. The concentration of notified chemical used in the guinea pig maximisation study was 50%w/v, which is lower than the concentration workers involved in formulation of masterbatch plastics, would be exposed to (80%).

Repeated Dose Toxicity
Based on a 28-day subacute oral toxicity study in rats, the No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day.

Mutagenicity
The notified chemical was found to be non-mutagenic in the Ames tests. The notified chemical was not clastogenic in an *in vitro* chromosomal aberration tests in cultured CHL cells.

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

Based on the available data, the notified chemical is expected to be of low hazard but is a slight skin and eye irritant.

Batching and Extruding
Exposure and hence the risk of adverse effects is most likely during the initial transfer of the notified chemical in powder form to the blending vessel. Reasonable worst-case exposure to the notified chemical was estimated to be 46.6 mg/kg bw/day. Based on an NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 21. MOE greater than or equal to 100 are considered acceptable to account for intra and inter-species differences. Whilst this margin of exposure is lower than the acceptable value, actual exposure is expected to be lower than that estimated due to the use of worst-case assumptions (including 100% dermal absorption). The level of worker exposure would be mitigated by the use of PPE (coveralls, gloves, eye protection and disposable dust mask where necessary) and the presence of adequate exhaust ventilation.

As the notified chemical is a slight eye and skin irritant these control measures would also reduce the risk of adverse effects.

Following formulation and pelleting, the risk of adverse effects from exposure to masterbatches is expected to be low due to the low bioavailability of the notified chemical.

9.2.5. Public health – risk characterisation

Exposure of the general public as a result of transport and disposal of products containing the notified chemical is assessed as being negligible. Although members of the public may make dermal contact with plastic products containing the notified chemical, it is expected to be of low toxicological hazard, is present at low concentrations in products and is not expected to be bioavailable. Therefore the risk to public health is considered to be low.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC Approved Criteria for Classifying Hazardous Substances.

As a comparison only, the classification of the 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.

It is not a regulatory requirement in Australia to classify chemicals with respect to the environment. Based on the available data, the notified chemical does not meet the criteria for classification under the GHS 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 No Significant 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 product containing the 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 product containing the 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:
  - Local exhaust ventilation

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Respiratory protection (where introduced in the powder form respiratory protection should be capable of filtering out respirable particles)
  - Overalls
  - Safety glasses
  - Gloves.

  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 via incineration in the presence of excess air. Non-recyclable waste arising from article manufacturing sites should be disposed to landfill.

Emergency procedures

- Spills and accidental releases of the notified chemical should be containers as described in the MSDS (i.e. contain with absorbent material and transfer to a sealable waste container) and the resulting waste disposed to landfill.

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical; or

or

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

The Director will then decide whether secondary notification is required.

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NOTOX (2001i) Determination of the Flammability (Contact with Water) of [Notified Chemical]. Project 323066. NOTOX B.V., 's-Hertogenbosch, The Netherlands (unpublished report submitted by notifier)

NOTOX (2001j) Statement of the Explosive Properties of [Notified Chemical]. Project 323088. NOTOX B.V., 's-Hertogenbosch, The Netherlands (unpublished report submitted by notifier)

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