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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Pigment Yellow 8882C/Cromphtal Yellow HRP-NGa

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Director
NICNAS

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Pigment Yellow 8882C/Cromphtal Yellow HRP-NGa

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Limited (ABN: 97 005 061 469)
235 Settlement Rd,
THOMASTOWN VIC 3074

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Chemical name, CAS No., molecular weight, molecular and structural formulae, spectral data, import volume and number and identity of sites at which the product will be used.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
Italy (Notification number: 02-05-8882-00)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Pigment Yellow 8882C / TKP 50059

MARKETING NAME(S)
Pigment Yellow 8882C / Cromphtal Yellow HRP-NG

SPECTRAL DATA

METHOD	Ultraviolet Visible, Infrared and ^{1}H-Nuclear Mangnetic Resonance spectroscopy.
Remarks	Reference spectra were provided.
TEST FACILITY	Ciba Specialty Chemicals, Basel, Switzerland.

METHODS OF DETECTION AND DETERMINATION

METHOD	High Performance Liquid Chromatography (HPLC).
Remarks	A HPLC method was developed for the notified chemical.

3. COMPOSITION

DEGREE OF PURITY
> 80%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

Four non-hazardous impurities each at < 5%

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The product will be imported, normally in FCL by sea, unloaded at the wharf and transported to the notifier's warehouse at Thomastown Vic by road, from which it will be dispatched to customers, also normally by road.

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

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

USE
The notified chemical is a colourant to be used to colour polymer masterbatches or plastic articles. The pigment will be present in masterbatches at up to 10% and in articles up to a maximum of 1%. The chemical will be used only at facilities for the production of specialised masterbatches or plastic articles, and will not be sold to the public.

The notified chemical imparts extended life to articles by minimising defects such as change of colour in response to sunlight. As the pigment will replace existing yellow pigments, the environmental load will not increase.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne.

TRANSPORTATION AND PACKAGING
Imports normally by sea (by air rarely). Packed in 10 kg triple-layer bags.

5.2. Operation description

The notified chemical will be imported incorporated into a ready-to-use pelleted (granular) form. It will be sold mainly for the purpose of being incorporated into masterbatch formulations of the base polymer at the rate of up to 10% and also in end use polymer products at a concentration of 0.1% to 1.0%. The substance is added to the polymer granule/additive blender and extruded to form masterbatch granules for conversion to end products in other factories. Some masterbatch factories may also covert the masterbatches to articles or films for end use.

Masterbatch Compounding: The pigment granules will be weighed in a dispensary into a tote bin under the influence of local exhaust ventilation. The mixture is then blended to achieve homogeneity, followed by transfer into the feed hopper of an extruder, normally in a closed system (screw conveyer). Strands of 2 to 3 mm diameter are extruded from the hot end of the extruder bin under the influence of local exhaust ventilation and the molten strands are chopped and cooled. The resulting granules of solid polymer blend are packed off.

Each "empty" import container is shaken or vacuumed into the blending process. Containers that are then virtually free of notified substance will be sent to a landfill accredited by the state EPA for the disposal of industrial packaging.

Product Repacking: Repacking, if any, will be carried out at the notifier's Thomastown warehouse, where facilities exist for the safe handling of hazardous substances. In a down-flow booth in which

dyes are re-packed, the airflow is away from the operators. In these facilities, the capture velocity for particulates is exceeded, so that exposure approaches zero. It is estimated that less than 50 kg will need to be re-packed each year.

Article forming: Although not known accurately, it is estimated that 10 to 25 article forming facilities may ultimately use masterbatches containing the notified chemical**.** In usage of the compounded polymer in the form of a masterbatch, the handling work would involve the charging of masterbatch (in which the pigment has already been encapsulated), to heat-forming machines for the production of articles or films.

5.3. Occupational Exposure

Number and Category of Workers

Masterbatch preparation – per facility

Category of Worker	*Number*	*Exposure Duration Hr/day*	*Exposure Frequency Days /year*
Operator: Warehouseperson	2	0.25 - 0.5	60 – 120
Operator: Weighing and blending	2	1 - 2	60 – 120
Lab person: Laboratory testing	2	0.5 - 2	60 – 120
Operator: Transferring and packing-off	2	4 - 8	60 – 120

Article forming – per facility

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration Hr/day*	*Exposure Frequency Days /year*
Operator: Warehouseperson	2	4 - 8	60 – 120
Operator: Extruder/moulding machine operator	2	4 - 8	60 – 120
Lab person: Laboratory testing	2	4 - 8	60 – 120
Operator: Transferring and packing-off	2	4 - 8	60 – 120

Exposure Details

For the blending of masterbatches, specialised equipment is used to ensure the safety measures are adequate to protect workers from particulates and vapours produced during mixing and extrusion of the masterbatch pellets. These measures, such as local exhaust ventilation, together with the PPE to be used, ensure that exposure is minimised.

For polymer forming, the pigment is already encapsulated in the resin matrix and no significant exposure is possible.

5.4. Release

RELEASE OF CHEMICAL AT SITE

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 city 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 the warehouse, at the masterbatch manufacturer or in transit and incompletely emptied containers are disposed to landfill. It is estimated 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 practices of thoroughly emptying containers into the process ensures that insignificant residue remains in empty containers. Equipment cleaning material from campaign change or for maintenance is retained for internal recycle. 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.

RELEASE OF CHEMICAL FROM USE
It is estimated that 10-25 article forming facilities may ultimately use masterbatches containing the notified chemical. In the usage of the compounded polymer in the form masterbatch, it would involve the charging of masterbatch to heat forming machines for the production of articles or films. 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.

5.5. Disposal
The notified chemical is to be disposed of by incineration or landfill.

5.6. Public exposure
In the final plastic product, the chemical will be encapsulated in the cured masterbatch polymer matrix and therefore no public exposure is possible.

The opportunity for public exposure to the notified chemical is limited by the very few application sites in Australia (up to 3) and the absence of any likely release via effluent. It is unlikely to be released into a compartment of the environment that could lead to direct exposure of members of the public or via the food chain. Additionally, the notified chemical represents a low bioaccumulation hazard.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Yellow granules

Melting Point/Freezing Point No melting between 25ºC and 385ºC. Decomposition above 250ºC

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Method: Differential scanning calorimetry.
TEST FACILITY	Notox (2001a)

Boiling Point Not determined.

Density 1660 kg/m^3 at 20ºC

METHOD	EC Directive 92/69/EEC A.3 Relative Density. OECD TG 109 Density of Liquids and Solids.
Remarks	Method: Gas comparison pycnometer.
TEST FACILITY	Notox (2001b)

Vapour Pressure $2.8 \times 10^{-4} \pm 2 \times 10^{-5}$ kPa at 20ºC

METHOD	EC Directive 92/69/EEC A.4 Vapour Pressure OECD TG 104 Vapour Pressure.
Remarks	The vapour pressure was measured using a static technique with a capacitance manometer. With respect to the environment, this is classified as moderately volatile (Mensink *et al* (1995)).
TEST FACILITY	Notox (2001c)

Water Solubility 681 mg/L at 20ºC

METHOD	EC Directive 92/69/EEC A.6 Water Solubility. OECD TG 105 Water Solubility.
Remarks	Analytical Method: HPLC, pH = 7.3 (approx.). With respect to the environment,

this is classified as moderately soluble (Mensink *et al* (1995)).
TEST FACILITY Notox (2001d)

Hydrolysis as a Function of pH Hydrolytically stable.

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

pH	*T (°C)*	*$t_{½}$ years*
4	25	> 1
7	25	> 1
9	25	> 1

Remarks The notified chemical was found to be hydrolytically stable by HPLC analysis.
TEST FACILITY Notox (2001e)

Partition Coefficient (n-octanol/water)

	Log P_{OW}	
	Estimation Method	Shake Flask Method
Peak 1	≤-3.7	≤-2.7
Peak 2	≤-4.4	≤-1.8
Peak 3	≤-3.7	≤-1.5

METHOD OECD TG 107 Shake Flask Method
EEC Directive 92/69 EEC, Part A.8 "Partition Coefficient".
Remarks The notified chemical is a salt, consisting or an organic part and in inorganic part. Therefore, neither the "Shake Flask" method nor the "HPLC" method are applicable, and the "Estimation" method was used instead in which the solubility in n-octanol (0.230 mg/L) was determined and compared with the water solubility. In order to confirm the results of the estimation method, it was decided to additionally perform the "Shake Flask" method using HPLC analysis. The results of these two methods were not in agreement, and are therefore, reported separately.
TEST FACILITY Notox (2001f)

Surface Tension 72.6 mN/m at 20ºC and ~613 mg/L

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Ring Tensiometer Method. The surface tension of a 90% saturated solution was determined (~613 mg/L). The notified chemical is concluded not to be surface active.
TEST FACILITY Notox (2001g)

Adsorption/Desorption log $K_{oc} \leq 0.24$ at ~18°C.
– screening test

METHOD EU Technical guidance on Risk Assessment 1996.
Remarks QSAR, using the equation: log K_{OC} = 0.52 log P_{OW} + 1.02 ≤ 0.24, where log $P_{OW} \leq -1.5$, a worst-case scenario.
TEST FACILITY Notox (2002a)

Particle Size Not relevant, as compound is imported already formulated into polymer granules.

Flash Point Test not relevant to a solid.

Flammability Limits The compound is not pyrophoric, is not a highly flammable solid, and is not dangerous in contact with water.

METHODS EC Directive 92/69/EEC A.10 Flammability (Solids).
EC Directive 92/69/EEC A.12 Flammability (Contact with Water).

Remarks	Flammability was tested with the flame of a gas burner. Pyrophoric properties were predicted from structure.
TEST FACILITY	Notox (2001h), Notox (2001i), Notox (2001j)

Autoignition Temperature From 260°C.

METHOD	92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	Substance is self-ignitable at temperatures above 260°C. An exothermic reaction occurs above that temperature.
TEST FACILITY	Notox (2001k)

Explosive Properties Not explosive

Remarks	A negative result is predicted on the basis of chemical structure.
TEST FACILITY	Notox (2001l)

Oxidising Properties Not oxidising.

Remarks	Not oxidising, predicted on the basis of chemical structure.
TEST FACILITY	Notox (2001m)

Reactivity

Remarks	The notified chemical is predicted to be stable under normal environmental conditions, based on autoignition and flammability studies.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Results and conclusion*
Rat, acute oral	LD50 > 2000mg/kg bw, low toxicity
Rat, acute dermal	LD50 > 2000mg/kg bw, low toxicity
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Slightly irritating
Skin sensitisation – Guinea pig maximisation test	No evidence of sensitisation
Rat, repeat (oral) dose toxicity – 28 days.	NO(A)EL = 1000 mg/kg
Genotoxicity – bacterial reverse mutation	Non-mutagenic
Genotoxicity – in vitro – Cultured peripheral human lymphocyte cells	Non-clastogenic
Toxicokinetic studies	Not expected to accumulate

7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 96/54/EC B.1 tris Acute Toxicity-Oral – Acute Toxic Class Method

Species/Strain: Rat/Wistar Crl: (WI) BR

Vehicle: 1% aqueous carboxymethyl cellulose

Remarks - Method:
- No significant protocol deviations
- The compound was homogenised in vehicle to a visually acceptable level.

RESULTS

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

LD50: > 2000 mg/kg bw

Signs of Toxicity: Lethargy, hunched posture and/or piloerection were noted among the animals between days 1 and 3.

Yellow faeces, caused by the staining properties of the test substance, were noted in all animals on days 2 and 3.

The mean body weight gain shown by the animals over the study period was considered to be normal.

Effects in Organs: No abnormalities were found at macroscopic post mortem examination of the animals.

Remarks - Results: None

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

TEST FACILITY: NOTOX (2001n)

7.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

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

Species/Strain: Rat/Wistar Crl: (WI) BR

Vehicle	1% Aqueous carboxymethyl cellulose
Type of dressing	Occlusive
Remarks - Method	• No significant deviations from the test method. • Test substance was homogenised in vehicle to a visually acceptable level.

RESULTS

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

LD50	>2000 mg/kg bw (dermal)
Signs of Toxicity - Local	Yellow staining, scales and/or erythema in the treated skin area, yellow staining of the left flank, scales and/or scabs on the neck were seen among the animals during the observation period.
Signs of Toxicity - Systemic	Lethargy, chromodacryorrhoea, hunched posture, piloerection, ptosis, uncoordinated movements and/or tremors were all noted among the animals between days 2 and 5. One female showed chromodacryorrhoea on day 15.
Effects in Organs	No macroscopic abnormalities were found after post mortem examination of the animals.
Remarks - Results	None

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

TEST FACILITY NOTOX (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
Number of Animals	3 males
Vehicle	Test powder was moistened with water and applied.
Observation Period	48 hours
Type of Dressing	Semi-occlusive
Remarks - Method	• Rabbits were only observed for 48 hours after removal of the dressings and test substance (see Remarks – Results, below).

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	0	0
Oedema	0	0	0	0	0	0

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

Remarks - Results	• Inadvertently, the 72 hour observation was not performed, however, it was considered that this deviation from the guideline did not affect the study integrity, as no irritation was observed at the earlier time points. • Yellow staining of the treated skin by the test substance was observed throughout the observation period but did not affect readings.

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

TEST FACILITY NOTOX (2001p)

7.4. Irritation – eye

TEST SUBSTANCE Notified chemical.

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

Species/Strain Rabbit/New Zealand White
Number of Animals 3 males
Observation Period 72 hours
Remarks - Method Single samples of approximately 58 mg of the notified chemical, ground into a fine powder (approximately 0.1 ml) were instilled into one eye of each of three rabbits.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	0	0.3	2	48 hrs	0
Conjunctiva: chemosis	0	0	0	1	24 hrs	0
Corneal opacity	0	0	0	0		0
Iridial inflammation	0	0	0	1	24 hrs	0

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

Remarks - Results
- Instillation of the test substance resulted in effects on the iris and conjunctivae. Iridial irritation (grade 1) was observed, which resolved within 24 hours. Irritation of the conjunctivae was seen as redness, chemosis and discharge, which also completely resolved within 24 hours in one animal and within 48 hours in the other animals.
- Remnants of the test substance were present in the eyes of one animal on day 1. Yellow staining of the fur on the head and paws, caused by the test substance, was noted during the observation period.

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

TEST FACILITY NOTOX (2001q)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 406 Skin Sensitisation – Maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitisation

Species/Strain Albino Guinea pig/Dunkin Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration: 10% (w/w)
intradermal: 1% (w/w)
topical: 20% (w/w)
MAIN STUDY
Number of Animals Test Group: 10 females Control Group: 5 females
INDUCTION PHASE Induction Concentration:
intradermal: 1% (w/w)
topical: 20% (w/w)

Signs of Irritation	Intradermal injection: Erythema 3/10 moderate (score 3); 7/10 well-defined (score 2). No signs of necrosis or oedema were found. Epidermal exposure: No erythema, necrosis or oedema was observed. Sites were not pre-treated with Sodium lauryl sulphate before topical induction.
CHALLENGE PHASE	
1st challenge	intradermal: topical: 10%
Remarks - Method	• No significant protocol deviations. • A maximum concentration of 10% was considered the highest that would technically be able to pass through the injection needle. Also, the 20% (w/w) concentration that was applied topically was considered the highest concentration that could be prepared to an acceptably homogenous level.

RESULTS

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

Remarks - Results	• No skin reactions were evident after the challenge exposure in the experimental and control animals. • Yellow staining was observed at the test substance treated skin sites, 24 hours after challenge. This staining did not hamper the scoring of the skin reactions.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	NOTOX (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). Substance Law 1987, notification of Dec 1986 by EA, MHW and MITI.
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	1 % aqueous carboxymethyl cellulose
Remarks - Method	• Minor (noted) deviations from protocol occurred that were unlikely to have any effect on the outcome of the study. • In addition, due to the absence of any functional or ophthalmic abnormalities during week 4, these tests were not repeated in week 6.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
1 (control)	5/sex	0 (vehicle)	0
1 (recovery)	5/sex	0 (vehicle)	0
2 (low dose)	5/sex	50	0

3 (mid dose)	5/sex	150	0
4 (high dose)	5/sex	1000	0
4 (recovery)	5/sex	1000	0

Mortality and Time to Death

No mortality observed.

Clinical Observations

No clinical signs of toxicity were observed that were considered to be related to the treatment with the notified chemical. All mid- and high-dose group animals produced yellow faeces until necropsy, which was considered to be due to the staining properties of the notified chemical.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No changes were observed that could be related to treatment with the notified chemical.

Effects in Organs

No changes in organs were observed macroscopically or microscopically; individual organ weights were unaffected relative to controls.

Remarks – Results

No toxic effects were observed that could be related to treatment with the notified chemical, even in the highest dose group (1000 mg/kg bw/day).

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of any toxic effects that could be considered to be a result of treatment.

TEST FACILITY NOTOX (2002b)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 67/548/EC B. 13/14 Mutagenicity – Reverse Mutation Assay using Bacteria. Guidelines stipulated by the Japanese Ministry of Labor and Japanese Ministry of International Trade and Industry.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, and TA100 *E. coli*: WP2*uvr*A
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver (5% or 10% (v/v) S9 mix).
Concentration Range in Main Test	a) With metabolic activation: 10-5000 µg/plate b) Without metabolic activation: 10-5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	• No significant protocol deviations. • The highest concentration of the notified chemical used in the first instance was one at which it exhibited limited solubility. Slight precipitates formed above 333 µg/plate, so a concentration range of 3-333 µg/plate was used in the second experiment.
RESULTS	The notified chemical did not induce any increase in the number of revertant colonies with any of the bacterial strains used, either in the absence or presence of S9-metabolic activation. These results were confirmed in a second experiment, repeated independently.
Remarks - Results	• The notified chemical was not cytotoxic. The background bacterial lawn was not reduced at any concentration tested and no biologically

relevant decrease in the number of revertants was observed.
- Adequate positive and negative controls indicate that the assay was conducted appropriately.

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

TEST FACILITY: NOTOX (2001s)

7.9. Genotoxicity – *in vitro*

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test.
Guidelines stipulated by the Japanese Ministry of Labor and the Japanese Ministry of International Trade and Industry.

Cell Type/Cell Line: Human cultured peripheral human lymphocytes
Metabolic Activation System: S9 Arocolor-1254 induced rat liver fraction
Vehicle: Dimethyl sulfoxide
Remarks - Method
- At a concentration of 1000 µg/ml, the notified chemical precipitated in the cell culture medium. Therefore, this concentration was used as the highest for a dose rage finding test (table below), performed to determine the effect on mitotic indices.
- The cytogenetic assay was carried out with only minor modifications to the protocol.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hrs)*	*Harvest Time (hrs after exposure)*
Absent			
Test 1	420, 480*, 520*, 560*, 650[1], 750[1]	3	24
Test 2	10, 33*, 100*, 333*, 420, 560	24	24
	10, 33, 100*, 167*, 333, 420*	48	48
Present			
Test 1	333, 420*, 560*, 580*[1]	3	24
Test 2	333, 420*, 560*, 580*[1], 600[1], 620[1], 650[1]	3	48

Notes: [1] Cromophtal Yellow HRP-NG/TKP 50059 precipitated in the culture medium
* Cells treated with these concentrations were selected for scoring of chromosomal aberrations

RESULTS

		Test Substance Concentration (µg/mL) resulting in:			
Metabolic Activation	*Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Reduction in mitotic index*	*Precipitation*	*Genotoxic Effect*
Absent	>1000				
Test 1		≥650	≥480	≥750	Negative
Test 2 (24 hr)		None	>33	>560	Negative
Test 2 (48 hr)		None	>100	>420	Negative
Present	>1000				
Test 1		>580	≥333	≥580	Negative
Test 2		None	≥333	≥580	Negative

Remarks - Results
- Either in the presence or absence of S9 mix, the notified chemical did not induce any statistically significant increases in the number of cells showing chromosomal aberrations, in two independently

repeated experiments.
- Positive and negative controls gave appropriate responses, indicating that the assay was performing appropriately.

CONCLUSION	The notified chemical was not clastogenic to human peripheral lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	NOTOX (2001t)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. EEC Directive 92/69, C.4-C
Inoculum	Activated Sludge
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 Evolution
Remarks - Method	The notified chemical was tested at 62 mg per 2 L, corresponding to 12 mg TOC/L. The theoretical CO_2 production of the notified chemical was calculated to be 1.43 mg CO_2/mg. Since the notified chemical is only moderately soluble in water, 10 mL Milli-RO water was added to each weighing bottle containing the notified chemical. After thorough mixing, the resulting suspensions were quantitatively added to the test media. The test solutions were continuously stirred throughout the test.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
14	1	14	64
28	2	28	74

Remarks - Results	The relative degradation values calculated from the measurements performed during the test period revealed no significant degradation of the notified chemical. In the toxicity control, the notified chemical was found to be not inhibitory on microbial activity. Since all acceptability criteria prescribed by the protocols were met, this study was considered to be 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 $P_{OW} \leq -1.5$. 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 chemical.
METHOD	OECD TG 203 Fish, Acute Toxicity Test – 96 h Static Test; and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – 96 h Static Test.
Species	Carp (*Cyprinus carpio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC

Remarks – Method	Solubility pre-tests for the aquatic studies confirmed that the notified chemical was well soluble in Milli-Q water at 100 mg/L, but in test (ISO) medium, the notified chemical could not be completely dissolved at 100 mg/L. Two test solutions were prepared at a nominal 100 mg/L. After stirring for 24 h and ultrasonification, one of the solutions was filtered (5 µm) to remove any larger undissolved notified chemical particles. The unfiltered solution was a yellow dispersion with undissolved notified chemical particles, while the filtered solution was a light yellow solution.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal		*1h*	*24h*	*48h*	*72h*	*96h*
0	7	0	0	0	0	0
100	7	0	0	0	0	0

LC50	>100 mg/L WAF at 96 hours.
NOEC	100 mg/L WAF at 96 hours.
Remarks – Results	Analysis of the samples taken from the unfiltered test solution showed that the concentration measured in the water phase decreased during the test period from 35.9 to 6.6 mg/L due to precipitation and deposition of the undissolved notified chemical particles. The concentration measured in the filtered test solution decreased from 11.8 to 4.7 mg/L during the test period. This was also expected to be related to the limited solubility in test medium as a precipitate was observed after 24 h of exposure. Note that these determinations were based on the least soluble major peak, with the other two staying above 80% of the initial concentration. No mortality was observed in the control group, thereby validating the test. Further, all test conditions remained within the ranges prescribed by the protocol.
CONCLUSION	The 96 h LC50 for Carp exceeded the maximum solubility of the notified chemical in the test medium at a loading rate of 100 mg/L.
TEST FACILITY	NOTOX (2001v)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical.
METHOD	ISO 6341: "Water quality – Determination of the inhibition of the mobility of *Daphnia magna* Straus – Acute toxicity test, Third Edition, 1996-04-01. OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	Solubility pre-tests for the aquatic studies confirmed that the notified chemical was well soluble in Milli-Q water at 100 mg/L, but in test (ISO) medium, the notified chemical could not be completely dissolved at 100 mg/L. In the combined range-finding test, daphnids were exposed to 0.1, 1.0 and 10 mg/L. These concentrations were prepared starting with a stock solution at 10 mg/L that completely dissolved in test medium after a short

period of treatment with ultrasonic waves and magnetic stirring.

Two test solutions were prepared at nominal 100 mg/L. After stirring for 30 min and ultrasonification, one of the solutions was filtered (0.45 μm) to remove any undissolved notified chemical particles. The final test solutions range from clear and slightly yellow (0.1 mg/L) to clear yellow (100 mg/L filtrate). The unfiltered solutions were turbid with fine undissolved material dispersed through the medium and precipitate.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	10	0	0
0.1	10	0	0
1	10	0	0
10	10	0	5
100	10	0	0

EC50 >100 mg/L WAF at 48 hours

NOEC (or LOEC) 100 mg/L WAF at 48 hours

Remarks - Results No immobility was observed in the highest loaded solutions, either filtered or unfiltered prepared nominally at 100 mg/L. Unexpectedly, 50% of the daphnids became immobilised at nominally 10 mg/L, while no biologically significant immobilisation was observed in the lower test concentrations of 0.1 and 1.0 mg/L. The reasons for this are unclear.

Samples taken at the end of the test period from the filtrate prepared at 100 mg/L and nominally 10 mg/L were analysed to check for a possible mix-up of concentrations. Analysis showed a measured concentration of 76 mg/L in the filtrate and 9.1 mg/L at nominally 10 mg/L.

Analysis of the samples taken from the unfiltered test solution showed that the concentration measured in the water phase decreased during the test period from 69.2 to 13.1 mg/L due to precipitation and deposition of the undissolved notified chemical particles. The concentration measured in the filtered test solution decreased from 48.2 to 35.5 mg/L during the test period. Hence, the measured concentration in the filtered solution remained relatively stable in comparison to the higher decrease of measured concentration in the unfiltered solution. Again, this is based on the main component (92.5%)

In the control, no daphnids became immobilised, and not more than 10% become trapped at the surface of the water. Owing to the very low solubility of the notified chemical, the actual concentrations could not be maintained at more than 80% of the initial concentration. Otherwise, all test conditions remained within the ranges prescribed by the protocol.

CONCLUSION Under the conditions of the test, the notified chemical induced no visible effects in *Daphnia magna* exposed to a filtered or unfiltered supersaturated solution prepared at nominal 100 mg/L. Therefore, the 48 h EC50 for *Daphnia magna* exceeded the maximum solubility of the notified chemical, in test medium at a loading rate of 100 mg/L.

TEST FACILITY NOTOX (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	
Exposure Period	72 hours
Concentration Range	Nominal: 10, 18, 32, 56 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	Solubility pre-tests for the aquatic studies confirmed that the notified chemical was well soluble in Milli-Q water at 100 mg/L, but in test (ISO) medium, the notified chemical could not be completely dissolved at 100 mg/L. Preparation of test solutions for the range-finding test started with stock solutions of 10 and 100 mg/L applying a 15 minute treatment period with ultrasonic waves followed by 5 minutes of magnetic stirring. Both solutions were then filtered (>5 µm). The final test solutions were all clear and, with increasing concentration, increasingly yellow coloured. 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	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L at 72 h*	*mg/L at 72 h*	*mg/L at 72 h*
42 (95% C.I. 11-160)	- - -	>100	10

Remarks - Results

Calculation of the EC50 values was based on linear regression analysis of the percentages of growth inhibition and the percentages of growth rate reduction versus the logarithms of the corresponding nominal concentrations of the test substance. Only the filtered 100 mg/L solution significantly inhibited algal cell growth in the range finding test. The E_rC50 was expected to be above a 5 µm filtered solution prepared at nominally 100 mg/L. In the final test, measured concentrations were in agreement with nominal concentrations (87%-101%) despite the fact that all solutions had been filtered.

Inhibition of cell growth increased with increasing concentration of the notified chemical, resulting in approximately 56% inhibition at 56 and 100 mg/L. Statistically significant inhibition of cell growth was found at all test concentrations according to the Williams' test (P=0.05). However, multiple comparisons of data according to Tukey test (P=0.05) showed that the lowest concentration tested, i.e. 10 mg/L, was not statistically significant from the control.

Growth rates were less than 10% reduced during the 72-hour test period at 10 and 18 mg/L, whereas test concentrations higher than 18 mg/L showed a maximum reduction of approximately 17%. Reduction of growth rate appeared to decrease as exposure progressed at all test substance concentrations.

Statistically significant reduction of growth rate was found at test concentrations of 18 mg/L and higher (Tukey and Williams' test: P=0.05).

In the controls, cell density increased by an average factor >16 within three days, and analysis of samples taken during the final study showed that the actual exposure concentration remained above 80% relative to the

	initial concentration. Further, all test conditions remained within the ranges prescribed by the protocol.
CONCLUSION	Under the test conditions, the notified chemical reduced growth rate of fresh water algae significantly at 18 mg/L and higher.
TEST FACILITY	NOTOX (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	Activated sewage sludge
Exposure Period	30 minutes
Concentration Range	Nominal: 100 mg/L
Remarks – Method	Since the notified chemical was poorly soluble in water, the notified chemical was ground and quantitatively added to the test vessels to achieve a nominal concentration of 100 mg/L. In parallel, a control and reference test using 3,5-dichlorophenol were tested.
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
Remarks – Results	No inhibition in respiration rate of the sewage sludge was recorded at nominal 100 mg/L. The duplicate measurement confirmed the result of the first measurement; therefore, no further testing was needed. The respiration rates of the controls were within 15% of each other, and the EC50 of the reference substance was 8 mg/L thus validating the test.
CONCLUSION	The notified chemical was found to be not toxic to sewage sludge bacteria at a nominal concentration of 100 mg/L.
TEST FACILITY	NOTOX (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 city 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 46 mg/L. A predicted No Effect Concentration was calculated to be 460 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

General: Appropriate measures to reduce exposure to workers are described in the MSDS. PPE such as respirators, PVC industrial gloves, safety glasses and protective clothing are all advised to reduce exposure. Additionally, engineering controls are recommended to avoid dust formation and the exposure of workers to dusts. As the compound is a combustible solid, ways to limit hazards during use and storage are listed.

Transport & Storage: Occupational exposure to the notified chemical during transport and storage of granular preparations containing the notified chemical is only likely in the event of accidental spillage rupture of the triple-layered packaging occurs. Such exposure is expected to occur only rarely, for short periods of time, and is expected to be limited by use of appropriate PPE during clean-up operations.

Masterbatch Compounding: Dermal exposure is the most likely route by which weighing and blending operators could be exposed to the notified chemical, the likelihood of which will be reduce by appropriate PPE (described in the MSDS). Ocular and inhalation exposure could

occur with fugitive dusts although the notified chemical is in a granular form designed to minimise dust generation. Even so, specialized equipment is used to ensure the safety measures are adequate to protect workers. These measures such as local exhaust ventilation, together with the PPE to be used, should ensure that exposure to any ingredient is minimised. "Empty" import packaging is shaken or vacuumed into the blending process by the blending operators such that a negligible amount of the notified chemical remains in the packaging for disposal (approximately 5 g/import bag).

The resulting granules of solid polymer blend are packed, and it is expected that only minimal re-packing will be required. The level of exposure during the packing of polymer pellets is negligible, as the notified chemical is trapped in the polymer matrix. Nonetheless, it will be performed in a down-flow booth where the airflow is away from operators.

Article forming: Personnel will not be significantly exposed to the notified chemical during polymer forming, as it is encapsulated in the resin matrix.

9.2.2. Public health – exposure assessment

Public exposure during the transport of the imported notified chemical is only possible in the event of an accident. Public exposure is unlikely to occur during the production of plastic articles except in the event of a major industrial incident.

In the final plastic product, the chemical will be trapped inside the cured polymer matrix and therefore not accessible to pose public exposure risk.

9.2.3. Human health – effects assessment

The notified chemical exhibited low toxicity in acute toxicity studies following either oral or dermal exposure (LD50 > 2000 mg/kg bw/day). In repeated dose toxicity studies in rats, the notified chemical was found to have a NOAEL of 1000 mg/kg bw/day, based on the absence of observed toxic effects. It was non-irritating to the skin and eyes of rabbits, and did not cause skin sensitisation in Guinea pigs. Additionally, it was found not to cause genetic changes in both bacteria and cultured human cells.

Extensive toxicokinetic studies were not performed, and these would probably be of limited value given the notified chemical's apparent low level of toxicity. An assessment of the anticipated toxicokinetic behaviour of the test substance was provided, summarised here:

> Dissolution of a compound is required for absorption from the gastro-intestinal tract into the blood. The notified chemical will probably be absorbed to only a relatively low extent from the gastro-intestinal tract, because of the extremely polar groups present in the molecule. Once it is absorbed, it will probably be distributed throughout total body water. The volume of distribution is expected to be about 670 mL/kg and the compound will partially bind to plasma proteins. The notified chemical is likely to be metabolised by cytochrome P450-mediated hydroxylation of the aromatic regions of the compound. These hydroxy-metabolites will probably be conjugated and excreted via urine or bile. Rapid metabolism and excretion will probably result in a relatively short elimination half-life, and so the test substance will likely not accumulate in the body after prolonged exposure. This is supported by the lack of toxicity in the 28-day oral repeat dose study in rats with this chemical.
>
> It is generally accepted that substances with a $\log P_{ow}$ ranging from -1 to 4 penetrate the skin easily, although absorption is also dependent on molecular volume. Given that the notified chemical's maximum determined $\log P_{ow}$ was –1.5, it should be absorbed poorly through the skin. Uptake of the notified chemical by inhalation is not likely to occur, because of its granular nature.

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

Masterbatch compounding: The likelihood of dermal exposure to the notified chemical is very low, given the use of appropriate PPE, including gloves and protective clothing. In animal toxicological studies the notified chemical was non-irritating and exhibited low acute oral and dermal toxicity, no target organ toxicity was observed in a subchronic study and it was not likely to be a skin sensitiser. No genotoxicity was observed in *in vitro* experiments.

The inhalation exposure level is likely to be low, given the granular form in which the notified chemical is imported and the use of LEV.

Article forming: Exposure to the notified chemical during article forming processes (involving solid polymer pellets and plastic articles) is expected to be low due to it being trapped within the polymer matrix. Therefore the risk of adverse health effects during these operations is considered to be negligible.

Disposal: The notified chemical will only be disposed of at trace levels in its import packaging, and these quantities present a very low risk to workers, which would be minimised by the appropriate use of PPE. Disposal of masterbatch polymer granules presents a negligible degree of risk, due to the notified compound being bound within the polymer matrix.

9.2.5. Public health – risk characterisation

Based on the low probability of public exposure to the notified chemical, and the available toxicological data, the public risk 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*.

and

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

Based on the available data, the notified chemical does not meet the criteria for the Classification and Labelling of Chemicals according to the United Nations (2003) Globally Harmonised 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 Negligible Concern to public health when used as a colourant to be used to colour polymer masterbatches or plastic articles.

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

- 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 landfill or incineration.

Emergency procedures

- Spills/release of the notified chemical should be contained, collected and stored in a labelled, sealable container ready for 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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