File No: NA/599

May 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Phosphine oxide, phenylbis (2,4,6-trimethylbenzoyl)-

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Family Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

Monday - Wednesday	8.30 am - 5.00 pm
Thursday	8.30 am - 8.00 pm
Friday	8.30 am - 5.00 pm

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9466 FAX (61) (02) 9577-9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Phosphine oxide, phenylbis (2,4,6-trimethylbenzoyl)-

1. APPLICANT

Ciba Specialty Chemicals of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for Phosphine oxide, phenylbis (2,4,6-trimethylbenzoyl)-

2. IDENTITY OF THE CHEMICAL

Chemical Name: phosphine oxide, phenylbis (2,4,6-trimethylbenzoyl)-

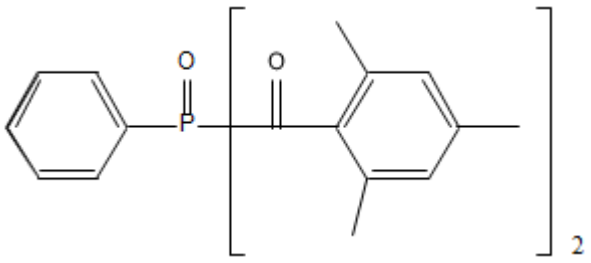
Chemical Abstracts Service (CAS) Registry No.: 162881-26-7

Other Names: TKA 40135/CGI 819

Trade Name: Irgacure ® 819

Molecular Formula: $C_{26}H_{27}O_3P$

Structural Formula:



Molecular Weight: 418.5

Spectral Details: UV/Vis spectrophotometry in neutral, basic, and acid solution:

	neutral solution: λ_{max} = 282 nm (ε_{max} = 7 931) 296 nm (ε_{max} = 7 953) basic solution: λ_{max} = 219 nm (ε_{max} = 27 288) 265 nm (ε_{max} = 7 281) acidic solution: λ_{max} = 282 nm (ε_{max} = 7 908), 297 nm (ε_{max} = 7 945) shoulder at 233 nm in spectra measured under neutral and acid conditions
Method of Detection and Determination:	ultraviolet/visible (UV/Vis) spectrophotometry, infrared (IR) spectroscopy and nuclear magnetic resonance (NMR) spectroscopy have been used to characterise the notified chemical

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white to yellowish powder
Particle size:	10.1% < 4 μm
Melting Point:	127-131.4°C
Boiling Point:	> 168°C
Specific Gravity/Density:	1 190 $kg.m^{-3}$ at 21°C
Vapour Pressure:	5 x 10^{-10} kPa at 25°C
Water Solubility:	< 0.1 $mg.L^{-1}$ at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = 5.77
Hydrolysis as a Function of pH:	not determined
Adsorption/Desorption:	log K_{oc} = 3.85 (HPLC screening method)
Dissociation Constant:	not determined
Flash Point:	not determined
Surface Activity:	~ 71 $mN.m^{-1}$ at 20 °C
Flammability Limits:	not flammable

Autoignition Temperature:	no self-ignition
Explosive Properties:	not considered explosive through contact with heat or shock
Reactivity/Stability:	photosensitive; considered to be void of any oxidisation potential

Comments on Physico-Chemical Properties

Tests were performed according to OECD/EEC test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

The water solubility of the notified chemical was determined to be lower than the detection limit (0.1 $mg.L^{-1}$). However, the solubility of the notified chemical was determined[a] by HPLC analysis and UV/VIS-detection to be 0.8 $\mu g.L^{-1}$ for the acute toxicity to *Brachydanio rerio* test [1].

Hydrolysis testing was not performed as the water solubility is below the detection limit for that particular test protocol. Hydrolysis is not expected and would be precluded by the notified chemical's very low water solubility. The notified chemical does not contain any dissociable groups.

Based on the adsorption coefficient (log K_{oc} 3.85), the chemical is expected to be immobile in soil [2].

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 $mN.m^{-1}$.

4. PURITY OF THE CHEMICAL

Degree of Purity:	typical concentration 98.4% 95% lower limit; 99.5% upper limit
Toxic or Hazardous Impurities:	< 0.19%
Chemical name:	toluene
CAS No.:	108-88-3
Weight percentage:	0.14%
Toxic properties:	irritant [3]
Chemical name:	n-hexane

[a] This experiment was not performed according to the principles of GLP.

CAS No.:	110-54-3
Weight percentage:	< 0.05%
Toxic properties:	irritant [3]

Non-hazardous Impurities (> 1% by weight): unidentified organic components at 1.3%

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported into Australia in a ready-to-use form in 20 kg net plastic lined fibreboard boxes. Some limited re-packing for supplying samples or material for plant trials may be required, however generally the product containing the notified chemical will not be re-packaged in Australia.

The notified chemical is used as a photoinitiator in synthetic coatings for metal, wood, plastic, paper and optical fibres as well as printing inks. The chemical has characteristics that widen the effective use of UV curing resins, providing a high rate of curing in opaque formulations such as white pigmented or glass reinforced polyester/styrene systems. The notifier claims that due to “enhanced photosensitivity at longer wavelengths” the chemical overcomes the filtering effects of UV absorbers.

The notified chemical will be used at the rate of 0.1% to 1% (or up to 1.5% in inks) in solvent free mixtures of oligomers and monomers.

Import volumes for the notified chemical are less than 20 tonnes per annum.

6. OCCUPATIONAL EXPOSURE

Some re-packing of the product containing the notified chemical (less than 100 $kg.annum^{-1}$) for the purposes of supplying samples or material for plant trials may be required in the future. This will occur in a purpose-built facility with downdraft ventilation designed to capture fine particles of dust, hence worker exposure is unlikely. Worker exposure during handling and transportation is only likely in the event of an accidental spill.

On receipt by resin formulators, the notified chemical will be weighed out in a dispensary equipped with local exhaust ventilation. This in combination with the low vapour pressure of the notified chemical is likely to limit inhalational exposure of workers to dusts and aerosols. However, there is potential for dermal and ocular exposure of workers during this phase of operations. The manual addition of the notified chemical to the blending vessels is via a manhole fitted with local exhaust ventilation which should minimise the potential for dermal and/or ocular

Following the blending process, the formulation containing the notified chemical is transferred to drums for sale or internal use. At this stage of operations the potential for dermal and/or ocular exposure of workers still exists albeit at lower concentrations.

Application of coatings is unlikely to result in substantial worker exposure. Coating operators do not come into contact with the coating formulation containing the notified chemical. Generally the resin formulation will be applied by a curtain coater system. This method of application involves flat or slightly curved surfaces, and those with raised decorations and mouldings being carried on a conveyor through a continuous falling curtain or 'waterfall' of liquid coating material. The film is then allowed to smooth down and it is pre-gelled using fluorescent lamps that provide low-level UV radiation. The film is then fully cured using red-shifted medium pressure mercury lamps. Other applications include incorporation in printed films or graphics.

Levels of the notified chemical remaining within the cured matrix are expected to be small since it is decomposed during the curing process.

7. PUBLIC EXPOSURE

Most of the notified chemical will enter the public domain as cured film on a range of articles eg. furniture surfaces, graphic images. Although public contact will occur with objects coated with products containing the notified chemical, the notified chemical is converted to organo- phosphorous residues and will be encapsulated within the polymer matrix. Migration of these residues to the surface is expected to be negligible, hence public exposure to the notified chemical is also likely to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

The commercial form containing the notified chemical will be mixed at the rate of 0.1% to 1% (or up to 1.5% in inks) with other ingredients in a blending vessel to produce the coating formulation. This formulation will be transferred to drums for sale or internal use.

During use, the formulated product will be pumped through a closed system to the coating heads. The notifier claims that waste during this process is limited to traces remaining from the clean-up of any spill, trace residues in empty packaging and materials used to clean-down equipment. The volume of the latter should be low as manufacturers have adopted the process where cleaning agents are recycled into the product stream.

Residues in empty containers should be minimal. Contaminated packaging and

Incineration products include oxides of carbon and acidic phosphorus combustion products (in the absence of strong acid receptors).

Repacking, if any, will be undertaken at the notifier's warehouse where facilities for the safe handling of hazardous substances are employed. Any wastes generated are expected to be minimal.

Fate

The fate of the chemical is tied to the fate of the products to which it is applied. The chemical generates free radicals within the coating films or sections of the reinforced plastic by means of exposure to UV light. The free radicals are consumed (destroyed) in the curing process, with limited residual notified chemical in fully cured films. Organo-phosphorus residues are encased in the polymer matrix and do not migrate.

Should uncured product be disposed of to landfill, e.g. as residues in contaminated packaging, it should be adsorbed to soil, based on its very low water solubility and high adsorption coefficient. As the chemical is a photoinitiator, it would be expected to rapidly degrade in the environment upon exposure to natural light.

The notified chemical was determined to be not readily biodegradable in the OECD Test for Ready Biodegradability (CO_2 Evolution Test (Modified Sturm) TG 301D) with cumulative CO_2 production negligible (1% of the theoretical value) after 28 days [4]. The notified chemical was found to be non-inhibitory to the activity of the inoculum.

Bioaccumulation testing was not undertaken. Given the notified chemical is not expected to readily biodegrade, has a log P_{ow} value of 5.8 and molecular weight of approximately 420 $g.mol^{-1}$, bioaccumulation could be a perceived risk [5]. However, the very low water solubility (less than 0.1 $mg.L^{-1}$), low environmental exposure and expected degradation upon exposure to natural light should limit bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 $mg.kg^{-1}$	[6]
acute dermal toxicity	rat	LD_{50} > 2 000 $mg.kg^{-1}$	[7]
skin irritation	rabbit	non-irritant	[8]
eye irritation	rabbit	slight irritant	[9]
skin sensitisation	guinea pig	moderate sensitiser	[10]

9.1.1 Oral Toxicity [6]

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2 000 $mg.kg^{-1}$ of the notified chemical in distilled water given by gavage
Clinical observations:	piloerection in all rats; recovery complete by day 3; a slightly low bodyweight gain was reported in one male at day 15
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (Limit Test) [11]
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity [7]

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days

	distilled water applied to the shaved skin of each animal using semi-occlusive dresssing for 24 hours
Clinical observations:	low body weight gain was noted in some animals at days 8 and 15
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (Limit Test) [11]
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

The notifier has requested variation on this test on the grounds of the low vapour pressure of the notified chemical, the low oral toxicity and the anticipated negligible exposure of the respiratory system of workers handling powders of the notified chemical. This request has been granted, but it is noted that the respirable fraction of dusts of the notified chemical is relatively high (ie 10% of particle sizes are less than 4 μm). Inhalation of such dusts may have adverse effects on the respiratory system of exposed workers.

9.1.4 Skin Irritation [8]

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	3/male
Observation period:	72 hours
Method of administration:	0.5 g of the notified chemical which was moistened with distilled water was applied to intact shaven skin of each animal using semi-occlusive wrap for a period of 4 hours
Comments	no irritation effects noted, all Draize scores were zero
Test method:	similar to OECD guidelines [11]
Result:	the notified chemical was not irritating to the skin of rabbits

9.1.5 Eye Irritation [9]

Species/strain: rabbit/New Zealand white

Number/sex of animals: 3/male

Observation period: 4 days

Method of administration: ~ 73 mg of the solid notified chemical was place into the conjunctival sac of the left eye of each animal

Draize scores [12] of unirrigated eyes:

	Time after instillation									
Animal	***1hr***		***1 day***		***2 days***		***3 days***		***4 days***	
Conjunctiva	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***
1	2	1	1	1	1	1	1	1	0	0
2	2	1	2	1	2	1	1	1	0	0
3	2	1	1	0	1	0	0	0	-	-

[1] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Comments: iridal inflammation was observed in one animal 24 hours after treatment, disappearing by 48 hours; no corneal effects were observed; well defined conjunctival irritation was observed

Test method: similar to OECD guidelines [11]

Result: the notified chemical was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation [10]

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 5 control; 10 test

Induction procedure: day 0 - test animals given three pairs of intradermal injections:

- 0.1 mL of 50% Freund's complete adjuvant (FCA) in distilled water;
- 0.1 mL of notified chemical (1% w/v) in 5%

acetone in Alembicol;
- 0.1 mL of notified chemical (1%w/v) in 50:50 aqueous FCA (50%) and 5% acetone in Alembicol;

control animals given the same injections without the notified chemical

day 6 - topical application site treated with 10% (w/w) sodium lauryl sulphate in petrolatum

day 7 - 0.4 mL of the notified chemical in acetone (70% w/v) was applied to the skin of each animal and held in place for 48 hours using semi-occlusive wrap

control animals treated in same manner with the exception that the notified chemical was omitted

Challenge procedure: both control and test animals challenged topically 2 weeks after the topical induction application using the notified chemical, 35% (posterior site) and 70% w/v (anterior flank site) in acetone; application with semi-occlusive wrap for 24 hours

Challenge outcome:

challenge	***test animals***			***control animals***		
	24 hours*	***48 hours****	***72 hours****	***24 hours****	***48 hours****	***72 hours****
35%	2/10**	3/10	2/10	0/5	0/5	0/5
70%	0/10	5/10	3/10	0/5	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response

Comments: the report stipulates that the scores for 4 out of 10 animals were inconclusive, but that 3 of the test animals produced evidence of skin sensitisation; because the controls were all zero, the localised dermal reactions were taken as positive scores; in any case the number of scores were sufficient for the notified chemical to be classified as a skin sensitiser in an adjuvant-type test

Result:	the notified chemical was moderately sensitising to the skin of guinea pigs

9.2 Repeated Dose Toxicity [13]

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	30/sex
Method of administration:	the notified chemical in a 1% methylcellulose vehicle (10 mL) was administered daily by gavage
Dose/Study duration::	four dose groups 0 $mg.kg^{-1}.day^{-1}$ 15 $mg.kg^{-1}.day^{-1}$ 150 $mg.kg^{-1}.day^{-1}$ 1 000 $mg.kg^{-1}.day^{-1}$ for 28 days
Clinical observations:	one female found dead in week one, but death considered to be accidental
Clinical chemistry/Haematology	no findings of toxicological importance
Histopathology:	no treatment-related changes; incidents of microscopic pathology noted in control animals
Test method:	similar to OECD guidelines [11]
Result:	the notified chemical was of low toxicity when administered daily over a 28-day period; small changes were noted, however these were not associated with specific organ toxicity

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium*/*Escherichia coli* Reverse Mutation Assays [14]

Strains:	TA 98, TA 100, TA 102, TA 1535 and TA 1537; WP2 uvrA
Concentration range:	312.5 - 5 000 $\mu g.plate^{-1}$ of the notified chemical in DMSO with and without S9

	metabolic activation
Comments:	precipitation of notified chemical at a concentration of 625 μg.plate^{-1}, however the change in number of revertants at concentrations below this solubility threshold was negligible; cytotoxicity observed at concentrations greater than 5 000 μg.plate^{-1} in main test with S9 metabolic activation and 2 500 μg.plate^{-1} without S9 metabolic activation
Test method:	similar to OECD guidelines [11]
Result:	under the conditions of the experiments, the notified chemical was not mutagenic in bacterial cells

9.3.2 Chromosomal Aberration Assay using Cultured Peripheral Human Lymphocytes [15]

Cells:	peripheral human lymphocytes
Doses:	10 - 100 μg.mL^{-1} with or without S9 metabolic activation in DMSO vehicle; exposure time of 3 hours
Comments:	cytotoxicity observed at concentrations exceeding 100 μg.mL^{-1}
Test method:	similar to OECD guidelines [11]
Result:	the notified chemical was not clastogenic in peripheral human lymphocytes under the conditions of the experiment

9.4 Overall Assessment of Toxicological Data

The notified chemical was of low oral and dermal toxicity in the rat with both LD_{50} values greater than 2 000 mg.kg^{-1}. The notified chemical was not irritating to the skin of rabbits, however it was irritating to rabbit eyes, producing reversible effects in the conjunctiva of the animals. No iridal or corneal effects were noted. Results were not at a level that requires classification as a hazardous substance.

The notified chemical was found to be a moderate skin sensitiser to the skin of guinea pigs in an adjuvant-type test, with 50% of the test animals scoring a positive response after challenge with a 70% solution of the notified chemical, and 30% of the test animals scoring a positive response

after challenge with a 35% solution of the notified chemical.

A repeat-dose study with the rat showed that the notified chemical was of low toxicity when administered daily over a 4-week period. No specific organ effects were noted.

The notified chemical found not to be mutagenic in bacterial or mammalian cells. The notified chemical was also found not to be clastogenic in an *in vitro* chromosomal aberration assay using human lymphocyte cells. Both experiments were carried out under photolaboratory conditions due to the instability of the notified chemical under normal light.

Given that the notified chemical induces skin sensitisation in animals and that it is sold in the powder form, there is a possibility that respiratory effects, including sensitisation, could be induced in susceptible individuals.

Based on the skin sensitising properties of the notified chemical, it would be classified as hazardous according the criteria of the National Occupational Health and Safety Commission.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods at facilities complying with OECD Principles of Good Laboratory Practice.

Test	Species	Results (Measured [a])	Ref
Acute Toxicity 96 hours OECD TG 203	Zebra fish (*Brachydanio rerio*)	LC_{50} > 90 $\mu g.L^{-1}$ NOEC $\geq$ 90 $\mu g.L^{-1}$	[16]
Acute Immobilisation 48-hour OECD TG 202	Water flea (*Daphnia magna*)	EC_{50} > 1 175 $\mu g.L^{-1}$ NOEC = 3.1 $\mu g.L^{-1}$	[17]
Growth Inhibition 72 hour OECD TG 201	Algae (*Scenedesmus subspicatus*)	$EC_{50(b\&m)}$ > 260 $\mu g.L^{-1}$ NOEC = 260 $\mu g.L^{-1}$ LOEC > 260 $\mu g.L^{-1}$	[18]
Respiration Inhibition 3 hour OECD TG 209	Aerobic Waste Water Micro-organisms	EC_{50} > 100 $mg.L^{-1}$	[19]

a. Respiration inhibition to aerobic waste water micro-organisms test which is expressed as nominal.

Fish

The acute toxicity to zebra fish was determined in a 96-hour semi-static test with daily test medium renewal. Due to the very low water solubility of the notified chemical, a supersaturated stock suspension was prepared with a nominal concentration of 100 $mg.L^{-1}$. This was continuously stirred in the dark at room temperature for 2 hours, then filtered. The undiluted filtrate was used as the highest test concentration. Additionally, the dilutions 1:2, 1:4, 1:8 and 1:16 of the filtrate and a control were used.

The undiluted supersaturated stock suspension concentration on sampling days 0 and 3 was 170 and 67 $\mu g.L^{-1}$, respectively. Over 24 hours the test substance concentration in the test medium decreased to a value of 29 $\mu g.L^{-1}$. Thus, the measured concentrations were clearly above the solubility limit, with measured losses attributed to precipitation of previously colloidal dissolved parts of the notified chemical. Photodegradation can be excluded as this test was performed under light protection. All results are related to the mean measured test substance concentration of 90 $\mu g.L^{-1}$ (calculated as the average over all measurements in the undiluted filtrate during the test period).

In the control and all test concentrations, all fish survived until the end of the test and no signs of intoxication were observed. Therefore, the notified chemical can be classified as non-toxic to fish up to the limit of its solubility.

Water flea

A supersaturated stock solution was prepared in a similar process to that outlined above for the fish toxicity testing. The undiluted filtrate was used as the highest test concentration. Additionally, the dilutions 1:3.2, 1:10, 1:32, 1:100, 1:320 and 1:1 000 of the filtrate and a control were used.

The mean analytically determined notified chemical concentration in the test medium of the undiluted filtrate of the supersaturated stock suspension was determined to be 1 175 $\mu g.L^{-1}$. The test dilutions were determined to be (mean) 99, 15, 4.4 and 3.1 $\mu g.L^{-1}$ respectively. The dilutions 1:320 and 1:1 000 were not determined as they were below the 48 hour NOEC. Thus, the measured concentrations were clearly above the solubility limit, with measured losses attributed to precipitation of previously colloidal dissolved parts of the notified chemical. Photodegradation can be excluded as this test was performed under light protection.

After 2 hours, one daphnid was immobile at 1 175 $\mu g.L^{-1}$ and 15 $\mu g.L^{-1}$. The 24-hour EC_{50} was determined to be > 1 175 $\mu g.L^{-1}$. After 48 hours, the toxicity to *Daphnia magna* had increased. However, this toxicity may have been due to the physical effect of the notified chemical, i.e. from the test concentration of 4.4 $\mu g.L^{-1}$ up to the undiluted filtrate, the test animals were trapped on the surface of the water where at the higher test concentrations a part of the test substance was floating. Immobilisation rates increased with higher concentrations, e.g. one at

4.4 μg.L^{-1}, two at 15 μg.L^{-1}, four at 99 μg.L^{-1} and seven at 1 175 μg.L^{-1} (the undiluted filtrate).

Nonetheless, all immobilisation recordings were at concentrations higher than the water solubility of the notified chemical. Therefore, the notified chemical can be classified as non-toxic to invertebrates up to the limit of its solubility.

Algae

A supersaturated stock solution was prepared in a similar process to that outlined above for the fish toxicity testing. The filtrate was used as the test medium as well as a control. The test included two parts. The first part of the test the filtrate was incubated before the start of the test for 24 hours and illuminated at about 9 200 Lux. Due to the photosensitivity of the notified chemical, it reacted to degradation products. In the second part the filtrate was freshly prepared before the start of the test.

The analytically determined notified chemical concentration in the freshly prepared (undiluted) filtrate amounted to 260 μg.L^{-1} at the start of the test. The test medium decreased in concentration during the test period (but without algae) to 12 μg.L^{-1} at the end of the test. In the filtrate illuminated for 24 hours before the start of the test (first part), the concentration of the notified chemical amounted to 18 μg.L^{-1}. The notifier attributes the decrease of the notified chemical's concentration as a consequence of the intense radiation of the samples rather than precipitation of particulate amounts, as the treatment samples were continuously stirred during the test. All biological results are related to the concentration of 260 μg.L^{-1} (measured at the start of the test).

The mean algal cell densities in the test media of both filtrates at all counting dates were nearly identical with those in the parallel control cultures. Thus the notified chemical and its degradation products had no inhibitory effect on the growth of *Scenedesmus subspicatus* during the exposure period of 72 hours. Therefore, the notified chemical can be classified as non-toxic to algae up to the limit of its solubility.

Waste Water Micro-organisms

The inhibitory effect of the notified chemical on the respiration rate of aerobic waste water micro-organisms of activated sludge was investigated in a 3-hour respiration test. The study examined the five nominal test concentrations 6, 12, 24, 50 and to 100 mg.L^{-1}, and three inoculum controls. An obvious excess of test substance was present at all nominal concentrations, but the test substance was generally finely distributed.

In comparison to the controls, the respiration rate of the activated sludge was practically not inhibited (-5.7 to 5.7%) up to 100 mg.L^{-1} nominal (or the limit of water solubility).

The environmental hazard through the use of the notified chemical is expected to be low.

Use (formulation and application) of the notified chemical will be limited to a maximum of ten industrial sites in Australia. Losses associated with these processes are expected to be minimal. The notified chemical is destroyed during the curing process of the resin coating. Any organo-phosphorus residues will be encased in the polymer matrix and unable to migrate.

Wastes generated during the formulation and application processes are expected to be minimal. Waste product will be disposed of to secured landfill sites where it is expected to remain. Should the uncured chemical be exposed to the aquatic compartment, it is expected to rapidly photodegrade upon exposure to (UV containing) natural light. Regardless, the notified chemical was determined to be non-toxic to the aquatic organisms tested up to the limit of its solubility.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The major concern for workers handling the notified chemical is the potential for it to induce skin sensitisation and possibly respiratory effects (eg. sensitisation) in exposed individuals. Slight conjunctival irritation shown in animal eye irritation studies suggest that ocular exposure is also a potential hazard.

Worker exposure to the notified chemical occurs essentially at two different levels. During pre-blending operations (weighing, transferal to blender, minor re-packaging), exposure to the 90 -100% pure powder form of the notified chemical is possible. Thereafter, workers are at maximum exposed to 1.5% concentrations in the formulated resins. Workers exposed to the formulated product are likely to be at less risk of developing adverse health effects following systemic exposure because of the greater than 80-fold dilution of the notified chemical. However, they are still at risk of developing contact hypersensitivity to the notified chemical. Respiratory exposure is likely to be low on account of the low volatility of the notified chemical.

In the case of the former group, potential for exposure is most significant during weighing of the notified chemical and transfer to the blending vessel. Both these procedures are performed manually. Weighing will be carried out under local exhaust ventilation by workers fitted with long sleeve gloves and protective clothing. These measures should limit inhalational, ocular and dermal exposure of workers.

The transfer of the notified chemical to the blending vessel is carried out using a closed container, thus it is unlikely that workers will be exposed to the notified chemical during this operation.

does not come into contact with the coating formulation. Once applied, the coating is cured using UV lamps and the notified chemical is immobilised.

The genotoxicity studies indicate that the chemical is not genotoxic under photolaboratory conditions (ie no UV light). Experiments performed using UV light may show a different genotoxic profile, since UV light will induce the formation of radical species. This would require verification through additional testing. In any case, the possibility of genotoxic effects in the skin of workers who become dermally contaminated and exposed to UV light are not likely to be significant due to the relatively low intensity of natural UV light.

The notifier has indicated that engineering controls should ensure that inhalational exposure will be negligible. However, the risk of potential adverse respiratory effects is of concern and the notifier should emphasise this in the MSDS to ensure worker safety.

As the notified chemical will be used exclusively in an industrial environment, there will be negligible public exposure to the notified chemical. Public contact with products coated with formulations containing the notified chemical will be extensive. Exposure and risk will be negligible because residues of the notified chemical are encapsulated within the polymer matrix

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 [20] to comply with Australian/New Zealand Standard (AS/NZS) 1337 [21];
- Industrial clothing should conform to the specifications detailed in AS 2919 [22];
- Impermeable gloves or mittens should conform to AS 2161 [23];
- All occupational footwear should conform to AS/NZS 2210 [24];
- Spillage of the notified chemical should be avoided, and should be cleaned up promptly with absorbents which should then be put into containers for disposal; respirators should be worn in such operations and conform to AS/NZS 1716 [25]
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* [26].

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. In addition, secondary notification will be required if any adverse health effects in workers handling the notified chemical are noted. No other specific conditions are prescribed.

16. REFERENCES

1. Schreitmuller J, *Determination of the Concentrations of TKA 40135 (CGI 819) in Test Medium of an Acute Semi-Static Fish Toxicity Test*, . 1997, RCC Umweltchemie AG: Intingen, Switzerland.

2. McCall JP Laskowski RL & Dishburger HJ. *Measurement of Sorption Co-efficients of Organic Chemicals and Their Use in Environmental Fate Analysis In Test Protocols for Environmental Fate and Movement of Toxicants*. in *Proceedings of a Symposium of the Association of Official Analytical Chemists*. 1981. Washington DC.

3. National Occupational Health and Safety Commission, *List of Designated Hazardous Substances [NOHSC:10005(1994)]*. 1994, Canberra: Australian Government Publishing Service.

4. Jenkins WR, *TKA 40135 (CGI 819): Assessment of Ready Biodegradability - Modified Sturm Test*, . 1997, Huntingdon Life Sciences Ltd: Cambridgeshire, England.

5. Connell, D.W., *General characteristics of organic compounds which exhibit bioaccumulation*, in *Bioaccumulation of Xenobiotic Compounds*, D.W. Connell, Editor. 1989, CRC Press: Boca Raton.

6. Mc Rae L A, *TKA 40135 (CGI 819) Acute Oral Toxicity to the Rat*, . 1996, Huntingdon Life Sciences Ltd: Cambridshire, England.

7. Mc Rae L A, *TKA 40135 (CGI 819) Acute DermalToxicity to the Rat*, . 1996, Huntingdon Life Sciences Ltd: Cambridshire, England.

8. Parcell B I, *TKA 40135 (CGI 819) Skin Irritation to the Rabbit*, . 1996, Huntingdon Life Sciences Ltd: Cambridshire, England.

9. Parcell B I, *TKA 40135 (CGI 819) Eye irritation to the Rabbit*, . 1996, Huntingdon Life Sciences Ltd: Cambridshire, England.

10. Johnson I R, *TKA 40135 (CGI 819) Skin Sensitisation in the Guinea Pig*, . 1997, Huntingdon Life Sciences Ltd: Cambridshire, England.

11. Organisation for Economic Co-operation and Development, *OECD Guidelines for the Testing of Chemicals on CD-Rom*. 1995-1996, Paris: OECD.

12. Draize, J.H., *Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics.* Association of Food and Drug Officials of the US, 1959. **49**: p. 2-56.

13. Deoraj, P., *TKA 40135 (CGI 819) Four Week Oral Toxicity Study in the Rat with a Two Week Recovery Period*, . 1997, Huntingdon Life Sciences Ltd: Cambridshire, England.

14. Deparade E, *Salmonella and Escherichia/Mammalian-Microsome Mutagenicity Test*, . 1997, Genetic Toxicology CIBA-GEIGY Ltd: Basle, Switzerland.

15. Bertens, *Evaluation of the Ability of TKA 40135 (CGI 819) to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes (with independent repeat)*, . 1997, NOTOX: Hertogenbosch, The Netherlands.

16. Hertl J, *Acute Toxicity of TKA 40135 (CGI 819) to Zebra Fish (Brachydanio rerio) in a 96-hour Semi-Static Test*, . 1997, RCC Umweltchemie AG: Itingen, Switzerland.

17. Hertl J, *Acute Toxicity of TKA 40135 (CGI 819) to Daphnia magna in a 48-hour Immobilisation Test*, . 1997, RCC Umweltchemie AG: Itingen, Switzerland.

18. Hertl J, *Acute Toxicity of TKA 40135 (CGI 819) to Scenedesmus subspicatus in a 72-hour Algal Growth Inhibition Test*, . 1997, RCC Umweltchemie AG: Itingen, Switzerland.

19. Grutzner I, *Assessment of the Acute Toxicity of TKA 40135 (CGI 819) on Aerobic Waste Water Bacteria*, . 1997, RCC Umweltchemie AG: Itingen, Switzerland.

20. Standards Australia, *Australian Standard 1336-1994, Eye protection in the Industrial Environment*. 1994, Sydney: Standards Association of Australia.

21. Standards Australia/Standards New Zealand, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*. 1992, Sydney/Wellington: Standards Association of Australia/Standards Association of New Zealand.

22. Standards Australia, *Australian Standard 2919-1987, Industrial Clothing*. 1987, Sydney: Standards Association of Australia.

23. Standards Australia, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*. 1978, Sydney: Standards Association of Australia.

24. Standards Australia/Standards New Zealand, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*. 1994, Sydney/Wellington: Standards Association of Australia/Standards Association of New Zealand.

25. Standards Australia/Standards New Zealand, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices*. 1994, Sydney/Wellington: Standards Association of Australia/Standards Association of New Zealand.

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

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe