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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CGL 400

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

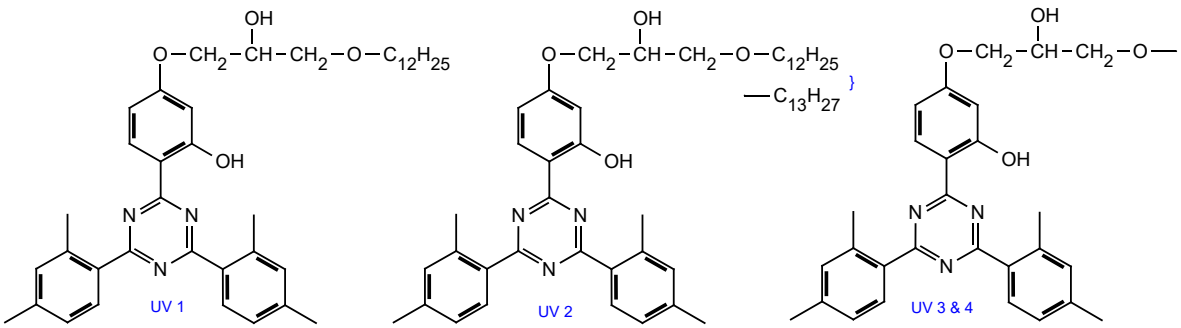
CGL 400

1. APPLICANT

CIBA-GEIGY Australia Ltd of 140 Bungaree Road PENDLE HILL NSW 2145 has submitted a standard notification in support of their application for an assessment certificate for CGL 400.

2. IDENTITY OF THE CHEMICAL

Chemical name:	reaction product of technical 2-(2,4-dihydroxyphenyl)-4,6-bis-(2,4-dimethylphenyl)-1,3,5-triazine and oxirane, mono[C10-C16-(alkoxy) methyl] derivatives, predominantly C12-C13
Chemical Abstracts Service (CAS) Registry No.:	153519-44-9
Other names:	CGL-400, TK 13340
Trade name:	Tinuvin 400 (85% formulation in 15% 1-methoxy-2-propanol)
Molecular formula:	cannot be given, product by reaction process
Structural formula:	the reaction product has 5 active UV-absorbers, UV1, UV2, UV3, UV4 and BP2; their respective contributions to UV absorption are 1%, 87%, 2%,1% and 1%



Molecular weight: > 1000, the molecular weight cannot be accurately determined due to variation of side chains amongst the components of the reaction product

Method of detection and determination: by ultraviolet-visible, infrared and nuclear magnetic resonance spectral analysis

Spectral data: major peaks in the infrared spectrum at: 620, 665, 700, 735, 845, 860, 900, 950, 1000, 1060, 1150, 1180, 1200, 1240, 1360, 1395, 1430, 1470, 1500 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	viscous yellow liquid
Odour:	aromatic odour
Boiling Point:	564°C (extrapolated from the vapour pressure curve)
Density:	1.081 g/ml
Vapour Pressure:	5 X 10^{-9} Pa at 25°C
Water Solubility:	$\leq$ 0.019 mg/L at 20°C
Fat Solubility:	98.6 g/100g at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	$\geq$ 11 (calculated, fragment method)
Hydrolysis as a function of pH:	could not be performed as the solubility in water of the test article is < 2 mg/L
Adsorption/Desorption:	not determined
Dissociation Constant pK_a**:**	not determined
Flash Point:	183°C
Flammability Limits:	not determined
Combustion Products:	oxides of carbon, nitrogen and other toxic gases
Decomposition Temperature:	not determined

Decomposition Products: not determined

Autoignition Temperature: 405°C

Explosive Properties: not explosive

Reactivity/Stability: not determined

Comments on Physico-Chemical Properties:

Hydrolysis as a function of pH was not determined due to the very low solubility of the chemical. Considering the chemical's solubility of 1.9×10^{-5} g/L, to estimate hydrolysis the detection limit of the analytical method must be at least 1/40th of the solubility, ie 4.8×10^{-7} g/L. This is beyond the detection limit of the available analytical methods. There are no functional groups likely to hydrolyse in the environmental pH range of 5 to 9.

The notifier states that due to the extremely lipophilic nature and very low water solubility of the substance, neither an experimental determination of Log Pow nor a meaningful preliminary experiment could be carried out. The Log Pow was therefore estimated using the calculation method (OECD No. 117 Annex) and the computer program CLOGP. As the notified substance consists of a mixture of several components, the component UV1 (see above) which is likely to be the least lipophilic one was used in this calculation. The Log Pow of this component was estimated as 11.875 and based on this the mixture was assumed to have a Log Pow of 11.

Adsorption/desorption data cannot be obtained due to the very low solubility of the chemical in water. The notifier has requested for an exemption of this data on the basis that the chemical is encapsulated in cured polymer films during applications. The high Log Pow indicates that the chemical is likely to sorb strongly to sediment particulates.

Dissociation constant was not measured due to the very low solubility and relatively high molecular weight. The aromatic OH groups are expected to give slight acidity and a pKa between 9.5-10.

The substance is not surface active.

4. PURITY OF THE CHEMICAL

Degree of purity: 85-96% (main products UV1+UV2+UV3+UV4+BP2)

chemical name	components
2-[4,6-bis (2,4-dimethylphenyl) -1,3,5 - triazine-2-yl]-5-(3-dodecyloxy-2-hydroxypropoxy) phenol	UV1
2-[4,6-bis (2,4-dimethylphenyl) -1,3,5 - triazine-2-yl]-5-(3-tridodecyloxy-2-hydroxypropoxy) phenol 2-[4,6-bis (2,4-dimethylphenyl) -1,3,5 - triazine-2-yl]-5-{(2-hydroxypropoxy-3-[1-(chloromethyl)-2-dodecyloxy)ethoxyl]}-phenol 2-[4,6-bis (2,4-dimethylphenyl) -1,3,5 - triazine-2-yl]-5-{(2-hydroxypropoxy-3-[1-(chloromethyl)-2-dodecyloxy)ethoxyl]}-phenol and corresponding bis-β-chloroether	UV2
2-[4,6-bis (2,4-dimethylphenyl) -1,3,5 - triazine-2-yl]3-hydroxyphenol	BP2
higher homologues of the above components	UV3 & UV4

Toxic or hazardous impurity/impurities:

. **Chemical name:** oxirane
Synonym: monoglycidyl ether
CAS No.: 68081-84-5
Weight percentage: <0.1%
Toxic properties: toxic through inhalation, irritating to eyes, skin and respiratory system, no Australian NOHSC exposure standard assigned

. **Chemical name:** chlorine
CAS No.: 7778-54-3
Weight percentage: 1.4%
Toxic properties: toxic by inhalation, irritating to eyes, skin and respiratory system, there is currently no Australian NOHSC exposure standard, American standards (ACGIH) recommend TWA 1.5 mg/m^3

. **Chemical name:** xylene
CAS No.: 1330-2-7
Weight percentage: <0.1%
Toxic properties: harmful in contact with skin or swallowed, skin irritant, WSA standard TWA 350 mg/m^3

Non-hazardous impurities (> 1% by weight):

Chemical name	Weight %
2-[4,6-bis (2,4-dimethylphenyl) -1,3,5-triazin-2-yl] -5-(3-dodecyloxy-2-hydroxypropoxy)-1-{[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazine-2-yl]oxy}-benzene 2-[4,6-bis (2,4-dimethylphenyl) -1,3,5-triazin-2-yl]-5-(3-tridodecyloxy-2-hydroxypropoxy)-1-{[4,6-bis(2,4-dimethylphenyl) -1,3,5-triazin-2-yl]oxy}benzene	2-10%
[4,6-bis(2,4-dimethylphenyl) -6-methoxy] -1,3,5 - triazine	0.5-2%

Additives/Adjuvants: none

5. INDUSTRIAL USE

The CGL-400 will be imported as a viscous yellow liquid to be used as the major component in a ultra-violet (UV) light absorber (Tinuvin 400) to be incorporated into surface coatings to counteract long term breakdown by UV light. CGL - 400 will be imported as 85% of the Tinuvin 400 formulation in steel drums. The amount of the notified chemical to be imported will be from 1-2 tonnes in the first year, rising to 15 tonnes per year after 5 years.

6. OCCUPATIONAL EXPOSURE

The notified chemical, imported in Tinuvin 400, will be transported to sites for batching operations. There is a potential for transport or handling incidents in which individual exposure is possible, but this is unlikely given the packaging in steel drums.

There will be approximately 20-30 sites involved in the batching of the notified chemical into paints. There will be approximately five employees at each site consisting of three plant operators and two laboratory technicians. They will be involved in weighing out the liquid formulation and adding this to a blending vessel (not necessarily closed). Workers will be potentially exposed to the notified chemical at 85% of the Tinuvin 400 or as a 0.5-5% proportion of the blended paints. While the notifier has no control over the work practices used by each customer, they will recommend the use of engineering controls such as mechanical ventilation.

The paint will mainly be used by Original Equipment Manufacturers (OEM's), each employing up to twenty spray painters in the painting of motor vehicles, aircraft and trains. Spray painters will be potentially exposed to the notified chemical as a 0.5-5% proportion of the paint. The number of workers exposed to the notified chemical may be reduced in some instances with the introduction of robotic spraying by some OEM sites.

The paint containing the notified chemical may be used by spray painters in the vehicle repair industry. It is estimated that there may be up to one thousand spray painting establishments throughout Australia, each employing between one to three spray painters. These workers would be potentially exposed to the notified chemical at levels between 0.5-5% in the paint use. It would be anticipated that engineering controls and personal protective equipment utilised would be similar to OEM sites.

A possible minor application of the notified chemical will be in the production of thermoplastics, however this would be not be a significant application as solvent based additives are rarely used in thermoplastic production. If it is to be utilised it will be during the preparation of Masterbatch concentrates. This would involve between twenty to forty more operators. The notified chemical in Tinuvin 400 would be weighed and added to a blender with polymers and pigments (not necessarily in a closed system). The molten mixture would then be extruded, cooled and pelleted. These pellets/granules will find further application in the production of polycarbonate sheets and plastic components for industrial application.

7. PUBLIC EXPOSURE

The notified reaction product will be transported in 50 kg steel drums to approximately 20-30 sites. The use of sturdy containers should minimise public exposure during transport.

There exists little possibility for public exposure to the notified chemical during normal use of the product, since the substance is incorporated into surface coating material by encapsulation in cured resins (paint films), or where the paint is applied to surfaces.

The exposure of members of the public to the notified substance through polishing of cars coated with paints containing this chemical is likely to be negligible because of the encapsulation of the substance into the polymer substrate and also because of the infrequency with which members of the public carry out cutting back of car paint finishes.

The major risk of public exposure would occur during a transport accident in which drums of Tinuvin 400 were ruptured.

8. ENVIRONMENTAL EXPOSURE

. Release

Formulation, handling and disposal

Tinuvin 400 will be formulated at a level of 0.5-5% in surface coatings is a simple weighing and blending operation at a late stage in the manufacturing process. Incorporation of the stabiliser can be carried out as the final formulation step. The blending process is facilitated by the fact that Tinuvin 400 is a liquid.

It is stated that no waste is generated during these formulations but this appears to overlook that routine cleaning of the process equipment may be needed to prevent product contamination and maintain operational efficiency (1). Wastage from such operations however would be low because most of the residues are likely to be collected and used in other batches.

Incineration and disposal to landfill are the recommended methods of disposal, with incineration being the preferred method. Spillages of the notified substance would be absorbed on an inert material before disposal in a suitable manner. The notifier has stated that the 50 kg metal drums used for the transport of the stabiliser are expected to be washed (multiple rinsing) with solvents used in the production process which are later used in further formulations. Disposal instructions for empty containers indicate that after suitable rinsing, the drums should be holed and crushed before disposal.

The notifier indicates that the stabiliser may eventually be used as an additive in selected thermoplastics. If this use is pursued, it would entail blending of the stabiliser at comparable concentrations to those used for surface coatings.

Use

Tinuvin 400 will be used as an additive UV absorber in surface coatings to counteract the long term breakdown of such coatings by ultraviolet light and weather. During exposure to UV light the UV absorber converts the energy of the UV radiation to heat through molecular rearrangements, the compound itself remaining undamaged and available for further energy conversion. It is expected to replace some of the other UV stabilisers currently used in the surface coating industry due to superior qualities such as very high UV screen activity, low volatility, high stability to heat and light and possibility of using with amine or metal catalysed coating systems without the development of colouration.

The substance is added at the rates of 0.5% - 5% to the surface coating material at a late stage in the manufacture before testing and filling. Being a liquid, it is poured into a dispensing container, weighed and transferred to the mixing tank.

Three possible routes by which the chemical may enter the environment through its use are (a) gradual weathering of coatings containing the notified substance (b) discard of coated articles to landfill or for incineration and (c) volatilisation during curing. None of these routes are likely to give rise to significant environmental release of the chemical which is expected to remain encapsulated in the plastic because of its minimal water solubility, very low volatility and stability to heat and light.

The most significant route for entry into the environment will be disposal of waste from spraying operations. Conventional liquid spray technology relies on air pressurised sprayers and transfer efficiencies can sometimes be as low as 50% (1). However there is rapid move towards the use of spray guns with higher transfer efficiencies and robotic spraying. Implementation of such new technology should lead to a reduction of waste during spray operations. The notifier has indicated that

OEM manufacturers, the main users of the chemical, will use advanced robotic spraying techniques with less than 20% waste.

The second significant source of release during spray operations is the cleaning of painting equipment using solvents. These washings however are expected to be re-used in the production process. The notifier states that Tinuvin 400 is not recommended for use in emulsion paints and as such disposal as emulsion paint from brush and container washings will not be an issue.

The overspray in the air is often exhausted through an aqueous scrubber, which removes the waste paint as a sludge. Scrubber water is usually recycled and solids are drummed for disposal as hazardous waste, either through incineration or secure landfill. If disposed to landfill, the notifier claims that the chemical in the paint particles will not be any more leachable than from finished films and the paint particles will contain on average about 3% of the notified chemical.

. Fate

Tinuvin 400 is expected to remain encapsulated within the cured polymer material. Due to its very low solubility, leaching of the chemical from waste disposed to landfill or during slow weathering of articles is unlikely. The low solubility and high Log Pow indicate that the chemical will bind strongly to sediment particles in soil. Incineration will break down the chemical producing water vapour and oxides of carbon and nitrogen.

Ready biodegradability investigated in a modified Sturm test (OECD guideline No. 301 B) showed that after 28 days, the biodegradation was only 10% at a solution concentration of 10.1 mg/L and 3% at a concentration of 20 mg/L. Hence the notified chemical is not readily biodegradable.

Although the chemical has a very low water solubility (<1.9 x 10^{-5} g/L) and a high fat solubility (98.6 g/100 g fat) resulting in a high calculated Log Pow of >11 the notifier has not carried out a bioaccumulation test because significant bioaccumulation would be unlikely owing to the lack of a delivery mode through water to aquatic organisms. This is acceptable. Bioaccumulation of substances with Log Pow >7.5 is very slow (2).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of CGL-400

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(3)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(5)
Skin Irritation	Rabbit	non irritant	(6)
Eye irritation	Rabbit	non irritant	(8)
Skin sensitisation	Guinea-pig	non sensitising	(9)

9.1.1 Oral Toxicity (3)

Species/strain:	Tif: RAI f (SPF)) Albino rats
Number/sex of animals:	5 males and 5 females
Observation period:	14 days
Method of administration:	a single oral dose of 2000 mg/kg was administered at 10 ml/kg by gastric intubation (gavage). Rats were observed daily and submitted to a gross necropsy at the end of the observation period
Clinical observations:	piloerection, hunched posture, exophthalmos and dyspnea were seen in both sexes immediately after administration. The animals recovered within 3 days. There is insufficient evidence to conclude that these effects are treatment related
Mortality:	none
Morphological findings:	no abnormal pathology
Test method:	according to OECD Test Guideline 401 (4)
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was not found to be harmful by acute oral administration. There was no abnormal pathology identified during necropsy. The clinical observations were seen immediately after administration of the chemical and so may have been a result of the administration procedure rather than the notified chemical

9.1.2 Dermal Toxicity ( )

Species/strain:	Tif: RAI f (SPF)) Albino rats
Number/sex of animals:	5 males and 5 females
Observation period:	14 days
Method of administration:	a single dose of 2000 mg/kg was administered at 2 ml/kg to the shaved back of each rats and covered with a semi-occlusive dressing. After 24 hours the dressing was removed, the skin cleaned and the skin reaction appraised for 14 days. Animals were submitted to a gross necropsy at the end of the observation period
Clinical observations:	piloerection, hunched posture and dyspnea were seen and reduced activity were observed in all animals during immediately after application. All animals recovered within 5 days. There is insufficient evidence to conclude that these effects are treatment related
Mortality:	none
Morphological findings:	no abnormal pathology
Test method:	according to OECD Test Guideline 402 (4)*:*
LD_{50}*:*	> 2000 mg/kg
Result:	the notified chemical was not found to be harmful by acute dermal administration. There was no abnormal pathology identified during necropsy. The clinical observations may have been a result of the administration procedure rather than the notified chemical

9.1.3 Skin Irritation (6)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	3 females
Observation period:	7 days
Method of administration:	a gauze patch bearing 0.5 g of the undiluted

test article was applied to the shaved right flank of each animal. A control gauze patch was applied to the contralateral flank. Both patches were moistened before application with 0.5% (w/v) carboxymethylcellulose in 0.1% (w/v) aqueous polysorbate 80. These patches were removed after four hours and the skin reactions evaluated after 1, 24, 48, 72 hours and 7 days

Draize scores (7)[i]:

	Time after treatment (days)				
animal #	***60 min***	***1***	***2***	***3***	***7***
Erythema					
1	1	1	1	1	0
2	1	2	2	1	0
3	1	1	1	1	0
Oedema					
1	0	0	0	0	0
2	0	1	0	0	0
3	0	0	0	0	0

[i] see Attachment 1 for Draize scales

Test method: according to OECD Test Guideline 404 (4)

Result: the notified chemical is a mild skin irritant based on the erythematic reaction obtained in all rabbits. The notified chemical cannot be classified as hazardous on this basis however

9.1.4 Eye Irritation (8)

Species/strain: New Zealand White rabbits

Number/sex of animals: 3 female

Observation period: 7 days

Method of administration: 0.1 ml of the undiluted test article was placed into the conjunctival sac of the left eye of each animal, the right eye remaining untreated and serving as a control. The ocular reactions were evaluated 1, 24, 48, 72 hours and 7 days

after instillation.

Draize scores (7)[i] of unirrigated eyes:

	Time after instillation									
Animal	***60 min***		***1 days***		***2 days***		***3 days***		***7 days***	
Cornea	***o[a]***		***o[a]***		***o[a]***		***o[a]***		***o[a]***	
1	0		0		0		0		0	
2	0		0		0		0		0	
3	0		0		0		0		0	
Iris										
1	0		0		0		0		0	
2	0		0		0		0		0	
3	0		0		0		0		0	
Conjunctiva	***r[b]***	***c[c]***	***r[b]***	***c[c]***	***r[b]***	***c[c]***	***r[b]***	***c[c]***	***r[b]***	***c[c]***
1	2	1	1	1	1	0	1	0	0	0
2	2	1	2	0	1	0	1	0	0	0
3	2	1	2	1	1	0	1	0	0	0

[i] see Attachment 1 for Draize scales
[a] opacity [b] redness [c] chemosis

Test method: according to OECD Test Guideline 405 (4)

Result: based on the positive conjunctiva reactions obtained in all rabbits the notified chemical is a mild eye irritant. The notified chemical cannot be classified as hazardous on this basis however

9.1.5 Skin Sensitisation (9)

Species/strain: Pirbright White Strain (Tif:DHP) Guinea Pig

Number of animals: 10 male and 10 female

Induction procedure: in the first week of induction three pairs of intradermal injections (0.1 ml per injection) were made simultaneously into the shaved neck of the guinea pigs as follows: 1) Bacto adjuvant/saline mixture 1:1 (v/v), 2) test article in sesame oil (5%) and 3) test article in Bacto

	adjuvant saline mixture (5%). In the second week of induction the test article was incorporated into vaseline at 10% and applied on a filter paper patch to the neck of the animals (0.4 g per patch, occluded administration for 48 hours). During weeks 3 and 4 no treatments were performed. A control group was treated with adjuvant and vehicle during the induction period
Challenge procedure:	animals were tested on the flank with the test article in vaseline (3%) and the vehicle alone (0.2 g per patch, occluded administration for 24 hours). Evaluation was made 24 hours after removing the dressings with a second evaluation made after 48 hours
Test method:	there was an absence of any significant skin reactions to the test article. The notified chemical is not a skin sensitiser
Result:	according to OECD Test Guideline 406 (4)

9.2 Repeated Dose Toxicity (10)

Species/strain:	Tif: RIA f (SPF) albino rats
Number/sex of animals:	50 males and 50 females
Method of administration:	the test article was administered orally in the diet (admixed to pelleted food)
Dose/Study duration::	the test article was administered for 28 days at dose levels 0, 120, 600, 3000 and 12000 ppm. Haematological and pathological examinations were performed on all surviving rats at the end of the treatment period. An additional group of rats from each treatment dose were allowed a 4 week recovery period before being sacrificed for analysis
Clinical observations:	there were no clinical signs of systemic toxicity during the study. No treatment related deaths occurred during the study
Clinical chemistry/Haematology	a slightly higher number of blood platelets were noted in males and females at 12000 ppm. This effect was found to be reversible within the recovery period. A slight

	prolongation of the prothrombin time in males receiving 3000 and 12000 ppm was noticed but no additional effects were observed to indicate that this was treatment related
Histopathology:	at the end of the treatment period, the mean liver weight of 12000 ppm females was increased 28%. The liver to body-weight ratio of these animals was increased by 14% compared to control values. This effect was reversible within the recovery period. This may be indicative of the liver being a target organ for toxicity for the notified chemical. There were no significant treatment related macroscopic or microscopic changes observed
Test method:	according to OECD Test Guideline 407 (4)
Result:	the only major treatment related effect observed was a 28% increase in the mean liver weight in female rats fed 12000 ppm of the notified chemical. While this indicates that the liver may be a target organ for toxicological effects, there were no additional microscopic or macroscopic effects to support this. There were no other treatment related effects observed. The notified chemical was not found to be harmful by repeat oral administration

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (11)

Strains:	*Salmonella typhimurium* TA 100, TA 1535, TA 98, TA 1537 and *Escherichia coli* WP2uvrA
Concentration range:	the notified chemical was tested for mutagenic effects with and without S9 rat liver microsomal activation at a range of 312.5 to 5000 μg/ plate
Test method:	according to OECD Test Guideline 471 (4)
Result:	in an original and confirmatory experiment, the notified chemical did not lead to an increase in the incidence of either histidine- or tryptophan-phototrophic mutants by

comparison with the negative control. The notified chemical is not a mutagen

9.3.2 Cytogenetic Test on Chinese Hamster Cells *In Vitro* (12)

Species/strain:	Cell line ATCC CC 61 (Ovary, Chinese Hamster)
Doses:	eight dose levels of between 5.23 and 670 µg/ml of the test article dissolved in acetone were used for all experiments
Method of administration:	four experiments were performed: 1) the cells were exposed to the test article for 18 hours without S9 rat liver metabolic activation, 2) the cells were exposed to the test article for 3 hours with microsomal activation, 3) the cells were exposed to the test article for 42 hours without microsomal activation, and 4) the cells were exposed to the test article for 3 hours with microsomal activation. Immediately after removal of the test article the cells were washed and incubated in new culture for 39 hours. Both positive and negative controls were used in all experiments
Test method:	according to OECD Test Guideline 473 (4)
Result:	in studies performed without metabolic activation using 18 and 42 hours incubation, there were no significant increases in the number of chromosomal aberrations observed. In the experiments performed in the presence of a metabolic activation system, there were no marked increases in the number of specific chromosome aberrations

9.4 Overall Assessment of Toxicological Data

The notified chemical was not found to be toxic in rats by acute oral or dermal administration (LD_{50} > 2000 mg/kg). Some minor clinical observations such as piloerection and dyspnea were evident in both studies but there was no clear evidence to indicate that this was treatment related. The notified chemical produced minor skin and eye irritation to rabbits but neither were sufficiently severe to be considered a hazard. The notified chemical did not exhibit skin sensitisation. There was a significant increase in the liver weight of female rats administered high doses of the notified chemical, indicating that the liver may be a target organ for toxicity. However, there was no macroscopic or microscopic evidence of toxicity, indicating that the notified chemical is not toxic by repeated dose. Reverse Mutation assays failed to find a significant increase in histidine or tryptophan phototrophic mutants, and the *in vitro* cytogenetic test on Chinese Hamster ovary cells failed to find any significant increase in chromosomal aberrations.

The notified chemical is not classed as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (13).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The concentration of the chemical recorded in the various aquatic tests listed below were very much higher than its water solubility (1.9×10^{-5} g/L). These higher concentrations were achieved with the aid of the solubilisation agent made of a mixture of NMP (N-Methyl-2-Pyrrolidone) and TEG (triethyleneglycol).

<u>Zebra fish</u>

A static acute toxicity study (OECD-guidelines No. 203) with Zebra fish (*Brachydanio rerio*) was performed in de-chlorinated tap water maintained at a temperature of 21-25´C and a pH of 8.0. No fish mortalities were observed at any of the concentrations up to 96 h. Daily observations also indicated that there was no effect of the chemical on the swimming behaviour, loss of equilibrium, respiratory function, exophthalmos or the pigmentation of the fish. The test revealed the NOEC to be 2.8 mg/L and the 96 h LC_{50} to be > 2.8 mg/L. The notified substance is therefore not toxic to fish up to the limit of its solubility (at worst moderately toxic).

The concentrations of the notified chemical used in the study are listed in the table below. A large difference between the nominal dose and the measured dose is evident. Although the substance was homogeneously distributed in the stock solution by means of NMP, large precipitation occurred when the stock solutions were diluted with water to prepare the test solutions. This explained the large differences in nominal and measured concentrations. The measured concentrations at the end of the exposure (96 h) are higher than the concentrations at the start (0 h). The notifier suggest that this may be due to further slow solubilisation of the test substance during the 96 h test period.

Nominal concentration (mg/L)	Measured conc. 0 h (mg/L)	Measured conc. 96 h (mg/L)
10	0.08	0.5
18	0.2	2.7
32	0.3	2.3
58	0.5	5.2
100	6.5	2.8

Water flea

Static acute toxicity testing on the water flea *Daphnia magna* (OECD-guidelines No. 202) was carried out with 20 individuals per test concentration. The test showed the NOEC (48 h) to be = 0.2 mg/L and the 48 h EC_{50} for immobilisation to be = 0.6 mg/L (95% confidence limits = 0.51-0.77 mg/L). Hence the notified substance is highly toxic to *Daphnia*.

The nominal and measured concentrations given below again indicate significantly lower measured concentrations particularly at 48 h. This is probably explained by the precipitation of the chemical during the test period as observed in the fish test. In contrast to the observation in the fish test, here the measured concentrations at the end of the test (48 h) were significantly lower than the concentrations at the start (0 h). The notifier attributed this to a possible settling down of the precipitated particles of the chemical with time.

Nominal concentration (mg/L)	Measured conc. 0 h (mg/L)	Measured conc. 48 h (mg/L)
1.8	0.6	0.08
3.2	1.3	0.2
5.8	2.4	0.4
10	3.8	0.8
18	6.7	1.6

Microbial activity

An activated sludge from a sewage treatment plant was used to assess the effect of the notified chemical on the respiration of aerobic waste water bacteria. The testing protocol was according to the document OECD Guideline No. 209 (April 1984) except that a settled sludge was used instead of a centrifuged sludge and the test substance was added directly to the medium without preparing a stock solution. No solubiliser was used and it is not known how much of the chemical was in solution. Bacterial oxygen consumption was not affected at any of the added concentrations of the chemical. After 3 h testing the inhibitory concentrations IC_{50}, IC_{20} and IC_{80} (based on nominal concentrations) were all determined to be >100 mg/L, a result indicating that the notified substance had no inhibitory effect on microbial respiration at the concentrations studied.

Algal growth

Algal growth inhibition test has not been carried out. Low water solubility of the substance and improbable exposure of algae because of the manner of use of the substance have been suggested as the reasons for not carrying out the algal test. This is not quite acceptable as these arguments can apply equally well to fish, *Daphnia* and microbial activity tests, yet tests on these organisms have been carried out. The action on algae, however, is likely to be somewhat similar to that on bacteria and the toxicity on algae can be expected to be minimal.

Results of environmental effects testing are summarised below.

Species	Test	Toxicity
Zebra fish *(Brachydanio rerio)*	Static acute toxicity test (mortality and functional disorders)	NOEC (96 h) = 2.8 mg/L LC_{50} (96 h) $\geq$ 2.8 mg/L
Water Flea *(Daphnia magna)*	Static acute toxicity test (immobilisation)	NOEC (48 h) = 0.2 mg/L EC_{50} (48 h) $\geq$ 0.6 mg/L
Sewage sludge bacteria	Respiration inhibition test	EC_{50} (3 h) $\geq$ 100 mg/L
Algae	Growth Inhibition (not carried out)	Unknown

Conclusion

Tinuvin 400 is highly toxic to aquatic organisms such as *Daphnia* but is not toxic to fish up to the limit of its solubility (at worst moderately toxic). It has no major effect on aerobic bacteria.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The proposed use of the notified substance in surface coatings will result in its encapsulation within polymer matrices. This combined with the extremely low solubility of the chemical in water indicate that the leaching of the chemical to the environment would be negligible.

Assuming that most OEM's use advanced robotic technology for applying surface coatings, up to 20% of the paint used (equivalent to 3 tonnes of Tinuvin 400) can be lost as waste, and would require disposal by either landfill or incineration. In the waste disposed to landfill the proportion of Tinuvin 400 would be small (<5%) and is expected to remain associated with such wastes.

The high Log Pow (calculated >11) and the high lipid solubility (98.6 g/100 g fat) indicate that the notified chemical has potential to bioaccumulate, particularly in the aquatic compartment. However the very low water solubility of the chemical (1.9×10^{-5} g/L) clearly indicates that water does not provide an effective transport vehicle for the mobilisation of the notified chemical. Therefore the potential impact of the notified chemical on aquatic species is limited.

Although the toxicity of the notified substance to fish and bacteria appears to be low it shows a high toxicity to species such as *Daphnia*. However, in view of the very low solubility of the substance and its encapsulation during its proposed use, significant contamination of the aquatic compartment is not expected and the hazard appears minimal.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological studies presented suggest that the notified chemical would be unlikely to be toxic by acute dermal or oral exposure in humans. There also existed a lack of any sensitisation reaction, nor was there any evidence of the notified chemical being mutagenic or clastogenic. There is a possibility that humans may experience mild dermal or eye irritation should exposure occur via these routes, however it is unlikely that any significant reaction would occur. Similarly, there is some suggestion that the liver may be a target organ for any toxic reaction that might occur from repeated dose administration, however there is little pathological evidence support this.

The notified chemical will not pose any exposure risk during transportation due to its packaging in steel drums. However, should a spill occur clean-up procedures and personal protection should be as stated in the recommendations.

There exists a risk of dermal exposure and ingestion to the notified chemical as an 85% solution in Tinuvin 400 during the batching stage by splashing or aerosols generated from the mixing process. There is little risk of significant effects from exposure to the notified chemical, however the use of local exhaust ventilation to reduce exposure to any other solvents used in the paint will also serve to reduce exposure to aerosols of the notified chemical. Exposure through splashing will also be reduced through the use of closed system mixers and the employment of protective eye goggles, gloves, protective clothing and respirators should the ventilation prove to be insufficient protection.

The use of any paints containing the notified chemical (between 0.5-5%) will involve possible occupational dermal exposure or ingestion through aerosol generation or splashing during spray painting. It will be expected that adequate local exhaust ventilation will be at all sites of spray application, this to be supplemented by the appropriate respiratory protection, eye goggles, protective gloves and protective clothing. While this will serve to minimise exposure to possible hazardous constituents in the paint product it will also reduce incidental exposure to the notified chemical. It is expected that the use of robotic spray painters will reduce the risk of any human exposure to low levels.

The production of thermoplastics during the Masterbatch presents a risk of exposure to the notified chemical. The mixing of the notified chemical in formulation to the polymers may generate splashing or aerosols which may result in dermal exposure or ingestion. Closed mixing systems should be employed to reduce this risk. There is little potential for exposure to the notified chemical after the mixing process as it will be dissolved and encapsulated in the polymer. The use of local exhaust

ventilation and protective goggles, gloves and clothing are standard for the handling of heated thermoplastics, and will serve to reduce exposure to the notified chemical further. If exhaust ventilation is inadequate, respiratory protection should be employed.

Based on the information in public exposure, it is unlikely that the notified polymer would pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to CGL-400 the following guidelines and precautions should be observed:

- local exhaust ventilation should be employed where there is likelihood of aerosol generation or poor ventilation.

- if engineering controls and work practices are insufficient to reduce exposure to CGL-400 to a safe level, then:

  - the appropriate respiratory device should be selected and used in accordance to Australian Standard/ New Zealand Standard (AS/ NZS) 1715 (14) and should comply to AS/NZS 1716 (15).

  - eye protection should be selected and fitted in accordance to AS 1336 (16) and used in accordance to AS/NZS 1337 (17).

  - industrial clothing must conform to the specifications detailed in AS 2919 (18).

  - industrial gloves should conform to the standards detailed in AS 2161 (19).

- should a spill occur, the following procedures should followed:

  - eye protection should be selected and fitted in accordance to AS 1336 (16) and used in accordance to AS/NZS 1337 (17).

  - industrial clothing must conform to the specifications detailed in AS 2919 (18).

  - industrial gloves should conform to the standards detailed in AS 2161 (19).

  - prevent contamination of soil, drains and surface waters.

  - take up mechanically/manually and collect in a suitable container for disposal by incineration.

- storage should be in sealed airtight containers away from sources of ignition high temperatures, strong acids, bases or oxidising agents.

- good personal hygiene should be practised to minimise the potential for ingestion.

- a copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for CGL-400 was provided in an acceptable format according to Worksafe Australia's *National Code of Practice for the Preparation of Material Safety Data Sheets* (20).

This MSDS was provided by CIBA-GEIGY Australia Ltd as part of their notification statement. The accuracy of this information remains the responsibility of CIBA-GEIGY Australia Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

If uses are proposed where greater release to the aquatic component could occur, results of the algal growth inhibition test will be required.

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of CGL-400 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. Randall, PM, 1992, Pollution prevention methods in the surface coating industry. *Journal of Hazardous Materials* **29,** 275-295.

2. Connell, DW, 1989, General characteristics of organic compounds which exhibit bioaccumulation. In *Bioaccumulation of Xenobiotic Compounds*, DW Connell (ed). CRC Press, Boca Raton, USA.

3. Hartmann, HR, 1991, *Acute Oral Toxicity in the Rat*, CIBA-GEIGY Ltd, Test No. 904323.

4. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.

5. Hartmann, HR, 1991, *Acute Dermal Toxicity in the Rat*, CIBA-GEIGY Ltd, Test No. 904326.

6. Hagemann, C, 1991, *Acute Dermal Irritation/Corrosion Study in the Rabbit,* CIBA-GEIGY Ltd, Test No. 904325.

7. Draize J H, 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49**.

8. Hagemann, C, 1991, *Acute Eye Irritation/Corrosion Study in the Rabbit,* CIBA-GEIGY Ltd, Test No. 904324.

9. Maurer, T, 1991, *Skin Sensitisation in the Guinea Pig Maximisation Test*, CIBA-GEIGY Ltd, Test No. 904327.

10. Gerspach, R, 1991, *28-Days Subacute, Oral Toxicity Study in Rats (Administration in Food),* CIBA-GEIGY Ltd, Test No. 904282.

11. Ogorek, B, 1991, *Salmonella and Escherichia/Liver-Microsome Test*, CIBA-GEIGY Ltd, Test No. 904328.

12. Ogorek, B, 1991, *Cytogenetic Test on Hamster Cells In Vitro*, CIBA-GEIGY Ltd, Test No. 914036.

13. Worksafe Australia, 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)],* AGPS, Canberra.

14. Standards Australia, Standards New Zealand, 1994, *Australian/New Zealand Standard 1715-1994 Selection, Use and Maintenance of Respiratory Protective Devices.* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

15. Standards Australia, 1991, *Australian Standard 1716-1991 Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Australia.

16. Standards Australia , 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment.*, Standards Association of Australia Publ. Sydney, Australia.

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

18. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.

19. Standards Australia, 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney, Australia.

20. National Occupational Health and Safety Commission, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra.

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