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May 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Tinuvin 928

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Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Tinuvin 928

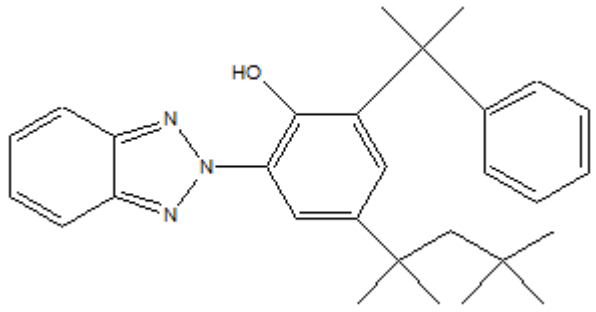
1. APPLICANT

Ciba Specialty Chemicals of 235 Settlement Road, Thomastown, Victoria 3074 has submitted a standard notification statement in support of their application for an assessment certificate for Tinuvin 928. No application has been made for information submitted for Tinuvin 928 to be exempt from publication.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	2-(2H-Benzotriazole-2-yl)-6-(1-methyl-1-phenylethyl)-4-(1,1,3,3-tetramethylbutyl)phenol
Chemical Abstracts Service (CAS) Registry No.:	73936-91-1
Other Names:	2-(2-hydroxy-3-α-cumyl-5-t-octylphenyl)-2H-benzotriazole; CGL-120/CA18-120
Marketing Name:	Tinuvin 928
Molecular Formula:	$C_{29}H_{35}N_3O$

Structural Formula:



Molecular Weight:	441
Method of Detection	The chemical was characterised by Nuclear Magnetic

and Determination:	Resonance spectroscopy, Fourier Transform Infrared spectroscopy, Mass spectroscopy and Ultraviolet/Visible spectroscopy.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Light yellow crystalline solid
Particle Size:	Mass median diameter 241μm; 3.3% below 9μm; <1.4% below 4μm.
Melting Point:	109 - 113°C. The chemical decomposes before boiling at 100kPa under N_2.
Boiling Point:	401 - 425°C
Density:	1140 kg/m^3 at 25°C
Vapour Pressure:	$6.3x10^{-10}$ kPa at 25°C
Water Solubility:	<69 μg/L at 20°C, determined using the flask method. The column method was not used due to the potential for altering the crystal form of the chemical.
Partition Co-efficient (n-octanol/water):	Not determined experimentally. An estimation of $logP_{ow}$ was determined computationally to be 10.6. This was outside the range for reliable experimental determination of $logP_{ow}$ by either the Shake Flask or HPLC method.
Hydrolysis as a Function of pH:	Not determined due to low water solubility. No functional groups usually considered hydrolysable are present. The phenol functionality is weakly acidic and the nitrogen atoms may be weakly basic but this would occur outside the environmental pH range of 4-9.
Adsorption/Desorption:	Log K_{oc} >>5.6. Using a HPLC-screening method, the adsorption/desorption coefficient was determined to be much greater than 5.6, the highest value determined by OECD Test Guideline 106. More precise measurement was prevented by retention times and capacity factors being outside calibration ranges.
Dissociation Constant:	Not determined
Surface Tension:	72.6-72.9 mN/m at 20°C on filtrate of 10.0 g/L suspension. No evidence of surface activity was observed.

Fat Solubility:	1000g/100g at 37°C. The chemical was found to be fully miscible with the stimulant.
Flash Point:	Not determined
Flammability Limits:	Nonflammable; combustible
Autoignition Temperature:	No autoignition observed up to the melting temperature of 119°C
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable

Comments on Physico-Chemical Properties

No additional comments.

4. PURITY OF THE CHEMICAL

Degree of Purity:	98.9%
Hazardous Impurities:	None known
Non-hazardous Impurities (> 1% by weight):	None known
Additives/Adjuvants:	None

5. USE, VOLUME AND FORMULATION

The notified chemical is an additive UV absorber for use in automotive clearcoat paints at 1.1% w/w. The chemical will not be manufactured in Australia but imported in the following volumes:

Year	Tonnes per year
1	1-10
2	5-10
3	5-15
4	10-20
5	15-20

The chemical will be imported as 100% active ingredient in 50kg polyethylene-lined fibreboard drums.

6. OCCUPATIONAL EXPOSURE

Import, Transport and Storage

The notified chemical will not be manufactured in Australia but imported in 50kg polyethylene-lined fibreboard drums in shipping containers. The drums will be transported by road to a single formulator to be blended into automotive clearcoat paint.

Two dockside personnel each working 2 hours per day for 10 days/year and 4 transport workers each working 4 hours/day for 10 days/year may be exposed to the notified polymer. However, since the polymer is imported in sealed drums which are not opened prior to use, the probability of exposure to the notified polymer during import, transportation and storage would be considered low and only envisaged following accidental puncture of the drums.

Manufacture of Paints (Formulation)

Automotive paint manufacture will occur at one site. For manufacture, the powdered chemical first will be batch-weighed into sealed paper bags. The chemical will be then transported to a paint mixing pot to be dissolved in solvent. The chemical in solvent then will be pumped to an enclosed paint mixer to be blended with additional paint components. The paint is then filtered, pumped into 200L steel drums and stored awaiting distribution. Weighing and mixing of paint components including the notified chemical and the filling of drums with the final formulated paint are all conducted under local exhaust ventilation.

During these procedures, 10 workers each working for 4 hours per day for 20 days per year potentially may be exposed to the notified chemical. Although the chemical is in powder form, exposure at this stage is unlikely because of the large particle size and small inspirable fraction, the nonvolatile nature of the chemical and the engineering controls used to limit exposure. From overseas studies for EC notification, a maximum exposure estimate of $0.1mg/m^3$ has been derived for handling tasks with the notified chemical. No further details were provided. However, there is the potential for spillage of solvent solution and paint during decanting and mixing procedures and occupational exposure to the notified chemical may occur, predominantly via the skin. To control this exposure, workers will wear impervious gloves, anti-static coveralls, anti-static footwear and eye protection conforming to the relevant Australian Standards.

Laboratory Testing

The paint is subject to laboratory quality control. During these processes, three workers may be exposed to the notified chemical each for 2 hours per day for 20 days per year. Worker exposure to the chemical and other paint ingredients in the laboratory environment is limited by ventilated fume cupboards and personal protective equipment consisting of coveralls/laboratory coats, impervious gloves and eyewear. Thus, the possibility of worker exposure during testing is low.

End Use (Paint Application)

The final paint will be sold and shipped by road transport in 200L drums to 2 automotive original equipment manufacturers (OEMs). The paint will then be applied to the external surfaces of automotive bodies by manual and automatic electrostatic atomised spray application techniques. Four workers involved in adding the final paint coating to an open circulation tank potentially will be exposed for 2 hours per day for 200 days per year.

Because of the possibility of spillage, dermal exposure to the notified chemical during this stage may occur.

For spray painting, 20 workers each spending 8 hours per day for 200 days per year are expected to be involved in applying the coating and 6 workers for 2 hours per day for 200 days per year will be involved in cleaning spray equipment. Given transfer efficiencies of approximately 35% and 80% for manual and automatic electrostatic spray applications respectively, it is at this point of manual application and cleaning of spray equipment that occupational exposure to the notified chemical (at 1.1% w/w) and other paint components may be considered most likely.

Typically, the spray painters who potentially will be exposed to the notified chemical will be fully TAFE trained and coating of automobile components will be conducted in a laminar flow downdraft spray booth which is designed to rapidly remove aerosol particles and solvent vapour from the atmosphere. Several possible booth designs may be used. In a dry floor booth, overspray will be collected in filters contained in the floor of the booth and any unremoved particulates will reach the exhaust stack with the solvent vapours. In a wet floor booth, overspray will collect in a pool of water below the grill floors or in a wet scrubber in the exhaust and will be removed in a filter.

The residual solids will be disposed of to secure landfill. The spray booths are subject to Australian/New Zealand Standards - AS/NZS/4114.1: 1995 Spray Painting Booths - Design, Construction and Testing (Standards Australia/Standards New Zealand, 1995a) and AS/NZS/4114.2: 1995 Spray Painting Booths – Selection, Installation and Maintenance (Standards Australia/Standards New Zealand, 1995b).

Spray painters will wear personal protective equipment consisting of impervious nylon overalls, calico hoods, cartridge type respirators and nylon gloves conforming to the relevant Australian Standards.

After application of the paint coating, the automotive bodies are heated to cure the coating to form a stable film. After this stage, the notified chemical is immobilised within a resin matrix and not available for exposure to workers.

7. PUBLIC EXPOSURE

Public exposure is only likely after surface coatings containing the notified chemical have been applied to the exterior of car bodies. Although there may be dermal contact, there is negligible potential for exposure of the public to the notified chemical since it is strongly bound in polymer matrices and present in low concentrations.

8. ENVIRONMENTAL EXPOSURE

Release

There is potential for release during coating manufacture and application. The manufacturing process will take place at one plant and any spills that occur will be contained by bunding. During the manufacturing process, the notifier estimates that up to 50 kg per year of waste chemical would be generated. This waste will be treated by the Dusol process in which the

waste resin and coating are dissolved and the residue converted to an inert solid, which will be incinerated.

The notifier has estimated that approximately 50 kg per year of the notified chemical will remain in the emptied import containers. These containers will be collected and disposed of by licensed contractors.

The coating is applied to motor vehicles with approximately 35% efficiency for hand spraying and 80% for automatic techniques in a spray booth with control measures, such as a filtering system and masking materials, in place. The notifier estimates that overall approximately 25% (up to 5 tonnes/annum) of the notified chemical will be lost through overspray and collected in the spraybooth air and water filters. The waste material generated by the cleaning of the spray gun and mixing equipment and booths (including the filters) will be collected, treated and disposed of by incineration by licensed contractors. It is estimated that up to 50 kg of waste chemical would be generated from equipment cleaning.
Approximately 50 kg annum of the notified chemical contained in the clearcoat product will remain as residues in the 200 L drums after the drum has been emptied. This material will be disposed of by licensed drum reconditioners who incinerate the drums then wash and recycle them.

Further release of the chemical may occur in the form of either inert flakes of cross linked coating or on objects painted with the new polymer when panels are consigned to metal reclamation or landfill.

Fate

The solid waste generated in the manufacturing, formulation and application of the coating will be disposed by incineration, also producing oxides of carbon and nitrogen. Any chemical that may be accidentally released to landfill would be unlikely to leach into the aquatic environment due to its low water solubility.

The notified chemical was found to be not readily biodegradable (-4.4 to 3.4%) in the "28 Day Modified Sturm Test" OECD TG 301B. Fifty-seven milligrams of the test chemical (providing 15 mg/L total organic carbon - TOC) were mixed with 100 or 110 mL of aqueous test medium. The control solution containing 75 mg of aniline was biodegraded by 62.5% after 14 days of exposure within the 10-day window, thus conforming to test guidelines.

The notifier does not expect the chemical to bioaccumulate with the intended use pattern. If the chemical were improperly disposed to the aquatic environment it may pose a bioaccumulation hazard due to its low water solubility and high expected log P_{ow}. Once cured into the paint matrix of the motor vehicle bodies the chemical would not be an environmental hazard as it will be inert and not easily leached.

There will minimal release of the uncured paint containing the chemical to the aquatic environment with accidental spills being the most likely cause. All of the waste produced in the reformulation and application processes is expected to be disposed of by incineration.

The final fate of the chemical applied to motor vehicle panels will be the same as the panels, ie. crushed and recycled or landfilled. During the recycling process the coating (incorporating the chemical) will likely be destroyed in the smelting process. Incineration of the coating film would emit noxious fumes including oxides of carbon and nitrogen.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Tinuvin 928

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000mg/kg	Arcelin (1996b)
acute dermal toxicity	rat	LD_{50} > 2000mg/kg	Arcelin (1996a)
skin irritation	rabbit	Non-irritant	Braun (1997b)
eye irritation	rabbit	Slight irritant	Braun (1997a)
skin sensitisation	guinea pig	Not sensitising	Arcelin (1997)

9.1.1 Oral Toxicity (Arcelin, 1996b)

Species/strain:	Rats, Hanlbm:Wist
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Gavage
Test method:	OECD TG 401
Mortality:	None
Clinical observations:	No clinical signs of toxicity were observed during the observation period and the body weights of the animals were within the ranges of physiological variability.
Morphological findings:	No macroscopic organ abnormalities were observed at necroscopy.
LD_{50}:	>2000 mg/kg
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Arcelin, 1996a)

Species/strain:	Rats, Hanlbm:Wist
Number/sex of animals:	5 males, 5 females

Observation period:	14 days
Method of administration:	The notified chemical was applied evenly on intact skin at 2000 mg/kg and covered with a semi-occlusive dressing.
Test method:	OECD TG 402
Mortality:	None
Clinical observations:	Neither clinical signs of systemic toxicity nor skin irritation at the site of application was observed during the observation period. A slight loss of body weight was observed in one female animal during the first and second observation week and in two female animals during the second observation week.
Morphological findings:	No macroscopic organ abnormalities were observed at necropsy.
LD_{50}:	> 2000 mg/kg
Result:	The notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

An acute inhalation toxicity test was not provided by the notifier.

9.1.4 Skin Irritation (Braun, 1997b)

Species/strain:	Rabbits, New Zealand White
Number/sex of animals:	1 male, 2 females
Observation period:	72 hours
Method of administration:	0.5g of the test article applied to 6cm^2 of shaved, intact skin on the dorsal trunk for 4 hours. The area was then covered with surgical gauze and secured with a semi-occlusive dressing.
Test method:	OECD TG 404
Comment:	Neither erythema nor oedema was observed in any animal at 1, 24, 48 or 72 hours. All Draize scores were zero. No staining of the treated skin was observed.
Result:	The notified chemical was not irritating to the skin of

rabbits.

9.1.5 Eye Irritation (Braun, 1997a)

Species/strain: Rabbits, New Zealand White

Number/sex of animals: 1 male, 2 female

Observation period: 72 hours

Method of administration: 0.1g of test article (undiluted) was applied to the conjunctival sac of left eyes. Eyelids were then held together for one second to prevent loss of the test article. Right eyes remained untreated.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

Draize scores for corneal and iridal changes were all zero.

Time after Instillation

Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	1	-	1	1	-	0	0	-	0	0	-
2	1	1	-	0	0	-	0	0	-	0	0	-
3	1	1	-	1	1	-	0	0	-	0	0	-

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Mean scores (24, 48, 72 hours observation):

Animal	***Corneal opacity***	***Iridial inflammation***	***Conjunctival redness***	***Conjunctival chemosis***
1	0	0	0.3	0.3
2	0	0	0	0
3	0	0	0.3	0.3

Comment: Slight redness and slight swelling of the conjunctivae, as well as slight watery discharge (not scored quantitatively) were noted in all animals after one hour. Hyperemia of the scleral blood vessels was seen in one animal only after one hour. The remaining two animals had slight reddening and swelling of the conjunctivae combined with slight watery discharge (not scored quantitatively) after 24 hours. All findings were reversible after 48 hours. No staining of the

cornea, sclera or conjunctivae of treated eyes was observed.

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

9.1.6 Skin Sensitisation (Arcelin, 1997)

Species/strain: Guinea pigs, Himalayan Spotted

Number of animals: 15 males for main study

Induction procedure:

Test group:

Day 0 — Three pairs of 0.1mL intradermal injections were given to the dorsal skin of the scapular region: FCA/saline, 5% notified chemical in water and 5% notified chemical in FCA/saline 1:1.

Day 7 and 8 — Test area massaged with 10% sodium lauryl sulphate in paraffin oil. Then, a 2 x 4 cm patch of filter paper was saturated with 0.3mL of 25% notified chemical in water and secured to the injection sites with an elastic plaster for 48 hours.

Control group:

Day 0 — Three pairs of 0.1mL intradermal injections were given to the dorsal skin of the scapular region: FCA/saline, water vehicle and water vehicle in FCA/saline 1:1.

Day 7 and 8 — Test area massaged with 10% sodium lauryl sulphate in paraffin oil. Then, a 2 x 4 cm patch of filter paper was saturated with 0.3mL of water vehicle and secured to the injection sites with an elastic plaster for 48 hours.

Challenge procedure:

Day 22 — Left flanks received 2 x 2cm patch of filter paper saturated with 0.2mL of 15% of notified chemical in water. Right flanks received filter paper saturated with water vehicle only. Patches were held in place with elastic plaster for 24 hours.

Test method: OECD TG 406

Challenge outcome:

No animal exhibited positive responses. Draize scores for erythema and oedema were zero for all animals at 24 hours and 48 hours following removal of challenge patches.

Result:	The notified chemical was not sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (McKeon, 1997)

Species/strain:	Rats, Sprague-Dawley
Number/sex of animals:	10 males, 10 females per dose plus 5 males, 5 females (control plus high dose) for post-treatment recovery period.
Method of administration:	Gavage in corn oil
Dose/Study duration:	0 (control), 10, 100, 1000 mg/kg/day for 28 days, then 14 day recovery period.
Test method:	OECD TG 407

Clinical observations

All animals survived to their scheduled sacrifice and gained weight during the course of the study. Mean body weight gains and food consumption values were comparable between notified chemical-treated and control groups. There were no treatment-related clinical observations or opthalmoscopic findings.

Clinical chemistry/Haematology

Total protein and globulin levels were elevated in male treatment animals at day 30 but not at day 44. Also on days 30 and 44, total protein levels were elevated in female animals treated with the highest dose. Despite these findings, no evidence of consistent significant treatment-related changes in haematology or serum chemistry values could be observed.

Gross pathology

Gross pathological abnormalities were noted in the liver (pale appearance and/or dark areas) and kidney (pale appearance, dilated and/or fluid filled pelvises, cysts) of some control and treated animals at sacrifice. These were not considered treatment-related as they occurred in control animals at similar frequency and were not related to dose. Recovery animals had normal gross observations at sacrifice.

Significant organ weight increases (absolute brain/stem and kidney) were observed in terminal sacrifice males receiving the highest dose of 1000 mg/kg/day. Absolute, relative-to-body and relative-to-brain liver weight increases were also observed in recovery-sacrifice females receiving 1000 mg/kg/day. These changes are considered incidental as they were without histologic correlation.

Histopathology

No treatment-related histomorphologic lesions were observed. On day 28, one male rat treated with a moderate dose of the notified chemical showed multifocal areas of moderate

granulomatous inflammation associated with hepatocellular necrosis, biliary hyperplasia and fibrosis and mineralisation. Another treated with the highest dose showed focal areas of infarction associated with fibrosis. One female rat treated with the highest dose showed severe chronic kidney pyelitis associated with moderate transitional cell hyperplasia. A single male rat treated with a moderate dose showed basal cell carcinoma of the skin. These isolated findings were considered incidental and unrelated to treatment.

Comment: There were no consistent, significant clinical, pathological and histopathological findings.

Result: A no-observed-adverse-effect-level (NOAEL) of 1000 mg/kg/day for the notified chemical was established.

9.3 Genotoxicity

9.3.1 Reverse Mutation Assay (Wollny, 1997)

Strains: *Salmonella typhimurium* TA 1535, TA1537, TA98, TA 100; *Escherischia coli* WP2 uvrA

Concentration range: 33.3, 100, 333.3, 1000, 2500 and 5000 μg/plate

Metabolic activation: Aroclor 1254-induced rat liver homogenate, S9 fraction

Test method: OECD TG 471, 472

Comment: Plates incubated with the notified chemical showed normal background growth up to 5000μg/plate with and without rat liver S9 homogenate.

No toxic effects evidenced by reductions in the number of revertants occurred in test groups with and without S9 metabolic activation. No significant or reproducible increase in revertant colonies were observed for any of the colony strains in the presence or absence of metabolic activation for any dose level of the notified chemical. However, a slight increase in the number of revertants was observed in the E. coli strain at 2500 μg/plate in the duplicate experiment. This effect could not be repeated in an additional experiment. Reference mutagens used as positive controls showed expected increases in revertant colonies.

Result: The notified chemical was not mutagenic at doses up to 5000μg/plate in bacteria in the presence or absence of metabolic activation induced by rat liver S9 homogenate.

9.3.2 *In vitro* Chromosome Aberration Assay in Chinese Hamster Cells (Czich, 1997)

Cells:	Chinese Hamster Ovary, V79
Doses:	**18 hour preparation interval:** 5, 10*, 30*, 50*, 100, 800* μg/mL **without** rat liver S9 metabolic activation; 3, 5*, 10*, 20, 30*, 100, 800* μg/mL **with** rat liver S9 activation. **28 hour preparation interval:** 30, 50*, 100, 800* μg/mL **without** rat liver S9 metabolic activation; 10, 20, 30*, 100, 800* μg/mL **with** rat liver S9 metabolic activation. * indicates evaluated experimental points.
Method of administration:	The notified chemical was pre-dissolved in acetone vehicle and then dissolved in culture medium. Cells were cultured with medium containing the notified chemical for 4 hours.
Test method:	OECD TG 473
Comment:	Ethylmethane sulfonate (EMS) and Cyclophosphamide (CPA) were used as positive controls. Culture medium and acetone vehicle minus the notified chemical were used as negative controls. Examination of the cultures 4 hours after treatment revealed some precipitation of the notified chemical at concentrations of 50μg/mL and above without S9 mix and 30μg/mL and above with S9 mix. EMS and CPA produced highly statistically significant increases in numbers of cells with aberrations in chromosome structure. In contrast, neither biologically relevant nor statistically significant increases in chromosome abnormalities were observed at any dose of the notified chemical. In addition, no significant reductions in mitotic indices were observed and no relevant increases in frequencies of polyploid metaphases were found.
Result:	The notified chemical was not clastogenic at doses up to 800μg/mL in mammalian cells *in vitro* in the presence or absence of metabolic activation induced by rat liver S9 homogenate.

9.4 Overall Assessment of Toxicological Data

Acute oral and dermal toxicity of the notified chemical was found to be very low and low respectively, with a rat LD_{50} for both exposure routes > 2000mg/kg. In a skin irritation study in the rabbit, the notified chemical showed no acute skin irritation with neither erythema nor oedema observed in any animal during the observation period. In an eye irritation study in the rabbit, the notified chemical was shown to be slightly irritating. Slight conjunctival redness and swelling was noted in all animals after one hour. These signs persisted in two animals for 24 hours. A skin sensitisation maximisation test in guinea pigs failed to show positive

responses in any animal indicating that the notified chemical was not sensitising.

In a 28-day repeated dose oral toxicity study in rats, the notified chemical produced no changes in haematology parameters and minimal changes in serum chemistry parameters. Although pathological abnormalities were noted in the liver and kidney of some animals, the responses were not dose-related, not consistent within groups and so not considered related to the notified chemical. Similarly, organ weight increases were observed in some animals (males only) but these were not considered treatment-related due to a lack of histologic evidence of toxicity. Overall, the notified chemical showed low repeated dose oral toxicity with a NOAEL of 1000mg/kg/day.

The notified chemical was not mutagenic in a *Salmonella typhimurium* reverse mutation assay at doses up to 5000µg/plate neither in the presence nor absence of metabolic activation. Similarly, an *in vitro* chromosome aberration showed neither biologically relevant nor statistically significant increases in chromosomal structural abnormalities, nor significant reductions in mitotic indices or increases in polyploid metaphases. The notified chemical was considered not to be clastogenic at doses up to 800µg/mL in mammalian cells *in vitro*.

From the toxicological data, the notified chemical is not classified as a hazardous substance according to the NOHSC Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission, 1999a).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity tests were performed in accordance with OECD Test Guidelines.

Test	***Species***	***Results***
Acute toxicity OECD TG 202	Zebra fish (*Brachiodanio rerio*)	LC50(96 h) = >0.33 mg/L NOEC = >0.33 mg/L
Acute toxicity	*Daphnia magna*	EC50(48 h) = >0.9 mg/L NOEC = >0.9 mg/L
Growth Inhibition OECD TG 201	Freshwater algae *(Scenedesmus subspicatus*)	EC50(72 h) = >0.66 mg/L NOEC = >0.66 mg/L
Sludge Inhibition OECD TG 209		EC50(30 min) = >100 mg/L

* NOEC - no observable effect concentration

Zebra Fish (*Brachydanio rerio*)

Due to the low water solubility of the notified chemical, the test solutions used in the above study were prepared by making a supersaturated stock solution of 100 mg/L concentration. The stock was stirred for over 2 hours at room temperature then filtered, with the filtrate used as the test substance. The average concentration of the chemical in the filtrates used for the fish tests was analytically determined to be 0.33 mg/L and all biological measurements used in these tests are related to this mean measured test substance concentration.

The ecotoxicity tests on the Zebra fish were performed using a semi-static test methodology. Groups of 7 fish were exposed to the 0.33 mg/L undiluted filtrate and control solution. During the test the dissolved oxygen was always >8.0 mg/L and pH ranged from 8.0-8.6. The temperature of the test solutions ranged from 22-23°C and the solutions appeared slightly turbid. In the control and at the mean measured test concentration of 0.33 mg/L all fish were observed at 2, 24, 48, 72 and 96 hours and showed no signs of intoxication and no deaths occurred. Therefore the NOEC (96 h) and LC_{50} were determined to be greater than 0.33 mg/L.

Daphnia magna

Due to the low water solubility of the notified chemical the test solutions used in the above study were prepared by making a supersaturated stock solution of 100 mg/L. This stock was stirred for over 2 hours at room temperature then filtered, with the filtrate used as the test substance. The average concentration of the chemical in the filtrates used for the daphnia tests was analytically determined to be 0.9 mg/L and all biological measurements used in these tests are related to this mean measured test substance concentration.

The tests on *Daphnia magna* were performed using a 48 hour static acute immobilisation study. Two groups of 10 daphnids were used as test subjects for the 0.9 mg/L highest test medium concentration and subsequent test solutions at dilutions of 1:2, 1:4, 1:8 and 1:16 and control subjects. During the test the dissolved oxygen was always >8.2 mg/L and pH ranged from 7.8-8.0. The temperature of the test solutions ranged from 20-21°C. In the control test one animal was immobile at the 24 h observation, which is acceptable under the guidelines. In the test solutions no immobility or mortality of the test animals was observed.

Algal Growth Inhibition (*Scenedesmus subspicatus*)

Due to the low water solubility of the notified chemical the test solutions used in the above study were prepared by making a supersaturated stock solution of 100 mg/L. The stock was stirred for over 2 hours at room temperature then filtered, with the filtrate used as the test substance. The average concentration of the chemical in the filtrates used for the fish tests was analytically determined to be 0.66 mg/L and all biological measurements used in these tests are related to this mean measured test substance concentration.

Algal cells at 1 x 10^4 cells/mL were added to the 3 replicate test solutions and 6 replicate controls in 50 mL Erlenmeyer flasks. Samples of the algal populations were removed daily and cell concentrations determined for each control and treatment group. The mean algal cell densities in the test medium at all counting dates were nearly identical with the parallel control cultures. The EC_{50} was determined to be greater than the 0.66 mg/L concentration of the chemical in solution.

Activated Sludge Inhibition

The inhibition of activated sludge respiration by Tinuvin 928 was tested using concentrations of 1.0, 3.2, 10, 32, 50 and 100 mg/L in duplicate and aerated for 30 minutes at 21°C in the presence of activated sludge. The rate of respiration was measured after 30 minutes and the respiration of aerobic waste water bacteria was slightly inhibited by 9.9% at 100 mg/L. The EC_{50} (30 min) was determined as >100 mg/L. A reference compound, 3,5-dichlorophenol, tested under the same conditions as the test substance had an EC_{50} of 19.1 mg/L which is within test guidelines.

The ecotoxicology results indicate that Tinuvin 928 is not toxic to the organisms tested up to the limits of its water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Once the coating is applied, the chemical will be incorporated in an inert film and should not present a hazard. Any chips, flakes or fragments will be inert.

The majority of waste containing the chemical will be generated during the manufacture and use of the coatings (up to 5.2 tonnes/year). This waste will ultimately be disposed of by incineration. Any chemical that is accidentally released to the environment through spills will become associated with the soils and sediments and would not be likely to leach into the aquatic compartment due to its low water solubility. The majority of the chemical will be present within the cured inert coating matrix, and be unavailable for leaching. The ecotoxicology results indicate that Tinuvin 928 is not toxic to the organisms tested up to the limits of its water solubility.

Tinuvin 928 was found to be not readily biodegradable by the Modified Sturm Test. However, significant bioaccumulation is unlikely given the intended use pattern of the notified chemical and the intended method of residue disposal, by incineration. Once cured into the paint matrix of the motor vehicle bodies it should not be an environmental hazard as it will be inert and not easily leached.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard assessment

Toxicological data have been provided for the notified chemical. Acute oral and dermal toxicity, repeated dose oral toxicity, skin irritation, skin sensitisation properties and genotoxicity for the chemical were all low. An eye irritation study revealed the notified chemical as a slight eye irritant. Acute inhalation data were not provided. In accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission, 1999a) the chemical is determined not to be a hazardous substance.

Occupational Health and Safety

The notified chemical will not be manufactured in Australia but imported in polyethylene-lined fibreboard drums in shipping containers. Occupational exposure to the notified polymer during import, transport and storage would only be envisaged following accidental puncture of the drums. This combined with the low systemic toxicity of the chemical renders the health risk low.

Automotive paint will be manufactured at a single customer site. Exposure to the notified chemical is most likely during the initial manual batch weighing of chemical in powder form and transfer to the solvent mixing pot. Despite the notified chemical being in powder form,

the large particle size, low vapour pressure and the combination of local exhaust ventilation and personal protective equipment worn by workers makes dermal, ocular and inhalation exposure unlikely. If spillage does occur to the eyes, slight eye irritation may result.

During blending, filtration and storage of paints and addition of paints to circulation tanks prior to spraying, there exists potential for spillage and exposure predominantly via the skin and eyes. Inhalation exposure is also possible. Given the toxicity profile of the notified chemical and dilution of the chemical with other paint components (1.1%), the health risk to workers would be assessed as low. Exposure will be minimised by the use of personal protective equipment required for handling the other paint components such as solvents.

The final paint will be shipped in 200L drums by road transport to automotive OEMs who will apply the coating by manual and automatic electrostatic atomised spray application techniques. Given transfer efficiencies of approximately 35% and 80% for manual and automatic electrostatic spraying respectively, occupational exposure to the notified polymer may be considered most likely at this point of application. Spraying procedures produce a dense aerosol of paint particles which would likely impact on human health even in the absence of additional hazardous solvents, stabilisers and other components.

During paint preparation and spray painting procedures, worker exposure needs to be limited through a combination of engineering controls such as exhaust ventilated paint kitchens and laminar spray booths and personal protective equipment consisting of impervious nylon overalls, calico hoods, cartridge type respirators and nylon gloves. These controls are to conform to the relevant Australian Standards. Under these circumstances, given the low toxicity of the notified chemical and the equipment used to control exposure, the health risk during end use is considered low.

It should be noted that the final applied paint product contains extra ingredients including pigments, stabilisers and solvents and it is important that appropriate measures include control of exposure to these components. The paint should be applied and overspray controlled in a manner conforming to appropriate occupational health and safety regulations such as the *NOHSC Spray Painting Guidance Material* (National Occupational Health and Safety Commission, 1999b) and employers are to ensure that the exposure standards for any solvents or other ingredients are adhered to in the workplace.

Following curing of the paint, the notified chemical will be cross-linked with other paint components to form a high molecular weight stable film. In this form, it is essentially unavailable for absorption and thus the health risk to workers from the notified chemical after paint curing would be negligible.

Public Health

Surface coating products containing the notified chemical will be used only in the automotive industry. Although members of the public will make dermal contact with articles coated with products containing the notified chemical, exposure will be negligible because of the low concentrations of the notified chemical when used in the proposed manner. Based on the toxicity profile and use pattern of the notified chemical, it is considered that the notified chemical will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Tinuvin 928 the following guidelines and precautions should be observed:

- The paints containing the notified polymer should be applied in accordance with the National Guidance Material for Spray Painting (National Occupational Health and Safety Commission, 1999b);
- Employers should ensure that NOHSC exposure standards for all ingredients in the final paint are not exceeded in the workplace;
- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- 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 a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

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 may be required if any of the circumstances stipulated under section 64 of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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Standards Australia/Standards New Zealand (1995b) Australian/New Zealand Standard 4114.2-1995, Spray painting booths - Selection, installation and maintenance. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

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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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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