File No: NA/853

December 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Triglycidyl Trimellitate

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Triglycidyl Trimellitate

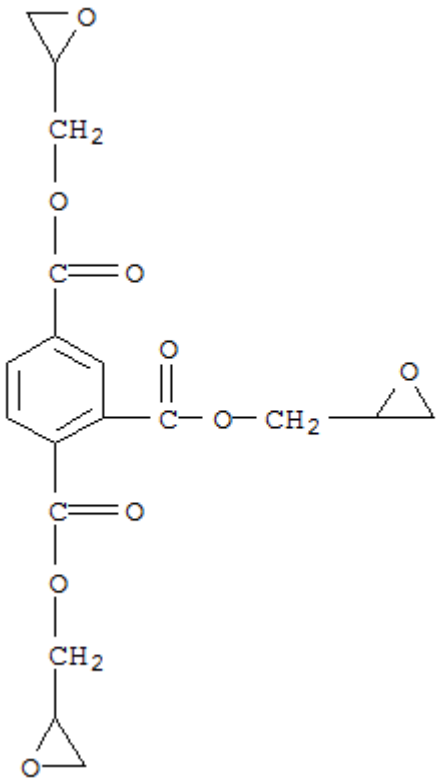
1. APPLICANT

Vantico Pty. Ltd. (ACN: 091 627 879) of 235 Settlement Road Thomastown Victoria 3074 has submitted a standard notification statement in support of their application for an assessment certificate for Triglycidyl Trimellitate.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	1,2,4-benzenetricarboxylic acid, tris(oxiranylmethyl) ester
Chemical Abstracts Service (CAS) Registry No.:	7237-83-4
Other Names:	1,2,4-benzenetricarboxylic acid, tris(2,3-epoxypropyl) ester 1-propanol, 2,3-epoxy-, 1,2,4-benzenetricarboxylate Triglycidyl trimellitate TGTMA TKK 30009 CO 69/23 CO 69/18 PF LMB 5196
Marketing Name:	trimellitic acid triglycidyl ester Araldite PT 910 (product containing the notified chemical)
Molecular Formula:	$C_{18}H_{18}O_9$

Structural Formula:



The notified chemical is a low molecular weight ester based on an aromatic centre and contains a high proportion of reactive epoxide groups. These epoxide groups are capable of reacting with functional groups such as hydroxy or amine groups in other polymers, and so the chemical functions as a crosslinking agent for production of rigid chemically cured polymer coatings. Although the structural formula above depicts the triglycidyl ester of mellitic acid, gel permeation chromatography indicates that this comprises only around 50% of the commercial product, and that substantial amounts of higher oligomers (eg dimers, trimers etc.) are also present in the commercial imported product. The prevalence of the oligomers in the material is reflected in the polydispersity of 1.55 derived from the GPC data. Other data derived from high performance liquid chromatography (HPLC) also noted the presence of higher oligomers, but indicated that the notified chemical (ie. the "monomer") comprised 83% of the test material. The molecular weight and formulae given above are applicable to the parent "monomer".

However, despite their presence in the commercial material the higher molecular weight oligomers will also have residual reactive epoxide groups, and would also act as crosslinking agents for reactive polymers.

Molecular Weight: 378

Number-Average Molecular Weight (NAMW): 461

Weight-Average Molecular Weight: 714

Polydispersity:	1.549
Method of Detection and Determination:	The chemical was detected by infrared (IR) spectroscopy and characterised by gel permeation chromatography (GPC) and high pressure liquid chromatography (HPLC).
Spectral Data:	IR spectra were provided by the notifier.

3. PHYSICAL AND CHEMICAL PROPERTIES

Unless otherwise indicated the following data are for the product Araldite PT 910 or have been estimated by use of ACD software.

Appearance at 20°C & 101.3 kPa:	Viscous yellowish liquid (notified chemical, TKK 30009). White waxy solid (Araldite PT 910)
Melting Point:	-21.5°C (TKK 30009).
Boiling Point:	278°C (TKK 30009).
Specific Gravity:	1320 kg/m3 at 25ºC.
Vapour Pressure:	< 0.00001 kPa at 20°C.
Water Solubility:	> 1.211 g/L at 20°C (TKK 30009).
Partition Co-efficient (n-octanol/water):	log Pow 1.45 (TKK 30009).
Hydrolysis as a Function of pH:	$t_{1/2}$ at pH 1.0 = 14 $\pm$ 0.6 min (TKK 30009).
Adsorption/Desorption:	log Koc = 2.71 (estimate for notified chemical). log Koc = 0.47 (estimate for the hydrolysed form of the notified chemical).
Dissociation Constant:	The notified chemical does not contain any groups which may undergo dissociation.
Flash Point:	> 150°C (closed cup method).
Flammability Limits:	Not flammable.
Autoignition Temperature:	> 200°C.
Explosive Properties:	Not explosive.

Reactivity/Stability:	Stable under normal conditions of use.
Particle Size:	Not applicable for notified chemical as it is a liquid. Granules of > 100 micron and < 3 mm for Araldite PT 910. Average particle size of 40 micron (Range = 5 - 90) for powder coatings.

3.1 Comments on Physico-Chemical Properties

No measured data on the vapour pressure of the compound were provided but the notified chemical is a resin which cannot be easily dispersed in water, and so the water solubility was determined (Ciba-Geigy, 2001a) by adsorbing the test material onto diatomaceous earth, and suspending this (with agitation) in water at 30°C for periods of 24, 48 and 72 hours, using duplicate samples for each period. Following these periods of "dissolution", each sample was equilibrated at 20°C for 24 hours, centrifuged to separate the diatomaceous earth and other undissolved particulate material and then aliquots of the clear aqueous phases were analysed for the compound using High Performance Liquid Chromatography (HPLC). Due to instrument problems it was not possible to analyse the samples directly after the centrifugation and this was not done till 72 hours later. Nevertheless, all six samples had concentrations of the test compound of 1057 - 1164 mg/L regardless of whether they had been stirred for 24, 48 or 72 hours, which indicates that saturation is reached within 24 hours. However, it was noted that the dissolved compound was undergoing hydrolysis, and subsequent analysis of the six samples after 120 hours (after centrifugation) found concentrations of the test substance between 578 and 632 mg/L which indicated decomposition through hydrolysis. Consequently, the water solubility of saturated solutions was determined as > 1121 mg/L, which is the average of the six results found 72 hours after centrifugation. The pH of the saturated suspensions was measured as approximately 7.3 for all samples.

The notifier provided a summary report (Ciba-Geigy, 1990) on the hydrolysis of the compound in 0.1M HCl, and reported a half life of 14 minutes (apparently at room temperature). Reasonably fast hydrolysis of the epoxide groups is to be expected under acidic conditions due to acid catalysed opening of the epoxide ring and subsequent reaction with water. Under less acidic conditions hydrolysis would not be as rapid, and as noted above during the test on water solubility, hydrolytic degradation of the compound in aqueous solutions was observed. From the data provided in this report the half life for degradation may be estimated as 2-3 days at room temperature and at pH 7.3.

The partition coefficient was determined (Ciba-Geigy, 2001b) using the HPLC method, whereby the retention time of the test column on a C18 chromatography column is compared with those for a series of standard compounds of generally similar chemical structure and known values for log Kow. In the present case the retention times of 8 standard compounds with known values of log Kow between 0.29 (2-butanone) and 2.11 (anisole) were used to construct the calibration curve, and the retention time of the new compound on the column was found to correlate with a log Kow value of 1.45. This is a reasonably low value, and reflects the relatively low molecular weight and high content of polar epoxide groups. The relatively low value is also in general agreement with the appreciable water solubility of > 1121 mg/L.

No adsorption/desorption data were provided, but the high water solubility and relatively low value of log Kow indicates that the chemical would have little affinity for organic matter.

The chemical contains no acidic or basic functional groups so that dissociation constant data are not relevant.

4. PURITY OF THE CHEMICAL

Degree of Purity: >75%

Hazardous Impurities:

Chemical name:	1-chloro-2,3-epoxypropane
Synonyms:	epichlorhydrin
CAS No.:	106-89-8
Weight percentage:	0.01%
Toxic properties:	Carcinogen, May cause cancer (R45, Cat. 2); Toxic, Toxic by inhalation, in contact with skin and if swallowed R23/24/25); Corrosive, Causes burns (R34); May cause sensitisation by skin contact (R43)

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

Chemical name:	Oligomers of the notified chemical (396-470 g/mol)
Weight percentage:	Approximately 14%
Chemical name:	Oligomers of the notified chemical (562 g/mol)
Weight percentage:	< 0.5%
Chemical name:	Oligomers of the notified chemical (700-792)
Weight percentage:	Approximately 6%
Chemical name:	Oligomers of the notified chemical (1004-1022 g/mol)
Weight percentage:	< 1%

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

Customer identities and details of the formulation of Araldite PT 910, which contains the notified chemical, have been exempted from publication in the Full Public Report and the Summary Report.

The notified chemical is used as a cross-linking agent for polyester or acrylic powder coatings. The powder coatings can be applied to a wide range of products including outdoor furniture, car parts as well as architectural components such as window frames and doors.

The notified chemical, TKK 30009, will be imported at less than 50% as a component in the product Araldite PT 910, at approximately 2-15 tonnes per annum for the first five years. No manufacturing of the notified chemical will take place in Australia.

Araldite PT 910 is to be imported as solid, waxy granules, which will be sold to coating manufacturers for reformulation into powder coatings. The powder coatings are produced by blending Araldite PT 910 with resins, pigments and other ingredients. After blending the mixture is heated and the resulting 'flowable' material is extruded as flat, thin sheets. Upon cooling the material solidifies and is ground into a fine powder, which is sold to coating companies. The notified chemical will be present in the final product at a maximum concentration of up to 1.8% and will only be used by industrial applicators.

6. OCCUPATIONAL EXPOSURE

Category & Number of Workers	*Maximum Potential Exposure Duration & Personal Protective Equipment*
Importation : Waterside workers, 5-10.	1-10 hours/day; 20-240 days/year.
Transport and Storage, 10-20.	Personal protective equipment consisting of long sleeved overalls (either disposable or poly-cotton, laundered daily), Class P1 disposable dust masks, PVC or nitrile rubber gloves and safety boots should be worn by warehouse personnel when cleaning up spills or taking samples.
Reformulation : Warehouse Workers, 5-10. Reformulation Plant Operators, 3-30.	10-15 hours/day; 90-200 days/year. Industrial standard overalls (either disposable or poly-cotton, laundered daily), Class P1 disposable dust masks, PVC or nitrile rubber gloves and safety boots and chemical goggles.
Quality Control workers : 2-5.	10-15 hours/day; 90-200 days/year. Laboratory coat and disposable dust masks.

R & D Technicians : 5-10.	5-10 hours/day; 90-200 days/year. Laboratory coat, gloves, safety glasses and Class P1 disposable dust masks as required.
Maintenance Workers: 5-11.	4-8 hours/day; 90-200 days/year. Disposable dust masks and gloves.
Production Administration Workers : 2-5.	2-4 hours/day; 90-200 days/year. Dust coats and disposable dust masks.
Application Plant Operators : 600-1000	4-6 hours/day, 300-400 days/year Respiratory protection, chemical goggles or face shield, disposable overalls and gloves

Transport and Storage

The notified chemical will be imported as a component of Araldite PT 910. Araldite PT 910, which exists as solid, waxy granules, will be imported in 25 kg polythene bags contained in cardboard boxes or multi-walled bags placed on shrink-wrapped pallets. The shrink-wrapped pallets are unloaded by waterside workers and transported to a warehouse where the 25 kg polythene bags are unpacked and stored until distributed to powder coating manufacturers. The manufactured powder coating products, which contain partially cross-linked Araldite PT 910, will be packed into polythene bags and the filled bags placed into cardboard boxes for transportation. Waterside, transport and storage workers will not be directly exposed to the notified chemical except in the event of a spill.

Reformulation Plant Operators

At reformulation sites, Araldite PT 910 is weighed in a designated area, put into plastic bags and then emptied from the bags into a mixing hopper. Alternatively, it is added to the mixing hoppers, directly from the imported 25 kg bags using metal scoops. Other raw materials are added to the mixing hopper and dry blended in a sealed mixer. The mixture is then transferred to an extruder by gravity in a closed system. In some cases the mixed raw materials will be stored in 1000 kg containers or in open 500 kg mixing bowls until required. The mix in the then heated until it melts (> 100ºC). The semi-solid melt is remixed and then extruded onto a roller which spreads the extrudate into a thin sheet. The extrudate solidifies when cooled to < 40ºC. The solid sheets are chipped, milled, sieved and packaged.

The potential for inhalation, dermal and ocular exposure to the notified chemical exists during weighing, addition to and extraction from the mixing hoppers, at the outlet of the extruder, during milling and packaging and on disposal of empty containers. Weighing is to occur in a weigh-booth equipped with local exhaust ventilation to draw dust away from the plant operators to a central baghouse. In addition, all other areas where dust containing the notified chemical is generated will be fitted with ducted exhaust ventilation to draw dust away from the plant operators to a central baghouse. Reformulation workers must wear personal protective equipment as described in the table above.

Quality Control Workers

Quality control personnel will collect samples of the solid homogeneous extrudate in the form of flakes and finely milled powder. The flakes are milled by quality control personnel into a fine powder. The fine powders are sprayed onto test panels for curing and evaluation. The potential for inhalation, dermal and ocular exposure to the notified chemical exists during the collection of samples, the milling of solid flakes and during the spraying of the finely milled powders onto test panels. All spraying and cleaning is to be performed in a spray booth with exhaust ventilation. Quality control personal will wear personal protective equipment as described in the table above.

Research and Development

Research and development personnel would be exposed to the notified chemical while working with the granules of Araldite PT 910, the dry-blended reformulated mixture, the melt mix, and final paint products. The potential for inhalation exposure to the notified chemical exists during handling of Araldite PT 910, the dry-blended mixture and final paint products although the frequency of exposure may be intermittent. All research and development is to be performed within a controlled laboratory fitted with local dust extraction system. Research and development personnel will wear personal protective equipment as described in the table above.

Maintenance Workers

Maintenance workers may be exposed to dusts containing the notified chemical left on machinery they are required to service. Maintenance workers must wear personal protective equipment consisting of PVC or nitrile rubber gloves and disposable dust masks. In some cases the equipment will be cleaned by plant operators prior to servicing by contract maintenance workers.

Production Administration Workers

Production administration workers are expected to have intermittent contact with the notified chemical. Whenever production administration workers are to spend lengthy periods of time in the production area they must wear personnel protective equipment as described in the table above.

Application Plant Operators

The final powder coating product will be manually loaded into a hopper that automatically feeds a spray gun. The spray gun delivers the powder coating onto an electrostatically charged metal surface. Following spraying, the metal items are cured in an oven at 200ºC. All spraying is to be performed in a spray booth fitted with local exhaust ventilation that generates a minimum airflow of 0.5 meters per second.

Oversprayed powder may be collected from the booths using cyclones and used in future spraying operations or, in the case of a lighter fraction, vented to air. Larger facilities employ a recovery system where oversprayed powder is collected and fed directly back to the bulk feeding system. Unwanted powder is collected using vacuum cleaners and stored in bags or drums prior to disposal to landfill.

The potential for inhalation, dermal and ocular exposure to the notified chemical exists during manual loading and application of final paint products, equipment maintenance, cleaning and repairs, removal of overspray and spillages, during the removal of coated components from hot ovens and the disposal of empty containers.

Application plant operators must wear personal protective equipment as described in the table above.

7. PUBLIC EXPOSURE

Products containing the notified chemical are not available for sale to the public and will only be used in industrial powder coating facilities. The potential for public exposure to the notified chemical during transport, reformulation, use and disposal is assessed as negligible. Members of the public may make dermal contact with items coated with products containing the notified chemical. However, exposure will be negligible because the notified chemical is likely to be bound within a cured resin coating.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Powder Coating Reformulation
During manufacture of the powder coatings there is a possibility of some release of particulate material containing the notified chemical to the atmosphere. However, all air from the plant is comprehensively treated by cyclones and then through a baghouse before being released to the outside atmosphere. After these treatments only small quantities of particulate material are released to the atmosphere from such plants. The notifier provided data relevant to one such plant which showed that the maximum release of particulate matter each day (from all operations) is around 1.5 kg/day. Assuming that all this dust resulted from manufacture of powder coating containing a maximum of 2% of the notified chemical, the maximum total daily release of the compound would be 30 grams, or 10.5 kg/year. However, realistically the plants would only be manufacturing powder coatings containing the notified chemical approximately 15% of the time, and so actual releases would be closer to 12 grams each day, or 5 kg each year.

Solid material collected in the baghouse filters is disposed of into landfill, and the company indicated that at a typical plant producing polymer master-batch products, approximately 750 kg of solid wastes (including floor sweepings and solids collected in the filter bags) may be collected and be placed into landfill each day. If it is assumed that all this waste material contains 2% of the notified chemical, then 15 kg of the chemical would be placed in landfill each day or 5.4 tonnes each year. However, since the plant would process the notified chemical only 15% of the time these quantities are reduced to approximately 2.5 kg/day or 0.8 tonnes each year. These estimates must also be regarded as worst case since it is unlikely that all the solid waste collected each day would originate from activities associated with use of Araldite PT 910 (TKK 30009), and much of the collected dust and solid material would contain no notified chemical. There could be traces of the notified chemical left in the emptied bags which would also be placed into landfill. The notifier indicated that this could amount to 0.2% of the total contents, and based on total imports of up to 15 tonnes per

annum, an additional 30 kg of TKK 30009 may be placed into landfill.

A small quantity of TKK 30009 may also be discharged to sewer, and the company indicated a maximum release of 18 g/day (6 kg each year) at a maximum concentration of 6 mg/L. This would be further diluted in the sewer system, again during the sewage treatment process and finally on discharge of the sewage effluent to the receiving waters.

Since three plants could be involved in manufacturing the coatings, the release figures above should be multiplied by three, giving the following maximum annual release estimates –

To air	3 X 5 kg =	15 kg
To Landfill	3 X 0.8 tonnes =	2.4 tonnes
	+ 30 kg (from emptied bags) =	2.43 tonnes
To sewer	3 X 6 kg =	18 kg

Assuming a total import of 15 tonnes, the total losses amount to a maximum of 16.4 % of imports.

Powder Coat Application

The spray coatings are applied to articles such as outdoor furniture, doors and windows using dry spraying techniques, with these applications being performed in specialised spray booths. It is an unavoidable consequence of all spray application techniques that a high proportion of the sprayed material is lost as "overspray", and in the present case the company indicated that this could be up to 25%. However, since the spray application is performed in an enclosed area it is often possible to collect the unused powder, and use it in subsequent applications. Nevertheless, any unused spray coating would be placed into landfill, and assuming in the worst case of no recycling of oversprayed material, then based on annual imports of 15 tonnes up to 3.75 tonnes of TKK 30009 could be placed into landfill with unused powder coating material.

At the end of their useful lives, metal articles coated with polymer cured with the new compound would be either placed into landfill, or possibly be recycled for metal recovery.

8.2 Fate

From the above discussion on release patterns, it is apparent that the fate of most of the new chemical will be involved with degradation processes taking place in landfill situations.

The notifier provided a report on the ready biodegradation of the formulation Araldite PT 910 (Notox, 1996a). The test conducted was a CO_2 evolution test (modified Sturm test) performed according to the protocols of OECD TG 301 B. Two duplicate tests were conducted with the test material (nominal concentration equivalent to 12 mg/L organic carbon) incubated with sewage sludge over a 28-day test period. The quantity of CO_2 evolved was monitored over this period, with the results indicating 28 and 33% degradation respectively over the 28-day test period. While the formulation may not be described as being readily biodegradable, it appears to be ultimately degraded under aerobic conditions. In contrast to these results, a reference compound (sodium benzoate) was degraded to > 80% over the test period, which demonstrated the viability of the bacteria used in the test. A toxicity control test where both sodium benzoate and the test substance were incubated together with the sludge indicated that the presence of the test material (Araldite PT 910) had no inhibitory effect on the respiration of the sewage bacteria.

During biodegradation under aerobic conditions the compound would eventually be mineralised to water and carbon dioxide, while in anaerobic environments the products would be water and methane as well as oxides of carbon.

Most of the compound deposited into landfill will be enclosed within a polymer matrix – either cured or uncured, with only the small amount of residue left in the emptied bags being in the free state. Nevertheless, as the polymer matrices are broken down by the slow biological and abiotic processes operative in landfills the compound will be "liberated" and would then be itself slowly attacked and degraded by the native bacteria.

Small amounts of the compound may also be released to sewer and to air. The low value of log Kow and relatively high water solubility indicate that the compound would have little affinity for the organic component of soils and sediments, but in the sewer system the compound is expected to slowly degrade through biological (bacterial) action. The small particles released into the atmosphere would eventually settle to the ground and would then also undergo biodegradation as above.

During metal recovery operations it is usual for the discarded articles to be charged into furnaces with other scrap metal, and under these conditions any associated polymer coating containing the notified chemical would be destroyed by incineration.

Very little of the chemical is expected to enter the water compartment, but the notifier supplied an estimated bioconcentration Factor (BCF) of 42.9 for the new compound calculated using a Quantitative Structure Activity Relationship (QSAR).

The relationship used was based on an estimated value for log Kow of 2.45, and use of the measured value for this parameter (1.45) would have provided a lower estimate of the BCF (Lyman *et al*, 1990). This QSAR estimate can only be regarded as accurate with an "order of magnitude" but indicates little potential for bioaccumulation. Qualitative considerations based on its relatively high water solubility and low value of log Kow also indicate very low potential for bioaccumulation (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

The majority of the toxicity studies submitted were conducted using the notified chemical. The notifier stated that acute dermal and repeat dose toxicity studies are not available for the notified chemical or the product Araldite PT 910. Instead the notifier has submitted acute dermal and repeat dose toxicity studies using the chemical Araldite GY 250, which is a resin of an analogous chemical, bisphenol A diglycidyl ether. Araldite GY 250 has the same epoxy reactive functional groups and similar molecular weight and logP values.

Product:	Araldite GY 250
Ingredients:	Bisphenol A diglycidyl ether
CAS No.:	25068-38-6
Weight percentage:	100%

9.1 Acute Toxicity

Summary of the acute toxicity of TKK30009 and Araldite GY 250 (acute dermal toxicity only)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	Very low toxicity	Ciba-Geigy (1992a)
acute dermal toxicity	rat	Low toxicity	Ciba-Geigy (1985)
skin irritation	rabbit	Slight skin irritant	Ciba-Geigy (1992b)
eye irritation	rabbit	Moderate to severe irritant	Ciba-Geigy (1992c)
skin sensitisation	guinea pig	Sensitiser	Ciba-Geigy (1992d)

9.1.1 Oral Toxicity (Ciba-Geigy, 1992a)

The test material used for this study was TKK30009.

Species/strain:	Rat / Tif: RAI f (SPF)
Number/sex of animals:	5 males and 5 females
Observation period:	14 days
Method of administration:	2000 mg/kg, by oral gavage, delivered at 10 ml/kg; vehicle oleum arachidis.
Test method:	OECD TG 401
Mortality:	None.
Clinical observations:	Slight to moderate piloerection, hunched posture and dyspnoea were observed on days 0 to 5. Slightly reduced locomotor activity, slight ataxia and slight exophthalmous (female only) were also observed on day 0. Slight respiratory sounds were also heard in females on days 1 to 3. All signs of toxicity were reversible by day 6.
Morphological findings:	No treatment-related macroscopic findings were observed.
LD_{50}:	>2000 mg/kg
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Ciba-Geigy, 1985)

Araldite GY 250, a substance analogous to the notified chemical, was tested in this study

Species/strain:	Rat / Tif: RAI f (SPF)
Number/sex of animals:	5 males and 5 females
Observation period:	14 days
Method of administration:	2000 mg/kg test chemical applied undiluted for 24 hours to shaven, intact skin, under semi-occlusive dressing.
Test method:	OECD TG 402
Mortality:	None.
Clinical observations:	Slight dyspnoea, exophthalmous, ruffled fur and abnormal body posture were noted up until day 9. All signs of toxicity were reversible by day 10.
Morphological findings:	No signs of local toxicity or macro- or microscopic findings were reported.
LD_{50}:	> 2000 mg/kg
Result:	The tested chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

An acute inhalation toxicity study was not provided.

9.1.4 Skin Irritation (Ciba-Geigy, 1992b)

The test material used for this study was TKK30009.

Species/strain:	Rabbit / New Zealand White
Number/sex of animals:	3 females
Observation period:	10 days
Method of administration:	A 4-hour application of 0.5 ml undiluted liquid test substance was made to shaven intact skin, under semi-occlusive dressing.
Test method:	OECD TG 404

Draize scores:

Time after treatment (days)	***Animal #***		
	1	***2***	***3***

Erythema			
1	1[a]	1	1
2	1	1	1
3	1	1	1
7	0	1	0
10	0	0	0
Oedema			
1			
2	Zero scores were recorded in all animals at all time points.		
3			
7			
10			

[a] see Attachment 1 for Draize scales

Mean Individual Scores (24, 48 & 72 hour observation	Erythema and scab formation: 1,1,1. Oedema: 0,0,0.
Comment:	All signs of irritation were reversible by day 10.
Result:	The notified chemical was slightly irritating to the skin of rabbits.

9.1.5 Eye Irritation (Ciba-Geigy Limited, 1992c)

The test material used for this study was TKK30009.

Species/strain:	Rabbit / New Zealand White
Number/sex of animals:	3 females
Observation period:	14 days
Method of administration:	0.1 ml of test substance placed into the conjunctival sac of the left eye of each animal, with the right untreated eye serving as control.
Test method:	OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation					
Animal	***1 day***	***2 days***	***3 days***	***7 days***	***10 days***	***14 days***
Cornea						
1	1[1]	1	1	0	0	0

2	1		1		1		0		0		0	
3	1		1		1		0		0		0	
Iris												
1	1		1		1		0		0		0	
2	1		1		0		0		0		0	
3	1		1		1		0		0		0	
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***
1	3	2	3	2	3	2	1	0	1	0	0	0
2	2	2	3	2	2	1	1	0	1	0	0	0
3	3	2	3	2	3	1	2	1	1	0	0	0

[1] see Attachment 1 for Draize scales
r = redness c = chemosis

Individual mean scores at 24, 48 & 72 hours :
Corneal opacity: 1.0, 1.0, 1.0;
Iridial lesions: 1.0, 0.67, 1.0;
Conjunctival redness: 3.0, 2.33, 3.0;
Conjunctival chemosis: 2.0, 1.67, 1.67.

Comment:
Corneal and conjunctival scores equivalent or less than those recorded at 24 hours, were recorded at 1 hour. Iris scores at 1 hour were zero.
By the fourteenth day post-treatment, all signs of irritation had disappeared.
Area of the cornea affected and conjunctival discharge were not reported.

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

9.1.6 Skin Sensitisation (Ciba-Geigy, 1992d)

The test material used for this study was TKK30009.

Species/strain:
Guinea pig / Pirbright White

Number of animals:
Treatment: 10 males and 10 females;
Control: 10 Guinea pigs.

Induction procedure:

Test animals, Week 1
Three pairs of intradermal injections (0.1 ml) into the dorsal skin of the scapular region:
- Freund's Complete Adjuvant (FCA) in saline (1:1);
- TKK30009 at 1% w/v in Oleum arachidis;
- TKK30009 at 1% w/v in a (1:1) mixture of FCA and saline;

Test animals,
A 48-hour occluded application of 0.4 g of neat TKK30009 to the treated area;

Week 2

Control animals, Weeks 1 & 2	Treated similarly to the test animals omitting the test substance from the intradermal injections and topical application

Challenge procedure:

Test and Control animals, Week 5:	A 24 hour, occluded application of 50% w/v TKK30009 in vaseline, at a different site than that used at induction.
Test method:	OECD TG 406

Challenge outcome:

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
50%	14/20**	20/20	1/10	0/10

* time after patch removal
** number of animals exhibiting positive response (Draize score $\geq$ 1)

Result: The notified chemical is a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (Ciba-Geigy, 1984)

Araldite GY 250, a substance analogous to the notified chemical, was tested in this study.

Species/strain:	Rat / RAI f (SPF)
Number/sex of animals:	5 males and 5 females per treatment and control group
Method of administration:	Orally by gavage.
Dose/Study duration:	0, 50, 200 and 1000 mg/kg/day, in carboxymethyl-cellulose 0.5% with 0.1% Tween 80, for 28 consecutive days.
Test method:	OECD TG 407

Clinical observations:
No deaths occurred. There were no significant differences in body weight gain and no signs of toxicity.

Clinical chemistry/Haematology
No treatment-related findings were observed.

Histopathology:
No treatment-related macro- or microscopic findings were observed.

Result:

A No Observed Effect level of 1000 mg/kg/day, the highest does tested was identified for the test chemical.

9.3 Genotoxicity

9.3.1 Bacterial Reverse Mutation Assay (Ciba-Geigy, 1992e)

The test material used for this study was TKK30009.

Strains:	*Salmonella typhimurium*: TA98, TA100, TA1535, TA1537; *Escherichia coli*: WP2 uvrA.
Metabolic activation:	Aroclor-induced rat liver S9
Concentration range:	Without exogenous metabolic activation : Expt 1 : 156.25, 312.5, 625, 1250, and 2500 μg/plate. Expt 2 : 19.5, 39.1, 78.1, 125.25 and 312.5 μg/plate. With exogenous metabolic activation : Expt 1: 312.5, 625, 1 250, 2500 and 5000 μg/plate Cytotoxicity tests : 20.6, 61.7, 185.2, 555.6, 1666.7 and 5000 μg/plate. Dimethylsulphoxide was used as vehicle throughout. Appropriate strain specific positive control reference substances were used.
Test method:	OECD TG 471
Comment:	There were dose-related increases, reaching more than 2-fold, in the numbers of revertant colonies in Expt. 1, with S9, with strains TA 100, TA 1535 and WP2 uvrA. Greater than 2-fold increases in the numbers of revertant colonies in Expt. 1 & 2, without S9, with strains TA 100, TA 1535 and WP2 uvrA were also observed. However a dose-response relationship was not evident without S9, with increases only being seen with the lower concentrations, and toxicity being evident at the higher concentrations. No precipitation was noted. Concurrent positive controls induced marked increases in the frequency of revertant colonies.
Result:	The notified chemical was mutagenic under the conditions of the test

9.3.2 *In vitro* Mammalian Cell Mutagenicity Assay at the Thymidine kinase (tk)-Locus (Ciba-Geigy, 1992f)

The test material used for this study was TKK30009.

Cells:	L5178Y Mouse Lymphoma cells (tk +/-)
Metabolic activation system:	Aroclor-induced rat liver S9
Dosing schedule:	With exogenous metabolic activation : Expt 1 : 2.25, 4.5, 9, 18 and 36 μg/ml, for 4 hours. Expt 2 : 2.25, 4.5, 9, 18 and 54 μg/ml, for 4 hours. Without exogenous metabolic activation : Expt 1 : 0.02, 0.04, 0.08, 0.15 and 0.3 μg/ml, for 4 hours Expt 2 : 0.02, 0.04, 0.08, 0.15 and 0.45 μg/ml, for 4 hours After a 2 day expression period, mutations in the thymidine kinase-locus were selected for by a 1-2 week treatment with 5-trifluorothymidine (TFT). Tests were conducted in duplicate with positive and negative controls.
Test method:	OECD TG 476
Comment:	Statistically significant and dose-related increases in mutation frequency were observed in Expt 1 & 2 with and without exogenous activation. Toxicity was observed in the presence and absence of activation with the highest concentrations. The mutation frequency of positive and negative controls were within normal ranges.
Result:	The notified chemical was mutagenic under the conditions of the test.

9.3.3 Micronucleus Assay in rat Bone Marrow Cells (Ciba-Geigy, 1993)

The test material used for this study was TKK30009.

Species/strain:	Rat / Tif: MAGf
Number and sex of animals:	5 males and 5 females per group
Doses:	2500 mg/kg in Arachis oil BP
Method of administration:	Gavage
Test method:	OECD TG 474

Comment:	Polychromatic erythrocytes were examined at 16, 24, and 48 hours after administration of test substance. There were no increases in the percentage of micronucleated polychromatic cells. Neither were there any decreases in the P/N ratio. However, toxicity was evident with 3000 and 5000 mg/kg in the range finding study, including death in 1 of 2 rats treated with 5000 mg/kg. Therefore it is assumed that the test chemical was absorbed and was likely to have reached the target cells. Positive control animals, treated intraperitoneally with cyclophosphamide, produced the expected results.
Result:	The notified chemical was not clastogenic under the conditions of the test.

9.3.4 In vivo Mammalian Germ-cell Cytogenetics Assay in Mice (Ciba-Geigy, 1991)

The test material used for this study was TKK30009.

Species/strain:	Mice / B6D2F1
Number and sex of animals:	5 males per group
Doses:	0, 90, 180, 360 and 720 mg/kg in 1% methyl cellulose, administered on 5 consecutive days.
Method of administration:	Gavage
Test method:	OECD TG 483
Comment:	Animals were treated with colchicine, 4-hours prior to sacrifice and sacrificed 6 hours after the last dose. 250 spermatogonia per testes, both testes per animal, were scored for chromosome aberrations. There were no increases in the frequency of cells with chromosomal aberrations, including and excluding gaps. Neither were there any significant decreases in the cytotoxic ratio. However the doses administered were based on a range finding study in which an LD50 value of 1100 mg/kg was identified. It is therefore assumed that absorption occurred in the study. Positive control animals, sacrificed 24 hours after a single intraperitoneal dose of mitomycin, produced the expected results.
Result:	The notified chemical was not clastogenic under the conditions of the test, however it is not clear whether the notified chemical reached the target cells.

9.4 Overall Assessment of Toxicological Data

The notified chemical is considered to be of very low acute oral toxicity in rats with a LD50 value of > 2000 mg/kg. An acute toxicity study using an alternative route of exposure was not available for the notified chemical. However the results from a dermal acute toxicity study, conducted using a structurally similar chemical, indicate that the notified chemical is likely to be of low acute dermal toxicity. A LD50 value of > 2000 mg/kg was obtained for the structural analogue. The notified chemical is a slight skin irritant and a moderate to severe eye irritant. It is a skin sensitiser in guinea pigs.

A repeated dose toxicity study is not available for the notified chemical. However the results from a 28-day study, conducted using a structurally similar chemical, indicate that the notified chemical is likely to be of low repeated dose toxicity. A NOEL of 1000 mg/kg/day, the highest dose tested, was identified for the structural analogue.

Results from a reverse mutation assay in bacterial cells and a forward mutation assay in mammalian cells were positive. Negative results were obtained in an *in vivo* micronucleus study and an *in vivo* germ-cell cytogenetics study although it is not clear if the chemical reached the target cells. It is noted that this pattern of results in genotoxicity studies is similar to that obtained with other aromatic glycidyl ethers.

Overall, based on the submitted information, the notified chemical would be classified as an eye irritant and a skin sensitiser according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). Consequently labelling with R36: Irritating to eyes and R43: May cause sensitisation by skin contact is appropriate.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicity reports specific to the new compound were provided, although the company did provide test reports (Notox 1996b, 1996c, 1996d) on the acute toxicity of the formulation Araldite PT 910 to the fresh water species, *Cyprinus carpio* (carp), *Daphnia magna* and the bacteria *Pseudomonas putida*. The tests were conducted according to OECD or German test protocols, and during the tests physical conditions such as pH, temperature and dissolved oxygen levels were within the tolerances of the guidelines. Due to the apparent insolubility of the test material in water, all tests solutions were prepared using serial dilutions of a 100 g/L stock solution of the chemical in acetone.

Test	***Species***	***Results (nominal)***
Acute toxicity to Fish	*Cyprinus carpio*	96 h LC50 = 8.8 mg/L
OECD TG 203	carp	96 h NOEC = 5.6 mg/L
Acute toxicity	*Daphnia magna*	48 h EC50 = 81 mg/L
OECD TG 202		48 h NOEC = 32 mg/L
Bacterial reproduction	*Pseudomonas putida*	3 h EbC10 > 10000 mg/L
DIN 38412 Part L8		

* NOEC - no observable effect concentration

These test data indicate that Araldite PT 910 is moderately toxic to fish, slightly toxic to daphnia and appears to be non toxic to the bacterial species against which it was tested (Mensink *et al*, 1995). In this regard, it is relevant to note that in the assessment of biodegradation potential, the test material was shown not to be inhibitory to respiration of sewage bacteria.

Since the ecotoxicity tests were performed with a mixture of the new compound (< 50%) with terephthalic acid diglycidyl ester, it is not possible to definitely ascribe the observed toxic effects to the new compound, but assuming that the observed effects are due entirely to the notified chemical, by dividing the experimental LC50 for fish (the most sensitive species) by 5 (corresponding to 20% content of TKK30009) the resultant LC50 is around 2 mg/L, and so at worst the compound may be described as being moderately toxic to fish (Mensink *et al*, 1995).

However, very little of the notified chemical is likely to reach the water compartment, and so toxic effects to aquatic organisms are not expected.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is not expected that the notified chemical will constitute a hazard to the environment when used as a curing agent for powder coatings in the manner indicated by the notifier.

A maximum of 2.5 tonnes of the chemical are expected to be placed into landfill each year with waste resulting from formulation and manufacture of powder coatings. A further maximum of 3.75 tonnes per annum may be lost from overspray during application of the powder coatings to metal articles in spray booths, and while some of this would be collected and re-used, most would be either placed into landfill with other waste, or could possibly be incinerated. Although not readily biodegradable, the compound is expected to slowly mineralise to water and landfill gases as a result of slow biological and abiotic processes. Incineration would destroy the compound with liberation of water vapour and oxides of carbon.

After application of the coating to metal articles it is cured in a hot oven, and the notified chemical is tightly covalently bound into the polymer matrix with no potential for release.

At the end of their useful lives coated articles would be either placed into landfill or smelted in a blast furnace for metal recovery. Smelting would destroy the notified chemical, while in a landfill the polymer coating would eventually degrade through slow biological and abiotic processes.

Ecotoxicicity studies indicate that the notified chemical, at worst, may exhibit slight to moderate toxicity to fish and daphnia. However, very little of the notified chemical is expected to reach receiving waters and is unlikely to present a hazard in this compartment. The chemical is not expected to bioaccumulate.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Assessment of Toxicological Hazard

Based on the results of studies of either the notified chemical or a structural analogue, the notified chemical is considered to be of very low acute oral toxicity and low acute dermal toxicity in rats. It is a slight skin irritant, a moderate to severe eye irritant and a skin sensitiser.

The notified chemical is considered to be of low repeated dose toxicity, with a NOEL of 1000 mg/kg/day, the highest dose tested, being identified for the structural analogue.

Positive findings were obtained in *in vitro* genotoxicity studies but negative findings were obtained in two *in vivo* studies. Therefore the notified chemical cannot be classified as a mutagen.

Overall, based on the submitted information, the notified chemical would be classified as an eye irritant and a skin sensitiser according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999). Consequently labelling with risk phrases R36 and R43 is appropriate.

Occupational Health and Safety

Transport and Storage
The notified chemical is not manufactured in Australia, but will be imported as a component in Araldite PT 910 at < 50%. Araldite PT 910 exists as solid, waxy granules, which are not inhalable. The notified chemical is of low volatility and is therefore unlikely to be available for inhalation from the imported product. Waterside workers and transport and storage personnel will only handle Araldite PT 910 as it is imported; in 25 kg polythene bags, contained in outer packaging. The 25 kg polythene bags will not be opened until arrival at reformulators. Therefore waterside, transport and storage workers will not be directly exposed to the notified chemical except in the event of spills.

Reformulation Plant Operators
At reformulation sites, Araldite PT 910 granules are manually weighed and poured from bags or shovelled using metal scoops, into mixing hoppers. Other raw materials are added and the mixture is transferred to an extruder either under gravity in a closed system, or poured manually in an open system. The mix is heated until it melts (>100ºC), remixed and then extruded onto a roller, where it is spread into a thin sheet. The melted mix solidifies on cooling and the solid sheets are chipped, milled, sieved and packaged.

The potential for inhalation exposure to the notified chemical in the form of dust exists during weighing, addition to and extraction from mixing hoppers, during milling and packaging activities and on disposal of empty containers. According to the notifier local exhaust ventilation will be in use in all areas where dust containing the notified chemical may be generated. Dermal exposure may also occur during these activities and also to the melt as it leaves the extruder. According to the notifier reformulation workers must wear personal protective equipment consisting of long sleeved overalls, disposable dust masks or a powered air supplied respirator, chemical goggles, rubber gloves and safety boots, which will contribute to reducing exposure. Also, the notified chemical is only present at a maximum of 50% in the Araldite PT 910 granules and 1.8% in the extrudate and solidified final product.

However the notified chemical is a skin sensitiser and therefore exposure to small concentrations may lead to adverse health effects. Also, there is potential for respiratory sensitisation from breathing of dust containing the notified chemical. Therefore if local ventilation fails or appropriate PPE is not correctly used as advised there is potential for adverse health effects to occur.

Quality Control Workers
Quality control personnel will be exposed to the solid extrudate in the form of flakes and powders during collection of samples, to finely milled powder during milling of the flakes, and when spraying the fine powders onto test panels. All milling, spraying and cleaning of laboratory equipment is to be performed in a spray booth with exhaust ventilation. Quality control personnel will wear personal protective equipment consisting of laboratory coats and use either powered air respirators or disposable dust masks. Also the notified chemical will be present at a maximum concentration of approximately 1.8%. Overall, if all control systems are correctly employed, the risk of adverse health effects should be low in this group of workers.

Research and Development
Research and development personnel will potentially be exposed to the notified chemical via inhalation and dermally while working with the granules of Araldite PT 910, the dry-blended reformulated mixture, the melt mix (dermal exposure only) and final paint products. They will therefore be exposed to mixtures containing a maximum of 50% notified chemical. However all research and development is to be performed within a controlled laboratory fitted with local dust extraction system. Research and development personnel will wear personal protective equipment consisting of laboratory coats, rubber gloves, safety glasses, and disposable dust masks. As above, if all controls systems are correctly employed, the risk of adverse health effects should be low in this group of workers.

Maintenance Workers
Maintenance workers may be exposed via inhalation and dermally to dusts containing the notified chemical left on the machinery they are required to service. They will therefore be exposed to mixtures containing a maximum of 50% notified chemical. Local exhaust ventilation will not be available, although according to the notifier maintenance workers must wear personal protective equipment consisting of PVC or nitrile rubber gloves and disposable dust masks. Due to the nature of the work, the lack of exhaust ventilation and assuming that all other control systems, such a PPE are correctly employed, the risk of adverse health effects in this group of workers is at least equal to that of the reformulators noting that maintenance of equipment should not occur frequently.

Production Administration Workers
Production administration workers are expected to have intermittent contact with the notified chemical, although when they are to spend lengthy periods of time in the production area they must wear personal protective equipment consisting of dust coats, and disposable dust masks. Overall, it is considered that administration workers are unlikely to come into direct contact with the notified chemical and hence the risk of adverse health effects should be low in this group of workers.

Application Plant Operators
Applicators will potentially be exposed to the notified chemical in the final product at a maximum concentration of 1.8% when manually loading the hoppers which automatically

feed the spray gun and when collecting oversprayed coating. However, exhaust ventilation is used in the loading area and oversprayed powder may be collected using vacuum cleaners. Exposure may also potentially occur during spraying activities. However, according to the notifier, all spraying is to be performed in a spray booth fitted with local exhaust ventilation. Application plant operators must wear personal protective equipment consisting of disposable overalls and rubber gloves, chemical goggles or face shield and dust masks when exposure is considered to be minimal, otherwise full-face respirators. If all controls systems are correctly employed, the risk of adverse health effects should be low in this group of workers.

Overall, the greatest risks of workers experiencing adverse health effects, such as skin sensitisation and eye, respiratory and skin irritation, due to exposure of the notified chemical, are considered to be with the maintenance workers and the reformulators. The risks for these workers are considered to be low.

Public Health

The notified chemical will be used as an ingredient in powder coatings for use on items such as outdoor furniture, car parts and door and window frames. Products containing the notified chemical are not available for sale to the public. Members of the public may make dermal contact with items coated with products containing the notified chemical. However, the risk to public health from the notified chemical will be negligible because the notified chemical is present a low concentrations and is likely to be bound within a cured resin coating, from which it is unlikely to be bioavailable.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R36: Irritating to eyes
  - R43: May cause sensitisation by skin contact

  and use of the safety phrase:

  - S22: Do not breathe dust

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - $\geq$ 20%: R36
  - $\geq$ 1%: R43

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced and in final powder coating products:
  - spray painting of powder coatings should be performed in a booth;

- spray painting booths and equipment should be in accordance with Australian Standard AS3754 -1990 - *Safe Application of Powder Coatings by Electrostatic Spraying*;
- local exhaust ventilation should be used when spraying, during filling of hoppers, when reclaiming powder and during clean-up;
- automatic spray guns, feed lines and feed equipment should be used;
- spray gun air pressure should be minimised to prevent overspray as this could result in unnecessary powder build-up within the spray booth;
- the power supply and powder coating feedlines should be interlocked with the air extraction system so that if a fault develops in the ventilation system, the powder coating and power supplies are cut off;
- the spread of dust within the powder coating building should be minimized;
- circumstances leading to draughts and air turbulence should be evaluated and controls implemented;
- operations of opening powder coating packages, loading of hoppers and reclaiming powder should be contained to prevent or minimise the generation of dusts;
- the layout of the workstation and the size of the hopper opening should be such that generation of dust is minimised in filling the hopper, other methods in the use of hoppers should be considered, namely: large hoppers should be used to avoid frequent refilling of smaller units, and preference should be given to the use of powder coatings supplied in drums which allow mechanical transfer of the powder to hoppers.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and in final powder coating products:
  - work practices designed to avoid the generation of dust;
  - restricting access to spray painting areas;
  - designing a safe workplace so that the spray painter is never between the object to be sprayed and the airflow of contaminated air;
  - situating the articles to be sprayed sufficiently within the booth to avoid ricochet;
  - implementing good personal hygiene practices, for example, powder coating dust should not be allowed to collect on the face, exposed body areas should be thoroughly washed and overalls should be regularly cleaned;
  - storing powder coating and waste powder in a designated area and access restricted;
  - cleaning booths and surrounding areas on a regular basis;
  - promptly cleaning-up spills of powder coatings;
  - not using compressed-air or dry sweeping during clean-up operations;
  - using a spark-proof squeegee when a wet clean-up is required;
  - emptying vacuum cleaners in the booth and under exhaust ventilation;
  - taking care to avoid the generation of dust during disposal of waste powder;
  - waste powder being baked in the original box for disposal to landfill as a solid;
  - vacuuming primary decontamination of work clothing;
  - checking regularly the cleaning and maintenance of plant equipment, including ventilation and spray equipment and filters;
  - to minimise electrical hazards associated with electrostatic spraying all equipment, including spray guns and booth, should be earthed; all hooks used to suspend objects to be sprayed should be cleaned prior to re-use in order to maintain effective metal contact.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and in final powder coating products:
  - overalls, gloves (PVC or nitrile rubber), head and eye protection and respiratory protection; for spraying the respiratory protective equipment should provide head covering to avoid dust build-up around the edges of the face masks; during manual spraying, the gun-hand must not be insulated from the gun, either the gun hand should be cowled by a cover sleeve or the palm of an insulating glove may be cut out; operators standing outside a booth and spraying inside a booth through an aperture should wear this type of protective equipment; and anti-static and conductive footwear should be provided.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Atmospheric monitoring of dust levels should be conducted to measure workplace concentrations during formulation and use of the notified chemical.

- A copy of MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

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* (NOHSC, 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 subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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

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