File No: NA/838

December 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Component of Epicure 3292-FX-60

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Director
Chemicals Notification and Assessment

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Component of Epicure 3292-FX-60

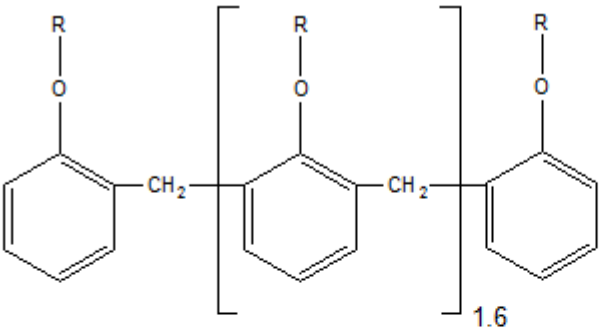
1. APPLICANT

Shell Company of Australia Ltd (Shell Chemicals) of 1 Spring St Melbourne VIC 3000 (ABN 46 004 610 459) has submitted a standard notification statement in support of their application for an assessment certificate for Component of Epicure 3292-FX-60. No exempt information has been requested.

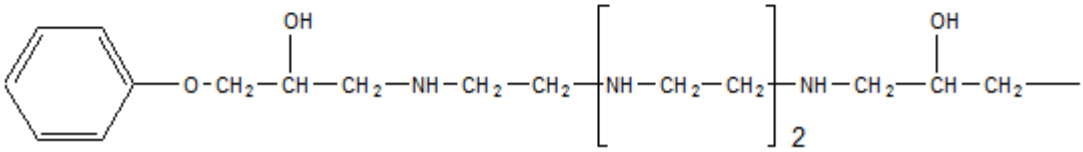
2. IDENTITY OF THE CHEMICAL

Chemical Name:	phenol, polymer with formaldehyde, glycidyl ether, polymers with [(methylphenoxy)methyl]oxirane and triethylenetetramine
Chemical Abstracts Service (CAS) Registry No.:	99377-78-3
Other Names:	polyethylene polyamine adduct
Marketing Name:	Epicure 3292-FX-60 (solution) Epicure 3292 (notified chemical)
Molecular Formula:	$(C_{10}H_{12}O_2.C_6H_{18}N_4.C_9H_{10}O_2.CH_2O)_n$
Number-Average Molecular Weight (NAMW):	913
Weight-Average Molecular Weight:	1055
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	10.9
Molecular Weight < 1 000:	65.2

Structural Formula:



Where R is the group-



Weight Percentage of Ingredients:

No separate listing of ingredients was required for assessment. The stoichiometry of the notified chemical was indicated by Field Desorption Mass Spectroscopy. The average degree of polymerisation of the phenol, polymer with formaldehyde, is approximately 2. Each phenol group is converted to a glycidyl ether and reacted with triethylenetetramine (trien). The product is then reacted with an excess of o-cresol glycidyl ether, giving up to two substituents per trien unit. A major impurity produced by reaction of trien with o-cresol glycidyl ether is also present.

The notifier provided some GPC molecular weight data which gave unrealistic (very low) values for the Number Average Molecular Weight (NAMW) and Weight Average Molecular Weight (WAMW). This was probably due to experimental difficulties associated with the high amino function content of the material. More acceptable data was obtained using Field Desorption Mass Spectroscopy indicating the presence of fractions with MW between 107 and 2000 in the notified chemical, with the most abundant component around 934. The mass spectroscopy data was then used to produce a simulated GPC trace and slice data, giving the molecular weight data tabulated above. However, the notifier indicated that the major component of the notified chemical typically has a an NAMW of around 1700 corresponding to near complete coupling between a phenolic resin of average degree of polymerisation of 3.6 and the amino functional glycidyl ether. The presence of a significant contribution (actual percentage not specified) of major impurity described above, with a molecular weight of 475 skews the overall number average molecular weight to between 900 and 1000.

The notified chemical contains a high content of secondary amine functionality, and the Functional Group Equivalent Weight (FGEW) of the amine groups is estimated as around 142.

The FIMS data did not indicate the presence of high levels of unreacted starting materials.

Method of Detection and Determination:	infrared spectroscopy
Spectral Data:	3400 (br), 3300, 2920, 2830, 1600, 1500, 1460, 1250, 1120, 1040, 930, 820, 750, 715 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is imported as the product Epicure 3292-FX-60, containing approximately 60 % notified chemical in xylene and n-butanol. The physico-chemical properties tabulated below are for the pure notified chemical unless otherwise specified. Except for the determination of the n-octanol/water partition coefficient, a summary report only on the determination of the important physico-chemical properties was submitted. It was not stated whether recognised OECD test methodologies were used for the various determinations.

Appearance at 20°C & 101.3 kPa:	clear yellow viscous liquid with ammonia odour (solution as imported, approximately 60 % notified chemical); notified chemical is a yellow crystalline solid under ambient conditions
Melting Point:	80°C (commences melting)
Boiling Point:	333 - 384°C (decomposition, commences 250°C)
Specific Gravity:	1.1551
Vapour Pressure:	1.3×10^{-3} kPa at 150°C
Water Solubility:	< 10 mg/L at 25°C, pH 7 < 50 mg/L at 25°C, pH 1 < 50 mg/L at 25°C, pH 10
Partition Co-efficient (n-octanol/water):	log P_{ow} = 4.0 (see comments below)
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 $T_{1/2}$ at pH 7.0 $T_{1/2}$ at pH 9.0
Adsorption/Desorption:	log K_{oc} = 2.1 – 3.5 (calculated)
Dissociation Constant:	pK_a ~ 10.1, 9.3, 6.8, 3.4
Flash Point:	28°C (for the solution)

Flammability Limits:	Upper Explosive Limit = 7 % Lower Explosive Limit = 1 % (for the solution)
Autoignition Temperature:	not determined
Explosive Properties:	not expected to be explosive
Reactivity/Stability:	stable under normal environmental conditions

3.1 Comments on Physico-Chemical Properties

The melting point of the notified chemical was determined using differential scanning calorimetry, and the material melted over a wide temperature commencing at 80ºC. The notified chemical decomposed at temperatures above 250ºC with 86.7 % weight loss between 333 and 384ºC.

The vapour pressure (VP) was determined using a gas saturation method whereby a stream of an inert gas (helium) is passed over a heated sample of the material, and this then passed into a cold trap to allow the volatilised material to condense. After a specified time the weight of recovered material is determined and this is then used in conjunction with the gas flow rate, molecular weight of the material and sample temperature to determine the VP through use of the gas law equation. The low vapour pressure found at 150ºC is in accord with the molecular weight, and at ambient temperatures the VP would be considerably lower.

The summary report on determination of the water solubility provided only scant description of the test procedure and did not provide any details of analytical methodology used. Nevertheless, attempts to determine water solubility at pH 1, 7 and 10 were apparently made by stirring excess of the notified chemical into the test water and determining the concentrations of the test material. The solubilities at pH 1, 7 and 10 were stated as < 10, < 50 and < 50 mg/L respectively, although it was also indicated that the material is soluble at pH 1. The summary report appears to be incomplete. However, considering the high content of amine groups (FGEW around 142) which are basic and expected to be protonated in the environmental pH region where 4< pH < 9 (pK_a estimated between 9.5 and 10.5), and the molecular weight, it is probable that the notified chemical is appreciably water soluble under acidic conditions. However, in respect of this Total Organic Carbon (TOC) measurements performed in conjunction with ecotoxicity tests (see further below) indicated water solubility of 3 - 7 mg/L at pH 7 - 8.5.

The notified chemical contains no functionalities which will be susceptible to hydrolysis at environmental pH of 4 - 9.

The n-octanol/water partition coefficient was determined using reverse phase HPLC method according to OECD TG 117 (Jacobs & Nixon, 1998). The retention time of the notified chemical on a standard C18 column when eluted with 50 % acetonitrile/water was compared with the retention time for nine reference compounds with known values for Log P_{ow} between 1.5 (phenol) and 5.7 (triphenylamine). The chromatogram of the component of Epicure 3292-FX-60 had three major peaks with retention times corresponding to Log P_{ow} 1.4, 2.7 and 4.0. The major fraction corresponded to the material with Log P_{ow} of 4. The notifier indicated that

the other observed peaks corresponded to the solvents, xylene and n-butanol. However, the Log P_{ow} value is strictly applicable to the neutral form of the molecules, and since the amino groups would be protonated (positive charge) under usual environmental conditions, the effective partitioning to the oil phase from water may be significantly lower than indicated by the determined Log P_{ow} values.

No experimental determination of the adsorption/desorption coefficient (K_{oc}) was undertaken, but instead estimates made on the basis of a Quantitative Structure Activity Relationship (QSAR) between Log K_{oc} and the experimental value for Log P_{ow} were provided. The QSAR used is equation 4.8 given by Lyman et al (1982) and is –

Log K_{oc} = 0.544 × Log P_{ow} + 1.377.

This provides estimates for Log K_{oc} of 2.1, 2.8 and 3.5 corresponding to Log P_{ow} of 1.4, 2.7 and 4.0, respectively. The value of 3.5 for Log K_{oc} for the notified chemical indicates that it may have some affinity for soils and sediments, but lower MW components may be mobile in these media. As the effective Log P_{ow} values under environmental conditions are likely to be lower than those used above, the Log K_{oc} values will be correspondingly lower. Consequently, binding to soils and sediments may not be very strong and the notified chemical may be mobile in these media.

The notified chemical contains secondary amine functionalities which have typical pK_a values between 9.3 and 10.5, and will be protonated in aqueous environments.

4. PURITY OF THE CHEMICAL

Degree of Purity: not specified as the notified chemical is a UVCB compound (reaction products)

Hazardous Impurities: not specified as the impurities constitute part of the UVCB mixture

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants:

Chemical name:	xylene (mixed isomers)
CAS No.:	1330-20-7
Weight percentage:	30 % in imported product
Regulatory Controls:	National exposure standard 80 ppm TWA, 150 ppm STEL (NOHSC, 1995)
Toxic properties:	R20/21 Harmful by inhalation and in contact with skin R38 Irritating to skin (NOHSC, 1999b)

Chemical name:	1-butanol
Synonyms:	n-butyl alcohol
Weight percentage:	10 % in imported product
CAS No.:	71-36-3
Regulatory Controls:	NOHSC exposure standard 50 ppm peak limitation (skin notation) (NOHSC, 1995)
Toxic properties:	R20 'Harmful by inhalation' (NOHSC, 1999b)

5. USE, VOLUME AND FORMULATION

The notified chemical is used as a component of a two part epoxy based anticorrosive paint for steel.

The notified chemical is imported as the product Epicure 3292-FX-60, containing approximately 60 % notified chemical in xylene and n-butanol, in 200 L drums. It will be reformulated in Australia to produce the paint component, which contains approximately 40 – 50 % Epicure 3292-FX-60 (up to 30 % notified chemical), by blending with other paint components. The paints will be packaged in 5 L cans. The paint components are mixed with the other part of the epoxy in a ratio of 1:3 and applied to articles by spraying under factory conditions.

The notifier estimates that the import volume will be 200 tonnes of Epicure 3292-FX-60 per annum (120 tonnes notified chemical per annum) during the first five years of importation.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
Waterfront, transport and warehouse workers are not expected to be exposed to the notified chemical except in the case of an accident involving spillage of the paint or resin solution. No details of the number of workers or frequency of handling the notified chemical was provided by the notifier.

Reformulation
The reformulation of the notified chemical solution to produce the paint components will occur at two sites. Mixing will occur in an enclosed blending vessel. The notified chemical will be decanted directly from the imported drums into the blending vessel. Dermal exposure to drips and spills of the 60 % solution of the notified chemical will be possible during handling of the import drum. The paint component will then be transferred to an enclosed semi-automated fill line, where it will be packed into 5 L cans. Dermal exposure to drips and spills of the paint (30 % notified chemical) will be possible in the case of accidents during filling.

Reformulation will involve six manufacturing operators and six packaging operators. Manufacturing operators will be involved in decanting and blending the notified chemical

solution for 1 hour per day, 100 days per year. After reformulation, the finished paints will be handled by packaging operators, for 2 hours per day, 1000 days per year.

Reformulation workers will wear gloves, goggles and a mask. The notifier indicates that the reformulation plants have good general ventilation.

End Use
The paints containing the notified chemical will be used only by professional spray applicators. It is estimated that there will be approximately 100 applicators using the paints containing the notified chemical, and that the frequency of exposure will be approximately 10 times per week, for 1 hour at a time. The spray applicators will mix the paint component containing the notified chemical with the other part of the paint, and load the final paint mix into spray guns prior to application of the paint.

The notifier indicated that spraying will occur in spray booths which are very well ventilated, and that the applicators will wear full protective equipment. Spray painting involves a high level of potential exposure by the dermal, ocular and inhalation routes, and should be carried out in accordance with the NOHSC *National Guidance Material for Spray Painting* (NOHSC, 1999c).

7. PUBLIC EXPOSURE

Paint products containing the notified chemical are not available for sale to the general public. The potential for public exposure to the notified chemical during transport, reformulation, end use and disposal is assessed as negligible. Members of the public may make dermal contact with steel 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 paint film.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Paint formulation and packaging
No exact estimates of release of the material during paint formulation were provided, although it was indicated that little of the Epicure 3292-FX-60 is expected to remain in the 200 L drums, since residues would be washed out with solvent containing resin which will cross link with the notified chemical. Presumably the solid cross linked mass would be disposed of to landfill. The empty drums would be crushed and then sent as scrap steel to metal recycling facilities. If it is assumed that 1 % of the Epicure 3292-FX-60 remains in the drums and is treated and disposed of as described above, then annually around 1.2 tonnes is expected to be placed into landfill from manufacturing activities.

Paint application
Application of the paint to steel items will be performed in special spray booths where it is expected that up to 30 % would be lost as overspray. Overspray would be cross-linked with other paint components to a semi-solid mass, and is expected to be collected and placed into landfill or incinerated. Assuming annual import volume of 120 tonnes, an expected maximum

of 36 tonnes of the notified chemical would be placed into landfill each year. Since the paint containing the notified chemical is expected to be used throughout Australia, this release will be diffuse.

Steel articles coated with the paint will be sold into the general community, and at the end of their useful lives these could be expected to be either placed into landfill or be recycled for metal recovery. Environmental release to landfill will be diffuse and involve the notified chemical as a cured paint. Steel articles recycled for metal recovery would be re-smelted in a furnace which would destroy the notified chemical.

8.2 Fate

The notified chemical has been shown not to be biodegradable in a closed bottle test conducted according to OECD TG 301 D (Schaefer, 1999). In this test duplicate samples containing sufficient of the solid notified chemical (apparently without any solvent) to give a nominal concentration of approximately 5 mg/L of the material in the test vessel were incubated with sewage bacteria at 20±3°C over a 28 day period. The decrease in dissolved oxygen in the test media was monitored periodically over the test period and compared with the theoretical chemical oxygen demand of the notified chemical (previously determined as 2.37 mg O_2 per mg of notified chemical) to calculate the degree of biodegradation. The chemical was found to be hardly degraded over the 28 day test period, in contrast to the results obtained using a reference material (sodium benzoate at 2 mg/L) which was degraded around 78 % within six days. The test material was introduced as a solid, which would not have favoured easy attack by bacteria.

Much of the notified chemical will be placed into landfill as a component of hardened epoxy paint. Over time this solid matrix would be broken down through slow biological and abiotic processes, and while the notified chemical is apparently resistant to biodegradation, it is expected to eventually mineralise to water, and oxides of carbon and nitrogen. Under anaerobic conditions degradation to methane and ammonia is expected.

Incineration of hardened paint containing the notified chemical would also destroy the chemical with release of nitrogen oxides.

Except in the case of transport accident very little of the notified chemical is likely to be released in the uncured form to the water compartment. However, due to the cationic nature of the protonated amine groups, strong binding to aquatic sediments is not likely and the chemical would be mobile in the sediments and may remain substantially associated with the water.

Although the Log P_{ow} of the major component was determined as 4.0, the effective value of this parameter is likely to be significantly lower due to protonation. This, together with the high molecular weight (NAMW = 913), indicates that the notified chemical has low potential for bioaccumulation (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Epicure 3292

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(Kern, 1999e)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(Kern, 1999c)
skin irritation	rabbit	slight irritant	(Kern, 1999b)
eye irritation	rabbit	slight irritant	(Kern, 1999d)
skin sensitisation	guinea pig	sensitiser	(Kern, 1999f)

9.1.1 Oral Toxicity (Kern, 1999e)

Species/strain: rat/Crl:CD(SD)IGS BR

Number/sex of animals: 5/sex/dose

Observation period: 14 days

Method of administration: gavage, dose levels 1183, 1538 and 2000 mg/kg; notified chemical administered as a suspension in corn oil; dose volume 20 mL/kg; dose administered in two halves given 4 hr apart

Test method: OECD TG 401

Mortality:
1183 mg/kg 1/10
1538 mg/kg 2/10
2000 mg/kg 2/10
one female in the 1183 mg/kg group died prior to administration of the second half of the dose; the other premature decedents died within 2 days of dosing

Clinical observations: 29 animals showed discoloured areas due to discharges or excretions (clear, red, yellow or brown) around the nose, mouth, hindlimbs, dorsal rump, ventral trunk, anogenital and/or urogenital area; 27 animals showed abnormalities in excretion (mucoid faeces, soft faeces and/or diarrhoea); hypoactivity was observed in six animals, predominantly in the 2000 mg/kg group

prostration, hypothermia and laboured respiration were noted in two of the animals which later died

other observations in one or two animals included impaired muscle coordination, clear ocular discharge, swollen nose and hair loss

	all observations with the exception of hair loss in one animal (till the study end) and soft faeces in one animal on day 10 had cleared by day 6
Body weight:	no significant body weight changes were observed
Morphological findings:	three premature decedents had yellow stomach contents, one of these had dark red lungs; no other gross pathological abnormalities were observed in these animals or at scheduled necropsy
Comment:	significant toxicity was observed at all doses tested
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Kern, 1999c)

Species/strain:	rat/Crl:CD(SD)IGS BR
Number/sex of animals:	two groups of 5/sex
Observation period:	14 days
Method of administration:	for group 1, the notified chemical was administered as solid moistened with water and removed with tepid water at the conclusion of exposure; for group 2, the notified chemical was administered as a 500 mg/mL solution in 1:1 isopropanol/acetone and removed with 1:1 isopropanol/ acetone the notified chemical was administered as a semi-occlusive patch; dose level 2000 mg/kg, for 24 hr
Test method:	OECD TG 402
Mortality:	no premature deaths occurred during the study
Clinical observations:	ten animals showed discolouration due to discharges around the eyes, nose, mouth, anogenital and/or urogenital region on days 0 and 1; soft faeces were observed in two animals on days 0 and 4
Body weight:	four females lost weight during the first week of the study; no other significant body weight changes were observed

Morphological findings: no gross pathological abnormalities were observed at scheduled necropsy

Dermal observations: group 1 animals retained a large amount of test material on the skin and remaining fur at the application site; some notified chemical also remained at the application site for the group 2 animals

desquamation was observed in eight group 1 and nine group 2 animals; focal eschar was observed in six group 1 and two group 2 animals; exfoliation was observed in a single animal of each group these commenced on day 3 for desquamation, day 4 for focal eschar and day 6 for exfoliation; all had cleared by day 13 except for desquamation (accompanied, in one case, by focal eschar) at the end of the study in two group 1 females

Draize scores for erythema and oedema are given below; the Draize scores were all zero for the later days not listed in the tables

Draize scores (Group 1):

Time after treatment (days)	***Animal #***									
	1♂	***2♂***	***3♂***	***4♂***	***5♂***	***6♀***	***7♀***	***8♀***	***9♀***	***10♀***
Erythema	[i]									
1	0	1	1	1	1	1	0	1	1	1
2	1	1	1	1	1	1	0	1	1	1
3	0	1	1	1	1	1	0	1	1	1
4	0	0	1	0	0	1	0	1	2	1
5	0	0	0	0	0	0	0	1	1	1
6	0	0	0	0	0	0	0	1	0	1
7	0	0	0	0	0	0	0	0	0	1
Oedema										
1	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0
4	0	1	1	0	1	0	0	1	1	1
5	0	0	1	0	0	0	0	0	1	0

Draize scores (Group 2):

Time after treatment	***Animal #***

(days)	*1*♂	*2*♂	*3*♂	*4*♂	*5*♂	*6*♀	*7*♀	*8*♀	*9*♀	*10*♀
Erythema										
1	1	0	0	0	0	0	0	0	0	0
2	1	0	0	0	1	1	0	1	1	0
3	1	0	0	0	1	1	0	1	1	0
4	1	0	0	0	0	1	1	1	1	1
5	1	0	0	0	0	1	1	0	0	0
Oedema	all Draize scores were zero									

[i] see Attachment 1 for Draize scales

Comment: the study authors concluded that the clinical and body weight observations were related to the wrapping procedure rather than being related to the notified chemical

LD_{50}: > 2000 mg/kg

Result: the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

No inhalation toxicity study was submitted by the notifier.

9.1.4 Skin Irritation (Kern, 1999b)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/sex

Observation period: 5 days

Method of administration: semi-occlusive patch; 4 hr exposure; dose 0.5 g; notified chemical moistened with deionised water; residual notified chemical removed with water at the end of the exposure time; incomplete removal was obtained and collars were applied to the animals for the entire study duration

Test method: OECD TG 404

Draize scores:

Time after treatment (days)	***Animal #***					
	1♂	*2*♂	*3*♂	*4*♀	*5*♀	*6*♀
Erythema						
0.5 – 1 hr	[a]0	0	1	1	1	1
1	0	1	1	1	0	1

2	0	0	1	1	0	1
3	0	0	0	0	0	1
4						1
5						0
Oedema	all Draize scores were zero					

[a] see Attachment 1 for Draize scales

Comment: an attempt was made to remove residual test material from the treatment site using isopropanol for animal 1

four animals lost weight during the study; the study authors attributed this to the wearing of collars for the study duration

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

9.1.5 Eye Irritation (Kern, 1999d)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/sex

Observation period: 21 days

Method of administration: 58 mg (0.1 mL) of notified chemical was instilled in the conjunctival sac of the right eye; the untreated eye served as control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation									
Animal	***1 hour***		***1 day***		***2 days***		***3 days***		***4 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1♂	[1]0	0	0	0	0	0	0	0		
2♂	0	0	1	1	1	2	2	3	2	3
3♂	0	0	0	0	0	0	0	0		
4♀	0	0	0	0	0	0	0	0		

5♀	0		0		0		0		0		0		0		0
6♀	0		0		0		0		0		0		0		0
Iris															
1♂		1			0			0			0				
2♂		0			1			1			1			1	
3♂		0			0			0			0			0	
4♀		0			0			0			0			0	
5♀		0			0			0			0			0	
6♀		0			0			0			0			0	
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1♂	1	1	1	1	0	0	0	0	0	0	0	0			
2♂	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2
3♂	1	1	1	1	0	0	0	0	0	0	0	0			
4♀	1	0	0	0	0	0	0	0	0	0	0	0			
5♀	1	0	1	1	0	0	0	0	0	0	0	0			
6♀	1	0	1	0	0	0	0	0	0	0	0	0			

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

Comment: test material adhered to the cornea of animal 2 and was still observable at day 21; for this animal Draize scores for days 7, 14 and 21 were

Time after instillation

Animal	***7 days***		***14 days***		***21 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***
2♂	2	4	2	4	2	3
Iris						
2♂	1		0		0	
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
2♂	2	2	2	2	2	2	2	2	1

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

9.1.6 Skin Sensitisation (Kern, 1999f)

Species/strain: guinea pig/Hartley [Crl:(HA)BR]

Number of animals: 10/sex (test group)
5/sex (control group)

Induction procedure:

test group:

day 0 — on a prepared area of skin from the shoulder region of test animals, three pairs of intradermal injections were administered as follows:

1. 0.1 mL of Freund's Complete Adjuvant (FCA) 50 % (v/v) in sterile saline;
2. 0.1 mL 5 % notified chemical in 70 % isopropanol in water;
3. 0.1 mL 5 % (w/v) notified chemical in sterile saline 50 % (v/v) with FCA

day 7 — notified chemical as supplied (0.8 g, moistened with 0.3 mL deionised water) was applied by occlusive patch to the same site that received the intradermal injections for 48 hours; application sites were observed for irritation 24 hours subsequently

control group:

day 0 — on a prepared area of skin from the shoulder region of test animals, three pairs of intradermal injections were administered as follows:

1. 0.1 mL of Freund's Complete Adjuvant (FCA) 50 % (v/v) in sterile saline;
2. 0.1 mL 70 % isopropanol in water;
3. 0.1 mL 70 % isopropanol in water 50 % (v/v) with FCA

day 7 — deionised water was applied by occlusive patch to the same site that received the intradermal injections for 48 hours; application sites were observed for irritation 24 hours subsequently

Challenge procedure:

day 21 — an occlusive chamber containing 0.2 mL of a 0.5 % concentration of notified chemical in 1:1 acetone and 99 % isopropanol was applied to the shaved anterior left flank of each animal under occlusive conditions for 24 hr; a similar chamber containing vehicle only was applied to the anterior right flank;

dermal reactions were scored at 24 and 48 hours after patch removal

Test method: OECD TG 406 (Magnusson and Kligman Method)

Challenge outcome:

Challenge	***Test animals***	***Control animals***

concentration	*24 hours**	*48 hours**	*24 hours*	*48 hours*
0.5%	**13/20	13/20	0/10	0/10

* time after patch removal

** number of animals exhibiting positive response (Draize score ≥ 1, eschar or focal eschar)

Comment: positive responses (eschar or focal eschar) were observed for the vehicle only test site for 3/20 test animals; the Sensitisation Incidence Index was determined by the study authors to be 55 % (11/20)

for the positive control, α-hexylcinnamaldehyde, a Sensitisation Incidence Index of 60 % was obtained

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

9.2 Dermal Repeated Dose Toxicity (Kern, 1999a)

Species/strain: rat/Crl:CD(SD)IGS Br

Number/sex of animals: 5/sex/group

Method of administration: dermal; occlusive patch; 6 hr exposure for 5 days per week for 4 weeks; notified chemical dissolved in 1:1 acetone:isopropanol at 5, 50 and 500 mg/mL; residual notified chemical was removed with water at the end of the exposure time; doses 0, 10, 100, 1000 mg/kg/day

Dose/Study duration: 27 days (20 exposures)

Test method: OECD TG 410

Clinical observations:
One 100 mg/kg/day male was euthanased *in extremis* on day 22; the cause of the illness was determined to be a lower urinary tract obstruction, with no apparent relation to treatment.

No test material related clinical signs of toxicity were observed. Body weight gains were unaffected by treatment.

Dermal observations:
For the 1000 mg/kg/day group, residual test material was present at most daily observations. Beginning as early as day 2, very slight to slight erythema was observed in all animals for the duration of the study, with one female exhibiting severe erythema with eschar during the final week. A limited incidence of oedema (1 male and 2 females, for several days only) was also observed. Focal eschar was observed in 4 males and all females beginning in the second week of exposure. Occasional desquamation was also observed in all animals.

For the 100 mg/kg/day group, residual test material was present for one male on one

occasion. Very slight to slight erythema was observed in 3 males and 3 females commencing in the third and fourth week of the study, respectively. No oedema was observed. Focal eschar was observed in 3 males on several occasions beginning in the second week of exposure. Occasional desquamation was also observed in all animals.

For the 10 mg/kg/day group, very slight erythema was observed in 1 female during the last week of the study. No oedema was observed. Focal eschar was observed in 1 male during the last week of the study. Occasional desquamation was observed in 3 males and 1 female during the last week of the study.

For the control group, dermal observations were limited to desquamation in one female during the last week of the exposure period.

Clinical chemistry/Haematology
No treatment related changes in haematology parameters were observed during the study.

There were significant increases in mean alkaline phosphatase in the 10 mg/kg/day and 1000 mg/kg/day males and in mean alanine aminotransferase in the 10 mg/kg/day males. These changes were due to high values in one or two members of the group, in each case. A slight decrease in mean serum chloride was observed in the 1000 mg/kg/day females, but no similar decrease was observed in the males.

Gross Pathology:
No macroscopic pathological changes apart from scabbing of the skin at the application site in 3 1000 mg/kg/day females were observed, except in the animal which died of non-treatment related causes. All values for organ weights were similar to those for the test group.

Histopathology:
Microscopic changes were limited to the treated skin. At 1000 mg/kg/day, minimal to mild subacute inflammation, primarily in the upper dermis, was observed in 4 males and 4 females. All animals in the group showed minimal to moderate epidermal hyperplasia, manifested as increased thickness with hyperkeratosis at the surface. Minimal to mild ulceration with exudate was observed for 3 females, and mild exudate without ulceration was observed for 1 male.

Minimal epidermal hyperplasia was present in three 100 mg/kg/day females, two 10 mg/kg/day females and one control female.

Comment:
Observations were generally limited to localised dermal irritation. The clinical chemistry changes observed in the males showed no dose relationship, and were not reproducible across the groups. The change in serum chloride for the females was very slight and was not reproduced in the males.

The death of one 100 mg/kg/day male from urinary tract obstruction was unlikely to be test material related.

Result:

A No Observed Adverse Effect Level (NOAEL) for systemic toxicity of ≥ 1000 mg/kg/day for males and females was established in this study. Localised skin irritation was observed at all doses.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium and Escherichia coli* Reverse Mutation Assay (Wagner & Twardzik, 1999)

Strains:	*Salmonella typhimurium* TA98, TA100, TA1535 and TA1537; *Escherichia coli* WP2uvrA(pKM101)
Test Material:	the test material was a clear yellow viscous liquid, identified as Epi-Cure 3292; this identification has normally been used for the pure notified chemical, which is a solid dosing vehicle was 1:1 acetone and isopropanol
Metabolic activation:	10 % rat liver S9 fraction (Aroclor1254-induced) in standard cofactors
Concentration range:	*S. typhimurium* –S9 0, 1.5, 5, 15, 50, 150, 500 μg/plate *S. typhimurium* +S9, *E. coli* –S9 0, 5, 15, 50, 150, 500, 1500 μg/plate *E. coli* +S9 0, 15, 50, 150, 500, 1500, 5000 μg/plate
Positive controls:	with S9: 2-aminoanthracene TA98, TA100, TA1535, TA1537: 1.0 μg/plate WP2*uvr*A: 10 μg/plate without S9 TA98: 2-nitrofluorene 1.0 μg/plate TA100,TA1535: sodium azide 1.0 μg/plate TA1537: 9-aminoacridine 75 μg/plate WP2*uvr*A: methyl methanesulphonate 1000 μg/plate
Test method:	OECD TG 471 and 472 (plate incorporation method)
Comment:	all concentrations were tested in triplicate and concurrent positive and negative controls responded appropriately precipitation was observed at 500 μg/plate and above; signs of appreciable toxicity manifested in thinning of the background lawn or a reduction in the number of spontaneous revertants was seen for concentrations of 150 μg/plate for *S. typhimurium* and 500 μg/plate for *E. coli*

	no positive responses were observed with any tester strain in the presence or absence of metabolic activation
	large increases in the number of revertant colonies were seen for the positive controls in all cases, indicating that the test system responded appropriately
Result:	the notified chemical was non mutagenic under the conditions of the test

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Ovary Cells (Gudi & Schadly, 1999)

Cells:	Chinese Hamster Ovary (CHO)
Test Material:	the test material was a clear yellow viscous liquid, identified as Epi-Cure 3292; this identification has normally been used for the pure notified chemical, which is a solid
	dosing vehicle was 1:1 acetone and isopropanol
Metabolic activation system:	2 % rat liver S9 fraction (Aroclor 1254-induced) in standard cofactors

Dosing schedule:

Metabolic Activation	Test Number	Test concentration (μg/mL)	Controls
-S9	1	treatment time = 4 hr with 16 hr recovery 5, 10*, 15*, 20*, 25, 30, 35, 40, 45	Positive: mitomycin C 0.08, 0.15 μg/mL
	2	treatment time = 20 hours 5, 10, 15, 20, 25, 30, 35, 40, 45	Negative: vehicle
	3	treatment time = 20 hours 0.5, 2, 4, 6*, 8*, 10*, 12	
	4	treatment time = 20 hours 4, 6*, 8*, 10*, 12, 15*	
+S9	1	treatment time = 4 hr with 16 hr recovery 25, 50, 60, 80, 90, 100, 110, 125	Positive: CP 10, 20 μg/mL
	2	treatment time = 4 hr with 16 hr recovery 20, 30*, 40*, 50*, 53, 57, 60	Negative: vehicle

EMS - ethyl methanesulphonate
CP - cyclophosphamide

DMSO – dimethylsulphoxide
* - cultures selected for metaphase analysis

Test method:	OECD TG 473
Comment:	colcemid (0.1 μg/mL) was added 2 hr before harvest to arrest cells in metaphase in non-activated test 2 (20 hr exposure) and S9 activated test 1, insufficient scorable concentrations were obtained due to toxicity, and non-activated test 3 and activated test 2 were performed; the sponsor requested non-activated test 4 after the observation of chromosomal aberrations in test 3 in non-activated test 1 (4 hr exposure) a reduction in mitotic index of 30 % was observed at 20 μg/mL; in S9 activated test 2, a reduction of mitotic index of 32 % was observed at 50 μg/mL; in non-activated test 3 (20 hr exposure) a reduction in mitotic index of 33 % was observed at 10 μg/mL; in non-activated test 4 (20 hr exposure) a reduction in mitotic index of 6 % was observed at 15 μg/mL in test 3 (20 hr exposure) in the absence of metabolic activation, a statistically significant and dose related increase in the percentage of cells with structural chromosomal aberrations was observed; no increase in the incidence of polyploidy was observed no statistically significant increases in the percentage of cells with structural chromosomal aberrations or in the incidence of polyploidy was observed in tests 1 and 4 in the absence of metabolic activation or in test 2 in the presence of metabolic activation; test 4 was carried out as a replication of test 3 and the observations in test 3 were not found to be reproducible; no explanation of this observation was advanced by the study authors the positive controls caused large, statistically significant increases in the proportion of aberrant cells in all cases, indicating that the test system responded appropriately
Result:	the notified chemical gave equivocal results in the absence of metabolic activation under the conditions of the test

9.4 Overall Assessment of Toxicological Data

The notified chemical was found to have very low acute toxicity in rats (LD_{50} > 2000 mg/kg) although some signs of toxicity including mortalities were observed. The major observations included discoloured stomach contents in the premature decedents, and signs of digestive

disorders including discharges and excretion abnormalities. The notified chemical is strongly basic, and digestive system irritation is therefore a likely consequence of ingestion of large doses.

The notified chemical was found to have low acute dermal toxicity (LD_{50} > 2000 mg/kg), although local irritant effects were observed. No inhalation toxicity study was submitted.

The notified chemical was found to cause slight skin irritation. Grade 1 erythema was observed in 5/6 animals. In four of these the response cleared by day 3, while in the fifth, it had cleared by day 5. Residual test material adhered to the skin in both the acute dermal toxicity and the dermal irritation studies. The notified chemical was found to be a slight eye irritant, with slight iris and conjunctival effects which cleared by day 2 in 5/6 animals. In the sixth animal, residual test material adhered to the cornea, and corneal opacity and conjunctival redness, chemosis and discharge of grade 2 and grade 1 iris effects were observed up till the termination of the study on day 21. The notified chemical was found to be a skin sensitiser, with a Sensitisation Incidence Index similar to that of the positive control, α-hexylcinnamaldehyde. The notified chemical should therefore be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999a), with the risk phrase R43, 'May cause sensitisation by skin contact'.

In a 28 day dermal repeat dose study in rats, a NOAEL of ≥ 1000 mg/kg/day for systemic toxicity was established. Local skin irritation was observed at the application site for all doses. The results are consistent with low dermal absorption of the notified chemical, due to its high molecular weight.

The notified chemical was not found to be mutagenic in an *in vitro* bacterial point mutation assay. Equivocal results were obtained in a structural chromosome aberration study in CHO cells, where, on 20 hr exposure to the notified chemical, dose related structural aberrations were observed but were not reproducible. The notified chemical was therefore concluded not to be clastogenic under the conditions of the experiment.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out using OECD Test Methods.

Test	***Species***	***Results (WAF - Nominal)***
Acute Toxicity of Solid Epicure 3292-FX-60 [OECD 203]	Fathead minnow *Pimephales promelas*	LL_{50} (96 h) = 54 mg/L NOEC = 23 mg/L
Acute Immobilisation of solid Epicure 3292-FX-60 [OECD 202]	Water flea *Daphnia magna*	LL_{50} (48 h) = 23 mg/L NOEC = 4.4 mg/L
Growth Inhibition of solid Epicure 3292-FX-60 [OECD 201]	Algae *Scenedesmus subspicatus*	EL_{50} (72 h) = 0.63 mg/L NOEC = 0.5 mg/L

* NOEC - no observable effect concentration
WAF - water accommodated fraction

Fish

The notifier provided a report on the toxicity testing of the notified chemical against Fathead minnow (Drottar & Krueger, 1998b). This test series was performed over a 96 hour period using a static methodology with 80 % renewal at 24, 48 and 72 hours. The test was performed in duplicate with controls using ten specimen fish per replicate at 22±2ºC. The tests were conducted using water accommodation fractions (WAFs) of the test substance made up at a nominal concentrations of 0 (control), 8.3, 14, 23, 38 and 64 mg/L. The individual WAFs were prepared by vigorously stirring weighed amounts of the test material (solid Epicure 3292-FX-60) with 20 L of the test water, previously aerated and filtered through sand filters, for approximately 21 hours, followed by a 2 hour settling period. The WAF media were syphoned off to the test chambers, and all were described as clear and colourless indicating the absence of undissolved test material. Throughout the 96 hour test duration the pH, dissolved oxygen and temperature of the test media were always 8.4±0.1, between 7.1 and 8.2 mg/L and 22±2ºC, respectively while the water hardness was 128 mg/L as $CaCO_3$.

After 96 hours exposure no mortality was observed among the test fish for all (nominal) WAF loadings of 23 mg/L and less, but 5 % of fish had died at nominal 38 mg/L WAF, and 80 % had died at nominal 64 mg/L WAF. Fish which survived after 96 hours exposure to the highest WAF were described as lethargic. The dose response curve was steep and binomial moving average analysis was used to determine the 96 hour LL_{50} as 54 mg/L (WAF) with the corresponding No Observed Effect Loading (NOEL) of 23 mg/L. Results suggest that the notified chemical is slightly toxic to this fish species. However, the result may underestimate the true toxicity since analysis of Total Organic Carbon (TOC) in the test media was never greater than 3 mg/L for all nominal WAF loadings, suggesting that lethal effects of the notified chemical may be manifest at significantly lower concentrations than inferred from the nominal WAF loadings.

Daphnia

The immobilisation tests with daphnia were also performed over a 48 hour period under semi-static conditions (Drottar & Krueger, 1998a) using WAFs of 0 (control), 2.2, 4.4, 8.8, 18 and 35 mg/L at 20±1ºC. The test at each WAF was conducted in duplicate with a control using ten daphnia per test vessel. Throughout the 48 hour test duration the pH, dissolved oxygen and temperature of the test media were always 8.5±0.1, between 8.6 and 8.9 mg/L and 20±1ºC, respectively while the water hardness was 128 mg/L as $CaCO_3$.

After 48 hours exposure no mortality was observed among the daphnia for the (nominal) WAF loadings of 4.4 mg/L and less, 15 % of the animals were immobile at nominal 8.8 mg/L WAF, 15 % immobilisation was observed at nominal 18 mg/L WAF, and some lethargy. 100 % had died at nominal 35 mg/L WAF. The dose response curve was steep and binomial moving average analysis was used to determine the 48 hour LL_{50} as 23 mg/L (WAF) with the corresponding No Observed Effect Concentration (NOEC) of 4.4 mg/L. Results suggest that the notified chemical is slightly toxic to this species. However, the result may underestimate the true toxicity since as with the fish test discussed above the mean measured TOC in the test media with a nominal 35 mg/L of test compound was never greater than 7.4 mg/L. Consequently, the lethal effects of the chemical may be manifest at significantly lower concentrations than inferred from the nominal WAF loadings.

Green Algae
Tests on algal growth inhibition were also performed over a 96 hour period with WAFs made up at the nominal concentrations of 0 (control), 0.063, 0.13, 0.25, 0.50 and 1.0 mg/L, using a static methodology (Drottar & Krueger, 1998c). The WAFs were prepared as described above and tests were conducted in triplicate. The temperature of the test vessels was always between 22.3 and 25.9ºC and the pH increased from around 7.4 on day 1 to around 8 on day 4.

The effect of the test material on algal growth was determined by measuring cell densities. While no statistically significant inhibition of algal growth was observed at and below the (nominally) 0.5 mg/L WAF over the 96 hour observation period, almost complete inhibition of growth was observed from day 1 for the highest WAF containing (nominally) 1.0 mg/L of the test material. The dose response curve was steep and Dunnett's test was used to calculate the 72 hour EL_{b50} of 0.63 mg/L. The NOEL was 0.5 mg/L. Results indicate that the notified chemical is toxic to this species of algae.

Conclusion
The ecotoxicity tests indicate that the notified chemical is at least slightly toxic to fish and daphnia and toxic to green algae. The toxicity to aquatic organisms of chemicals and polymers containing high content of amine functional groups is well recognised (Nabholz et al., 1993).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is assessed as low when it is blended into and used in paint for steel articles in the manner indicated by the notifier. There is little potential for significant release of the material during the blending operations which will be performed at dedicated facilities, although some minor release will inevitably occur as a result of paint spills during end use. End use spills would be cleaned up with rags or adsorbent materials and incinerated or sent to landfill.

Spray painting overspray will release around 30 % of the imported chemical (around 36 tonnes per annum) combined with other polymers in a cross-linked semi-solid mass, which would be placed into landfill or incinerated.

The notified chemical is at least slightly toxic to aquatic species, but except in the case of transport accident is not likely to reach the water compartment in large volumes. The chemical has low water solubility at environmental pH and a moderately high octanol/water partition coefficient (Log P_{ow} = 4). Any chemical released to the soil or water compartments is expected to bind to and associate with the organic component of soils and sediments, which would mitigate the toxic potential.

The notified chemical is not biodegradable, however is expected to be slowly degraded through aerobic and anaerobic biological action.

The notified chemical is not likely to present a hazard to the environment when it is stored, transported and used as described.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
The notified chemical is of very low oral toxicity in the rat (LD_{50} > 2000 mg/kg), although some signs of toxicity including mortalities were observed at all tested doses. It is of low dermal toxicity in rats (LD_{50} > 2000 mg/kg), but local irritant effects were observed. It is a slight irritant to rabbit skin and eyes. Persistent eye irritation (beyond 21 days) was observed in one case where the test material adhered to the cornea. The notified chemical was a skin sensitiser in guinea pigs. The notified chemical should therefore be classified as a hazardous substance in accordance with the Approved Criteria, with the risk phrase R43, 'May cause sensitisation by skin contact'.

In a 28 day dermal repeat dose study in rats, a NOAEL of ≥ 1000 mg/kg/day for systemic toxicity was established. Local skin irritation was observed at the application site for all doses. The results are consistent with low dermal absorption of the notified chemical, due to its high molecular weight. While it is likely that a lower NOEL would have been observed in a repeat dose oral study, based on the difference in observed toxicity in the acute oral and dermal toxicity studies, the dermal exposure more closely resembles the likely human exposure to the notified chemical. In addition, the effects observed in the acute oral toxicity study are likely to arise from gastric irritancy, rather than systemic toxicity of the notified chemical.

The notified chemical was not found to be mutagenic in an *in vitro* bacterial point mutation assay. Dose related structural aberrations in CHO cells were observed but were not reproducible and the notified chemical was concluded not to be clastogenic under the conditions of the experiment.

The Material Safety Data Sheet (MSDS) for the product containing the notified chemical, Epicure 3292-FX-60 Curing Agent, indicates that it is a hazardous substance. Apart from the health hazards described above, including gastric irritation if swallowed, it indicates health effects such as central nervous system depression, headaches, dizziness, nausea, respiratory irritation, pulmonary oedema, skin absorption and skin defatting. These additional hazards are likely to be due to the solvents, xylene and n-butanol.

Occupational Health and Safety
There is little potential for significant occupational exposure to the notified chemical in the transport and storage of Epicure 3292-FX-60 or the finished pain components containing the notified chemical. There may be exposure during the manufacture and reformulation of the notified chemical and during use of paint components containing the notified chemical.

During reformulation the main exposure route for the notified chemical will be dermal. While the mixing operations are enclosed, exposure to drips and spills of Epicure 3292-FX-60 (60 % notified chemical) and the paint components (up to 30 % notified chemical) is possible at points where these products are transferred. The notified chemical may adhere to skin, causing persistent irritation as well as sensitisation. Precautions should be taken to avoid ocular contact with the products containing the notified chemical, as eye irritation may occur, and this may be severe if the notified chemical adheres to the eye. The notifier has indicated that gloves, goggles and a mask will be worn during these operations. The MSDS indicates that the glove material should be PVC.

The finished paint component will be mixed with another component and applied by spray. The spraying procedure produces a dense aerosol of paint particles containing hazardous components including the notified chemical. This will result in potential exposure to the notified chemical by inhalation as well as dermal and ocular contact. The presence of these hazardous substances in the formulations requires the use of stringent engineering controls, such as a correctly constructed and maintained spray booth, and of a high level of personal protective equipment, such as impermeable overalls and gloves and a full face shield and respirator. The use of the paint containing the notified chemical should be in accordance with the NOHSC *National Guidance Material for Spray Painting* (NOHSC, 1999c).

Once the applied final paint mix has hardened, the notified chemical will not be separately available for exposure or absorption.

Public Health
Products containing the notified chemical are not available for sale to the general public. Members of the public may make dermal contact with steel items coated with paints containing the notified chemical. However, the risk to public health will be negligible because the notified chemical will be bound within a cured paint film, from which it is unlikely to be bioavailable.

13. RECOMMENDATIONS

To minimise occupational exposure to Component of Epicure 3292-FX-60 the following guidelines and precautions should be observed:

- Use of the paint containing the notified chemical by spray application should be in accordance with the NOHSC *National Guidance Material for Spray Painting* (NOHSC, 1999c);
- Employers should ensure that NOHSC exposure standards for all of the components of the final paint mix are not exceeded in the workplace;
- Safety goggles, chemical resistant industrial clothing and footwear and impermeable PVC gloves should be used while handling the product containing the notified chemical; where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, an air fed respirator should also be used;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

The following regulatory action is recommended:

- Nomination of the notified chemical to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC List of Designated Hazardous Substances.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161 (Standards Australia/Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994); for respirators, in AS/NZS 1715 (Standards Australia/Standards New Zealand, 1994) and AS/NZS 1716 (Standards Australia/Standards New Zealand, 1994).

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, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

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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.
		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

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol. Exp. Ther. 82 : 377-390.

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