File No: NA/502

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Propanol, [2-(1,1-dimethylethoxy)methylethoxy]-

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For Enquiries please contact the Administration Coordinator at:

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

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Propanol, [2-(1,1-dimethylethoxy)methylethoxy]-

1. APPLICANT

ARCO Chemical Australia Pty Limited of Suite 1, Level 3, 845 Pacific Highway CHATSWOOD NSW 2067 and W.R. Grace Australia Limited of 1126 Sydney Road FAWKNER VIC 3060 have jointly submitted a standard notification statement in support of their application for an assessment certificate for 'propanol, [2-(1,1-dimethylethoxy)methylethoxy]-'; hereafter referred to as DPTB. No requests for exempt information relating to the content of this report were made by the notifiers and the assessment report for the notified chemical is published here in its entirety.

2. IDENTITY OF THE CHEMICAL

Chemical Name: propanol, [2-(1,1-dimethylethoxy)methylethoxy]-

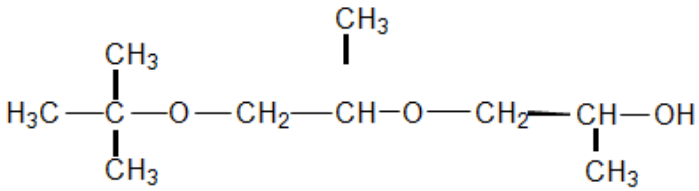
Chemical Abstracts Service (CAS) Registry No.: 132739-31-2

Other Names:
dipropylene glycol t-butyl ether
dipropylene glycol mono-tert-butyl ether
DPTB

Trade Name:
ARCOSolv® DPTB
DPTB-100
DPTB/DPG-211
Eclipse™

Molecular Formula: $C_{10}H_{22}O_3$

Structural Formula:



Molecular Weight: 190.3

Methods of Detection and Determination:	gas liquid chromatography (GLC)
Spectral Data:	ultraviolet/visible (UV/Vis), infrared (IR), nuclear magnetic resonance (NMR) and mass spectra were provided for the notified chemical; GLC data were also provided; major characteristic peaks were found in the infrared spectrum at: 3 436, 2 966, 2 916, 2 872, 1 392, 1 367, 1 234, 1 196 1 152 and 1 102 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	clear, colourless liquid
Melting Point:	less than -25°C (92/69/EEC: Method A1 {European Economic Community (EEC), 1992 #72})
Boiling Point:	213 - 219°C (92/69/EEC: Method A2 {European Economic Community (EEC), 1992 #72})
Specific Gravity:	0.90977 (92/69/EEC: Method A3 {European Economic Community (EEC), 1992 #72})
Vapour Pressure:	42.4 Pa at 25°C (92/69/EEC: Method A4 {European Economic Community (EEC), 1992 #72})
Water Solubility:	165.3 g/L at 20°C (pH 4.68-4.95) (92/69/EEC: Method A6 {European Economic Community (EEC), 1992 #72})
Partition Co-efficient (n-octanol/water):	log P_{ow} = 1.68 at 20°C (92/69/EEC: Method A8 {European Economic Community (EEC), 1992 #72})
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0, 7.0 and 9.0: greater than 1 year at 25°C (92/69/EEC: Method C7 {European Economic Community (EEC), 1992 #72})

Adsorption/Desorption:

Method	K_{OC}	$Log_{10}K_{OC}$
1	< 60.26	< 1.78
2	192.97	2.29
3	47.11	1.67

where method: 1. HPLC [OECD TG 117];
2. Kenaga/Goring Calculation method - using experimentally determined log_{10} P; and
3. Hodson/Williams Calculation method - using experimentally determined log_{10} P.

Surface Activity: 60.1 mN/m at 1.0489 g/L and 17.5°C
60.7 mN/m at 1.0153 g/L and 17.5°C
(92/69/EEC: Method A5 {European Economic Community (EEC), 1992 #72})

Dissociation Constant: pK_a: approx. 17 (estimated - see comments below)

Flash Point: 92°C (closed cup)

Flammability Limits: not flammable

Autoignition Temperature: 269°C

Explosive Properties: no visible or audible reaction was recorded in the mechanical sensitivity (shock) test; friction test not applicable, as notified chemical is a liquid

Reactivity/Stability: not performed

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines {European Economic Community (EEC), 1992 #72; Organisation for Economic Co-operation and Development, 1995-1996 #15} at facilities complying with OECD Principles of Good Laboratory Practice.

Adsorption/desorption results show that DPTB would be moderately to highly mobile in soil. The notifier claims that a structural assessment of DPTB would indicate a pK_a of approximately 17, which would remove it from any environmental significance. The chemical does not possess any dissociable groups.

By definition, a chemical has surface activity when the surface tension is less than 60 mN/m {, 1992 #72}.

4. PURITY OF THE CHEMICAL

Degree of Purity: 97-100% (typical concentration 98%)

Toxic or Hazardous Impurities: none

Non-hazardous Impurities:

Chemical Name	*CAS No.*	*Weight %*
dipropylene glycol	25265-71-8	0.5
dipropylene glycol di-tertiary-butyl ether	69506-59-8	1.0
water	7732-18-5	0.14

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported both in pure form and as a component (at a concentration of approximately 65%) of a blend which will be used as a concrete and mortar additive to reduce shrinkage in dry climates. The final concentration of DPTB in the concrete or mortar mix is not expected to exceed 0.5% by weight.

Estimated import volumes for the notified chemical over the next 5 years are as follows:

Year	*Import Volume (tonnes)*
1	10-100
2-4	100-1 000
5	1 000 - 10 000

6. OCCUPATIONAL EXPOSURE

The notifier did not describe the mode of transport used for import of DPTB (which will be imported in pure or blended form), however it will be shipped in bulk via truck or railcar from the point of import to the notifier's premises. Bulk transport will also be used to transport DPTB to concrete admixture producers, however a small amount may be transported in drums. Transport workers may be dermally exposed to the notified chemical during connection and disconnection of lines used to pump the material between vehicles and storage tanks. Inhalational exposure to vapours is unlikely, as the vapour pressure of DPTB is low. The notifier states that procedure and equipment for compressed air flushing of hoses has been installed on delivery vehicles to reduce the likelihood of spills and worker exposure from material left in hoses.

Workers involved with reformulating DPTB will be required to operate equipment which pumps admixture components and finished product between storage and mixing tanks for approximately 2 hours per day. Dermal exposure to DPTB in pure or blended form may occur during repackaging, dilution and/or reformulation. Drips and splashes may also cause accidental ocular contact. The notifier states that worker training in the storage and handling of chemicals will assist in reducing worker exposure.

The admixture products will then be distributed by road tanker to ready-mix concrete plants. Only a limited amount of material is expected to be moved in drum or pail quantities. DPTB will then be stored in tanks, which will be directly connected to dispensing systems which will add admixtures to concrete trucks, along with other concrete components. This automated system is intended to reduce worker exposure to a minimum, however concrete plant workers and truck drivers may be exposed to the notified chemical while cleaning dispensing equipment and trucks.

It is anticipated that DPTB will be used in concrete for bridge decks, parking garages and large factory/warehouse floors and may be used in public building constructions. Dermal exposure to low concentrations (< 0.5%) of the notified chemical may occur when workers are placing and finishing concrete at construction sites for periods of up to 8 hours per day. Should contact with the concrete occur, it may remain on the skin for some time, hence prolonging exposure.

There will be significant contact of workers with dried concrete containing the notified chemical. Once the concrete has hardened, however, DPTB is effectively sealed within the concrete and minimal volatilisation is expected to occur.

A number of other workers (quality control staff, technicians, supervisors, salesmen) may also come into limited contact with the notified chemical. In all instances, dermal exposure is likely to be the main route of contact, however, accidental ocular exposure may also occur.

Workers may also be exposed to other potentially hazardous substances while handling concrete admixtures and uncured concrete.

7. PUBLIC EXPOSURE

The notified chemical will not be sold directly to the public and will only be available for use in industry. The notified chemical will enter the public domain through use in concrete or mortar mixes, where the maximum concentration of the notified chemical is not expected to exceed 0.5% by weight of the total concrete mixture. It is not expected that the concrete will be used to construct domestic homes, however, it is possible that if could be used to construct public buildings. Therefore, direct public contact with the material should not occur.

8. ENVIRONMENTAL EXPOSURE

Release

During the admixture formulation process, empty drums and lines are flushed with water. This flush water is retained and used in standard admixture batches.

Once the preparation (admixture containing DPTB at approximately 65%) is added to the concrete, the maximum concentration of the notified chemical is not expected to exceed 0.5% by weight of the total concrete mixture. Once the concrete has cured (hardened) the notified chemical is essentially sealed (encapsulated) in the concrete. Test results have shown that less than 2% of the notified chemical was extracted from cured concrete when it was exposed to water continuously for 250 days.

Waste concrete containing DPTB is limited to the residual amounts left in the ready-mix concrete trucks after the load has been delivered to the construction site. Unused concrete at the end of the day will be used in the following ways: sold as a lower grade material, used at the concrete plant itself, or used to make concrete products. Wash water used to clean the concrete trucks will be kept and used in the next batch of concrete. Where this is not possible, the wash water will be discharged into a settling basin at the concrete plant. Clean water from this basin is then re-used in the concrete manufacturing process. A Level 1 Fugacity Model indicates that the majority (99.5%) will remain in the aqueous compartment at equilibrium.

Fate

The fate of DPTB is linked to the disposal of the concrete fabrications into which it is incorporated. Here the notified chemical will remain essentially immobile. The concrete rubble from building demolitions is usually directed to landfill where the notified chemical is expected to remain immobile and not leach.

The notified chemical was evaluated to be not readily biodegradable in the OECD TG 301D Closed Bottle Test {Organisation for Economic Co-operation and Development, 1995-1996 #15}. The notified chemical exhibited only 10% biodegradation after 28 days. No inhibitory effects to activated sewage sludge bacteria were found under the test conditions. The chemical's high water solubility (165.3 g/L), resistance to hydrolysis and low partition coefficient indicate that it should not bioaccumulate {Connell, 1989 #3}.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Propanol, [2-(1,1-dimethylethoxy)methylethoxy]-

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} = 2 600 mg/kg (combined sexes)	{Cerven, 1992 #73}
acute dermal toxicity	rabbit	LD_{50} > 2 000 mg/kg	{Cerven, 1992 #74}
skin irritation	rabbit	slight irritant	{Cerven, 1992 #75}
eye irritation	rabbit	mild to moderate irritant	{Cerven, 1992 #76}
skin sensitisation	guinea pig	mild sensitiser	{Allan, 1996 #77}

9.1.1 Oral Toxicity {Cerven, 1992 #73}

Species/strain: rat/Wistar

Number/sex of animals: 20/sex (5 males and/or 5 females at each dose level; see table below for details)

Observation period: 14 days

Method of administration: gavage; as more than 5 animals died at the initial dose level (5 000 mg/kg), the dosing regimen was as follows:

Dose (mg/kg)	*Number Treated M/F*
1 600	0/5
2 000	5/5
2 600	5/0
3 200	5/5
5 000	5/5

Clinical observations: animals in the 3 200 and 5 000 mg/kg groups began convulsing 5 minutes post-dose; deaths which occurred during the study were preceded by dyspnoea, emaciation, piloerection, lethargy, ataxia, convulsions, coma, flaccid muscle tone and wetness of the nose/mouth area; clinical observations

noted in survivors also included a number of the above effects

Mortality: deaths occurred by day 9; see table below for numbers

Dose mg/kg	***Mortality (males)***	***Mortality (females)***
1 600	NA	0
2 000	1/5	2/5
2 600	0/5	NA
3 200	3/5	4/5
5 000	4/5	5/5

Morphological findings: abnormalities of the lungs, liver and gastrointestinal tract were observed in animals that died during the study; there were no abnormal findings in surviving animals at termination of study

Test method: US EPA Health Effects Guidelines {Office of Toxic Substances, #78}

LD_{50} (combined sexes): 2 600 mg/kg; calculated using the method of Litchfield and Wilcoxon {Litchfield, 1949 #79}

Result: the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity {Cerven, 1992 #74}

Species/strain: rabbit/New Zealand White

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: single dermal application of 2 000 mg/kg test substance; site was covered by occlusive dressing for 24 hours; skin was irrigated with distilled water after dressing was removed

Clinical observations: diarrhoea and soiling of the anogenital area were observed in 3 animals in the second week of the study; 3 animals lost weight at some time during the study; these effects were thought to be stress-induced and not related to treatment with the test material

	9 animals had flaking skin at the test site on day 7; this persisted through to day 14 in 4 animals
Mortality:	none
Morphological findings:	one animal exhibited kidney abnormalities; this was considered to be unrelated to treatment with the test material
Test method:	US EPA Health Effects Guidelines {Office of Toxic Substances, #78}
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rabbits

9.1.3 Inhalation Toxicity

Not performed. The notified chemical is imported in liquid form, and the notifier states that there is limited potential for exposure via this route. The notified chemical has a low vapour pressure, and monitoring studies performed during pouring and curing of concrete indicate minimal release of the notified chemical once it is mixed into the concrete.

9.1.4 Skin Irritation {Cerven, 1992 #75}

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/sex
Observation period:	72 hours
Method of administration:	0.5 mL of test substance was applied to two intact and 2 abraded sites on each animal; the test site was covered with a semi-occlusive dressing for 4 hours; the site was irrigated with lukewarm water once dressing removed; the skin reactions were assessed at 4, 24, 48 and 72 hours after removal of the dressing and scored according to the method of Draize {Draize, 1959 #4} (see Attachment 1 for Draize scales).
Draize scores {Draize, 1959 #4}:	all animals had flaking skin at at least one test site during the test period

	Intact sites: 2 animals showed very slight erythema at one of the intact sites at the 24 hour reading; this persisted in one animal through to the 48 hour reading; a third animal developed slight erythema by the 48 hour reading; one animal had very slight oedema at one intact site at the 48 hour reading **Abraded sites:** 4 animals had very slight erythema at at least one of the abraded skin sites at the 24 hour reading; this persisted in two animals through to the 48 hour reading;
Test method:	EPA Health Effects Guidelines {Office of Toxic Substances, #78}
Result:	the notified chemical was a slight skin irritant to intact and abraded rabbit skin

9.1.5 Eye Irritation {Cerven, 1992 #76}

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males; 7 females
Observation period:	7 days
Method of administration:	0.1 mL of the test material was instilled in the conjunctival sac of one eye; untreated eye served as control; the treated eyes of 3 animals were irrigated for one minute with lukewarm water 20-30 seconds after instillation of the test material

Draize scores {Draize, 1959 #4}:

	Time after instillation							
Animal	**1 day**		**2 days**		**3 days**		**7 days**	
Cornea	**o[a]**	**a[b]**	**o[a]**	**a[b]**	**o[a]**	**a[b]**	**o[a]**	**a[b]**
1	0[1]	0	0	0	0	0	0	0
2	2	1	2	1	0	0	0	0
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	2	2	2	1	2	1	0	0
7*	2	2	2	1	2	1	0	0
8*	2	1	2	1	2	1	0	0
9*	0	0	2	1	0	0	0	0
Iris	rabbit number 9* had a Draize score of 1 for iridial effects at the 24 hour time point							

Conjunctiva	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**
1	2	1	0	0	0	0	0	0	0	0	0	0
2	2	1	0	1	1	0	0	0	0	0	0	0
3	2	2	0	1	0	0	0	0	0	0	0	0
4	1	2	0	0	0	0	0	0	0	0	0	0
5	2	2	2	2	2	2	1	0	0	0	0	0
6	3	3	2	1	2	1	1	1	0	0	0	0
7*	2	2	2	1	1	0	1	1	0	0	0	0
8*	2	2	2	1	0	0	1	0	0	0	0	0
9*	2	2	1	2	2	1	1	2	1	0	0	0

[1] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge
* the treated eyes of these animals were irrigated with lukewarm water for 1 minute following treatment

Irrigated eyes: irrigation did not have a palliative effect (see above table for individual results)

Comments: one animal vocalised immediately post dose; fluorescein retention was noted 24 hours post treatment in 5 out of 6 animals with unwashed eyes; this was also noted in all three animals with washed eyes; one instance of diarrhoea was noted during the test period

Test method: US EPA Health Effects Guidelines {Office of Toxic Substances, #78}

Result: the notified chemical was a mild to moderate eye irritant in rabbits

9.1.6 Skin Sensitisation {Allan, 1996 #77}

Species/strain: guinea pig/albino

Number of animals: 15 males; 10 test, 5 control

Induction procedure:

Day 1: 3 pairs of intradermal injections:
- 0.1 mL Freund's complete adjuvant (FCA):water (1:1(v/v))
- 0.1 mL of 1% concentration of test material in water
- 0.1 mL of 1% concentration of test material in FCA:water (1:1 (v/v))

Day 7: test area treated with 0.5 mL per injection site of 10% (w/w) sodium lauryl sulfate in petrolatum

Day 8: occluded application of 0.4 mL test material (as supplied) for 48 hours

Challenge procedure: Day 22: occluded application of test material (100% and 50% concentrations) for 24 hours

Challenge outcome:

	Test animals			***Control animals***		
Challenge concentration	***24 hours****	***48 hours****	***72 hours****	***24 hours***	***48 hours***	***72 hours***
50%	0/9**	0/9	0/9	0/5	0/5	0/5
100%	0/9	1/9	2/9	0/5	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response (one test animal was excluded from the study as the occlusive dressing became detached prior to the end of the challenge period)

Test method: EEC Methods for Determination of Toxicity {European Economic Community (EEC), 1967 #80}

Result: the notified chemical was a mild skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity

9.2.1 Subacute toxicity (14 day oral administration) {Connick, 1996 #81}

Species/strain:	rat/Crl:CD BR
Number/sex of animals:	20/sex (5/sex/dose group)
Method of administration:	gavage; the vehicle was distilled, deionised water
Dose/Study duration::	the test substance was administered daily for a period of 14 days: control: 0 mg/kg/day low dose: 100 mg/kg/day mid dose: 300 mg/kg/day high dose: 1 000 mg/kg/day all animals were sacrificed at the end of the treatment period
Clinical observations:	transient post-dose salivation was noted from day 7 of treatment for all animals in the high dose group, and 9/10 animals in the mid dose group; no obvious treatment-related effects were seen in body weight gain or food consumption

Clinical chemistry/Haematology	a slight reduction in alkaline phosphatase level was noted for females in the high dose group
Histopathology:	a marked increased in liver and kidney weight for some animals in the high and mid dose groups; this did not attain statistical significance microscopic examination showed a minor degree of centrolobular hepatocyte enlargement in males in the high dose group; eosinophilic droplet accumulation, considered to be α_2 microglobulin, was noted in the renal cortical tubular epithelia in the majority of treated males
Test method:	according to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	in the absence of any increase in marker liver enzymes in plasma samples, the liver changes in animals in the high dose groups are thought to be due to adaptive, rather than toxic, responses the kidney changes noted in males were considered to be a species-specific response to repeated administration of substances of this type and were therefore considered to be of limited relevance to humans

9.2.1 Subacute toxicity (90-day oral administration) {Crome, 1996 #82}

Species/strain:	rat/Crl:CD BR
Number/sex of animals:	80/sex; control and high dose groups: 25/sex low and mid dose groups: 15/sex
Method of administration:	gavage; vehicle was distilled, deionised water

Dose/Study duration::	the test substance was administered daily for a period of 90 days: control: 0 mg/kg/day low dose: 62.5 mg/kg/day mid dose: 250 mg/kg/day high dose: 1 000 mg/kg/day all animals were sacrificed at the end of the treatment period, with the exception of 10 animals of each sex from the control and high dose groups, which were maintained for a further 28 day recovery period
Clinical observations:	post-dosing salivation was noted throughout the study in the high dose group; this symptom increased with time; a small number of animals in the high dose group exhibited unsteady gait, collapsed posture, partially closed eyelids, body spasms and paddling of forelimbs from weeks 8-12 onward no treatment-related effects on body weight of food consumption were noted
Mortality:	one control animal died following blood sampling in recovery week 4
Clinical chemistry/Haematology	slight, but statistically significant reductions in white blood cell and lymphocyte counts were seen in weeks 5 (males, high dose group) and 13 (males and females, high dose group, females, mid dose group); values for test animals were within historical control ranges; these findings had reversed by the end of the 4 week treatment free period increases in albumin and globulin levels were noted in weeks 5 and 13 (both sexes, high dose group); these changes were probably associated with the liver changes outlined below
Ophthalmology and Neurotoxicology:	no treatment related effects at any level
Histopathology:	increased liver weight was noted in both sexes in the high dose group; this was

	associated with minimal centrilobular hepatocyte hypertrophy; these effects were reversed at the end of the 4 week treatment-free period increased kidney and adrenal weights were noted in both sexes in the high dose group and males in the mid dose group; this was associated with increased degree and incidence of cortical tubules with eosinophilic inclusions in males at all dose levels and a dose-related incidence of minimal basophilic cortical tubules in males only; cellular debris casts were present in small numbers of males; these changes had partially reversed by the end of the treatment free period; there were no equivalent treatment-related effects in females an increased incidence of minimally increased width of the zona faciculata was seen in female rats in the high dose group; this may have been related to the increased adrenal weight (adjusted for body weight) seen in this group; no microscopic changes were noted
Test method:	US EPA Health Effects Guidelines {Office of Toxic Substances, #78}; the neurotoxicity component was designed in accordance with EPA FIFRA Pesticide Assessment Guidelines {EPA, 1991 #83}
Result:	the findings of this 90-day subacute toxicity study indicate that treatment of rats with the notified chemical at high doses induces changes in the liver, adrenals, kidneys, and possibly white blood cell counts liver effects were thought to be adaptive metabolic changes, due to the absence of liver marker enzymes in the plasma and lack of other evidence of liver cell damage the kidney changes noted in males were considered to be a species-specific response to repeated administration of substances of this type, related to effects on α_2 microglobulin and protein recycling; these

changes were therefore thought to be of limited relevance to humans

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay {Kitching, 1996 #84}

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100
Concentration range:	50, 150, 500 1 500 and 5 000 μg/plate; vehicle was water; assays were carried out in the presence or absence of rat liver S9 fraction
Test method:	according to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	the notified chemical was not mutagenic in the bacterial strains tested in the presence or absence of metabolic activation provided by rat liver S9 fraction; concurrent positive controls demonstrated the sensitivity of the assay

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse {Proudlock, 1996 #85}

Species/strain:	mouse/SPF CD-1
Number and sex of animals:	65/sex; a further 40 male mice were included in a supplementary test
Doses:	0, 200, 400, 600, 800 mg/kg; vehicle was 1% methylcellulose
Method of administration:	test substance and negative control were administered by intraperitoneal injection; positive control (mitomycin C) given by gavage
Comments:	11/15 male mice and 3/15 female mice died within 30 minutes of treatment with the test substance at 800 mg/kg, no adverse reactions were seen at 200 and 400 mg/kg; in a supplementary test, some males dosed at 600 mg/kg exhibited symptoms (such as

	disturbances of gait and respiration), but there were no deaths
Test method:	according to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	the notified chemical did not show any evidence of causing chromosome damage or bone marrow cell toxicity when administered by intraperitoneal injection at levels up to the maximum tolerated dose

9.4 Overall Assessment of Toxicological Data

The combined oral LD_{50} for both sexes for the notified chemical was found to be 2 600 mg/kg in rats. The dermal LD_{50} in rabbits was found to be greater than 2 000 mg/kg in a limit test. Inhalational toxicity tests were not performed. The notified chemical was a mild to moderate eye irritant and slight skin irritant in rabbits, and was a mild skin sensitiser in guinea pigs.

Fourteen-day and 90-day repeat oral dose studies in rats showed effects on the kidneys, liver, adrenal glands and alterations in some haematological parameters. Changes in the liver were considered to be adaptive, rather than toxic effects, related to the metabolism of the chemical. Effects noted in the kidneys were only found in males and were considered to be species-specific and of limited relevance to humans.

The notified chemical was not mutagenic in bacteria and did not cause chromosome damage in mouse bone marrow cells *in vivo*.

Based on the toxicological studies provided by the notifier, DPTB would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* {National Occupational Health and Safety Commission, 1994 #9}.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods {Organisation for Economic Co-operation and Development, 1995-1996 #15}.

Test	*Species*	*Results (Nominal◊)*
Acute Toxicity (Semi-static†) [OECD TG 203]	Rainbow Trout (*Oncorhynchus mykiss*)	96 hour NOEC ≥ 100 mg/L 96 hour LC_{50} > 100 mg/L
Acute Immobilisation (Static) [OECD TG 202]	Water Flea (*Daphnia magna*)	48 hour NOEC ≥ 100 mg/L 48 hour EC_{50} > 100 mg/L
Growth Inhibition (b = biomass; μ = growth) [OECD TG 201]	Algae (*Scenedesmus subspicatus*)	NOEC (μ) ≥ 100 mg/L 72 hour E_bC_{50} > 100 mg/L 72 hour $E_\mu C_{50}$ > 100 mg/L
Respiration Inhibition [OECD TG 209]	Aerobic Waste Water Bacteria	3 hour EC_{50} > 100 mg/L

◊ All results are expressed in terms of nominal concentrations. In the fish toxicity test measured concentrations were 92% of nominal at 0 and 24 hours, and 98% of nominal at 72 and 96 hours. In the water flea toxicity test the measured concentrations were 101% and 100% of nominal at 0 hours and 48 hours, respectively. Measured concentrations were 94% of nominal at 0 hours and 99% of nominal at 72 hours in the algae growth inhibition test.

† Animals were exposed to the test media with daily batchwise renewal.

The ecotoxicity data for the notified chemical indicate that the notified chemical is practically non-toxic to fish, water fleas and algae. No inhibition of microbial respiration of the notified chemical was seen in the study for the 3 hour contact time.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical is unlikely to present a hazard to the environment when it is added into the concrete mix and applied in the proper manner. The majority of the imported notified chemical will be incorporated into the concrete, becoming encapsulated when the concrete cures. Tests indicate that little of the notified chemical (< 2%) will migrate from the cured concrete when exposed continuously to water (for 250 days). This is expressed as a worst-case scenario as the chemical additive is designed to be used in drier climates to reduce shrinkage.

Environmental exposure may also occur in the case of landfill disposal of waste concrete and demolished concrete fabrications. However, since the notified chemical is encapsulated, and expected to remain within the concrete matrix, the predicted environmental hazard is minimal.

The adsorption/desorption data, showing moderate to high mobility in soils, and the high water solubility indicate a strong potential for leaching before becoming a part of a cured cement fabrication. Aquatic exposure may occur in the event of an accident involving the release of the notified chemical. Adequate warnings exist on the Material Safety Data Sheet (MSDS) that accompany loads in transit to alert clean-up crews to the need to prevent release to sewers/drains and restrict water use during clean-up.

Wash waters containing the notified chemical may be released to on-site settling basins. The majority of this water will be kept and used in subsequent cement

batches. However, the notified chemical should only be present in these wash waters at low concentrations, and it was shown that the notified chemical is practically non-toxic to aquatic species. The majority of the notified chemical should remain with the aquatic fraction in the basin, according to fugacity modelling. The environmental hazard through this disposal is predicted to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The occupational risk for transport workers is considered to be low. These workers may be exposed to the notified chemical in neat form, as well as blends containing approximately 65% of the notified chemical. Exposure to the notified chemical is expected to occur when workers are connecting and disconnecting hoses from bulk storage and transport tankers. The toxicity of the notified chemical is expected to be low and the main route of exposure for these workers is expected to be dermal. A dermal toxicity study carried out in rabbits did not show any conclusive signs of systemic toxicity following exposure. Given the low molecular weight of the notified chemical, however, skin absorption may occur and, based on the outcome of a rabbit study, slight skin irritation may also result. Accidental ocular contact may result in mild to moderate irritation, but permanent damage would not be expected, based on the results of a rabbit study. Inhalation is not likely to be a major route of exposure if the notified chemical is only used at room temperature, given the low vapour pressure. The notifier states, however, that there have been three reports of minor throat and eye irritation following exposure to the notified chemical in confined spaces.

Workers at concrete admixture plants may also be exposed to the notified chemical in pure form, or as a component (approximately 65%) of blended admixture products. Exposure for this group of workers is also expected to be relatively low, and the occupational health risk to these workers is low, for the reasons outlined above.

The occupational health risk for workers handling concrete containing the notified chemical is expected to be low. While exposure could potentially occur on a frequent basis, and for prolonged periods, the notified chemical will be present at low levels (< 0.5%).

Due to the potentially combustible nature of DPTB and of the DPTB blend, they should be isolated from open flames. Workers should also be aware that exposure to other potentially hazardous components of concrete and admixture products may occur and appropriate personal protective equipment should be worn when necessary to reduce exposure.

Public exposure to DPTB is possible in the event of an accident during transport and storage. The likelihood of this occurring is low, in view of the quality accredited transport and clean up and disposal protective measures. Public exposure may also occur through accidental contact with concrete during the construction of public buildings. However, the potential of this occurring is low, and is further

decreased because as the concrete cures, DPTB cross-links in the matrix of the concrete and is virtually sealed in the concrete. Volatilisation of DPTB from the hardened concrete is negligible, with no volatile emission being detected under controlled laboratory conditions. As a result, public exposure to the notified chemical in the occupancy of public buildings is anticipated to be negligible.

13. RECOMMENDATIONS

To minimise occupational exposure to propanol, [2-(1,1 dimethylethoxy) methylethoxy]- (DPTB) the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 {Standards Australia, 1994 #21} to comply with Australian/New Zealand Standard (AS/NZS) 1337 {Standards Australia/Standards New Zealand, 1992 #23};
- Industrial clothing should conform to the specifications detailed in AS 2919 {Standards Australia, 1987 #18};
- Impermeable gloves or mittens should conform to AS 2161 {Standards Australia, 1978 #17};
- All occupational footwear should conform to AS/NZS 2210 {Standards Australia/Standards New Zealand, 1994 #24};
- 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;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* {National Occupational Health and Safety Commission, 1994 #13}.

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

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

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

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Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
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