File No: PLC/205

January 2001

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

# **FULL PUBLIC REPORT**

#### IAPM4-2050

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals* (Notification and Assessment) Act 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director Chemicals Notification and Assessment

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# **FULL PUBLIC REPORT**

#### IAPM4-2050

# 1. APPLICANT

Grace Australia Pty Ltd of 1126-1134 Sydney Rd Fawkner VIC 3060 (ABN 41 080 660 117) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC) IAPM4-2050.

#### 2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report.

Marketing names: ADVA, WRDA, Daracem, MIRA

#### 3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

#### 4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

# 5. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer will be produced as a 50 % aqueous solution and is never isolated; the physical and chemical properties listed below are for the aqueous solution unless otherwise specified.

Property	Result	Comments
Appearance	colourless to light orange clear to cloudy or turbid liquid	
<b>Boiling point</b>	> 100°C	

**Density**  $1100 \text{ kg/m}^3$ 

Water solubility > 550 g/L the notified polymer is produced

as a 50% (w/w) solution containing 550 g/L notified

polymer

Particle size not applicable the notified polymer is never

isolated from solution

Flammability not flammable

Explosive properties not explosive

**Stability/reactivity** expected to be stable under

normal environmental

conditions

Hydrolysis as function

of pH

not determined

hydrolysis is not expected in the

environmental pH range

**Dissociation constant** not determined the notified polymer contains

partially neutralised carboxylate groups; the pH of the 50 %

(w/w) solution is 7

### 6. USE, VOLUME AND FORMULATION

#### Use:

The notified polymer will be used as a concrete additive, to reduce the water content in concrete mix production at the same time producing concrete mix with improved workability.

# Manufacture/Import volume:

The notifier has estimated that the import volume will be < 100 tonnes per annum in each of the first five years of importation.

#### Formulation details:

The notified polymer will be imported as a component of semi-finished or finished concrete additives under the names of ADVA, WRDA, Daracem, MIRA and possibly others. It will comprise approximately 25 % notified polymer in water, with other additives, including diethylene glycol, triethanolamine, defoamers, preservatives and surfactants. It will initially be imported as finished products, but may at some later date be imported in semi-finished form and reformulated in Australia by addition of additives such as defoamers. The additives containing the notified polymer will be diluted in concrete to a maximum notified polymer concentration of approximately 0.1 %.

The additives containing the notified polymer will be imported in 200 L drums and 1000 L totes, and possibly in future in bulk shipments.

# 7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
Reformulation		
Plant Operator	(10 workers, 2 hr/day, 20 days/year)	
dermal, 25 % solution	exposure to drips and spills in possible while connecting an disconnecting transfer hoses; only when reformulation of semi-finished products commences	d face shield or goggles if splashes y are likely; impervious gloves
Supervisor (5 we	orkers, 1 hr/day, 20 days/year)	
dermal, 25 % solution	limited exposure is expected; exposure scenarios should be similar to plant operators	safety glasses with side shields; face shield or goggles if splashes are likely; impervious gloves
Quality Control	(5 workers, 1 hr/day, 20 days/year)	
dermal, 25 % solution	dermal exposure to small quantities during sampling and testing reformulated products	safety glasses with side shields; face shield or goggles if splashes are likely; impervious gloves
Distribution		
Salesman (15 we	orkers, 4 hr/day, 6 days/year)	
dermal, 25 % solution	dermal exposure is possible during hand dispensing of additive and mixing concrete in small batch test runs	safety glasses with side shields; face shield or goggles if splashes are likely; impervious gloves
Technical Service	ce (5 workers, 4 hr/day, 12 days/year)	
dermal, 25 % solution	exposure scenarios should be similar to salesmen	safety glasses with side shields; face shield or goggles if splashes are likely; impervious gloves
Dispenser Techn	nician (5 workers, 4 hr/day, 5 days/yea	r)
dermal, 25 % solution	potential dermal exposure to additive and concrete mix during trials of newly installed automatic dispensing systems	safety glasses with side shields; face shield or goggles if splashes are likely; impervious gloves
Concrete Produ	ction	
Quality Control	(25 workers, 4 hr/day, 20 days/year)	
dermal, 25 % solution	exposure scenarios should be similar to salesmen; also exposure to concrete mix during sampling and testing	rubber boots, impervious gloves
Batch Superviso	r (25 workers, 0.5 hr/day)	
dermal. 0.1 %	little exposure is expected due to	additive dispensing via automated
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in concrete	automated nature of mixing equipment	equipment; rubber boots, impervious gloves
Concrete Truck I	Driver (400 workers, 4 hr/day, 10 days	s/year)
dermal. 0.1 % in concrete	exposure to fresh concrete while connecting and disconnecting delivery equipment and while washing out the truck	rubber boots, impervious gloves
Labourer (100 w	orkers, 4 hr/day, 10 days/year)	
dermal. 0.1 % in concrete	general labour at concrete production plant; possible exposure to fresh concrete during a variety of tasks	rubber boots, impervious gloves

### Concrete End Use

Placing and Finishing Crew (1000 workers, 8 hr/day, 10 days/year)

dermal. 0.1 % widespread dermal exposure to rubber boots, impervious gloves fresh concrete while shovelling, in concrete consolidating raking, and trowelling poured concrete

Job-site Technicians (100 workers, 6 hr/day, 10 days/year)

dermal. 0.1 % exposure to small quantities of rubber boots, impervious gloves fresh concrete during sampling in concrete and testing

# Transport and storage

Truck Driver (10 workers, 40 days/year)

dermal, 25 % exposure expected for protective equipment solution deliveries in drums or totes; packaged delivery; safety glasses with side shields; face shield or dermal exposure to drips and spills is likely for truck drivers goggles if splashes are impervious gloves, in case of bulk connecting and disconnecting transfer hoses during bulk deliveries deliveries

Forklift Driver (8 workers, 20 days/year)

the notified polymer will only be none none

handled in sealed containers and no exposure is expected except in

case of an accident

#### 8. **PUBLIC EXPOSURE**

Public exposure to the notified polymer is not expected prior to incorporation into concrete, as it will only be used in an industrial environment. The notified polymer is expected to be present at a concentration of approximately 0.1 % in a typical batch of concrete. Once the

for

concrete has hardened the notified polymer will be bound within the concrete matrix with minimal migration. Therefore, public exposure to the notified polymer is expected to be low.

#### 9. ENVIRONMENTAL EXPOSURE

# 9.1. Release

#### Reformulation Site

The notifier states that release of the notified polymer will be limited to fugitive emissions, including loading and unloading of containers, and during transport, but has not provided an estimation of the quantities. Spillage of ADVA is expected to occur during transfer from importation containers to bulk delivery tankers, it is estimated that up to 1 % (< 1 tonne per annum) will be lost in this way. Any material spilt at these sites will be contained by secondary containment and will be directed to water recycling tanks. The transfer lines and transport tankers will be cleaned and any resultant wash water will be recycled in to the bulk storage tanks.

The residue in transport drums is estimated to be 1%, which equates to a maximum of 1 tonne per annum of the notified polymer.

# Concrete Production Site

The unloading of ADVA from the tanker trucks to the on-site storage tank will be via a sealed delivery system, thus minimising any loss due to spills. The amount of loss due to spills is likely to be less than 1 %, or 1 tonne of notified polymer per annum.

There is also potential for release of notified polymer via waste water from external and internal washing of ready mix concrete mixing trucks. The notifier stated that the drum of a concrete truck is washed after each load. The resultant wash water (approximately 189 L) will be kept in the drum and used to make up the next batch or sent to concrete settling basins. The trucks are completely washed at the end of each day with the wash water (approximately 568 L) going to the settling basins. This waste water is stored temporarily in concrete settling bays and then reused in subsequent admixtures. The notifier estimates the maximum amount of the notified polymer in the settling basin is approximately 50 ppm. Assuming the settling bay has a volume of 30000 L, and a concentration of 50 ppm, at 50 % capacity (ie 15000 L) approximately 0.75 kg of notified polymer will be present in the water. Any solids that may settle out of the washwater are likely to be disposed of in accordance with State regulation, which means it is likely that they go to landfill.

Any surplus wet concrete will be returned to the producer's site. The notifier has stated that the majority of the notified polymer will be bound within the concrete matrix where minimal migration of the notified polymer is expected.

The potential total release of notified polymer, from the reformulation site and the concrete producer and users, is estimated to be less than 2000 kg per annum. However, this value is likely to be reduced further where spillage and contaminated wash out water is contained and reused to make subsequent admixtures.

#### 9.2. Fate

The majority of the notified polymer will be bound within the matrix of the concrete and once hardened, it will remain immobile. Thus its fate will be linked to the disposal of the concrete fabrications into which it has been incorporated. The concrete rubble from building demolitions is usually directed to landfill where the notified chemical is expected to remain immobile and not leach out.

If spilt material cannot be recycled then it is likely that it will end up in landfill, along with spill clean-up absorbants. Container residue may be disposed of to landfill if it cannot also be recycled. Due to its solubility, the notified polymer is not likely to adsorb to soil but rather to leach out. It is possible that the notified polymer may enter the aquatic compartment in drum and truck wash-out water.

No information was provided regarding the degradability of the notified polymer. It is possible that the notified polymer will partition between solution and sorbed phase (bound to aquatic sediments and organic particles in suspension) through the presence of reactive carboxyl and ether functional groups. Under these circumstances it is anticipated that the notified polymer will degrade very slowly via biotic and abiotic processes. Polymers of high molecular weight are considered to be impermeable to biological membranes (Connell, 1990) and consequently bioaccumulation of the notified polymer is not expected.

#### 10. EVALUATION OF TOXICOLOGICAL DATA

#### **10.1** Acute Toxicity

Toxicity testing was performed using IAPM4-2050, containing 50 % notified polymer (v/v) in water.

# **Summary of the acute toxicity of IAPM4-2050**

Test	Species	Outcome	Reference
acute oral toxicity	rat	$LD_{50} > 2000 \text{ mg/kg}$	(Graver, 2000)
acute dermal toxicity	rabbit	$LD_{50} > 2000 \text{ mg/kg}$	(Cerven, 2000a)
skin irritation	rabbit	non-irritant	(Hoff, 2000)
eye irritation	rabbit	slight irritant	(Cerven, 2000b)
skin sensitisation	guinea pig	non-sensitiser	(Hall, 2000a) (Hall, 2000b)

# **10.1.1 Oral Toxicity (Graver, 2000)**

Species/strain: rat/Wistar

Number/sex of animals: 5/sex

*Observation period:* 14 days

Method of administration: gavage; used as received; dose level 2000 mg/kg

Test method: OECD TG 401

Mortality: there were no premature decedents during the study

Clinical observations: one female lost weight during the second week of the study;

no other clinical signs of toxicity were observed

Morphological findings: no gross abnormalities were observed at necropsy

 $LD_{50}$ : > 2000 mg/kg

Result: the test substance was of very low acute oral toxicity in rats

# 10.1.2 Dermal Toxicity (Cerven, 2000a)

Species/strain: rabbit/New Zealand White

*Number/sex of animals:* 5/sex

*Observation period:* 14 days

Method of administration: occlusive patch; test substance used as received; dose level

2000 mg/kg; 24 hr exposure

Test method: OECD TG 402

Mortality: there were no premature decedents during the study

Dermal observations: no erythema or oedema were observed

Clinical observations: one male lost weight during the first week of the study and

one female lost weight during the second week of the study; instances of few faeces were noted in one male; one female (F2707) had a prolapsed vagina with reddish discharge; no

other clinical signs of toxicity were observed

Morphological findings: one female (F2707) had a discoloured kidney and bladder;

no other gross abnormalities were observed at necropsy

 $LD_{50}$ : > 2000 mg/kg

Result: the test substance was of low dermal toxicity in rats

# 10.1.3 Skin Irritation (Hoff, 2000)

Species/strain: rabbit/New Zealand White

*Number/sex of animals:* 3 female

Observation period: 3 days

Method of administration: semi-occlusive patch; test substance used as received; dose

0.5 mL; 4 hr exposure

Test method: OECD TG 404

Comment: all Draize scores for erythema and oedema were zero

Result: the test substance was not irritating to the skin of rabbits

# 10.1.4 Eye Irritation (Cerven, 2000b)

Species/strain: rabbit/New Zealand White

*Number/sex of animals:* 4 male 2 female

Observation period: 21 days

Method of administration: 0.1 mL test substance (as received) was placed in the

conjunctival sac of one eye; the other eye served as control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

# Time after instillation

Animal	1 h	our	1 0	lay	2 d	lays	3 d	ays	7 d	ays
Cornea	0	а	0	a	0	а	0	a	0	a
1♂	<sup>1</sup> 0	0	0	0	0	0	0	0	0	0
2♂	2	1	2	1	2	1	2	1	2	1
3♀	0	0	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♂	(	)	(	)	(	C	(	)	(	)
2♂	(	)	(	)	(	)	(	)	(	)
3♀	1	1	(	)	(	)	(	)	(	)
4♂	(	)	(	)	(	)	(	)		
5♂	(	)	(	)	(	O	(	)		
6♀	(	)	(	)	(	)	(	)		

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

<sup>1</sup> see Attachment 1 for Draize scales

o = opacity a = area r = redness c = chemosis d = discharge

Comment: three animals were treated initially

the corneal scores for animal 2 remained unchanged to the study termination at day 21; the conjunctival effects for this animal algored by day 10.

animal cleared by day 10

the scores for animal 2 were considered by the study authors to possibly be due to a self-inflicted injury and a further group of 3 animals were treated; no similar effects were

observed

Result: the test substance was slightly irritating to the eyes of rabbits

#### 10.1.5 Skin Sensitisation

# (a) Buehler Method (Hall, 2000a)

Species/strain: guinea pig/Hartley Albino

Number of animals: test group: 10/sex

control group: 5/sex

*Induction procedure:* 

test group:

days 1, 8, 15 0.4 mL of test substance (as received) was applied by

occlusive chamber to a clipped area of the left shoulder for 6 hr; residual test substance was removed with distilled water

control group: control group animals were not treated during the induction

phase

Challenge procedure:

day 29 0.4 mL of test substance (as received) was applied by

occlusive chamber to a clipped area of the left hip for 6 hr,

for both test and control groups

# Challenge outcome:

	Test a	nimals	Control animals		
Challenge concentration	24 hours*	48 hours*	24 hours	48 hours	
100 %	**0/20	0/20	0/10	0/10	

<sup>\*</sup> time after patch removal

Result: the test substance was not sensitising to the skin of guinea

pigs

# (b) Maximisation Method (Hall, 2000b)

Species/strain: guinea pig/Hartley Albino

Number of animals: test group: 10/sex

control group: 5/sex

Induction procedure:

test group:

day 1

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 distilled water;
- 2. 0.1 mL 75 % test substance in distilled water;
- 3. 0.1 mL 75 % test substance in distilled water 50 % v/v with FCA

day 7

local irritation was induced at the shaved test site for both test and control groups by application of 0.5 mL of sodium lauryl sulphate

day 8

test substance as supplied (approximately 0.2 mL) was applied by occlusive patch to the same site that received the intradermal injections for 48 hours

control group:

day 1

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 distilled water;
- 2. 0.1 mL distilled water;
- 3. 0.1 mL of Freund's Complete Adjuvant (FCA) 50 % v/v in distilled water;

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<sup>\*\*</sup> number of animals exhibiting positive response

day 7,8

a similar topical induction procedure to that for the test animals was used but distilled water was used in place of the test substance

# Challenge procedure:

day 22

patches of approximately 2 cm square were saturated with approximately 0.1 mL of test substance as received and applied to the shaved left flank of each animal under occlusive conditions for 24 hr

dermal reactions were scored at 24 and 48 hours after patch

removal

Test method:

OECD TG 406 (Magnusson and Kligman Method)

# Challenge outcome:

	Test a	nimals	Control animals		
Challenge concentration	24 hours*	48 hours*	24 hours	48 hours	
100 %	**0/20	0/20	0/10	0/10	

<sup>\*</sup> time after patch removal

Comment: erythema Grade 1 was observed in 10 test animals and

erythema Grade 2 was observed in 3 test animals following

topical induction

one test animal lost weight; instances of diarrhoea, soiling of the anogenital area, few faeces and emaciation were

observed during the observation period

Result: the test substance was not sensitising to the skin of guinea

pigs

# 10.2 Genotoxicity

# 10.2.1 Salmonella typhimurium Reverse Mutation Assay (Wagner & Klug, 2000)

Strains: Salmonella typhimurium TA98, TA100, TA1535 and

TA1537; Escherichia coli WP2uvrA(pKM101)

Metabolic activation: 10 % rat liver S9 fraction (Aroclor 1254-induced) in

standard cofactors

Concentration range: 5000, 3333, 1000, 333 and 100 µg/plate, dissolved in water

and plated as a 50 µL aliquot

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<sup>\*\*</sup> number of animals exhibiting positive response

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

WP2uvrA: 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

no precipitation or signs of appreciable toxicity manifested

in thinning of the background lawn were observed

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 test substance was non mutagenic under the conditions

of the test

### 10.3 Overall Assessment of Toxicological Data

The test substance, consisting of 50 % notified polymer (v/v) in water, was found to have very low acute oral toxicity in rats ( $LD_{50} > 2000/mg/kg$ ) and low acute dermal toxicity in rabbits ( $LD_{50} > 2000 \text{ mg/kg}$ ). It was not a skin irritant in rabbits, nor was it a skin sensitiser in guinea pigs when tested by both the Buehler and Maximisation methods. It showed slight eye irritation potential in rabbits, with iritis which cleared by 24 hours in one animal, and conjunctival effects which cleared by 72 hours in five out of six animals. The sixth animal showed conjunctival effects beyond seven days after treatment, and corneal opacity persisting beyond 21 days; it is possible that this animal had a self inflicted eye injury, as similar results were not observed for the other animals. The irritation scores are not sufficient for the test substance to be classified as an eye irritant in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999). The test substance was not found to be a mutagen in a bacterial mutagenicity assay.

No other toxicology studies were provided, and the test substance cannot be classified against the Approved Criteria for other end points.

The notified polymer is of very high molecular weight and low reactivity, and is not expected to easily cross biological membranes. It contains low levels of hazardous residual monomers.

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#### 11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

#### 12. ENVIRONMENTAL RISK ASSSESSMENT

The majority of the notified polymer will be incorporated into the matrix of the concrete. Once solidified, the notified polymer is expected to pose minimum risk to the environment.

There is potential for up to 2000 kg per annum of the notified polymer to be released into the environment as a consequence of spillage, drum residues and truck washing. The spillage is expected to be dispersed and not restricted to a single site. This would minimise the degree of risk to the environment at any given time. If the spilt imported material or raw product cannot be recycled then it is likely that it will end up in landfill adsorbed to the inert material used for the spill clean-up (such as sand), where it is likely to leach out in a diffuse manner at low concentrations.

The main environmental hazard would arise from release of the notified polymer during storage or transport. The use of bunded containment minimises the risk of release at storage sites. The Material Safety Data Sheet (MSDS) appears to adequately address spills and disposal.

A further environmental hazard could arise from release of untreated polymer-contaminated water into the aquatic compartment. This risk is greatly reduced by recycling truck wash water discharged into concrete settling basins for subsequent batches of cement.

The low expected environmental exposure of the notified polymer when integrated into concrete, suggest the overall environmental hazard should be minimal.

#### 13. HEALTH AND SAFETY RISK ASSESSMENT

#### 13.1. Hazard assessment

The notified polymer has very low acute oral toxicity ( $LD_{50} > 2000$  mg/kg) in rats and low dermal toxicity ( $LD_{50} > 2000$  mg/kg) in rabbits. It was found to not be irritating to rabbit skin or sensitising to guinea pig skin. It was a slight eye irritant in rabbits. It was found to be non-mutagenic in a bacterial point mutation assay. It is therefore not classified as a hazardous substance for these endpoints in accordance with the Approved Criteria. No data was provided for other endpoints, and no classification for these endpoints can be determined. The notified polymer is not highly reactive and has a high molecular weight, therefore it will not readily cross biological membranes.

The MSDS indicates that health effects such as eye, nose and throat irritation, headache, stomach pain, nausea and vomiting may occur on exposure to IAPM4-2050.

# 13.2. Occupational health and safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage of the concrete additives containing this polymer. There may be exposure during the reformulation of the semi-finished concrete additives and during preparation of concrete containing the polymer.

During reformulation and end use, the main exposure route for the notified polymer will be dermal. While the mixing and dosing operations are automated, exposure to drips and spills of the additives (approximately 25 % notified polymer) is possible at a number of points where these products are transferred. Once the additive has been dosed into concrete, the final concentration will be very low (< 0.1 %) and little exposure is therefore expected.

Precautions should be taken to avoid ocular contact with the products containing the notified polymer, as slight eye irritation may occur. The notifier stated that impermeable gloves and eye protection, including a face shield if splashes are considered likely, should be worn.

Once the final concrete mix, containing a maximum of 0.1 % notified polymer, has hardened, the polymer will not be separately available for exposure or absorption.

#### Conclusion

IAPM4-2050 is of low concern to human health and safety and no additional risk reduction measures are necessary.

#### 13.3. Public health

The imported IAPM4-2050 solution and additives containing the notified polymer will be used exclusively for industrial applications. The notified polymer is expected to be present at a very low concentration in the end use concrete mix. Once the concrete has hardened the notified polymer will be bound within the concrete matrix with minimal migration. The actual concentration of the notified polymer that the public may be exposed to is expected to be minimal, and will not post a significant health hazard.

#### 14. MSDS AND LABEL ASSESSMENT

#### 14.1. MSDS

The MSDS of the product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

# 14.2. Label

The label for the product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

#### 15. RECOMMENDATIONS

To minimise occupational exposure to IAPM4-2050, the following guidelines and precautions should be observed:

- Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the products containing the notified polymer;
- 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.

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

Guidance in selection of protective eyewear 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 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994).

#### 16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification may be required if:

- (i) any of the circumstances stipulated under subsection 64(2) of the Act arise. If any importer or manufacturer of the notified polymer becomes aware of any of these circumstances, they must notify the Director within 28 days; or
- (ii) the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

#### 17. REFERENCES

Cerven, D.R. (2000a) Acute Dermal Toxicity/LD<sub>50</sub> in Rabbits: RW 8040W, Project No. MB-99-7798.02, MB Research Laboratories, Spinnerstown, PA, USA (unpublished report).

Cerven, D.R. (2000b) Primary Eye Irritation/Corrosion in Rabbits: RW 8040W, Project No. MB-99-7798.04, MB Research Laboratories, Spinnerstown, PA, USA (unpublished report).

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

Graver, K.B. (2000) Single Dose Oral Toxicity in Rats/LD<sub>50</sub> in Rats: RW 8040W, Project No. MB-99-7798.01, MB Research Laboratories, Spinnerstown, PA, USA (unpublished report).

Hall, D. (2000a) Delayed Contact Dermal Sensitization Test – Buehler Method: IAPM4-2050, Project No. MB-00-8172.06, MB Research Laboratories, Spinnerstown, PA, USA (unpublished report).

Hall, D. (2000b) Guinea Pig Maximization Test (Magnusson-Kligman): RW 8040W, Project No. MB-99-7798.06, MB Research Laboratories, Spinnerstown, PA, USA (unpublished report).

Hoff, T. (2000) Primary Dermal Irritation/Corrosion in Rabbits: RW 8040W, Project No. MB-99-7798.03, MB Research Laboratories, Spinnerstown, PA, USA (unpublished report).

National Occupational Health and Safety Commission (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia/Standards Association of New Zealand.

Wagner, V.O. and Klug, M.L. (2000) Bacterial Reverse Mutation Assay: IAPM4-2050, Project No. PO 500581, BioReliance, Rockville, MD, USA (unpublished report).

#### **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	2 mod.	Obvious swelling with partial eversion of lids Swelling with lids half-	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
easily discernible		closed	3 mod.	Discharge with	3 severe
Diffuse beefy red	3 severe	Swelling with lids half- closed to completely closed	4 severe	moistening of lids and hairs and considerable area around eye	

# 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.