

File No: NA/505

Date: July 1997

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

2-Acrylamido-2-methylpropanesulfonic acid, ammonium salt

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 Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

Monday - Wednesday	8.30 am - 5.00 pm
Thursday	8.30 am - 8.00 pm
Friday	8.30 am - 5.00 pm

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**2-Acrylamido-2-methylpropanesulfonic acid, ammonium salt****1. APPLICANT**

Lubrizol International Inc. of 28 River Street SILVERWATER NSW 2141 has submitted a standard notification statement in support of their application for an assessment certificate for '2-acrylamido-2-methylpropanesulfonic acid, ammonium salt'. No requests for exempt information were made by the notifier and the assessment report for the notified chemical is published here in its entirety.

2. IDENTITY OF THE CHEMICAL

Chemical Name: 2-acrylamido-2-methylpropanesulfonic acid, ammonium salt

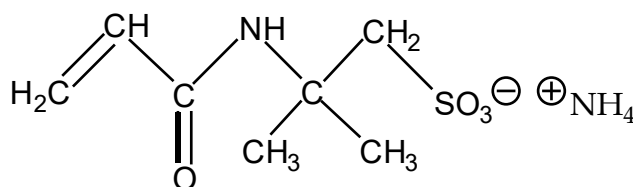
Chemical Abstracts Service (CAS) Registry No.: 58374-69-9

Other Names: OS 114452
Ammonium AMPS® (50% aqueous solution)
OS 114454 (50% aqueous solution)
OS 87613M (50% aqueous solution)

Trade Name: LZ 2411

Molecular Formula: C₇H₁₃NO₄.NH₃

Structural Formula:



Molecular Weight: 224 (calculated)

Methods of Detection and Determination: ultraviolet/visible, infrared and nuclear magnetic resonance spectra were provided for the notified chemical

Spectral Data: Major peaks were found in the infrared spectrum at: 3 304, 1 656, 1 625, 1 548, 1 465, 1 410, 1 376, 1 210, 1 041, 1 107, 965, 915 cm⁻¹

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white powder
Melting Point:	191°C [92/69/EEC A1 - Capillary Method (1)]
Boiling Point:	not determined
Specific Gravity:	1.39 at 22°C [92/69/EEC A3 - Pycnometer (1)]
Vapour Pressure:	7.4 x 10 ⁻¹² kPa at 25°C [92/69/EEC A4 - Vapour Pressure Balance (1)]
Water Solubility:	> 761 g/L at 25°C [92/69/EEC A6 - Shake flask (1)]
Partition Co-efficient (n-octanol/water):	log P _{ow} = -3.41 at 22°C [92/69/EEC A8 - Shake flask (1)]
Hydrolysis as a Function of pH:	not determined - see comments below
Adsorption/Desorption:	Soil Adsorption coefficient < 58.9 Log ₁₀ K _{oc} < 1.77 [draft German HPLC Screening Method (2)]
Dissociation Constant:	not determined - see comments below
Surface Activity:	65.8 mN/m at 18.5°C and 1 g/L [92/69/EEC A5 (1)]
Fat Solubility:	< 0.5 mg/100 g fat at 37.0°C [84/449/EEC A7 - Flask shaking (1)]
Flash Point:	not determined
Flammability Limits:	not highly flammable
Autoignition Temperature:	> 191°C
Explosive Properties:	nil

Reactivity/Stability: non oxidising, contains no oxidising groups

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice. The physical and chemical data are for the pure notified chemical (OS 114452).

Vapour pressure was determined using a vapour pressure balance with measurements being made at several temperatures and linear regression analysis used to calculate it at 25°C.

Hydrolysis testing was not performed. However, the notifier supplied test results for a similar material, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt (the notified chemical is the ammonium salt).

<i>pH</i>	<i>Temperature</i>	<i>% Hydrolysed</i>	<i>At time</i>
12	50°C	< 10%	7 days
12	80°C	50%	5 days

Hydrolysis results for the parent acid, 2-acrylamido-2-methylpropanesulfonic acid are as follows:

<i>pH</i>	<i>Temperature</i>	<i>% Hydrolysed</i>	<i>At time</i>
1	50°C	< 1%	7 days
1	80°C	50 %	7 days

Based on these results, and considering the notified chemical's structure, hydrolysis under environmental conditions is expected to be extremely slow, *ie* in the order of years.

The soil adsorption coefficient indicates that the notified chemical will be highly mobile in soils (3). This is consistent with its high water solubility. The notified chemical is an ammonium salt of a sulphonic acid, and as such is expected to remain highly ionised in the environment.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (1).

4. PURITY OF THE CHEMICAL

Degree of Purity: 95-100%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities: impurities were determined for the parent acid form of the notified chemical

Name	CAS Number	Weight
2-acrylamido-2-methyl-1,3-propane-disulfonic acid, ammonium salt	—	0.5 -1.5%
2-propenamide	79-06-1	846 ppm
2-propenenitrile	107-13-1	436 ppm
N-(1,1-dimethylethyl)-2-propenamide	107-58-4	2138 ppm
2-methyl-2-propene-1-sulfonic acid	3934-16-5	26.3 ppm
2-methylene-1,3-propanedisulfonic acid	1561-93-9	135 ppm

Additives/Adjuvants:

Name	CAS Number	Weight
4-methoxyphenol	150-76-5	424 ppm

5. USE, VOLUME AND FORMULATION

2-Acrylamido-2-methylpropanesulfonic acid, ammonium salt will not be manufactured in Australia but will be imported as a 50% aqueous solution for incorporation into polymers. These polymers are expected to be used mainly in the paints and adhesive industries.

In a typical polymer, the notified chemical will be at a concentration of approximately 5% by weight. It would be polymerised with other monomers such as ethyl acrylate, butyl acrylate, vinyl acetate, ethylene, styrene and/or butadiene. The resulting polymers will be used at a concentration of about 30% in paints or other coatings. The notified chemical will therefore be present as a polymer component at a concentration of approximately 1.5%.

Polymers containing 2-acrylamido-2-methylpropanesulfonic acid, ammonium salt are said by the notifier to have better mechanical stability, and to better stabilise the paint emulsion.

Overall import volume is expected by the notifier to increase progressively from 5 tonnes in the first year to 50 tonnes in the fifth year of imports.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported as a 50% aqueous solution. Transport of the chemical to industrial sites for paint or other polymer formation, is expected to be by truck or rail contained in drums or tank car. Transport workers may be dermally exposed to the notified chemical while transferring the notified chemical between bulk containers. During the first year of sales, transport is expected to be in smaller drum quantities, which will minimise exposure for transport workers.

In a typical application, acrylic monomers and the notified chemical are mixed together to give the desired latex and polymerisation is initiated. 2-acrylamido-2-methylpropanesulfonic acid, ammonium salt would typically represent approximately 5% by weight of the total monomers used. The notifier states that, production of the

latex is expected by to be a highly automated process utilising appropriate engineering controls and trained personnel. However the notifier states that they have no control over the processes employed by clients who purchase the notified chemical for industrial coatings manufacture. The polymerisation would typically involve up to four workers per shift, 8 hours per shift. The principal routes of exposure will be via the skin and inhalation during these processes.

Workers in paint and other surface coatings manufacturing industries may be exposed to the notified chemical via dermal and inhalation routes when workers prepare the polymer products. In a typical polymer, the notified chemical would be present at approximately 5% by weight. The resulting polymer, at about 30% concentration, is used to make up paints or other coatings where the notified chemical will be present as a component at approximately 1.5%.

There is also the potential for dermal, inhalational and ocular exposure to the notified chemical in the form of residual monomer in polymers. This may occur when professional painters and coating users apply the paint product using spray, brush or roller equipment. Should contact occur during mixing or application, the paint is likely to remain on the skin for some time, hence prolonging exposure.

7. PUBLIC EXPOSURE

The notified chemical will be distributed to customers in drums or tank cars by either truck or rail, and as such, no public exposure to the notified chemical is expected to occur during its distribution.

The notifier has stated that although they are not aware of details relating to the manufacture of polymers, paints and adhesives they anticipate that appropriate measures will be used to reduce the potential for public exposure to the notified chemical. Such measures would include, but not be limited to, catch pans, automated processes and the use of appropriate waste handling procedures.

Disposal of any waste notified chemical will be by incineration. It is anticipated that any spillage will be appropriately bunded and disposed of. Disposal of the notified chemical is not expected to result in significant public exposure.

Although the public may come into contact with paints and adhesives containing the notified chemical, given its low concentration in such end use products, exposure levels would be low.

8. ENVIRONMENTAL EXPOSURE

Release

The process by which the notified chemical is polymerised with other monomers is claimed to be highly automated, using appropriate engineering controls. As such, any release during the processing is expected to be properly contained. Water will be used to clean any equipment, such as transfer lines, after use. Any wastes from

this process, including wash waters, will be disposed of to either licensed facilities on-site, or to a contract waste water treatment facility. The notifier did not give an indication of the expected volume of monomer to be disposed of in this way. However, due to the highly automated process, it is expected that losses through this route will be small.

The monomer will be supplied to various industrial customers. Polymers, manufactured using the notified chemical at levels up to 5%, are expected to have residual levels of the monomer at less than 0.1%. The notifier claims that these polymers are stable and not expected to decompose or depolymerise to release the monomer under normal conditions. Thus exposure from the use of paints and other products containing a polymer manufactured with the notified chemical under normal conditions of use is minimal.

Fate

The majority of the notified chemical will be incorporated into polymers that will be used in the manufacture of paints and coatings. As such, the fate of the monomer is tied to the fate of the polymer, and thus the paint or coatings product. Generally, paints and coatings cross-link upon curing, resulting in the monomer becoming part of a solid polymer matrix. As part of a polymerised coat, no hydrolysis, movement, biodegradation or bioaccumulation of the polymer is expected. Incineration of the monomer is expected to produce water, and oxides of carbon, nitrogen and sulphur. Any chips and flakes of the cured paint or coating that occur (due to stone chips, accidents, wear and tear, etc) will be inert, diffuse and form part of the soil or sediments.

Losses through polymer manufacture will be sent to a waste water treatment process. Here the notified chemical is not expected to bind to the soil or organic fraction of the sludge. It is expected to remain in the aquatic compartment, entering the environment in the liquid effluent discharged from the plant.

The notified chemical (as a 50% aqueous solution) was evaluated to be not readily biodegradable in the OECD 301B CO₂ Evolution (Modified Sturm) Test (4). At the end of the 28 day test period, the notified chemical gave a degradation level of 3.22%. The chemical was found to be non-toxic to the microbial populations in the inoculum, which is consistent with the findings of the separate study, the activated sludge inhibition test (see the Environmental Effects section below).

The chemical's high water solubility (> 761 mg/L), resistance to hydrolysis, expected high degree of ionisation and low log partition coefficient (-3.41) all indicate that it should not bioaccumulate (5).

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicity tests were carried out on a number of forms of the notified chemical, as indicated below:

9.1 Acute Toxicity

Test Material	Test	Species	Outcome	Reference
OS 87613M (50% aqueous solution)	acute oral toxicity	rat	LD ₅₀ > 5 000 mg/kg	(6)
OS 114454 (50% aqueous solution)	acute dermal toxicity	rat	LD ₅₀ > 2 000 mg/kg	(7)
OS 114452 (notified chemical)	skin irritation	rabbit	non-irritant	(8)
OS 114452 (notified chemical)	eye irritation	rabbit	slight irritant	(9)
OS 114454 (50% aqueous solution)	skin sensitisation	guinea pig	non-sensitising	(10)

9.1.1 Oral Toxicity (6)

<i>Species/strain:</i>	rat/Crl:CD-BR (albino)
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Test material:</i>	OS 87613M (50% aqueous solution)
<i>Method of administration:</i>	gastric intubation
<i>Clinical observations:</i>	diarrhoea in 3 rats on the day of dosing only
<i>Mortality:</i>	nil
<i>Morphological findings:</i>	no test related gross findings
<i>Test method:</i>	similar to OECD guidelines (4)
<i>LD₅₀:</i>	> 5 000 mg/kg
<i>Result:</i>	the notified chemical was of very low acute toxicity in a limit test in rats

9.1.2 Dermal Toxicity (7)

<i>Species/strain:</i>	rabbit/New Zealand White
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Test material:</i>	OS 87613M (50% aqueous solution)

<i>Method of administration:</i>	single dose (2 000 mg/kg) applied to a clipped area of skin, covered with gauze patch and secured with non irritating tape; dressing was removed and wiped with deionised water at 24 hours
<i>Clinical observations:</i>	some local irritation was noted at the application site; all animals gained weight over period, no other test related clinical findings
<i>Mortality:</i>	nil
<i>Morphological findings:</i>	two animals with red lungs at autopsy; this result was not obviously test related
<i>Test method:</i>	according to OECD guidelines (4)
<i>LD₅₀:</i>	> 2 000 mg/kg
<i>Result:</i>	the notified chemical was of low acute dermal toxicity in rabbits

9.1.3 Inhalation Toxicity

Not performed.

9.1.4 Skin Irritation (8)

<i>Species/strain:</i>	rabbit/New Zealand White
<i>Number/sex of animals:</i>	3/sex
<i>Observation period:</i>	3 days
<i>Test material:</i>	OS 114452 (notified chemical)
<i>Method of administration:</i>	0.5 g single dose applied to a clipped area of skin, moistened with 0.2 mL deionised water, covered with gauze patch, over-wrapped with gauze binder, and secured with tape; dressing was removed and site wiped with tepid tap water at 4 hours
<i>Draize scores (11):</i>	all erythema and oedema scores from 1 day after treatment were zero
<i>Test method:</i>	similar to OECD guidelines (4)
<i>Result:</i>	the notified chemical was not a skin irritant in rabbits

9.1.5 Eye Irritation (9)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/sex

Observation period: 3 days

Test material: OS 114452 (notified chemical)

Method of administration: single 32 mg dose instilled into lower conjunctival sac of right eye, left eye used as control

Draize scores (11) of unirrigated eyes:

<i>Animal</i>	<i>Time after instillation</i>														
	<i>1 day</i>			<i>2 days</i>			<i>3 days</i>			<i>4 days</i>			<i>7 days</i>		
<i>Conjunctiva</i>	<i>r^a</i>	<i>c^b</i>	<i>d^c</i>	<i>r^a</i>	<i>c^b</i>	<i>d^c</i>	<i>r^a</i>	<i>c^b</i>	<i>d^c</i>	<i>r^a</i>	<i>c^b</i>	<i>d^c</i>	<i>r^a</i>	<i>c^b</i>	<i>d^c</i>
1	2	1	0	2	0	0	0	0	0	0	0	0	0	0	0
2	1	1	0	1	0	0	1	0	0	0	0	0	0	0	0
3	1	1	1	1	0	0	1	0	0	0	0	0	0	0	0
4	1	1	0	1	1	0	1	0	0	0	0	0	0	0	0
5	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
6	1	1	0	1	0	0	1	0	0	0	0	0	0	0	0

¹ see Attachment 1 for Draize scales

^a redness ^b chemosis ^c discharge

All corneal and iridial scores were zero at all times

Test method: according to OECD guidelines (4)

Result: the notified chemical is a slight eye irritant when tested in rabbits

9.1.6 Skin Sensitisation (10)

Species/strain: guinea pig/Dunkin-Hartley strain

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

Test material: OS 114454 (50% aqueous solution)

Induction procedure: Day 1: 3 pairs of intradermal injections:
- 0.1 mL Freund's Complete Adjuvant (FCA): bi-distilled water (1:1 (v/v))

- 0.1 mL of 20% concentration of test material in water
- 0.1 mL of 20% concentration of test material in FCA:saline (1:1 (v/v))

Day 7: occluded application of 20% concentration of test material in distilled water for 48 hours

Challenge procedure:

Day 14: occluded application of 10% and 5% solution of test material in distilled water for 24 hours

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	48 hours*	24 hours	48 hours
5%	0/10**	0/10	1/5	1/5
10%	1/10	1/10	0/5	0/5

* time after patch removal

** number of animals exhibiting positive response

Test method:

according to OECD guidelines (4)

Result:

the notified chemical shows minimal potential for skin sensitisation in guinea pigs

9.2 Repeated Dose Toxicity (12)

Species/strain:

rat/Sprague-Dawley Crl:CD-(SD)BR

Number/sex of animals:

40/sex; Group 1: 10/sex
Group 2: 5/sex
Group 3: 5/sex
Group 4: 10/sex
Group 5: 10/sex

Test material:

OS 114454 (50% aqueous solution)

Method of administration:

oral gavage

<i>Dose/Study duration:</i>	the test material was administered daily for a period of 28 days: Group 1: 0 mg/kg/day Group 2: 50 mg/kg/day Group 3: 150 mg/kg/day Group 4: 400 mg/kg/day Group 5: 1 000 mg/kg/day
	5 animals/sex were maintained from Groups 1, 4 and 5 were maintained for an additional 2 week treatment-free period before sacrifice
<i>Clinical observations:</i>	possible adverse signs (lethargy, watery stool, decreased faecal volume) in 1 male for first week in high dose group (1 000 mg/kg), recovered by end of week 2, no other treatment related observations
<i>Clinical chemistry/Haematology</i>	no treatment related findings
<i>Histopathology:</i>	no treatment related findings
<i>Test method:</i>	according to OECD guidelines (4)
<i>Result:</i>	the notified chemical has very low toxicity when administered to rats daily for a period of 28 days

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (13)

<i>Strains:</i>	<i>S. typhimurium</i> TA 98, TA 100, TA 1535, TA 1537
<i>Test material:</i>	OS 61349H (parent acid)
<i>Concentration range:</i>	0.015, 0.05, 0.15, 0.5, 1.5, 5 mg/plate with and without S9 mix
<i>Test method:</i>	according to OECD guidelines (4)
<i>Result:</i>	the notified chemical is non-mutagenic in this system at all concentrations tested

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (14)

<i>Species/strain:</i>	mice/albino Crl:CD-1 (ICR)BR
<i>Number and sex of animals:</i>	60/sex
<i>Test material:</i>	OS 114454 (notified chemical)
<i>Doses:</i>	175, 875, 1 750 mg/kg
<i>Method of administration:</i>	single intraperitoneal injection
<i>Test method:</i>	according to OECD guidelines (4)
<i>Result:</i>	the notified chemical was non-clastogenic at all doses tested

9.4 Overall Assessment of Toxicological Data

Aqueous solutions containing 50% of the notified chemical exhibited low acute oral and dermal toxicity in rats ($LD_{50} > 5\,000$ mg/kg, and 2 000 mg/kg respectively). Inhalational toxicity studies were not carried out. The notified chemical was non-irritant to rabbit skin and a slight eye irritant in rabbits. A 50% aqueous solution of the notified chemical showed minimal sensitisation potential when tested in guinea pigs.

A repeat dose 28 day oral toxicity study carried out in rats with a 50% aqueous solution of the notified chemical indicated no treatment related toxic effects.

The parent acid of the notified chemical did not induce a mutagenic response in bacteria and no clastogenicity was observed when a 50% solution of the notified chemical was tested in albino mice cells *in vitro*.

Based on the toxicological studies carried out on the notified chemical, a 50% aqueous solution of the notified chemical and the parent acid, 2-acrylamido-2-methylpropanesulfonic acid, ammonium salt would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (15).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. They have been performed on the notified chemical as a 50% aqueous solution (OS 114454), as imported into Australia. The tests were carried out to OECD Test Methods (4) at facilities complying with UK Principles of Good Laboratory Practice.

Test	Species	Results (Nominal)[◇]
Acute Toxicity (Semi-static [†]) [OECD TG 203 (4)]	Fathead Minnow (<i>Pimephales promelas</i>)	96 hour NOEC = 640 mg/L 96 hour LC ₅₀ = 1 400 mg/L
Acute Immobilisation (Static) [OECD TG 202 (4)]	Water Flea (<i>Daphnia magna</i>)	48 hour NOEC = 640 mg/L 48 hour EC ₅₀ = 1 200 mg/L
Chronic Toxicity (Reproduction/ Life-cycle) (Semi-static [†]) [OECD TG 202 (4)]	Water Flea (<i>Daphnia magna</i>)	Immobilisation (P₁) 21 day EC ₅₀ = 680 mg/L Reproduction* 21 day NOEC = 380 mg/L 21 day EC ₅₀ > 380 mg/L
Growth Inhibition [OECD TG 201 (4)]	Algae (<i>Selenastrum capricornutum</i>)	96 hour NOEC ≥ 2 000 mg/L 96 hour E _b C ₅₀ > 2 000 mg/L 0-24 hour E _μ C ₅₀ > 2 000 mg/L
Respiration Inhibition [OECD TG 209 (4)]	Aerobic Waste Water Bacteria (Activated Sludge)	3 hour EC ₅₀ > 10 000 mg/L

◇ All results are expressed in terms of nominal concentrations as analytical concentrations closely followed the nominal concentrations. In the fish toxicity test measured concentrations ranged from 100-103% of nominal at 0 hours, 99-105% at 24 hours and 101-103% of nominal at 96 hours. In the water flea acute toxicity test the measured concentrations ranged 93-98% and 95-100% of nominal at 0 hours and 48 hours, respectively. In the water flea chronic toxicity test, measured concentrations were shown to be near nominal except for the 12 mg/L test group on days 16 and 21 which showed measured concentrations of 218 and 214% of nominal respectively. Measured concentrations were 96-97% of nominal at 0 hours and 100-102% of nominal at 96 hours in the algae growth inhibition test.

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

* The 21 day EC₅₀ (reproduction) is considered to lie between 380 and 1 200 mg/L, given that on days 14 and 21, at the test concentration of 380 mg/L, there were no significant differences in terms of the number of young produced per adult when compared to the control. Statistical analysis for the 1 200 mg/L test group could not be carried out for days 14 and 21 as those surviving adults reaching maturity were observed to produce no offspring and were all eliminated by day 16 of the study. The total number of young produced over the 21 days for the 380 mg/L test concentration was observed to be 88% of the total number of young produced by the control.

The ecotoxicity data for the notified chemical indicate that the notified chemical (in its imported form as a 50% aqueous solution) is practically non-toxic to fish, water fleas and algae. No inhibition of microbial activity was seen in the study for the 3 hour contact time.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is rated as low. The majority of the monomer will be used in polymer manufacture. Residual levels of the monomer are expected to be present in the polymer at low levels (< 0.1%). Once the monomer is incorporated into the polymer, the properties and toxicity will change to reflect that of the polymer. Therefore, further environmental hazard can not be determined.

Aquatic exposure to the notified chemical is likely to occur through the release of

effluent from the waste water treatment plants. However, due to the automated processes involved in polymer formulation, losses through this route are expected to be small. Also, the notified chemical should only be present in the effluent at very low concentrations due to dilution factors. It was shown that the notified chemical is practically non-toxic to aquatic species. The environmental hazard through this disposal is predicted to be low.

The only other sources of environmental contamination are from accidental spills and disposal of packaging. The Material Safety Data Sheet (MSDS) is adequate to limit environmental exposure and therefore limit the environmental effects.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

2-Acrylamido-2-methylpropanesulfonic acid, ammonium salt is very water soluble with low molecular weight and likely to be highly chemically reactive through its acrylic moiety, which is active in the polymerisation reaction. Its physical properties are likely to aid in uptake through the skin or eyes if accidentally contacted.

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical under normal circumstances, although some dermal contact may occur when the notified chemical is transferred between bulk containers. Should exposure occur in the event of an accident, results of toxicity studies provided by the notifier suggest that there would not be significant hazard to workers acutely exposed in such an incident.

The occupational health risk posed to workers who will be involved in polymer manufacture is low. Exposure to the notified chemical is expected to be minimal, as the notifier states that polymer manufacturing processes will be highly automated. In addition, the toxicological hazard is low, based on the results of tests provided by the notifier.

The occupational health risk posed to workers in paint and other surface coatings manufacturing industries is also low, as the notified chemical will be present as a polymer component at a concentration of approximately 1.5%. As the notified chemical will be part of the polymer structure, it is not expected to be bioavailable in this form.

There is potential for dermal, inhalational and ocular exposure to the notified chemical in the form of residual monomers in polymers. Professional painters and coating users may be exposed when applying paint products using spray, brush or roller equipment. Should contact occur during mixing or application, the paint is likely to remain on the skin for some time, hence prolonging exposure. There may be significant worker contact in this way, however, the notified chemical should be almost completely reacted into the polymer and is unlikely to be bioavailable.

The results of toxicological tests supplied by the notifier suggest no significant hazardous properties for the notified chemical. However substituted acrylamides

have been shown in long range tests to possess neurotoxic and carcinogenic properties which may not be detected in the range of tests presently conducted (16). Workers who may be potentially exposed repeatedly over a long period should be careful to wear protective clothing and maintain good ventilation in the working environment to minimise the possibility of chronic exposure.

The public is not expected to be exposed to the notified chemical during the manufacture of polymers, paints and adhesives. Given its low concentration in such products, it is unlikely to constitute a hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to 2-acrylamido-2-methylpropanesulfonic acid, ammonium salt the following guidelines and precautions should be observed:

- It is good work practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (AS) 2919 (17) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (18) to minimise exposure when handling any industrial chemical;
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly and 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* (19).

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

1. European Economic Community (EEC) 1992, 'Methods for the Determination of Physico-Chemical Properties', in *EEC Directive 92/69, Annex V, Part A*, EEC Publication No. L383, EEC.
2. Kordel, W. , *HPLC-Screening Method for the Determination of the Adsorption-Coefficient on the Soil-Comparison of Different Stationary Phases*, Institut für Umweltchemie und Ökotoxikologie
3. McCall, J., Laskowski, R. & Dishburger, H. 1981, 'Measurement of Sorption Coefficients of Organic Chemicals and Their Use In Environmental Fate Analysis', in *Test protocols for environmental fate and movement of toxicants. Proceedings of a symposium*, Association of Official Analytical Chemists, Washington DC, pp. 89-109.
4. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.
5. Connell, D.W. 1989, 'General characteristics of organic compounds which exhibit bioaccumulation', in *Bioaccumulation of Xenobiotic Compounds*, CRC Press, Boca Raton.
6. Kiplinger, B. 1993, *Acute Oral Toxicity Study of OS#87613M in Albino Rats*, Project no., WIL-168097, WIL Research Laboratories, Inc., USA.
7. Varsho, B. 1996, *Acute Dermal Toxicity Study of OS 114454 in Albino Rats*, Project no., WIL-168111, WIL Research Laboratories, Inc., USA.
8. Varsho, B. 1996, *Primary Dermal Irritation Study of OS 114452 in Albino Rabbits*, Project no., WIL-168112, WIL Research Laboratories, Inc., USA.
9. Varsho, B. 1996, *Primary Eye Irritation Study of OS 114452 in Albino Rabbits*, Project no., WIL-168113, WIL Research Laboratories, Inc., USA.
10. Liggett, M. 1996, *OS 114454 Skin Sensitisation Study in the Guinea Pig*, Project no., LBL 20/960588/SS, Huntingdon Life Sciences Ltd, England.
11. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.
12. Bond, P. 1996, *A 4-Week Toxicity Study of OS 114454 in the Rat Via Oral Gavage Administration Followed by a 2-Week Recovery Period*, Project no., 95-2442, Huntingdon Life Sciences, USA.
13. Loveday, K. 1991, *Evaluation of OS 61349H in a Bacterial Mutagenesis Study*, Project no., 64919-11, Arthur D. Little, Inc, USA.

14. Stankowski, L. 1996, *In vivo Micronucleus Test with OS# 114454 in Mouse Bone Marrow Erythropoietic Cells*, Project no., 0309EL02.001, Pharmakon USA, USA.
15. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.
16. World Health Organisation (WHO) 1985, *Environmental Health Criteria 49: Acrylamide*, WHO, Geneva.
17. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australia, Sydney.
18. 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.
19. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, Australian Government Publishing Service, Canberra.

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