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May 2001

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**2-Butenedioic acid (2Z)-, ammonium salt, homopolymer, hydrolysed, sodium salts  
(Polyaspartic acid, sodium salts)**

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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## FULL PUBLIC REPORT

### 2-Butenedioic acid (2Z)-, ammonium salt, homopolymer, hydrolysed, sodium salts (Polyaspartic acid, sodium salts)

#### 1. APPLICANT

Bayer Australia Limited of 633-647 Springvale Road, Mulgrave North Victoria 3170 (ACN 000 691 690) has submitted a limited notification statement in support of their application for an assessment certificate for 'Polyaspartic acid, sodium salts'.

The notifier has not claimed any information to be exempt from publication in the Full Public Report.

#### 2. IDENTITY OF THE CHEMICAL

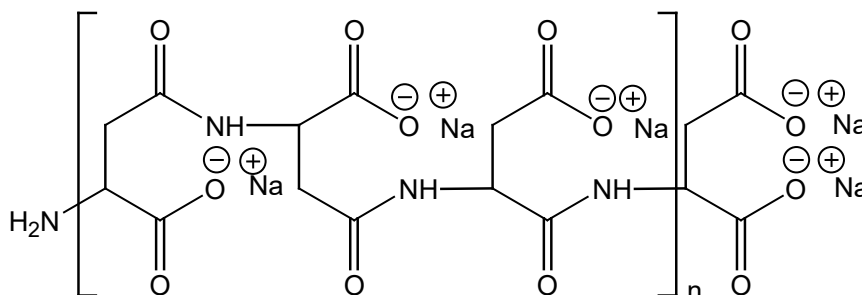
**Chemical name:** 2-butenedioic acid (2Z)-, ammonium salt, homopolymer, hydrolysed, sodium salts

**CAS number:** 181828-06-8

**Marketing names:** polyaspartic acid sodium salt TP OC 1001 (for the powder),  
polyaspartic acid sodium salt TP OC 1401 (for the solution)

**Molecular formula:**  $[C_4H_4NO_3Na]_x$

**Structural formula:**



#### Reactive functional groups:

The notified polymer contains one terminal amine group (high concern) and multiple carboxylate groups (as the sodium salt, low concern) per polymer molecule.

#### Functional group equivalent weight (FGEW):

1151 (for the amine group)

**Molecular weight (MW):**

| Number-average MW | Weight-average MW | % MW < 1000    | % MW < 500    | Method |
|-------------------|-------------------|----------------|---------------|--------|
| 1151-1259         | 2380-2505         | 20 % (approx.) | 8 % (approx.) | GPC    |

**Structural identification method:IR**

**Peaks at:** 3410(br), 3070, 2930, 1600, 1540, 1400, 1310, 1240, 1200, 1120 cm<sup>-1</sup>

### 3. POLYMER COMPOSITION AND PURITY

**Polymer constituents**

| Constituent                                  | CAS no.    | % weight | % residual                |
|--|------------|----------|---------------------------|
| 2-butenedioic acid ammonium salt homopolymer | 39444-67-2 | 92.7     | information not available |
| sodium hydroxide                             | 1310-73-2  | 7.3      | information not available |

**Purity (%):** 83%

**Hazardous impurities:**

| Chemical name           | Synonym      | CAS no.  | % weight |
|-------------------------|--------------|----------|----------|
| 2-butenedioic acid (Z)- | maleic acid  | 110-16-7 | 0.1      |
| 2-butenedioic acid (E)- | fumaric acid | 110-17-8 | 0.2      |

**Non-hazardous impurities at 1% by weight or more:**

| Chemical name      | Synonym             | CAS no.   | % weight |
|--------------------|---------------------|-----------|----------|
| water              |                     | 7732-18-5 | 11.5     |
| DL-aspartic acid   | DL-asparaginic acid | 617-45-8  | 3.1      |
| unknown impurities |                     |           | 2.1      |

**Additives/adjuvants:**

None stated

### 4. PHYSICAL AND CHEMICAL PROPERTIES

| Property                        | Result   | Comments  |
|---------------------------------|--|---|
| <b>Appearance</b>               | white powder; orange to brown liquid (solution)  |   |
| <b>Melting point</b>            | not determined   | decomposes at 140°C   |
| <b>Boiling point</b>            | 100°C  | solution (for water)  |
| <b>Density</b>                  | powder: 675 kg/m <sup>3</sup><br>solution: 1300 kg/m <sup>3</sup>  |   |
| <b>Vapour Pressure</b>          | not volatile   |   |
| <b>Water solubility</b>         | > 1000 g/L at 25°C   |   |
| <b>Partition coefficient</b>    | Log P <sub>ow</sub> = -2.4   |   |
| <b>Adsorption/desorption</b>    | not determined   |   |
| <b>Particle size</b>            | > 600 µm    0.1-1 %<br>315-600 µm    0.8-8 %<br>200-315 µm    11-14 %<br>100-200 µm    65-67 %<br>28-100 µm    1.1-5.8%<br>< 28 µm    0.05-0.4 % |   |
| <b>Flammability</b>             | not flammable  |   |
| <b>Autoignition temperature</b> | not expected to self ignite  |   |
| <b>Explosive properties</b>     | not expected to be explosive   | powder may result in dust explosions if dusts allowed to form             |
| <b>Stability/reactivity</b>     | not expected to degrade under ambient conditions or undergo hazardous polymerisation   | the powder may react with strong oxidising agents                         |
| <b>Dissociation constant</b>    | pKa = 4.87   |   |
| <b>Hydrolysis</b>               | not determined   | no groups are expected to hydrolyse under normal environmental conditions |

#### 4.1 Comments on Physico-Chemical Properties

The vapour pressure could not be determined because the notified polymer decomposed during the test (Bayer AG ZF-Zentrale Analytik 2000).

The water solubility was determined using a bending vibration method (Bayer AG ZF-Zentrale Analytik 1999a). The relative density of a solution containing the notified polymer was determined using an oscillating densitometer as described in OECD TG 109. The solubility of a compound is determined once the density of a saturated solution of known volume is obtained. The notified polymer (60 g) was added to a buffered solution (20 mL)

and the resulting viscous paste was stirred at 23°C. An U-formed tube, which can be made to vibrate, was calibrated with two liquids of known density. A known amount of the polymer paste (0.7 mL) was added to the U-formed tube and the density of the sample determined. This method indicated that the solubility of the notified polymer is > 1000 g/L.

The notified polymer contains amide linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.

The partition coefficient was determined using a shake flask method (Bayer AG ZF-Zentrale Analytik 1999b). The log P of the notified polymer is -2.4. This equates to a P value of  $3.98 \times 10^{-3}$  which indicates that the notified polymer may be considered to be hydrophilic.

No adsorption/desorption tests were conducted for this notification. The notified polymers partition coefficient would suggest that the notified polymer is not expected to adsorb to organic matter in soil or sediments. However, polyanionic compounds and polymers are known to absorb to soils and sediments, through their ability to chelate to metals.

Although no dissociation tests were conducted, based on the dissociation constant of propionic acid, the notifier expects that the notified polymer to have a pKa of approximately 4.87.

## 5. USE, VOLUME AND FORMULATION

### Use:

The notified polymer will be used by manufacturing companies as an ingredient in liquid formulations that are used within the water treatment industry. The products will be used by industrial/commercial customers within cooling and heating systems where they act as scale inhibitors to prevent deposits on cooling or heating circuits.

### Manufacture/Import volume:

The notified polymer is not manufactured in Australia. It is imported either as a powder (83 % pure notified polymer), in 160 kg plastic-lined fibre drums and 60 kg plastic drums, or as a 40 % aqueous solution in 1250 kg tank containers, 230 kg rolling drums or 250 kg polyethylene bung-hole containers.

The total maximum quantity to be imported annually for the first five years is 10 tonnes per annum.

### Formulation details:

Both the powder and aqueous forms of the polymer will be reformulated within Australia to produce water treatment products containing between 5 and 30 % notified polymer. Products will be contained within 20 or 200 L drums, or 1500 L IBCs. Typically, at customer sites the water treatment product containing the notified polymer will be pumped from a storage container to the process stream via a feed (transfer) system.

## 6. OCCUPATIONAL EXPOSURE

| Exposure route               | Exposure details | Controls indicated by notifier |
|------------------------------|------------------|--------------------------------|
| <hr/>                        |                  |                                |
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*Transport and Storage (2-3 hours/day, 12-15 days/year)*

*Waterside unloading (2-3 workers)*

|                      |  |                |
|----------------------|--|----------------|
| Dermal or inhalation | The imported containers will be transferred from ships to road trucks. Exposure is only likely following accidental spills or leaks. | None indicated |
|----------------------|--|----------------|

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*Transport and storage (3-4 workers)*

|                      |  |                |
|----------------------|--|----------------|
| Dermal or inhalation | Containers will be stored under cover. No repackaging will occur prior to reformulation. Exposure is only likely following accidental spills or leaks. | None indicated |
|----------------------|--|----------------|

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***Formulation (6-20 workers, 8 hours/day, 100-150 days/year)***

*Transfer from import containers*

|                      |   |  |
|----------------------|---|--|
| Dermal or inhalation | Manual handling is minimised by the use of metered dose pumps to transfer the polymer, in liquid or powder form, to 7000 L mixing tanks. Exposure may occur during connection and disconnection of pumping equipment. | Processes are automated. Also reformulation workers will wear impervious gloves, overalls, eye protection, safety boots and dust-masks if necessary. |
|----------------------|---|--|

*Mixing*

|                      |  |   |
|----------------------|--|---|
| Dermal or inhalation | Other ingredients are added by automated procedures and the mixing tanks are sealed. | Local and general ventilation are used. Also reformulation workers will wear impervious gloves, overalls, eye protection, safety boots and dust-masks if necessary. |
|----------------------|--|---|

*Dispensing*

|        |  |  |
|--------|--|--|
| Dermal | Product is dispensed automatically via hoses into 20 or 200 L drums, or 1500 L IBCs. Exposure may occur during the manual closing of containers. | Dispensing processes are automated. Also, reformulation workers will wear impervious gloves, overalls, eye protection, safety boots and dust-masks if necessary. |
|--------|--|--|

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***End use (50-100 workers)***

*Plant operators*

|        |   |   |
|--------|---|---|
| Dermal | End users may dilute the products further. Operators (1-2 per site) may be exposed (once per day for 0.5-1 hour/day) to a maximum concentration of 30 % notified polymer, when removing container bungs or lids and during connection of pumping equipment. | Typically plant operators are required wear impervious gloves, overalls and eye protection during connection and disconnection of feed lines. |
|--------|---|---|



## **7. PUBLIC EXPOSURE**

Public exposure to the notified polymer as imported, transported and stored will only occur with rupture of containers as a result of an accident. There is negligible public exposure due to factory processing and from waste product.

The notified polymer is not available for sale to the public. Industrial use may lead to release into the environment through leakage of storage containers and spillage of product at a maximum of 30 % of the notified polymer, or from cooling system discharge, manual system blowdown, and cooling tower drift at typical concentrations of 10 ppm. Public exposure will be limited and at very low concentrations, as the release will be into treatment systems that will further dilute the polymer or into the atmosphere away from normal public access and will thus be dispersed by the air.

## **8. ENVIRONMENTAL EXPOSURE**

### **8.1 Release**

After importation, the notified polymer will be transported via road without repackaging. The notifier expects that approximately 0.5 % of the total import volume will be released through spills prior to reformulation. This equates to a loss of 50 kg per annum of the notified polymer. The notifier estimates that 1 % of the notified polymer may be lost during formulation which would equal 100 kg per annum.

The notifier estimates that approximately 1 % or 100 kg per annum of the notified polymer will remain as residues in the importation drums. The import and reformulation drums containing residues will be disposed of by licensed waste disposal contractors. The IBCs are expected to be washed and drained thoroughly before reuse.

The notified polymer will be used for the treatment of water contained in closed systems at the end use site. During the water treatment, the efficacy of treatment polymer diminishes and new water treatment solution is continually added to the system. A continual bleeding and discharge of the treated water compensates replenishment of the polymer in the system.

The majority of the notified polymer will be released to the environment in this way as well as when cooling systems undergo either short-term manual system blowdown (BD) or total shut-down and are cleaned.

For example, the notifier indicates that the volume of purge or blowdown from a small site with a BD of 0.5 tonnes per hour with only one cooling tower would be approximately 4.5 ML/year. The quantity of the notified polymer released would be 22.5 kg/year. A large cooling plant system would have a BD of 21 tonnes per hour, which is equivalent to 170 ML/year. This equates to a release of approximately 850 kg/year of the notified polymer after on-site treatment.

The notifier indicates that most cooling towers operate with a maximum drift of 0.002% of the recirculation rate. The recirculation rate in a small site cooling tower may be 900

tonnes/hour. Assuming a 5 ppm concentration of notified polymer in the cooling tower, 9 g/hour or 79 kg/year would be lost due to drift. In a larger system the recirculation rate is in the order of 9000 tonnes/hour and this would result in 790 kg/year of notified polymer being released due to drift.

## 8.2 Fate

The notifier indicates that empty drums and their residues will be sent to either licensed drum reconditioners or the drums disposed of directly to a licensed landfill site. Presumably, drum reconditioners will also dispose of solid residue from drums to licensed waste landfill sites. While not specifically indicated by the notifier, presumably washings from pipes and mixing equipment will be use in the formulation of the next batch of water treatment solution.

The notifier has provided the results of a ready biodegradation test in an aerobic aqueous media following modified OECD screening test, OECD TG 301B (Bayer AG, Institut für Umweltanalyse 1997a). The biodegradation was determined by the measurement of dissolved organic carbon produced after the medium was inoculated with a mixed population of aquatic microorganisms and stored in the dark at 24°C for 28 days. Aniline was used as the standard material. The results indicated that 68 % of the polymer had degraded over this time, while 100 % of the standard degraded in 14 days. The results indicate that polyaspartic acid is not readily biodegradable as < 70 % had degraded within 10 days of 10 % having been reached.

During use the notifier indicates that the feed rate will be adjusted to maintain a concentration of up to 5 ppm of the active notified polymer in the cooling water system. The cooling tower concentrations of the notified polymer are, therefore, expected to be less that 5 ppm.

The notifier indicates that typically cooling water represents about 60 % of the total effluent volume discharged from a facility. The remaining water comes from boiler and process streams. The concentration of the notified polymer in the plant effluent would, therefore, be about 3 ppm. If a secondary effluent plant is used prior to discharge, the notifier estimates that this would involve a ten-fold dilution and 50 % of the notified polymer is expected to be removed through the waste treatment facilities as sludge and disposed of to landfill. Discharge from the plant would, therefore, contain < 0.2 ppm notified polymer. Subsequent treatment at local sewage treatment plants would further dilute and remove the notified polymer to very low concentration levels (< 0.02 ppm).

Based on these assumptions, it is expected that some of the notified polymer will find its way to landfill. Here it will be adsorbed to soil and sediment and be immobile due to its polyanionic nature. It should not bioaccumulate (Connell 1990) as the polymer is water soluble with a very low log  $P_{ow}$  value.

## 9. EVALUATION OF TOXICOLOGICAL DATA

### 9.1 Acute Toxicity

#### Summary of the acute toxicity of Polyaspartic acid, sodium salts

| <i>Test</i>         | <i>Species</i> | <i>Outcome</i>              | <i>Reference</i> |
|---------------------|----------------|-----------------------------|------------------|
| acute oral toxicity | rat            | LD <sub>50</sub> >2000mg/kg | Stropp, 1999a    |

|                       |            |                             |               |
|-----------------------|------------|-----------------------------|---------------|
| acute dermal toxicity | rat        | LD <sub>50</sub> >2000mg/kg | Stropp, 1999b |
| skin irritation       | rabbit     | non-irritant                | Stropp, 1998a |
| eye irritation        | rabbit     | non-irritant                | Stropp, 1998b |
| skin sensitisation    | guinea pig | non-sensitiser              | Stropp, 1999c |

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### 9.1.1 Oral Toxicity (Stropp, 1999a)

|                                  |  |
|----------------------------------|--|
| <i>Species/strain:</i>           | rat/Wistar   |
| <i>Number/sex of animals:</i>    | 3/sex  |
| <i>Observation period:</i>       | 14 days  |
| <i>Method of administration:</i> | gavage; 2000 mg/kg, as a 42.8 % aqueous solution                 |
| <i>Test method:</i>              | OECD TG 423 (Acute Toxic Class), Limit test                      |
| <i>Mortality:</i>                | none   |
| <i>Clinical observations:</i>    | no signs of toxicity were observed                               |
| <i>Morphological findings:</i>   | no treatment-related macroscopic findings were observed          |
| <i>LD<sub>50</sub>:</i>          | >2000 mg/kg  |
| <i>Result:</i>                   | the notified polymer was of very low acute oral toxicity in rats |

### 9.1.2 Dermal Toxicity (Stropp, 1999b)

|                                  |  |
|----------------------------------|--|
| <i>Species/strain:</i>           | rat/Wistar   |
| <i>Number/sex of animals:</i>    | 3/sex  |
| <i>Observation period:</i>       | 14 days  |
| <i>Method of administration:</i> | 2400 mg/kg under occlusive dressing for 24 hours, as a 42.8 % aqueous solution |
| <i>Test method:</i>              | OECD TG 402  |
| <i>Mortality:</i>                | none   |
| <i>Clinical observations:</i>    | no signs of local or systemic toxicity were observed                           |
| <i>Morphological findings:</i>   | no treatment-related macroscopic findings were observed                        |

*Comment:* the test method was modified in that a reduced number of animals were used

*LD<sub>50</sub>:* > 2400 mg/kg

*Result:* the notified polymer was of low dermal toxicity in rats

#### **9.1.4 Skin Irritation (Stropp, 1998a)**

*Species/strain:* rabbit/Himalayan

*Number/sex of animals:* 3 males

*Observation times:* 60 min, 24, 48 and 72 hours

*Method of administration:* 0.5 mL notified polymer, in a 42.8 % aqueous solution, under semi-occlusive dressing for 4 hours

*Test method:* OECD TG 404

*Comment:* no signs of erythema or oedema were seen in any of the animals at any of the observation times

*Result:* the notified polymer was not irritating to the skin of rabbits

#### **9.1.5 Eye Irritation (Stropp, 1998b)**

*Species/strain:* rabbit/Himalayan

*Number/sex of animals:* 3 males

*Observation times:* 60 min, 24, 48 and 72 hours

*Method of administration:* 0.1 mL of 42.8 % aqueous solution placed into conjunctival sac of one eye of each animal

*Test method:* OECD TG 405

*Comment:* no signs of irritation of the cornea, iris or conjunctivae were observed in any animal at any of the observation times

*Result:* the notified polymer was not irritating to the eyes of rabbits

#### **9.1.6 Skin Sensitisation (Stropp, 1999d)**

*Species/strain:* guinea pig/Hsd Poc:DH

*Number of animals:* 10 test and 5 control animals

*Induction procedure:*

test group:  
day 0 Three pairs of intradermal injections, of 0.1 mL volume, were made in the scapular region:

- FCA diluted 1:1 with physiological saline
- 5 % notified polymer in physiological saline
- 5 % notified polymer in FCA

day 7 0.5 mL of 100 % notified polymer applied topically, under occlusive dressings for 48 hours, to same skin area

*Challenge procedure:*

day 21 0.5 mL of 25 % notified polymer was applied topically to dorsal and flanks for 24 hours under occlusive dressing

*Test method:* OECD TG 406

*Challenge outcome:*

| <b>Challenge<br/>concentration</b> | <b>Test animals</b> | <b>Control animals</b> |
|------------------------------------|---------------------|------------------------|
|                                    | <b>48 hours*</b>    | <b>48 hours</b>        |
| 25%                                | 0/10**              | 0/5                    |

\* time after patch removal

\*\* number of animals exhibiting positive response

*Result:* the notified polymer was not sensitising to the skin of guinea pigs

## 9.2 Genotoxicity

### 9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Herbold, 1999)

*Strains:* TA 98, TA 100, TA102, TA1535, TA 1537

*Metabolic activation:* Aroclor-induced rat liver S9

*Concentration range:* 50 – 5000 µg/plate

*Test method:* OECD TG 471 (plate incorporation method)

*Comment:* the independent repeat test was performed using a 20 minute pre-incubation period; there were no signs of toxicity to any of the test strains at any of the concentrations employed

solvent control plates gave counts in the expected range and positive controls produced significant increases in the

revertant counts

*Result:* the notified polymer was non mutagenic under the conditions of the test

### 9.3 Toxicological hazards of constituents, impurities, additives and adjuvants

The health hazards of the constituents and hazardous impurities, additives and adjuvants are tabulated below.

| Chemical                      | Health hazards (NOHSC, 1999a)   | Regulatory controls |
|-------------------------------|---|---------------------|
| <b>Hazardous impurities :</b> |   |                     |
| maleic acid                   | R36/37/38: irritating to eyes, skin and respiratory tract (at $\geq 20$ %)<br>R22: harmful if swallowed ( $\geq 25$ %). | none                |
| fumaric acid                  | R36: irritating to eyes (at $\geq 20$ %)  | none                |

### 9.4 Overall Assessment of Toxicological Data

The notified polymer is a polymer of low reactivity and high molecular weight. It is of very low and low acute oral and dermal toxicity, respectively, with LD<sub>50</sub> values > 2400 and > 2000 mg/kg, respectively, being obtained in rodent studies. It is not a skin or eye irritant or a skin sensitizer according to standard toxicity studies. Neither does it induce gene mutations in a standard Ames test.

According to the available data the notified polymer is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

| Test                         | Species                                | Results   |
|------------------------------|--|---|
| 96 h Acute Toxicity          | Zebra fish<br><i>Brachydanio rerio</i> | 3160 mg/L < LC <sub>50</sub> > 10000 mg/L<br>NOEC = 3160 mg/L                                     |
| 48 h Acute Toxicity          | <i>Daphnia magna</i>                   | EC <sub>50</sub> = 3536 mg/L  |
| 72 h Algal Growth Inhibition | <i>Scenedesmus subspicatus</i>         | 72 h E <sub>b</sub> C <sub>50</sub> = 528 mg/L<br>72 h E <sub>r</sub> C <sub>50</sub> = 1070 mg/L |

\* NOEC - no observable effect concentration

The tests on fish (Bayer AG, Institut für Umweltanalyse 1997b) were performed using a static methodology. Observations were performed at 2, 24, 48, 72 and 96 hours. The test was

performed using ten specimen fish per test concentration at a temperature of 21°C. The tests were conducted using nominal concentrations of 3160 and 10000 mg/L. The results of the definitive study showed that no mortalities or sublethal effects were observed in the test vessel containing 3160 mg/L of the notified polymer. After 96 h, 80 % mortality was observed at a test concentration of 10000 mg/L. The 96-hour LC<sub>50</sub> for the notified polymer to *Brachydanio rerio* is therefore between 3160 and 10000 mg/L.

The immobilisation tests with *Daphnia magna* (Bayer AG, Institut für Umweltanalyse 1997c) were also performed under static conditions with observations performed at 24 and 48 hours. The test was performed using 10 daphnids per flask at a temperature of 20°C. The tests were conducted using nominal concentrations of 625, 1250, 2500, 5000 and 10000 mg/L. After 48 h, no immobilised daphnids were observed in the test vessels with less than 2500 mg/L of the notified polymer and 100 % mortality was observed after 48 h at test concentrations above 5000 mg/L. The 48-hour EC<sub>50</sub> for the notified polymer to *Daphnia magna* is 3536 mg/L of the notified polymer.

Algae were exposed to the test substance at concentrations of 125, 395, 1248 and 3959 mg/L for 72 h at 24°C under constant illumination and shaking (Bayer AG, Institut für Umweltanalyse 1997d). After 72 h, the percentage inhibition of biomass for the test vessels containing 125, 395, 1248 and 3959 mg/L of the notified polymer was 2.3, 48.1, 84.3 and 92.2 %, respectively, and the percentage inhibition of growth rate was 0, 25.0, 66.7 and 66.7 %, respectively. The 72 h E<sub>b</sub>C<sub>50</sub> and E<sub>r</sub>C<sub>50</sub> for the notified polymer to *Scenedesmus subspicatus* is 528 mg/L and 1070 mg/L, respectively.

The ecotoxicity data indicates the notified polymer is practically non-toxic to fish, daphnia and algae.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The intended use pattern of the notified polymer is expected to result in the majority of the polymer being eventually released to the environment. However, this will be in dilute manner as the notified polymer contained within the water treatment solution released from cooling towers will be at a low concentration. The notifier expects further dilution as well as adsorption will occur at on-site treatment plants. Discharge from the on-site treatment sites is expected to contain the notified polymer at a concentration of < 0.05 ppm. Subsequent treatment at local sewage treatment plants would further dilute and remove the notified polymer to very low concentration levels. If the notified polymer is used at other sites that do not have on-site treatment plants then environmental exposure is still expected to be low since the polymer is only expected to be used at a maximum concentration of 5 ppm. Furthermore, the ecotoxicity data provided indicates the notified polymer is practically non-toxic to fish, daphnia and algae and more than 3 orders of magnitude difference in predicted levels compared with toxic levels.

In a worst case based on maximum annual imports of 10 tonnes per annum, all of which is released to sewer and assuming that none is removed during sewage treatment processes, assuming a national population of 18,000,000 and that each person contributes an average 150 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 2.2 mg/L.

|   |                    |
|---|--------------------|
| Amount of Polyaspartic Acid entering sewer annually | 6000 kg            |
| Population of Australia                             | 18 million         |
| Amount of water used per person per day             | 150 L              |
| Number of days in a year                            | 365                |
| Estimated PEC                                       | 2.2 mg/L (2.2 ppm) |

When released to receiving waters the concentration is generally understood to be reduced by a further factor of at least 10, and so the Predicted Environmental Concentration (PEC) is around 0.2 mg/L. If the notified polymer were to be used in one major capital city, such as Sydney (pop. 3500000), the PEC in the receiving waters would be 11.4 mg/L.

The nationwide and larger cities PEC estimates indicate that after discharge to receiving waters the environmental concentration of the notified polymer will be 3 orders of magnitude less than the demonstrated toxicity to the *Daphnia* ( $EC_{50} = 3536$  mg/L).

Wastes containing the notified polymer including residues from imported drums, from formulation and sludge will be disposed of in landfill and are expected to be immobile. Even though the notified polymer is soluble in water, it will adsorbed to soil and sediment due to its high molecular weight and polyanionic nature.

Therefore, the environmental exposure and overall environmental hazard from the notified polymer is expected to be low.

## **12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS**

The notified polymer is of very low and low acute oral and dermal toxicity, respectively. Toxicity of inspirable dust, if formed, is also expected to be low. It is not a skin or eye irritant and is not a skin sensitiser. A bacterial gene mutation study demonstrates that mutagenicity is not expected to occur. The notified polymer is not flammable, nor is it expected to self ignite or be explosive.

### **12.1. Occupational health and safety**

Imported containers of the notified polymer in either powder or aqueous formulation will not be opened until arrival at formulation facilities. Therefore exposure of transport and storage workers to the notified polymer will only occur in the event of accidental spillage.

Dermal and/or inhalation exposure to the aqueous solution and the powder may occur during the connection and disconnection of transfer pumping equipment used in the (otherwise automated) formulating processes. Dermal exposure to the aqueous solution may similarly occur during the largely automated dispensing operation. However the extra controls specified in the notification (wearing of impervious gloves, overalls, eye protection, dust masks etc) will provide adequate protection against the low toxicity polymer.

Dermal exposure may occur to the formulated polymer, at a maximum concentration of 30 %, when opening product containers, during diluting procedures and when connecting and disconnecting pumping equipment to feed the product into water systems. However, the notifier has stated that typically plant operators are required to wear impervious gloves,



overalls and eye protection during connection and disconnection of feed lines. Such controls are considered sufficient to protect the workers against the low toxicity polymer.

Exposure to the low toxicity notified polymer is expected to be limited such that there are no concerns for health and safety during the occupational handling of the polymer. No specific risk reduction measures are necessary.

## **12.2. Public Health**

The notified polymer is not available for sale to the public. Releases from industrial use will have very low concentrations of the polymer (10 ppm) and these will be further diluted in the atmosphere or sewerage system. Release from cooling towers, which are located away from normal public access (e.g. on building roofs), allows dispersion of the polymer in the atmosphere. Releases from boiler systems are unlikely to occur in publicly frequented areas. These exposures are unlikely to pose a significant hazard to human health.

## **13. RECOMMENDATIONS**

To minimise occupational exposure to polyaspartic acid, sodium salts the following guidelines and precautions should be observed:

- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents (for the liquid) or swept up (for the powder) and put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

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

## **14. MATERIAL SAFETY DATA SHEET**

MSDS for the notified polymer, in powder and aqueous form, were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (1994).

These MSDS were provided by the applicant as part of the notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

## **15. REQUIREMENTS FOR SECONDARY NOTIFICATION**

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

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Stropp G (1998b) Acute Eye Irritation Study of Polyasparaginsäure, Na-Salz, Lösung by Instillation into the Conjunctival Sac of Rabbits. Study No. T 0067179, Bayer AG Werk Elberfeld, Institut für Toxikologie, Friedrich-Ebert-Strasse 217-333, D-42096 Wuppertal, Report No. R 7307

Stropp G (1999c) Study for the Skin Sensitisation Effect in Guinea Pigs. Study No. T 2067630, Bayer AG, Fachbereich Toxikologie, Friedrich-Ebert-Strasse 217-333, D-42096 Wuppertal, Report No. PH-28603