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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

SV93

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**SV93****1. APPLICANT**

MBT (Australia) Pty Ltd of 11 Stanton Rd Seven Hills NSW 2147 (ABN 46 000 450 288) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC) SV93.

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: SV93, Defoamer DF93, MVA 2424, MVA 2500

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

Property	Result	Comments
Appearance	yellow to brown liquid	60 % aqueous solution
Melting point	not determined	
Density	1100 – 1200 kg/m ³	60 % aqueous solution
Water solubility	> 690g/L	see comments below
Particle size		Not applicable as polymer is only

		used in solution form in Australia
Flammability	not flammable	Notified polymer is only used in aqueous solution in Australia
Explosive properties	not explosive	Based on structural features
Stability/reactivity	stable	Not expected to be reactive under normal environmental conditions
Hydrolysis as function of pH	not determined	see comments below
Partition coefficient	not determined	see comments below
Adsorption/desorption	not determined	see comments below
Dissociation constant	not determined	pH of a 60 % solution is 6.5 – 8, according to the Technical Data Sheet

5.1 Comments on physical and chemical properties

The notifier has stated that the water solubility of the notified polymer can be in excess of 690 g/L but the resulting solution becomes extremely viscous. The reported solubility is consistent with the high content of hydrophilic and ionic groups in the polymer.

The notified polymer contains functional groups that have the potential to hydrolyse given the high water solubility of the notified polymer but would not be expected to do so under environmental conditions (pH 4-9).

The partition coefficient of the notified polymer was not determined. However, its high water solubility indicates that it is likely to preferentially partition into the aqueous phase.

The adsorption/desorption properties of the polymer were not determined and its high water solubility indicates that it would be mobile in soils and sediments. However, there is evidence to suggest that polycarboxylates will adsorb to soil and wastewater sludge and are unlikely to leach into the aquatic environment once they do so (Hamilton et al, 1997).

The structure of the notified polymer shows that it is a sodium salt of a weak carboxylic acid (pKa~5) and has the potential to dissociate under environmental conditions (pH 4-9).

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer is a component of an additive to concrete which is designed to improve its workability and strength.

Manufacture/Import volume:

Less than 10 tonnes of the notified polymer will be imported per annum for each of the first five years of importation.

Formulation details:

The notified polymer will be imported as part of the products MVA 2500 and MVA 2424, which contain less than 2 % notified polymer, in bulk trucks, 1000 L totes or 200 L drums. The products may be directly added to the concrete mix by the customers. Alternately, the product may be diluted to a desired solids content at the notifier's site, with possible addition of other ingredients. The typical dose rate of the products in finished concrete will be less than 0.01 % notified polymer.

7. OCCUPATIONAL EXPOSURE

The product containing the notified polymer will be transported to an admixture plant and transferred to a storage tank. Exposure of workers during transport should be restricted to events where containers are breached and spillage occurs.

Unloading of the imported solution at the admixture plant involves one worker for 1 hour/day, 40 days/year, operating electronically controlled pumping to a storage tank. Dermal and ocular exposure from drips and spills are prevented by the use of goggles and gloves. Water and other additives may be added to the tank and emptied containers are rinsed with water and the resulting solution used in production.

From the storage tank the aqueous solution of the notified polymer pumped by one worker (2 hours/days, 40 days/year) to bulk transport tankers. At each of approximately four concrete plants, one worker (0.5 hours/day, 40 days/year) unloads the tanker into the holding tank. Workers use goggles and gloves to control exposure from drips and spills.

From the customer's holding tanks one worker per site (0.5 hours/day, 220 days/year) operates a dosage pump to a concrete mixing tank from where the concrete is pumped to concrete trucks for distribution. Three further workers (0.5 hours/day, 220 days per year) are involved in activities such as equipment cleaning. Workers use protective clothing, goggles and gloves to prevent exposure to the concrete. There will be negligible exposure to the notified polymer due to the low percentage in the finished concrete.

The concrete containing less than 0.01 % notified polymer is distributed to a variety of buildings sites where it is used for building structures, paths and driveways. Workers will use protective clothing and gloves to prevent exposure to the concrete.

8. PUBLIC EXPOSURE

Public exposure through importation, transportation and reformulation is not considered significant.

The notified polymer is used in a concrete additive. The concentration of the polymer in concrete will be less than 0.01 %. The additive will not be sold directly to the public. However, concrete produced using the additive may be used by the public (e.g. for driveways, etc) as such there is the potential for dermal contact. Public exposure is likely to be minimal.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

At the admixture site the polymer solution will be pumped into a storage tank where water and other components will be added to adjust the mixture to the desired concentrations. The empty containers will be rinsed with water and the wash solution will be recycled back into the formulation process.

The final product will be pumped from the storage tanks to be distributed from the admixture plant to customer concrete production plants by road in either bulk trucks or totes. Equipment used in this process will be rinsed and the resulting solution recycled back into the formulation process.

The final product containing the notified polymer is unloaded from trucks or totes at the concrete plants directly into storage tanks. The polymer solution is automatically pumped from these tanks into the concrete mixers as required to a concentration of less than 0.01 %. The concrete is then either poured into pre-cast molds or into ready-mix trucks for delivery to job-site molds.

The notifier has provided the following estimates for release of the notified polymer into the environment.

Life-cycle Activity	Release (kg/year)	Media of release
1. Admixture Plant/ storage	0.4	Waste water
2. Distribution to concrete plants	0.04	Waste water
3. Concrete plant/storage	0.04	Waste water
4. Concrete production/rinsing equipment	0.022	Solid concrete
5. Concrete production/ excess	0.022	Solid concrete
Total:	0.524	

The first three release points in the table relate to spillage and hose leakage during transfer and storage both at the admixture plant and the concrete plants. This polymer waste would be hosed into a pit and from there pumped to a storage tank in the on-site waste water treatment plant. Based on previous experience, it is possible that up to 1 % of the notified polymer may be released due to spills and hose leakage. This equates to a release of up to 20 kg per annum of the notified polymer.

The notifier has not provided an estimation of release due to the rinsing of empty trucks, empty totes and transfer lines because the material collected as a result of this activity is recycled back into production. However, it is likely that there will still be small releases as a result of the washing of equipment.

The final two release points in table give estimations of environmental release of the polymer during concrete production and use. The concentrations of the polymer involved are very low and any release would be dispersed across many sites. The notifier indicates that any concrete excess and material produced in the cleaning of ready-mix trucks will be transferred to dumpsters and allowed to set before disposal to landfill.

9.2. Fate

The majority of the notified polymer will be utilised in concrete production where it will become bound within the concrete matrix and not be released into the environment. The environmental fate of most of the notified polymer will therefore follow the fate of the concrete structures into which it is incorporated. Concrete waste from building demolition is usually disposed of to landfill where the polymer is expected to remain immobile and not leach out.

All concrete waste from the concrete plants and excess concrete from construction sites will be disposed of to landfill where the incorporated polymer will remain immobilised in the concrete matrix.

The inherent biodegradability of the notified polymer was tested (SafePharm, 1989a). The method used was the Inherent Biodegradability: Modified Zahn-Wellen Test according to OECD Test Guideline 302B. The inoculum used was a mixed activated sewage sludge. The notified polymer can be considered inherently biodegradable with 45–55 % degradation reached after 28 days. The reference material, diethylene glycol, was 100 % degraded within 6 days. Considering these results, it is expected that the notified polymer would not be highly persistent and should undergo biodegradation in the environment.

The small amount of notified polymer that may be released as waste water would be expected to disperse in the aquatic environment due to its high solubility in water. However, there is evidence that polycarboxylates such as the notified polymer have the propensity to adsorb to sludge at waste water treatment plants and that once this occurs they do not readily desorb (Hamilton, 1997). The notified polymer may also be precipitated by the neutralisation of the remaining carboxyl groups by counterions such as calcium. At the notifier's waste water treatment plant the solids will be separated by flocculation and removed from the water by filtration. The waste water sludge would be disposed of to landfill. In landfill the notified polymer is expected to degrade slowly through abiotic and biotic 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 HEALTH EFFECTS DATA

10.1 Acute Toxicity

10.1.1 Acute Oral Toxicity

TEST SUBSTANCE	Notified polymer.
METHOD	OECD 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Water (500 mg/mL)
Remarks - Method	A preliminary test was conducted using one animal per sex per dose, and doses of 5000, 3000, 1000 and 500 mg/kg bw. No significant protocol deviations occurred in the main study.

RESULTS

<i>Group</i>	<i>Number & Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	1/sex	500	0/2
II	1/sex	1000	0/2
III	1/sex	3000	0/2
IV	1/sex	5000	0/2
V	5/sex	5000	0/10

LD50 > 5000 mg/kg bw
Signs of Toxicity No clinical signs of toxicity were observed. All animals gained weight.
Effects in Organs No gross abnormalities were observed at necropsy.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY SafePharm Laboratories Ltd (1989b)

10.1.2 Skin Irritation

TEST SUBSTANCE Notified polymer.

METHOD OECD 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 male
Observation Period 3 days
Vehicle None.
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations.

RESULTS
Remarks - Results No signs of skin irritation were observed at 24, 48 or 72 hours after application of the notified polymer.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY SafePharm Laboratories Ltd (1989c)

10.1.3 Eye Irritation

TEST SUBSTANCE Notified polymer.

METHOD OECD 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 2 male, 1 female
Observation Period 3 days

Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	One animal showed slight conjunctival redness at 24 hr; otherwise no eye irritation was observed at the 24, 48 and 72 hour examinations. At 1 hr after instillation, all animals showed slight conjunctival redness and chemosis, one showed moderate discharge and one slight discharge.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	SafePharm Laboratories Ltd (1989d)

10.2 Genotoxicity

10.2.1 Genotoxicity-Bacteria

TEST SUBSTANCE	Notified polymer.
METHOD	OECD 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B. 14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	<i>S. typhimurium</i> : TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	S9 fraction from the liver of rats induced with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 8 – 5000 µg/plate. b) Without metabolic activation: 8 – 5000 µg/plate.
Vehicle	Water
Remarks - Method	Two independent tests were performed in triplicate. The first test used a wide concentration range, while the second test used a narrower range at the higher end of the tested concentrations.
RESULTS	
Remarks - Results	No precipitation or signs of toxicity were observed. No increases in the number of revertant colonies were seen for any of the strains, either in the presence or absence of metabolic activation. Appropriate positive controls were tested and all resulted in large increases in the number of revertant colonies, confirming the sensitivity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Ltd (1989e)

10.3 Overall Assessment of Toxicological Data

The notified polymer was found to have very low acute oral toxicity, to be non-irritant to skin and a minimal irritant to eyes, and non-mutagenic in a bacterial reverse mutation assay. No other toxicological reports were provided.

The notified chemical has a high molecular weight and does not contain functional groups apart from those classified as low concern, or reactive residual monomers. Therefore it is not expected to cross biological membranes, and systemic toxicity effects are not expected.

Based on the data provided, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999).

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

The following ecotoxicological data were provided by the notifier.

<i>Test organism</i>	<i>Test</i>	<i>Result</i>
<i>Daphnia magna</i>	48 h acute (OECD TG 202)	EC50 >100 mg/ml
Activated sludge micro-organisms	Respiration inhibition test (OECD TG 209)	EC50 >1000 mg/ml

Toxicity of the notified polymer to *Daphnia magna* was tested according to OECD Test Guideline 202. It was found that the notified polymer was practically non-toxic to *D. magna* with an EC50 after 48 h of >100 mg/L (SafePharm, 1989f).

Toxicity of the notified polymer to activated sludge microbes was tested according to OECD Test Guideline 209. It was found that the notified polymer was practically non-toxic to activated sludge micro-organisms with an EC50 of >1000 mg/ml (SafePharm, 1989g). The reference substance, 3,5-dichlorophenol had an EC50 of 16 mg/ml.

It has been reported that polycarboxylate polymers may be slightly toxic to algae. However, this apparent toxicity was associated with a water hardness of 15 mg/L that may be attributed to the sequestration of essential cationic nutrients by the polycarboxylates. Under water hardness conditions encountered in the environment algae do not appear to be sensitive to polycarboxylates (Hamilton et al, 1997).

Any ecotoxic effects of the notified polymer will be moderated by the expected low aquatic release.

12. ENVIRONMENTAL RISK ASSESSMENT

The majority of the imported polymer will be encapsulated at very low concentrations in the matrix of the concrete fabrications in which it is used. When the concrete sets the notified polymer will not be available to the environment and is therefore not expected to pose a risk to the environment.

There is potential for a small amount of notified polymer to be released to the environment as a consequence of spillage and leakage of hoses at the admixture plant. This release would be to waste water since the notifier indicates that this material would be washed into a holding pit connected to the on-site treatment plant. The notified polymer is likely to adsorb to waste water sludge at the on-site treatment plant thereby significantly reducing its release to the sewer. Therefore it is expected that exposure to the aquatic environment would be limited. If a small amount of the notified polymer leaches into water the risk to the aquatic environment would be low due to the high molecular weight of the notified polymer and its limited toxicity to aquatic organisms.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

The notified polymer was found to have very low acute oral toxicity, to be non-irritant to skin and a minimal irritant to eyes, and non-mutagenic in a bacterial reverse mutation assay. It is not expected to cross biological membranes, and systemic toxicity effects are not expected. Based on the data provided by the notifier, the notified polymer is not classified as a hazardous substance in accordance with the Approved Criteria.

13.2. Occupational health and safety

Dermal exposure to the imported products which contain < 2 % notified polymer may occur due to contact with drips and spills of the products during reformulation or addition to concrete. Exposure to the reformulated product containing a lower proportion of notified polymer may also occur during addition to concrete. There may also be dermal exposure to the concrete containing less than 0.01 % notified polymer. Exposure at this point will be very low due to the protective measures used to prevent contact with the fresh concrete.

Based on the low toxicological hazard presented by the notified polymer, the low concentrations present at all points, and the protective equipment specified in the MSDS (gloves, safety goggles and industrial clothing), the notified polymer will present a low risk to occupational health and safety.

13.3. Public health

The only significant public exposure is limited to concrete purchased by do-it-yourself handymen for such application as residential driveways. This will be limited to dermal exposure. The notified polymer is not a dermal irritant in rabbits. Based on the above information the notified polymer is unlikely to pose a significant risk to public health.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer and products containing the polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are 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 notified polymer and products containing the 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

Control Measures

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - impermeable gloves, safety goggles, industrial clothing.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

15.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

- (2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

16. REFERENCES

Connell, D.W. (1990). General Characteristics of Organic Compounds Which Exhibit Bioaccumulation. In: Bioaccumulation of Xenobiotic Compounds, CRC Press, Boca Raton, USA. p. 47-57.

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SafePharm (1989c). Rheobuild SV 87056: Acute Dermal Irritation Test in the Rabbit. Project No. 268/5, SafePharm Laboratories Ltd, Derby, UK. (unpublished report).

SafePharm (1989d). Rheobuild SV 87056: Acute Eye Irritation Test in the Rabbit. Project No. 268/6, SafePharm Laboratories Ltd, Derby, UK. (unpublished report).

SafePharm (1989e). Rheobuild SV 87056: Reverse Mutation Assay "Ames Test" using *Salmonella typhimurium*. Project No. 268/7, SafePharm Laboratories Ltd, Derby, UK. (unpublished report).

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