

File No: NA/769

23 April 2020

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**AQUALOC FC Polymers**

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.

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, National Occupational Health and Safety Commission, 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 |

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Coordinator at:

*Street Address:* 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA  
*Postal Address:* GPO Box 58, SYDNEY NSW 2001, AUSTRALIA  
*Telephone:* (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director  
Chemicals Notification and Assessment

## TABLE OF CONTENTS

|  |    |
|--|----|
| FULL PUBLIC REPORT.....  | 3  |
| 1. APPLICANT .....   | 3  |
| 2. IDENTITY OF THE CHEMICAL.....   | 3  |
| 3. PHYSICAL AND CHEMICAL PROPERTIES .....  | 3  |
| 3.1. Comments on Physico-Chemical Properties .....   | 4  |
| 4. PURITY OF THE CHEMICAL.....   | 4  |
| 5. USE, VOLUME AND FORMULATION .....   | 5  |
| 5.1. Manufacture/Import Volume.....  | 5  |
| 5.2. Formulation/Use .....   | 5  |
| 6. OCCUPATIONAL EXPOSURE .....   | 5  |
| 7. PUBLIC EXPOSURE .....   | 6  |
| 8. ENVIRONMENTAL EXPOSURE.....   | 6  |
| 8.1. Release .....   | 6  |
| 8.2. Fate.....   | 7  |
| 9. EVALUATION OF TOXICOLOGICAL DATA .....  | 7  |
| 9.1 Acute Toxicity .....   | 8  |
| 9.1.1a Oral Toxicity of AQUALOC FC-600K .....  | 8  |
| 9.1.1b Oral Toxicity of AQUALOC FC-900 .....   | 9  |
| 9.1.1c Oral Toxicity of AQUALOC FC-1000 .....  | 10 |
| 9.1.2a Dermal Toxicity of AQUALOC FC-600K.....   | 10 |
| 9.1.2b Dermal Toxicity of AQUALOC FC-1000 .....  | 11 |
| 9.1.3a Skin Irritation of AQUALOC FC-600K .....  | 11 |
| 9.1.3b Skin Irritation of AQUALOC FC-900 .....   | 12 |
| 9.1.3c Skin Irritation of AQUALOC FC-1000 .....  | 12 |
| 9.1.5a Eye Irritation of AQUALOC FC-600K.....  | 13 |
| 9.1.5b Eye Irritation of AQUALOC FC-900 .....  | 13 |
| 9.1.5c Eye Irritation of AQUALOC FC-1000 .....   | 13 |
| 9.2 Genotoxicity .....   | 14 |
| 9.2.1a <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> Reverse Mutation Assay of AQUALOC FC-600K ..... | 14 |
| 9.2.1b <i>Salmonella typhimurium</i> Reverse Mutation Assay of AQUALOC FC-900 .....                              | 15 |
| 9.2.1c <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> Reverse Mutation Assay of AQUALOC FC-1000 ..... | 16 |
| 9.3 Overall Assessment of Toxicological Data.....  | 16 |
| 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS .....  | 17 |
| 11. ASSESSMENT OF ENVIRONMENTAL RISK.....  | 17 |
| 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS .....  | 18 |
| 13. RECOMMENDATIONS .....  | 18 |
| 14. MATERIAL SAFETY DATA SHEET .....   | 19 |
| 15. REQUIREMENTS FOR SECONDARY NOTIFICATION .....  | 19 |
| 16. REFERENCES .....   | 20 |

**FULL PUBLIC REPORT****AQUALOC FC Polymers****1. APPLICANT**

MBT (Australia) Pty Ltd 11 of Stanton Road SEVEN HILLS NSW 2147 (ACN 000 450 288) has submitted a limited notification statement in support of their application for an assessment certificate for AQUALOC FC Polymers.

**Marketing Name:** Aqualoc FC-900; Aqualoc FC-944; Aqualoc FC-961;  
Aqualoc FC-600K and Aqualoc FC-1000

**2. IDENTITY OF THE CHEMICAL**

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

**3. PHYSICAL AND CHEMICAL PROPERTIES**

The data below relate to the notified polymer.

|  |  |
|--|--|
| <b>Appearance:</b>                               | light brown rubbery solid  |
| <b>Boiling Point:</b>                            | not measured (see comments below)  |
| <b>Specific Gravity/Density:</b>                 | 1.200  |
| <b>Vapour Pressure:</b>                          | expected to be very low (see comments below)                                     |
| <b>Water Solubility:</b>                         | highly soluble   |
| <b>Particle Size:</b>                            | not relevant, as the notified polymer will only be imported and used in solution |
| <b>Partition Co-efficient (n-octanol/water):</b> | $\log P_{ow} < -2$ (estimated)   |
| <b>Hydrolysis as a Function of pH:</b>           | no hydrolysis expected (see comments below)                                      |

|                                  |   |
|----------------------------------|---|
| <b>Adsorption/Desorption:</b>    | not measured  |
| <b>Dissociation Constant:</b>    | not measured (see comments below)   |
| <b>Flammability Limits:</b>      | not flammable, combustible  |
| <b>Autoignition Temperature:</b> | not appropriate, as the notified polymer is only used in aqueous solution |
| <b>Explosive Properties:</b>     | not expected to be explosive  |
| <b>Reactivity/Stability:</b>     | expected to be stable under normal environmental conditions               |

### 3.1. Comments on Physico-Chemical Properties

The polymer is supplied as an aqueous solution. The notifier has indicated that at room temperature the pure polymer is a rubbery solid and that with increased temperatures this does not alter.

Since the polymer has a high number average molecular weight, it is expected to have a low vapour pressure.

No test was done to determine the solubility of the polymer. It is supplied as an aqueous solution and when the concentration of the polymer in solution is increased its viscosity increases but there is no precipitation.

The notifier has indicated that the polymer is unlikely to hydrolyse. Bench tests of the storage stability of the product in solution (pH 7.3) and the cement water (pH 13) indicate that over a 50 and 20 day period, respectively, there is no change in the polymer.

The partition coefficient for the polymer was estimated using the atom/fragment contribution method via the KOWWIN estimation software (Syracuse Research Corporation, undated).

The adsorption/desorption was not determined due to the polymer's high water solubility and the estimated low partition coefficient, both of which indicate that the polymer is unlikely to adsorb to soils/organic material.

The polymer is a salt of a polyacrylic acid, and may therefore be basic in solution, particularly where it is fully neutralised. The notifier has indicated that the pH of the products is in the range 5.3 - 8.

## 4. PURITY OF THE CHEMICAL

|                              |   |
|------------------------------|---|
| <b>Degree of Purity:</b>     | 97 %  |
| <b>Hazardous Impurities:</b> | hazardous impurities consist of residual monomers and other reactants (see below) |

**Non-hazardous Impurities  
(> 1% by weight):** none

**Maximum Content  
of Residual Monomers:** residual monomer identities and concentrations have been exempted from publication; concentrations of residual monomers are all below the relevant cutoffs for the notified polymer to be classified as hazardous

**Additives/Adjuvants:**

|                           |                          |
|---------------------------|--------------------------|
| <i>Chemical name:</i>     | water                    |
| <i>CAS No.:</i>           | 7732-18-5                |
| <i>Weight percentage:</i> | 60 % in polymer solution |

## **5. USE, VOLUME AND FORMULATION**

### **5.1. Manufacture/Import Volume**

The notified polymer will not be manufactured in Australia. It will be imported into Australia in 1 tonne pallecons. The notified polymer will be imported in a 40 % solution. The import volumes for the notified polymer will be less than 1000 tonnes per annum over the next five years.

### **5.2. Formulation/Use**

The polymer will be used as a concrete additive.

It will not be manufactured in Australia but will undergo reformulation by dilution to products with 10 – 20 % notified polymer. In the reformulation process the solution will be pumped from the import containers into a 10000 L mixing tank, along with other ingredients (including non-hazardous wetting agents, surfactants and defoamers) and water. 7000 L of product is made at in a batch. The product, containing 25 – 50 % solids including 10 – 20 % notified polymer, is then transferred to a 20000 L bulk storage tank. The product is sent to customers, as required, in 1000 L lots in road bulk tankers. Once at the customer's site it is transferred into a designated storage tank on site.

At the customer's site the product is dispensed via an electronic computerised system that adds a measured amount to the concrete. The dose rate for the addition of the product to the concrete is between 0.5 and 0.8 L per 1000 L of concrete. The concentration of the notified polymer in the concrete will range from 0.005 % to 0.016 % depending on the combinations of dose and product used (ie 10 % polymer product at a dose of 0.5 L per 1000 L gives a concentration of 0.005 % in the concrete, while a 20 % polymer product at a dose of 0.8 L per 1000 L gives a concentration of 0.016 %).

## **6. OCCUPATIONAL EXPOSURE**

Following importation, the polymer solution, containing 40 % notified polymer, is pumped into a 10000 L open mixing vessel fitted with a mechanical stirrer. Other ingredients such as wetting aid, surfactant and defoamers are manually added into the mixing vessel through the open top of the mixing vessel. Water is pumped into the mixing vessel to make a 7000 L batch of finished product. Quality control technicians will test the quality of the finished product. Once tested, the finished product will be pumped into a 20000 L bulk storage tank prior to distribution to customers by road tanker. The finished product will contain 10 - 20 % notified polymer. Mixing vessel and transfer lines are washed with fresh water after each batch. Wash water is pumped into bulk storage tank where it is added to the finished product.

Between 1 and 3 workers will be involved in the formulation of the finished product.

The finished product is drawn in 1000 L lots from the bulk storage tank and transferred by pumping into a bulk transport tanker for delivery to customers when required.

At the customer site, the product is pumped from the bulk transport tanker into customer storage tanks for subsequent incorporation to concrete products by adding approximately 0.5 to 0.8 L of the formulated product in 1000 L of concrete using an electronic dispenser unit. The concrete product will contain approximately 0.005 % to 0.016 % notified polymer. The notifier indicated that the concrete products have various applications. Low risk of exposure to the notified polymer is expected since once the concrete is hardened, the notified polymer will be bound within the concrete matrix, and would not be available separately for exposure.

Worker exposure to the notified polymer is expected to be low since the dispensing and mixing involves automated processes. Exposure is limited to spills and drips of the product containing the notified polymer when connecting and disconnecting hoses during transfer and cleaning operations. Workers involved in handling the notified polymer as a polymer solution or as an ingredient in concrete will be equipped with personal protective equipment such as overall, safety shoes, helmet, goggles and gloves. Respiratory protection is not normally required; however, if specific use generates vapour or mist, purifying respirators designed to filter mist and organic vapours is recommended. Laboratory technicians are also required to wear laboratory coats. The mixing vessel is fitted with local exhaust ventilation.

## **7. PUBLIC EXPOSURE**

There is minimal potential for exposure of the public to the notified polymer contained in construction materials and the physical properties of the notified polymer mean that absorption and bioaccumulation are unlikely. The formulation is water-based so that inhalation exposure is unlikely. The low exposure indicates a negligible risk to public health.

## **8. ENVIRONMENTAL EXPOSURE**

### **8.1. Release**

The notified polymer may be released to the environment via spills during transport,

reformulation or end-use. The notifier has not provided an estimation of the quantities lost in this way. It has been estimated that up to 1 % may be lost via each of these stages, ie < 10 tonnes transport spills, < 10 tonnes reformulation spills and < 10 tonnes end-user spills. It is likely that any material spilt at the reformulation or end-user site will be recycled.

#### *Reformulation process*

The washwater from the cleaning of the reformulation process equipment and transfer lines is added to the product in the bulk storage tank. Any batches that are out-of-specifications are reworked/recycled.

The notifier has not indicated the amount of polymer that will remain in the import containers as residue. This has been estimated to be up to 1 %, which equates to < 10 tonnes of polymer per year.

It is likely that the road tankers are washed back at the reformulation site and the washwater recycled into the process.

#### *End-user Site – Concrete batching plant*

The dosing line will contain residual product, containing the notifier polymer. Presumably, this will be cleaned and the resultant washwater containing the notified polymer will be recycled.

The residual concrete in the concrete truck's barrel will be cleaned out at the concrete plant and the washwater is collected in a settling/drying pit. After the solids have been allowed to dry they are disposed of in accordance with State regulation, and most likely go to landfill.

It is likely that any surplus concrete will be allowed to dry and set at the site of use then be disposed of to landfill.

## **8.2. Fate**

Spilt imported material or raw product that cannot be recycled is likely to end up in landfill. Due to the solubility of the notified polymer it is likely to leach rather than adsorb to soil.

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

No information was provided regarding the degradability of the notified polymer. 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.

## **9. EVALUATION OF TOXICOLOGICAL DATA**

Toxicity testing was carried out using three different compositions of the notified polymer (varying in the proportions of constituent monomers), AQUALOC FC-600K (formerly 600S), AQUALOC FC-900 and AQUALOC FC-1000.

All tests were conducted in accordance with Good Laboratory Practice (GLP) standards and according to OECD Test Guidelines.

### Summary of the toxicity of AQUALOC FC-600K

| <i>Test</i>            | <i>Species</i> | <i>Outcome</i>                | <i>Reference</i> |
|------------------------|----------------|-------------------------------|------------------|
| acute oral toxicity    | rat            | LD <sub>50</sub> > 2000 mg/kg | (Crouch, 1994c)  |
| acute dermal toxicity  | rat            | LD <sub>50</sub> > 2000 mg/kg | (Crouch, 1994a)  |
| skin irritation        | rabbit         | non-irritating                | (Suzuki, 1994)   |
| eye irritation         | rabbit         | non-irritating                | (Arcelin, 1994a) |
| bacterial mutagenicity |                | not mutagenic                 | (Wollny, 1995a)  |

### Summary of the toxicity of AQUALOC FC-900

| <i>Test</i>            | <i>Species</i> | <i>Outcome</i>                | <i>Reference</i> |
|------------------------|----------------|-------------------------------|------------------|
| acute oral toxicity    | rat            | LD <sub>50</sub> > 2000 mg/kg | Pfister, 1995    |
| skin irritation        | rabbit         | slight irritant               | (Braun, 1995b)   |
| eye irritation         | rabbit         | non-irritating                | (Braun, 1995a)   |
| bacterial mutagenicity |                | not mutagenic                 | (Wollny, 1995b)  |

### Summary of the toxicity of AQUALOC FC-1000

| <i>Test</i>            | <i>Species</i> | <i>Outcome</i>                | <i>Reference</i> |
|------------------------|----------------|-------------------------------|------------------|
| acute oral toxicity    | rat            | LD <sub>50</sub> > 2000 mg/kg | (Crouch, 1994d)  |
| acute dermal toxicity  | rat            | LD <sub>50</sub> > 2000 mg/kg | (Crouch, 1994b)  |
| skin irritation        | rabbit         | non-irritating                | (Arcelin, 1994c) |
| eye irritation         | rabbit         | non-irritating                | (Arcelin, 1994b) |
| bacterial mutagenicity |                | not mutagenic                 | (Poth, 1994)     |

## 9.1 Acute Toxicity

### 9.1.1a Oral Toxicity of AQUALOC FC-600K (Crouch, 1994c)

|                                  |   |
|----------------------------------|---|
| <i>Species/strain:</i>           | rat/HanIbm:WIST (SPF)   |
| <i>Number/sex of animals:</i>    | 5/sex   |
| <i>Observation period:</i>       | 14 days   |
| <i>Method of administration:</i> | gavage; dose 2000 mg/kg of 40.1 % (w/v) aqueous solution; diluted in water to a dose volume of 10 mL/kg |



|                                |   |
|--------------------------------|---|
| <i>Test method:</i>            | OECD TG 401; EC directive 92/69/EEC, B.1.   |
| <i>Mortality:</i>              | no deaths were recorded during the study  |
| <i>Clinical observations:</i>  | no clinical signs of toxicity were observed during the course of the study  |
| <i>Morphological findings:</i> | no organ abnormalities were observed at necropsy  |
| <i>Comment:</i>                | the rate of body weight gain of the animals during the observation period was not affected by treatment with the test substance |
| <i>LD<sub>50</sub>:</i>        | > 2000 mg/kg  |
| <i>Result:</i>                 | the notified polymer (AQUALOC FC-600K) was of very low acute oral toxicity in rats  |

#### **9.1.1b Oral Toxicity of AQUALOC FC-900 (Pfister, 1995)**

|                                  |   |
|----------------------------------|---|
| <i>Species/strain:</i>           | rat/HanIbm:WIST (SPF)   |
| <i>Number/sex of animals:</i>    | 5/sex   |
| <i>Observation period:</i>       | 14 days   |
| <i>Method of administration:</i> | gavage; dose 2000 mg/kg of 40 % (w/v) aqueous solution; diluted in water to a dose volume of 10 mL/kg                           |
| <i>Test method:</i>              | OECD TG 401; EC directive 92/69/EEC, B.1.   |
| <i>Mortality:</i>                | no deaths were recorded during the study  |
| <i>Clinical observations:</i>    | no clinical signs of toxicity were observed during the course of the study  |
| <i>Morphological findings:</i>   | no organ abnormalities were observed at necropsy  |
| <i>Comment:</i>                  | the rate of body weight gain of the animals during the observation period was not affected by treatment with the test substance |
| <i>LD<sub>50</sub>:</i>          | > 2000 mg/kg  |
| <i>Result:</i>                   | the notified polymer (AQUALOC FC-900) was of very low acute oral toxicity in rats   |

### 9.1.1c Oral Toxicity of AQUALOC FC-1000 (Crouch, 1994d)

|                                  |   |
|----------------------------------|---|
| <i>Species/strain:</i>           | rat/HanIbm:WIST (SPF)   |
| <i>Number/sex of animals:</i>    | 5/sex   |
| <i>Observation period:</i>       | 14 days   |
| <i>Method of administration:</i> | gavage; dose 2000 mg/kg of 40.2 % (w/v) aqueous solution; diluted in water to a dose volume of 10 mL/kg   |
| <i>Test method:</i>              | OECD TG 401; EC directive 92/69/EEC, B.1.   |
| <i>Mortality:</i>                | no deaths were recorded during the study  |
| <i>Clinical observations:</i>    | no clinical signs of toxicity were observed during the course of the study  |
| <i>Morphological findings:</i>   | no organ abnormalities were observed at necropsy  |
| <i>Comment:</i>                  | the rate of body weight gain of males during the observation period was not affected by treatment with the test substance; females showed a significant decrease in the rate of body weight gain during the second week of the study; no associated signs of emaciation were observed |
| <i>LD<sub>50</sub>:</i>          | > 2000 mg/kg  |
| <i>Result:</i>                   | the notified polymer (AQUALOC FC-1000) was of very low acute oral toxicity in rats  |

### 9.1.2a Dermal Toxicity of AQUALOC FC-600K (Crouch, 1994a)

|                                  |  |
|----------------------------------|--|
| <i>Species/strain:</i>           | rat/HanIbm:WIST (SPF)  |
| <i>Number/sex of animals:</i>    | 5/sex  |
| <i>Observation period:</i>       | 14 days  |
| <i>Method of administration:</i> | semi-occlusive patch; dose 2000 mg/kg of 40.1 % aqueous solution, applied for 24 hr  |
| <i>Test method:</i>              | OECD TG 402; EC directive 92/69/EEC, B.3.  |
| <i>Mortality:</i>                | no deaths were recorded during the study   |
| <i>Clinical observations:</i>    | no clinical signs of systemic toxicity or local effects of the test substance on skin were observed during the course of the study |

|                                |   |
|--------------------------------|---|
| <i>Morphological findings:</i> | no organ abnormalities were observed at necropsy  |
| <i>Comment:</i>                | one female lost weight during the first week of the study; all other animals gained weight throughout |
| <i>LD<sub>50</sub>:</i>        | > 2000 mg/kg  |
| <i>Result:</i>                 | the test substance was of low dermal toxicity in rats   |

#### **9.1.2b Dermal Toxicity of AQUALOC FC-1000 (Crouch, 1994b)**

|                                  |   |
|----------------------------------|---|
| <i>Species/strain:</i>           | rat/HanIbm:WIST (SPF)   |
| <i>Number/sex of animals:</i>    | 5/sex   |
| <i>Observation period:</i>       | 14 days   |
| <i>Method of administration:</i> | semi-occlusive patch; dose 2000 mg/kg of 40.2 % aqueous solution, applied for 24 hr   |
| <i>Test method:</i>              | OECD TG 402; EC directive 92/69/EEC, B.3.   |
| <i>Mortality:</i>                | no deaths were recorded during the study  |
| <i>Clinical observations:</i>    | no clinical signs of systemic toxicity were observed during the course of the study; one male showed yellow colouration of the skin on days 3 and 4 |
| <i>Morphological findings:</i>   | no organ abnormalities were observed at necropsy  |
| <i>Comment:</i>                  | slightly reduced weight gain was observed in the females throughout the study; the males gained weight throughout                                   |
| <i>LD<sub>50</sub>:</i>          | > 2000 mg/kg  |
| <i>Result:</i>                   | the test substance was of low dermal toxicity in rats   |

#### **9.1.3a Skin Irritation of AQUALOC FC-600K (Suzuki, 1994)**

|                                  |  |
|----------------------------------|--|
| <i>Species/strain:</i>           | rabbit/Japanese white (Kbs: JW)  |
| <i>Number/sex of animals:</i>    | 6/male   |
| <i>Observation period:</i>       | 3 days   |
| <i>Method of administration:</i> | 0.5 mL test substance (40.1 % (w/v) aqueous solution of notified polymer) was applied to 3 separate clipped test sites |

|                     |  |
|---------------------|--|
|                     | under semi-occlusive conditions for 3 min, 1 hr and 4 hr               |
| <i>Test method:</i> | OECD TG 404  |
| <i>Comment:</i>     | no signs of skin irritation were observed; all Draize scores were zero |
| <i>Result:</i>      | the notified chemical was non-irritating to the skin of rabbits        |

### 9.1.3b Skin Irritation of AQUALOC FC-900 (Braun, 1995b)

|                                  |  |
|----------------------------------|--|
| <i>Species/strain:</i>           | rabbit/New Zealand white - CRL:KBL(NZW)BR  |
| <i>Number/sex of animals:</i>    | 1 male<br>2 female   |
| <i>Observation period:</i>       | 3 days   |
| <i>Method of administration:</i> | 0.5 mL test substance (40 % (w/v) aqueous solution of notified polymer) was applied a clipped test site under semi-occlusive conditions for 4 hr |
| <i>Test method:</i>              | OECD TG 404; EC directive 92/69/EEC, B.4.  |
| <i>Comment:</i>                  | the male showed very slight erythema (Draize score 1) at 1 hr and 24 hr; all other Draize scores were zero                                       |
| <i>Result:</i>                   | the notified chemical was slightly irritating to the skin of rabbits   |

### 9.1.3c Skin Irritation of AQUALOC FC-1000 (Arcelin, 1994c)

|                                  |  |
|----------------------------------|--|
| <i>Species/strain:</i>           | rabbit/New Zealand white - CRL:NZW(SPF)  |
| <i>Number/sex of animals:</i>    | 1 male<br>2 female   |
| <i>Observation period:</i>       | 3 days   |
| <i>Method of administration:</i> | 0.5 mL test substance (40.2 % (w/v) aqueous solution of notified polymer) was applied a clipped test site under semi-occlusive conditions for 4 hr |
| <i>Test method:</i>              | OECD TG 404; EC directive 92/69/EEC, B.4.  |
| <i>Comment:</i>                  | no signs of skin irritation were observed; all Draize scores were zero   |

*Result:* the notified chemical was non-irritating to the skin of rabbits

#### **9.1.5a Eye Irritation of AQUALOC FC-600K (Arcelin, 1994a)**

*Species/strain:* rabbit/Chbb: NZW (SPF)

*Number/sex of animals:* 1 male  
2 female

*Observation period:* 3 days

*Method of administration:* 0.1 mL test substance (40.1 % (w/v) aqueous solution of notified polymer) was placed in the conjunctival sac of the left eye; the untreated eye served as control

*Test method:* OECD TG 405; EC directive 92/69/EEC, B.5.

*Comment:* at the 1 hr observation, two animals showed conjunctival redness (Draize score 1) and two animals showed slight discharge; all Draize scores at 24, 48 and 72 hr were zero

*Result:* the notified chemical was non-irritating to the eyes of rabbits

#### **9.1.5b Eye Irritation of AQUALOC FC-900 (Braun, 1995a)**

*Species/strain:* rabbit/New Zealand white - CRL:KBL(NZW)BR

*Number/sex of animals:* 1 male  
2 female

*Observation period:* 3 days

*Method of administration:* 0.1 mL test substance (40 % (w/v) aqueous solution of notified polymer) was placed in the conjunctival sac of the left eye; the untreated eye served as control

*Test method:* OECD TG 405; EC directive 92/69/EEC, B.5.

*Comment:* no signs of eye irritation were observed; all Draize scores at 1, 24, 48 and 72 hr were zero

*Result:* the notified chemical was non-irritating to the eyes of rabbits

#### **9.1.5c Eye Irritation of AQUALOC FC-1000 (Arcelin, 1994b)**

*Species/strain:* rabbit/Crl: NZW (SPF)

|                                  |  |
|----------------------------------|--|
| <i>Number/sex of animals:</i>    | 1 male<br>2 female   |
| <i>Observation period:</i>       | 3 days   |
| <i>Method of administration:</i> | 0.1 mL test substance (40.2 % (w/v) aqueous solution of notified polymer) was placed in the conjunctival sac of the left eye; the untreated eye served as control        |
| <i>Test method:</i>              | OECD TG 405; EC directive 92/69/EEC, B.5.  |
| <i>Comment:</i>                  | at the 1 hr observation, one animal showed injected blood vessels of the sclera and all animals showed slight discharge; all Draize scores at 24, 48 and 72 hr were zero |
| <i>Result:</i>                   | the notified chemical was non-irritating to the eyes of rabbits  |

## 9.2 Genotoxicity

### 9.2.1a *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay of AQUALOC FC-600K (Wollny, 1995a)

|                              |   |
|------------------------------|---|
| <i>Strains:</i>              | <i>Salmonella typhimurium</i> TA98, TA100, TA1535 and TA1537; <i>Escherichia coli</i> WP2uvrA(pKM101)   |
| <i>Metabolic activation:</i> | 10 % rat liver S9 fraction (Aroclor1254-induced) in standard cofactors  |
| <i>Concentration range:</i>  | 0, 33.3, 100, 333.3, 1000, 2500, 5000 µg/plate, 40.1 % aqueous solution of notified polymer, dissolved in dimethylformamide and plated as a 100 µL aliquot  |
| <i>Positive controls:</i>    | with S9:<br>TA98, TA100, TA1535, TA1537: 2-aminoanthracene 2.5 µg/plate<br>WP2uvrA: 2-aminoanthracene 10 µg/plate<br><br>without S9<br>TA98, TA1537: 4-nitro-o-phenylenediamine 10 µg/plate<br>TA100,TA1535: sodium azide 10 µg/plate<br>WP2uvrA: methyl methanesulphonate 5 µL/plate |
| <i>Test method:</i>          | OECD TG 471 and 472 (plate incorporation method)  |
| <i>Comment:</i>              | all concentrations were tested in triplicate and concurrent positive and negative controls responded appropriately, two independent assays were performed<br><br>a slight toxic effect, indicated by a reduction in the number  |

of revertant colonies, was observed for TA98 in the absence of metabolic activation in the first experiment; this was not observed in the confirmatory assay; no precipitation or reduction in background lawn was observed in the other tests

no substantial increases in the number of revertant colonies were observed for any tester strain either in the presence or absence of metabolic activation

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

#### **9.2.1b *Salmonella typhimurium* Reverse Mutation Assay of AQUALOC FC-900 (Wollny, 1995b)**

*Strains:* *Salmonella typhimurium* TA98, TA100

*Metabolic activation:* 10 % rat liver S9 fraction (Aroclor1254-induced) in standard cofactors

*Concentration range:* 0, 33.3, 100, 333.3, 1000, 2500, 5000 µg/plate, 40 % aqueous solution of notified polymer, dissolved in water and plated as a 100 µL aliquot

*Positive controls:* with S9:  
TA98, TA100: 2-aminoanthracene 2.5 µg/plate

without S9  
TA98: 4-nitro-o-phenylenediamine 10 µg/plate  
TA100: sodium azide 10 µg/plate

*Test method:* OECD TG 471 (plate incorporation method and pre-incubation method)

*Comment:* all concentrations were tested in triplicate and concurrent positive and negative controls responded appropriately, two independent assays were performed; initially by the plate incorporation method and then by the pre-incubation method

no precipitation or reduction in background lawn was observed in the tests

no substantial increases in the number of revertant colonies were observed for either tester strain either in the presence or absence of metabolic activation

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

### 9.2.1c *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay of AQUALOC FC-1000 (Poth, 1994)

|                              |  |
|------------------------------|--|
| <i>Strains:</i>              | <i>Salmonella typhimurium</i> TA98, TA100, TA1535 and TA1537; <i>Escherichia coli</i> WP2uvrA(pKM101)  |
| <i>Metabolic activation:</i> | 10 % rat liver S9 fraction (Aroclor1254-induced) in standard cofactors   |
| <i>Concentration range:</i>  | 0, 33.3, 100, 333.3, 1000, 2500, 5000 µg/plate, 40.1 % aqueous solution of notified polymer, dissolved in water and plated as a 100 µL aliquot   |
| <i>Positive controls:</i>    | with S9:<br>TA98, TA100, TA1535, TA1537: 2-aminoanthracene 2.5 µg/plate<br>WP2uvrA: 2-aminoanthracene 10 µg/plate<br><br>without S9<br>TA98, TA1537: 4-nitro-o-phenylenediamine 10 µg/plate<br>TA100,TA1535: sodium azide 10 µg/plate<br>WP2uvrA: methyl methanesulphonate 5 µL/plate  |
| <i>Test method:</i>          | OECD TG 471 and 472 (plate incorporation method and pre-incubation method)   |
| <i>Comment:</i>              | all concentrations were tested in triplicate and concurrent positive and negative controls responded appropriately, two independent assays were performed; initially by the plate incorporation method and then by the pre-incubation method<br><br>no precipitation or reduction in background lawn was observed in the tests<br><br>no substantial increases in the number of revertant colonies were observed for any tester strain either in the presence or absence of metabolic activation |
| <i>Result:</i>               | the notified polymer was non mutagenic under the conditions of the test  |

### 9.3 Overall Assessment of Toxicological Data

The notifier provided reports of toxicity testing for acute oral and dermal toxicity and skin and eye irritation for three different compositions of the notified polymer. These tests were carried out using products which contained approximately 40 % notified polymer in aqueous solution, and no correction for the concentration of notified polymer was applied. The results



of the limit tests therefore apply to the formulation, rather than the notified polymer. However, no signs of toxicity were observed in any of the tests to indicate that higher doses may have significant toxicity.

The results of the study indicate that the formulations have very low acute oral toxicity in the rat, with  $LD_{50} > 2000$  mg/kg, and low dermal toxicity in the rat, with  $LD_{50} > 2000$  mg/kg. The formulations were at most slight skin eye irritants and were non-irritant to eyes. They were found to be non-mutagenic under the conditions of the tests in a bacterial system.

No other toxicity studies (e.g., for inhalation toxicity, skin sensitisation or repeated dose toxicity) were submitted.

### **Hazard classification**

The hazard classification of the notified chemical is limited to the consideration of the toxicity studies submitted by the notifier. According to these, the notified chemical does not meet the criteria for classification as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) (Approved Criteria).

The absence of data for other toxicity tests, however, does not exclude the possibility that the notified chemical may have toxic properties by other means of exposure, or have adverse effects on other organ systems or tissues.

## **10. ASSESSMENT OF ENVIRONMENTAL EFFECTS**

No ecotoxicological data were provided.

## **11. ASSESSMENT OF ENVIRONMENTAL RISK**

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

The main environmental hazard would arise from release of the notified polymer during storage or transport. The use of bunded containment minimises the risk of release at storage sites. The Material Safety Data Sheet (MSDS) appears to adequately address spills and disposal. There is potential for up to 30 tonnes of the raw notified polymer to be released into the environment as a consequence of spillage. This spillage is expected to be distributed across several sites and not restricted to a single site. This would minimise the degree of risk to the environment at any given time. If the spilt imported material or raw product cannot be recycled then it is likely to end up in landfill adsorbed to the inert material used for the spill clean-up (such as sand), where it is likely to leach out in a diffuse manner at low concentrations

A further environmental hazard could arise from release of untreated polymer-contaminated water into the aquatic compartment. Since the process equipment washwater and spill clean-up water are used, where possible, in the reformulation process, and considering the truck washing treatment described in the submission, this is highly unlikely.

The overall environmental hazard posed by the notified polymer should be low.

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

### *Hazard Assessment*

Toxicological information has been provided for oral and dermal toxicity and skin and eye irritation for products containing the notified polymer. The notified polymer is of very low oral toxicity in the rat ( $LD_{50} > 2000$  mg/kg) and low dermal toxicity in the rat ( $LD_{50} > 2000$  mg/kg). The formulations were at most slight skin irritants and were non-irritant to eyes. They were found to be non-mutagenic under the conditions of the tests in a bacterial system. The notified polymer cannot be assessed against the Approved Criteria for other toxicity endpoints.

The MSDS for the products containing the notified polymer indicate that they are not hazardous substances. The pH of the products containing the ionised polymer are given as being in the range of 5.5 to 8, and skin and eye irritation are therefore not expected on exposure to these products on the basis of pH.

### *Occupational Health and Safety*

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

During reformulation and end use, the main exposure route for the notified polymer will be dermal. While the mixing and dosing operations are automated, exposure to drips and spills of the polymer solution (40 % notified polymer (w/v)) and the reformulated product (10 – 20 % notified polymer (w/v)) is possible at a number of points where these products are transferred. Once the reformulated product has been dosed into concrete, the final concentration will be very low ( $< 0.16$  %) and little exposure is therefore expected.

Precautions should be taken to avoid dermal and ocular contact with the products containing the notified polymer, as slight skin and eye irritation may occur. The MSDS indicates that overalls, impermeable gloves and eye protection should be worn.

Once the final concrete mix, containing a maximum of 0.016 % notified polymer, has hardened, the polymer will not be separately available for exposure or absorption.

### *Public Health*

There is minimal potential for public exposure to the notified polymer arising from its use as a polymer admixture for use in construction materials. The low exposure and low toxicity of the products indicates a negligible risk to public health. It is therefore considered that the notified polymer will not pose a significant hazard to public health when used in the proposed manner.

## **13. RECOMMENDATIONS**

To minimise occupational exposure to Aqualoc FC Polymers the following guidelines and precautions should be observed:

- Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the products containing the notified polymer;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

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

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a).

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

The MSDS for the notified polymer (five different compositions) were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 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, 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

Arcelin G (1994a) Primary Eye Irritation Study with Aqualoc FC-600S in Rabbits, Project No. 378505, Research & Consulting Company, Ltd., Itingen, Switzerland.

Arcelin G (1994b) Primary Eye Irritation Study with Aqualoc FC-1000 in Rabbits, Project No. 378540, Research & Consulting Company, Ltd., Itingen, Switzerland.

Arcelin G (1994c) Primary Skin Irritation Study with Aqualoc FC-1000 in Rabbits (4-hour Semi-occlusive Application), Project No. 378641, Research & Consulting Company, Ltd., Itingen, Switzerland.

Braun WH (1995a) Primary Eye Irritation Study with Aqualoc FC-900 in Rabbits, Project No. 396145, Research & Consulting Company, Ltd., Itingen, Switzerland.

Braun WH (1995b) Primary Skin Irritation Study with Aqualoc FC-900 in Rabbits (4-hour Semi-occlusive Application), Project No. 396134, Research & Consulting Company, Ltd., Itingen, Switzerland.

Connell D. W. (1989) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

Crouch CN (1994a) Acute Dermal Toxicity Study with Aqualoc FC-600S in Rats, Project No. 378527, Research & Consulting Company, Ltd., Itingen, Switzerland.

Crouch CN (1994b) Acute Dermal Toxicity Study with Aqualoc FC-1000 in Rats, Project No. 378562, Research & Consulting Company, Ltd., Itingen, Switzerland.

Crouch CN (1994c) Acute Oral Toxicity Study with Aqualoc FC-600S in Rats, Project No. 378516, Research & Consulting Company, Ltd., Itingen, Switzerland.

Crouch CN (1994d) Acute Oral Toxicity Study with Aqualoc FC-1000 in Rats, Project No. 378551, Research & Consulting Company, Ltd., Itingen, Switzerland.

National Institute of Occupational Safety and Health (1998). Registry of Toxic Effects of Chemical Substances. 1998.

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.

National Occupational Health and Safety Commission (1999a) List of Designated Hazardous Substances [NOHSC:10005(1999)]. Australian Government Publishing Service, Canberra.

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

Pfister, Th. (1995) Acute Oral Toxicity Study with AQUALOC FC-900 in Rats, Project No. 396156, Research & Consulting Co., Ltd, Itingen, Switzerland.

Poth A (1994) *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay with Aqualoc FC-1000, Project No. 480700, Cytotest Cell Research GmbH & Co, Kg, Roßdorf, Germany.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

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

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

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

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

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

Suzuki K (1994) Primary Skin Irritation Study of Aqualoc FC-600S in Rabbits, Project No. H-94089, Nippon Experimental Medical Research Institute Co. Ltd., Gunma, Japan.

Syracuse Research Corporation. KOWWIN (V1.57).

Wollny E (1995a) *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay with Aqualoc FC-600S, Project No. 480700, Cytotest Cell Research GmbH & Co, Kg, Roßdorf, Germany.

Wollny E (1995b) *Salmonella typhimurium* Reverse Mutation Assay Screening Version with Aqualoc FC-900, Project No. 510500, Cytotest Cell Research GmbH & Co, Kg, Roßdorf, Germany.

## Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

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

The Draize scale (Draize *et al.*, 1944) for evaluation of eye reactions is as follows:

### ***CORNEA***

| <b><i>Opacity</i></b>  | <b><i>Rating</i></b> | <b><i>Area of Cornea involved</i></b> | <b><i>Rating</i></b> |
|--|----------------------|---------------------------------------|----------------------|
| 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***

| <b><i>Redness</i></b>   | <b><i>Rating</i></b> | <b><i>Chemosis</i></b>                              | <b><i>Rating</i></b> | <b><i>Discharge</i></b>  | <b><i>Rating</i></b> |
|---|----------------------|---|----------------------|--|----------------------|
| 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***

| <b><i>Values</i></b>  | <b><i>Rating</i></b> |
|---|----------------------|
| Normal  | 0 none               |
| Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light | 1 slight             |
| No reaction to light, haemorrhage, gross destruction                                    | 2 severe             |

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, *J. Pharmacol. Exp. Ther.* 82 : 377-390

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.