File No: NA/703

November 1999

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**Component of Q-1549**

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

## Component of Q-1549

## 1. APPLICANT

Rohm and Haas Australia Pty Ltd. of 969 Burke Road CAMBERWELL VICTORIA 3124 has submitted a standard notification statement in support of their application for an assessment certificate for Component of Q-1549.

## 2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of Component of Q-1549 to be exempt from publication in the Full Public Report. The data items were: chemical name; other name; names of analogs, CAS number; molecular and structural formulae; molecular weight, spectral data and purity.

**Marketing Name:** Component of Q-1549

**Method of Detection and Determination:** infrared spectroscopy (spectrum supplied)

## 3. PHYSICAL AND CHEMICAL PROPERTIES

The data for the physico-chemical properties were obtained via tests on a pure sample of Product A and a lyophilized subsample of this chemical, known as B

| | |
|---|---|
| **Appearance at 20°C and 101.3 kPa:** | clear colourless liquid with ammonia smell |
| **Boiling Point:** | >146 $\pm$ 5°C at 102 $\pm$ 1 kPa (the test was carried out using B which is the residue left after lyophilisation of the notified chemical and is expected to be similar to a pure sample of the notified chemical) |
| **Pour Point** | 20 $\pm$ 1°C |
| **Density:** | 1 150 kg/m$^3$ |
| **Vapour Pressure:** | <1.3 $10^{-2}$ kPa at 25°C |
| **Water Solubility:** | > 540mg/L at 23°C; at 970 mg/L the water was |

| | |
|---|---|
| | absorbed by the notified chemical forming a homogenous gel (test conducted on 100% notified chemical) |
| **Partition Co-efficient (n-octanol/water):** | log $P_{ow} \leq -1 \pm 0.1$ at 23°C |
| **Hydrolysis as a Function of pH:** | hydrolytically stable under pH 4, pH 7 and pH 9 |
| **Adsorption/Desorption:** | > 50% notified chemical would be adsorbed to soil and < 40% of the adsorbed active would be desorbed (25% notified chemical) |
| **Dissociation Constant:** | $pK_{a1} = 1.6$ and $pK_{a2} = 6.8$ (for the phosphate group, based on phosphorous acid) |
| **Flash Point:** | > 93°C |
| **Flammability Limits:** | not flammable |
| **Autoignition Temperature:** | does not autoignite |
| **Explosive Properties:** | not explosive |
| **Reactivity/Stability:** | stable under the condition of use |

**Comments on Physico-Chemical Properties**

Melting (Pour) point of B was tested using OECD TG 102.

The average boiling point of B was determined using the "modified principle" of the Siwoloboff method (OECD TG 103).

A modified pycnometer method (OECD TG 109) was used to determine density of B. This modified method was required due to the high viscosity of B.

The isoteniscope method was employed for vapour pressure determination (OECD TG 104). The detection limit was 13 Pa and the observed vapour pressure of B at 25°C was less than 13 Pa.

Solubility results were obtained from of B using OECD TG 105.

Hydrolysis was determined using HPLC based on OECD TG 111.

Partition Coefficient tests were performed on C, based on OECD TG 107.

The notified chemical is highly water soluble with a very low affinity for the organic phase. Log $K_{oc}$ and log $P_{ow}$ are low, indicating that if the chemical is released to the soil compartment, for example through disposal in landfill, it will be highly mobile and ultimately reach the water compartment.

Adsorption of C was calculated using molecular modelling computer algorithms. This approach was necessary because the HPLC-UV analytical method was not sufficiently sensitive and provided only qualitative results. The adsorption coefficient ($K_{oc}$) was calculated using software from Advanced Chemistry Development Inc. $K_{oc}$ is defined as the ratio of chemical adsorbed per unit weight of organic carbon ($C_c$) in the soil to the concentration of the chemical in solution at equilibrium ($Ca_q$):

$$K_{oc} = \frac{C_c}{C_{aq}}$$

The $K_{oc}$ of D was approximately 1, implying that approximately 50% would adsorb to soil containing organic matter.

The notified chemical contains a phosphate group, which is expected to have a $pK_{a1}$ of 1.6 and $pK_{a2}$ of 6.8, based on phosphoric acid. The $pK_a$ values indicate that in the environment the chemical would exist at least partially in the anionic forms.

## 4. PURITY OF THE CHEMICAL

**Degree of Purity:** 99.5% in Q-1549

**Toxic or Hazardous Impurities:**

| | |
|---|---|
| *Chemical name:* | diammonium phosphate |
| *Synonyms:* | dibasic ammonium phosphate |
| *CAS No.:* | 7783-28-0 |
| *Weight percentage:* | < 0.25% |
| *Toxic properties:* | low to moderate toxicity (Sax, 1996) |
| *Chemical name:* | p-dioxane |
| *Synonyms:* | diethylene dioxide |
| *CAS No.:* | 123-91-1 |
| *Weight percentage:* | < 0.015% |
| *Toxic properties:* | On the *List of Designated Hazardous Substances* (National Occupational Health and Safety Commission, 1999)<br>R 40<br>R 36/37<br>confirmed carcinogen with experimental carcinogenic, neoplastigenic, tumorigenic and teratogenic data<br>moderately toxic by ingestion and inhalation<br>skin and eye irritant<br>human systemic effect by inhalation: convulsions, conjunctival irritation, high blood pressure, unspecified respiratory and gastrointestinal system effects |

| | |
|---|---|
| | repeated exposure to low concentrations has resulted in human fatalities, the organs chiefly affected being the liver and the kidney<br>very dangerous fire and explosion hazard when exposed to heat or flame; reacts vigorously with oxidising agents |
| *Chemical name:* | ethylene oxide |
| *Synonyms:* | dimethylene oxide |
| *CAS No.:* | 75-21-8 |
| *Weight percentage:* | < 0.001% |
| *Toxic properties:* | On the *List of Designated Hazardous Substances* (National Occupational Health and Safety Commission, 1999)<br>R 12<br>R 45(2)<br>R 46(2)<br>R 23<br>R 36 (37) 38<br>oral rat $LD_{50}$ = 72 mg/kg<br>according to Sax (1996) the chemical is<br>confirmed carcinogen with experimental carcinogenic, neoplastigenic, tumorigenic and teratogenic data<br>skin and eye irritant<br>irritant to the respiratory tract; high concentrations can cause pulmonary edema<br>human systemic effects by inhalation: nausea, vomiting, olfactory and pulmonary changes<br>experimental reproductive effects<br>highly flammable liquid or gas; severe explosion hazard when exposed to flame |
| *Chemical name:* | acetaldehyde |
| *Synonyms:* | aceticaldehyde |
| *CAS No.:* | 75-07-0 |
| *Weight percentage:* | 0.001% |
| *Toxic properties:* | On the *List of Designated Hazardous Substances* (National Occupational Health and Safety Commission, 1999)<br>R 40<br>R 36/37<br>according to Sax (1996) the chemical is<br>confirmed carcinogen with experimental carcinogenic and tumorigenic data<br>respiratory irritant<br>a skin and severe eye irritant |

| | |
|---|---|
| | a human narcotic<br>experimental reproductive effects<br>highly flammable liquid; can react violently with acid anhydrides, alcohols, ketons, phenols, ammonia, hydrogen cyanide, hydrogen sulphide, halogens, phosphorous, isocyanates, strong alkalies and amines; reaction with oxygen may lead to detonation; when heated to decomposition it emits acrid smoke and fumes |
| **Non-hazardous Impurities (> 1% by weight):** | none |

**Additives/Adjuvants:**

| | |
|---|---|
| *Chemical name:* | water |
| *Synonyms:* | dihydrogen oxide |
| *CAS No.:* | 7732-18-5 |
| *Weight percentage:* | 75% |

## 5. USE, VOLUME AND FORMULATION

The notified chemical in Q-1549 is a surfactant, and will be used in the manufacture of acrylic emulsion polymers which in turn will be used as a raw material in the manufacture of interior and exterior aqueous house paints. It is expected that approximately 2 tonnes of the notified chemical will be manufactured in the first year, increasing to 10 tonnes per annum after five years.

The notified chemical will be manufactured in Australia. The concentration of the notified chemical in the manufactured product (Q-1549) is approximately 25%. The notifier states that the notified chemical and Q-1549 will be used on site in the manufacture of acrylic emulsion polymers. The acrylic emulsion polymers will be transported to paint manufacturing facilities Australia–wide in 15 – 25 tonne bulk road tankers or in 200 L steel drums. Manufactured paint will be sold through retail or wholesale outlets.

The concentration of notified chemical in acrylic emulsion polymers is 1 – 2% (w/w). The concentration of notified chemical in aqueous house paints is 0.1 – 0.3% (w/w).

## 6. OCCUPATIONAL EXPOSURE

The notified chemical will be manufactured in solution and reformulated to produce acrylic emulsion polymers. These will be used in manufactured house paint, to be widely applied to domestic and business premises.

*Manufacture*
Q-1549 is produced by neutralistion of the free acid parent (E) with ammonium hydroxide solution. The free acid will be pumped from 200 L steel drums to a pressure rated closed reaction vessel vented to a caustic scrubber to remove vapours that may be generated during

the reaction process. Ammonium hydroxide solution is introduced to the vessel from a bulk storage tank, via a hard pipe system. After completion of the reaction Q-1549 will be discharged from the reaction vessel and stored in 200 L drums ready for use on site. Washings from the reaction vessel will be piped to waste treatment pits.

The notifier states that there will be 5 workers involved in the production of Q-1549, operating the reactor, and loading and unloading the chemicals. These workers will be exposed to the 25% solution of chemical for an estimated maximum of 2 hours/day for 8 days/year. Workers may be exposed dermally, by direct contact with drips or spills of the liquids, or by ocular contact with liquid aerosols that might escape to the atmosphere during the reaction process. The notifier states that the workers involved in plant operation activities will be wearing face shields, impervious gloves, impervious aprons/overalls and safety boots.

*Reformulation*
The chemical in Q-1546 is pumped from the 200L storage drums to a pressurised, 5 000 kg capacity reaction vessel is vented to a caustic scrubber for vapour removal. Acrylic monomers and water are added to the reaction vessel to produce the polymer emulsion via an exothermic process. The polymer emulsion is then piped into a secondary holding vessel where water and more ingredients are added. After filtration to remove any coagulated solid material, the emulsion is piped into 20 000 L bulk storage tanks or 200 L steel sealed drums. Concentration of the notified chemical in the polymer emulsion is 1 - 2%.

The notifier states that there will be 15 to 20 workers involved in loading Q-1549 into the reactor, filtering and loading polymer emulsion to road tankers. These workers will be exposed for an estimated maximum of 0.5 hours/day for 60 days/year. Five quality control workers and 15 transport workers will also be exposed for a maximum of 0.5 hours/day for 60 and 100 days/year, respectively. Exposure will be mainly dermal or ocular during the above operations and the notifier states that the workers involved will wear safety glasses and impervious gloves.

The possibility exists that during manufacture of Q-1549 and polymer emulsion, the enclosed reaction vessel may rupture in the event of a pressure build-up caused by fire or extreme heat and release toxic oxides of phosphorous, nitrogen and carbon. The dry form of the notified chemical can also burn and is considered a fire hazard.

*Paint Manufacture*
Polymer emulsions containing the notified chemical is transported in 20 000 L bulk containers or 200 L steel drums to customer sites for paint manufacture. At the customer site the polymer emulsion is stored at 1 to 49°C to prevent coagulation. The polymer emulsion will be pumped from 200 L drums or piped from 20 000 L bulk containers to open or closed 500 to 10 000 L mixing vessels and blenders containing other ingredients. Local exhaust ventilation will be in place over the mixing vessels to capture any volatile material at the source. Mixing vessels are located in the bunded areas. Concentration of the notified chemical in the paint is up to 0.3%. The notifier did not provide details of the processes involved in transferring the paint from the mixing vessel to the filling cans, but has stated that paint is filled into epoxy-lined 1, 4, 10 and 20 L steel cans under exhaust ventilation. These are stored and transported as required by road and rail to retail outlets.

It is estimated that across all the paint manufacturing facilities, 40 to 50 paint makers will be involved in loading the polymer emulsion into the blender and carrying out quality control

sampling. The estimated maximum potential exposure is 4 hours/day for 30 days/year. Twenty paint technicians involved in laboratory manufacture and testing of paint will be exposed for 8 hours/day for 15 days/year and those conducting quality control testing will be exposed for 1 hour/day for 30 days/year. The twenty paint packers that fill paint into cans will be exposed for 8 hours/day for 30 days/year. Dermal and ocular routes would be the main avenues of exposure when connecting and disconnecting pipes, mixing and filling paint cans. The notifier states as a minimum, workers involved in paint manufacture should wear impervious (neoprene) gloves, coveralls and safety glasses.

*Paint Application*

The paint containing the notified chemical at up to 0.3% will be used by more than 100 paint sales people and contractors for 8 hours/day, up to 100 days/year. The paint sales people may make dermal contact with the notified chemical in the paint when tinting with colourants. The notifier states the personal protective equipment worn by these workers would vary and that generally any skin contact with paint would be washed off immediately. Also more than 1 000 do-it-yourself painters are estimated to use the paint for 8 hours/day up to 3 days/year. The paint will most commonly be applied manually by brush and/or roller, with application by spray equipment less likely. The notifier suggests that both professional paint contractors and do-it-yourself homepainters would follow safety instructions on the end use product when using the paint.

## 7. PUBLIC EXPOSURE

Manufactured paint will be sold through retail outlets. Concentration of the notified chemical in the paint will be up to approximately 0.3%. There is potential for exposure of the public to the notified chemical in paints used by do-it-yourself painters. The most likely routes of exposure to the notified chemical are skin and eye contact.

## 8. ENVIRONMENTAL EXPOSURE

### Release

Q-1549 will be produced by neutralisation of the parent free acid E with ammonium hydroxide solution. The parent free acid will be pumped from 200 L steel drums to a pressure rated reaction vessel vented to a caustic scrubber to remove any vapours. Ammonium hydroxide solution will be added to the vessel via a hard piped system from a bulk storage tank. The Q-1549 will then be discharged from the reaction vessel and stored in 200 L drums until required for use on site. Wash water from the vessel and piping will be transferred via piping to the plant waste treatment pits. It is estimated that approximately 100 kg of Q-1549 (25 kg notified chemical) will be lost to the wash water per 5000 kg batch. Approximately 5-10 batches of Q-1549 will be produced per annum, which equates to 250 kg per year of notified chemical.

The Q-1549 will be used as a component of acrylic polymer emulsions which will be manufactured at the same site. The Q-1549 will be pumped from the 200 L drums into a pressure rated, 5000 kg capacity reaction vessel, vented to a caustic scrubber. The polymer emulsions will be produced via exothermic thermal polymerisation of acrylic monomers in water. The emulsion is transferred through the hard piped system to a secondary holding vessel where more ingredients are added. The polymer emulsion is then filtered and transferred into bulk storage tanks (15-20 tonne). Losses of approximately 100 kg per batch are expected (equivalent to 2 kg of notified chemical), through washing of equipment, piping and minor spills. Approximately 60 batches of polymer emulsion will be manufactured per annum, leading to an annual loss of 120 kg of the notified chemical.

It is estimated that approximately 4 kg/drum (2% of drum contents, 1 kg of the notified chemical) of Q-1549 will be lost as residues in drums. Two drums of Q-1549 are used per batch of polymer emulsion. This equates to 120 kg per year of the notified chemical. The drum residues are disposed of via the on-site treatment plant.

Disposal of wash water at the Rohm and Haas site will be via the plant latex disposal system. The polymer in the wash water will either be concentrated by ultra-fine filtration and recycled or coagulated in treatment tanks with ferrous sulphate and sodium hydroxide. Sludge will be transferred to settling pits and dried before being removed off site for disposal to landfill by a licensed waste contractor. The supernatant is neutralised and clear waste water is pumped into an on-site holding pond for evaporation or used for irrigation of trees and lawns on site. There is no direct release to the sewer from the manufacturing process.

In summary, annual release of notified chemical at the Rohm and Haas site is as follows:

| | | |
|---|---|---|
| Manufacturing of Q-1549 | 250 kg | |
| Manufacturing of polymer emulsion | 120 kg | |
| Q-1549 drum residues | 120 kg | |
| Total | | 490 kg released to landfill after on-site treatment |

There is the potential for spillage of polymer emulsion containing the chemical in Q-1549 during paint manufacture at customer facilities. Such spills are expected to be contained within the plant by bunding. Wash water from paint manufacture is expected to be reused in subsequent batches of paint. Any residues or spills will be taken off-site by a licensed waste contractor for treatment and disposal at a licensed landfill site. It is estimated that 2.5 kg per year of notified chemical per customer site will be disposed of this way. It is difficult to estimate the number of companies who use this chemical, however, potential use may occur in the approximately 140 paint manufacturing sites in Australia (data provided by the Australian Paint Manufacturers Federation).

Polymer emulsions containing Q-1549 will be transported to customer sites in 15-25 tonne bulk road tankers or 200 L steel drums. The finished paint product will be stored in 1, 4, 10 and 20 L epoxy lined steel cans and transported by road and rail.

Releases to the environment will also occur during application of the paint and as a result of cleaning of painting equipment, ie. brushes, rollers and spray equipment. Washings from cleaning of equipment are likely to be washed down the drain with copious amounts of water. Any unused paint is usually kept in the original container and disposed of through collection programs operating at waste depots. It is estimated that approximately 500 kg per year or 1.37 kg per day of the notified chemical could be released in this manner. Assuming a disposal rate of domestic water of 190 L/person/day and a population of 18 million, the PEC can be estimated as follows:

1.37 kg/day/(190L/person/day x 18,000,000 people) = 0.4 μg/L

**Fate**

All of the notified chemical released to the environment is likely to enter the water compartment. The slow rate of biodegradation (see below) indicates that it would be persistent but eventually degrade through photolysis and slow biological processes to water and carbon dioxide. The phosphate component would be released as phosphate ions.

***Biodegradation***

The biodegradation of the notified chemical was tested using OECD Method 301D (Closed Bottle Test). Only 2% of the theoretical oxygen consumption occurred during the test period (30 days). The chemical was therefore found to be not readily biodegradable.

***Bioaccumulation***

No studies were provided. Given the low partition coefficient (log $P_{ow}$ <-1 ± 0.1 at 23°C) and the high water solubility, the notified chemical is not expected to exhibit significant bioaccumulation.

## 9. EVALUATION OF TOXICOLOGICAL DATA

Acute oral toxicity study, reverse mutation assay and in vivo mouse micronucleus assay were conducted using the notified chemical at 25%. Skin and eye irritation studies and a skin corrosion study were conducted using the analogue C.

Human skin sensitisation study was conducted using the analogue C.

Subacute feeding studies were conducted using the analogue E and mixtures of analogues.

The chemical structures were provided for assessment but are handled as exempt information.

### 9.1 Acute Toxicity

**Summary of the acute toxicity of the notified chemical and analogues.**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| acute oral toxicity (notified chemical) | rat | > 2 000 mg/kg | (Kresimir, 1998) |
| acute dermal toxicity | | not done | - |
| acute inhalation toxicity | | not done | - |
| skin irritation (F) | rabbit | severe irritant | (Burnette, 1980) |
| skin corrosion (F) | rabbit | corrosive | (Nitka, 1983) |
| eye irritation (F) | rabbit | severe irritant | (Burnette, 1980) |
| skin sensitisation (E) | humans | non-sensitiser | (Shelanski, 1959) |

#### 9.1.1 Oral Toxicity (Kresimir, 1998)

| | |
|---|---|
| *Species/strain:* | rat/CD® [Crl:CD®(SD)BR] |
| *Number/sex of animals:* | 5/sex for limit test |
| *Dose* | 2 000 mg/kg, notified chemical |
| *Observation period:* | 14 days |
| *Method of administration:* | 1.96 mL/kg of test substance administered orally by gavage |

| | |
|---|---|
| *Test method:* | OECD Guideline TG 401 |
| *Clinical observations:* | no signs of systemic toxicity |
| *Mortality:* | nil |
| *Morphological findings:* | none |
| *$LD_{50}$:* | > 2 000 mg/kg |
| *Result:* | the notified chemical was of very low acute oral toxicity in rats |

### 9.1.2 Dermal Toxicity

No data were submitted for acute dermal toxicity. The notifier states on the basis of very low acute oral toxicity, the expected low dermal absorption based on relatively high molecular weight (> 500) and low water-octanol partition coefficient (log $P_{ow}$ = -1), it is unlikely to be toxic via the dermal route.

### 9.1.3 Inhalation Toxicity

No data were submitted for inhalation toxicity. The notifier states on the basis of very low acute oral toxicity and the expected low vapour pressure it is unlikely to be toxic via the inhalation route.

### 9.1.4 Skin Irritation (Burnette, 1980)

The study was conducted using the analogue F.

| | |
|---|---|
| *Species/strain:* | rabbit/New Zealand White |
| *Number/sex of animals:* | 6/sex not identified |
| *Observation period:* | 72 hours |
| *Method of administration:* | 0.5 mL of test substance as supplied was applied to two sites, one abraded and one intact and held under semi-occlusive dressing; after 24 hours residual test substance was removed by gently wiping from the skin; test sites were examined for evidence of irritation and graded at approximately 24 and 72 hours after treatment; |
| *Test method:* | Consumer Product Testing (Fairfield, New Jersey, 1980); Draize, 1975 |

*Draize scores (Draize, 1959):*

| ***Rabbit Number*** | ***Site*** | ***24 hours E[1]*** | ***24 hours E[d]*** | ***72 hours E[1]*** | ***72 hours E[d]*** |
|---|---|---|---|---|---|
| 1 | 1[2] | 4 | 4b* | 4 | 2 |
| | A[3] | 4 | 4b | 4 | 2 |
| 2 | 1 | 4 | 4b | 4 | 3 |
| | A | 4 | 4b | 4 | 3 |
| 3 | 1 | 4 | 4b | 4 | 2b |
| | A | 4 | 4b | 4 | 2b |
| 4 | 1 | 4 | 4b | 4 | 2 |
| | A | 4 | 4b | 4 | 2b |
| 5 | 1 | 4 | 4b | 4 | 3 |
| | A | 4 | 4b | 4 | 3b |
| 6 | 1 | 4 | 4b | 4 | 2b |
| | A | 4 | 4b | 4 | 3b |
| Average | 1 | 4.0 | 4.0 | 4.0 | 2.3 |
| | A | 4.0 | 4.0 | 4.0 | 2.5 |

b* Blanching (loss of colour; skin is pale, grey-white)
E[1] erythema; E[d] edema
1[2] intact skin; A[3] abraded skin

*Comment:* severe erythema was observed in all animals at 24 and 72 hour time intervals; severe oedema and blanching observed at the 24 hour time interval was reduced to slight to moderate oedema at the 72 hour time interval

*Result:* F was a severe irritant to the skin of rabbits

### 9.1.5 Skin Corrosion (Nitka, 1983)

The study was conducted using the analogue F.

*Species/strain:* rabbit/New Zealand White

*Number/sex of animals:* 6/sex not known

*Observation period:* 7 days

*Method of administration:* 0.5 mL of test substance as supplied was applied to one site, and held under semi-occlusive dressing; after 4 hours residual test substance was removed from the skin; test sites were examined for evidence of corrosion and graded at approximately 24, 48 hours and 7 days after treatment;

*Test method:* Consumer Product Testing (Fairfield, New Jersey, 1980); Draize, 1975

*Draize scores (Draize, 1959):*

| ***Rabbit Number*** | ***4 hours*** | | ***24 hours*** | | ***48 hours*** | | ***7 days*** | |
|---|---|---|---|---|---|---|---|---|
| | ***E[1]*** | ***E[d]*** | ***E[1]*** | ***E[d]*** | ***E[1]*** | ***E[d]*** | ***E[1]*** | ***E[d]*** |
| 1 | 3 | 4B | 4 | 4B | 4 | 4BC | 4 | 4C |
| 2 | 3 | 4B | 4 | 4B | 4 | 4BC | 4 | 4C |
| 3 | 3 | 3B | 4 | 4B | 4 | 4B | 4 | 4C |
| 4 | 2 | 3B | 4 | 4B | 4 | 4BC | 4 | 4C |
| 5 | 3 | 3B | 3 | 3B | 4 | 4B | 4 | 4C |
| 6 | 3 | 2B | 4 | 3B | 4 | 4B | 4 | 4C |

B Blanching (loss of colour; skin is pale, grey-white)
$E^1$ erythema; $E^d$ edema
C crust (scab, dried exudate on the surface of a lesion)

*Comment:* severe erythema and edema was observed in all animals at 2 and 7 days; and blanching observed at 4, 24 and 48 hour, crust formation was observed in 3 animals at 48 hours and in all animals after 7 days

*Result:* F was corrosive to the skin of rabbits

### 9.1.6 Eye Irritation (Burnette, 1980)

The study was conducted using the analogue F.

*Species/strain:* rabbit/New Zealand White

*Number/sex of animals:* 6/sex not identified

*Observation period:* 1, 2, 3, 4 and 7 days

*Method of administration:* 0.1 mL of test substance was instilled into the lower everted lid of one eye of each animal and eyelids were held together for one second; the other eye served as the control; treated eyes were examined for irritation and graded at above time intervals

*Test method:* Consumer Product Testing (Fairfield, New Jersey, 1980) 405; Draize, 1975

*Draize scores (Draize, 1959) of unirrigated eyes:*

| | ***Time after instillation*** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| ***Animal*** | ***1 day*** | | ***2 days*** | | ***3 days*** | | ***4 days*** | | ***7 days*** | |
| ***Cornea*** | ***o*** | ***a*** | ***o*** | ***a*** | ***o*** | ***a*** | ***o*** | ***a*** | ***o*** | ***a*** |
| 1 | [1]3 | 2 | 3 | 1 | 4 | 1 | 4 | 1 | 3 | 4 |
| 2 | 3 | 2 | 4 | 2 | 4 | 2 | 4 | 2 | 4 | 2 |
| 3 | 3 | 2 | 3 | 4 | 3 | 4 | 4 | 1 | 4 | 3* |
| 4 | 2 | 2 | 2 | 4 | 4 | 2 | 4 | 1 | 3 | 4* |
| 5 | 3 | 4 | 3 | 3 | 4 | 2 | 4 | 2 | 4 | 2 |
| 6 | 3 | 3 | 4 | 1 | 4 | 2 | 4 | 2 | 4 | 2* |
| ***Iris*** | | | | | | | | | | |
| 1 | 1 | | 1 | | 1 | | 2 | | 1 | |
| 2 | 1 | | 1 | | 1 | | 1 | | 1 | |
| 3 | 1 | | 1 | | 1 | | 1 | | 1 | |
| 4 | 1 | | 1 | | 1 | | 1 | | 2 | |
| 5 | 1 | | 1 | | 1 | | 1 | | 1 | |
| 6 | 1 | | 1 | | 1 | | 1 | | 1 | |

| ***Conjunctiva*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 4 | 2b | 3 | 4 | 2 | 3 | 3 | 2b | 2 | 3 | 2 | 3 | 3 | 2 |
| 2 | 2 | 4 | 2 | 3 | 3 | 2 | 2 | 3 | 2b | 2 | 3 | 2b | 3 | 3 | 1 |
| 3 | 2 | 4 | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 3 | 1b | 3 | 2 | 1 |
| 4 | 2 | 4 | 2 | 2 | 2 | 1 | 3 | 3 | 2 | 3 | 3 | 1b | 2 | 1 | 1 |
| 5 | 2 | 4 | 2b | 2 | 2 | 1 | 3 | 3 | 2b ** | 2 | 3 | 1b | 3 | 3 | 2 |
| 6 | 2 | 4 | 2 | 2 | 2 | 1 | 3 | 4 | 2b ** | 2 | 3 | 1b | 2 | 3 | 1 |

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge
* = fibrovascular connective tissue ** = bloody discharge b = blanched

*Comment:* based on the above results the test substance should be considered a severe eye irritant

*Result:* F was a severe irritant to the eye of rabbits

### 9.1.6 Skin Sensitisation (Shelanski, 1959)

The study was conducted using the analogue G,

*Species/strain:* *homo Sapiens*

| | |
|---|---|
| *Number of humans:* | 50 |
| *Procedure:* | patch test was conducted on human volunteers by the application of test substance in 50% aqueous solution at a pH of 8.0; a total of 15 applications were made on the skin of each volunteer |
| *Test method:* | Shelanski and Shelanski, 1953; details of the experimental protocol were not provided |
| *Result:* | None of the tested subjects revealed a positive skin reaction to G. The authors concluded that the result indicates 95% certainty that the sensitising rate will be < 6% of exposed population. |

## 9.2 Repeat Dose Oral Studies

The study was conducted using the analogues E and a mixture of analogues containing G, H (similar to E) and I.

### 9.2.1 13 – Week Feeding Study (Worgareidge, 1967)

| | |
|---|---|
| *Species/strain:* | rat/FDRL strain |
| *Number/sex of animals:* | 22/sex/group |
| *Method of administration:* | in the diet |
| *Dose/Study duration:* | |
| Test: | the control group received basal diet only; the other 4 groups received X – Mix (E, H and I) or Y (G) for 13 weeks |
| | 254 mg/kg/day (group 1, X – Mix) |
| | 530 mg/kg/day (group 2, X – Mix) |
| Low dose: | 1 080 mg/kg/day (group 3, X – Mix) |
| Mid dose: | 1 080 mg/kg/day (group 4, Y) |
| High dose | |
| High dose | |
| *Test method:* | Based on Protocol Provided by Food and Drug Research Laboratories, New York, USA, 1967 |
| *Mortality:* | nil |

*Clinical observations:*

High (Y) dose male and female rats showed growth retardation compared to the controls

*Clinical chemistry/Haematology*

No effects observed that were described as treatment related

*Macroscopic findings:*

Dose related hepatomegaly was observed in all male animals fed with both X products. High and mid dose males fed with X-mix exhibited increased relative and absolute kidney weight high dose rats receiving Y showed a relative increase in kidney weight. Mid (X) and high (Y) dose males exhibited a significant mean absolute weight decrease in adrenals, however on a ratio to body weight basis only mid dose males exhibited a significant decrease in adrenal weight compared to the controls. High (X) dose females exhibited increased absolute liver weights compared to controls. High and mid (X) dose females exhibited an increase in absolute adrenal weight but the ratio of adrenal to body weight was not found to be statistically significant. Mid (X) dose females recorded a significant decrease in relative ovarian weights.

Dilation of the pelvis (hydropelvis) of the kidney was observed in all treated groups (not in all animals) but not in controls. The study states hydropelvis is a common occurrence in Wistar-derived strains and has been observed in many other studies carried out in this laboratory and hence it is unlikely to be treatment related with either of the X products.

*Histopathology:*

No effects were observed that could be described as treatment related.

*Result:*

There were no deaths in any group. Food and water consumption was similar in the control and treated groups. However the growth rate was significantly depressed in the high dose Y animals. No adverse effects in hematopoietic function or clinical parameters were observed. Absolute and relative increases in organ weights had no supportive histopathological changes. The NOEL was 530 mg/kg/day based on depressed growth rate at the high dose.

### 9.2.2 15 – Week Dog Feeding Study (Worgareidge, 1967)

| | |
|---|---|
| *Species/strain:* | dog/Beagle |
| *Number/sex of animals/group:* | 18/sex; control and Y 4/sex/group; X -Mix, 3/sex/group |
| *Method of administration:* | in the diet |
| *Dose/Study duration:* | |
| Test: | the control group received basal diet only; the other 4 groups received X (E, H and I) or Y (G) for 3 months |
| | 150 mg/kg/day (group 1, X – Mix) |
| | 300 mg/kg/day (group 2, X – Mix) |
| Low dose: | 600 mg/kg/day (group 3, X – Mix) |
| Mid dose: | 600 mg/kg/day (group 4, Y – RE) |
| High dose | |

High dose

*Test method:* Based on Protocol Provided by Food and Drug Research Laboratories, New York, USA, 1967

*Mortality:* nil

*Clinical observations:*

High dose (Y) male and females showed growth retardation compared to the controls. Other dogs, including controls, lost weight intermittently as food intake varied.

*Clinical chemistry/Haematology*

No effects observed that were described as treatment related.

*Macroscopic findings:*

The liver to body weight ratio was significantly increased in high (Y) dose males and high (Y and X-Mix) dose females, relating to the lower body weight in treated animals compared to controls. Females receiving Y exhibited an absolute kidney weight loss compared to the controls. However, a relative increase in kidney weight was observed in low and mid (X-Mix) dose females and in high (X-Mix and Y) dose males. This was attributed to the weight loss in high dose animals. Mid (X-Mix) dose females exhibited an absolute increase in ovarian weight and a relative increase at all three doses. Low (X-Mix) dose and high (Y) dose dogs exhibited a relative increase in adrenal weight compared to the control group. High (Y) dose males and females exhibited a relative increase in thyroid weight and an absolute decrease in brain weight, respectively.

*Histopathology:*

Chronic inflammatory cell accumulation in the submucosa of the gallbladder was observed in dogs given X-Mix at all doses and Y at high dose. The authors concluded this was not treatment related. Adrenal cortical hyperplasia was observed in 2 mid (X-Mix) and 4 high (X-Mix) dose animals and 4 high (Y) dose animals.

*Result:*

There were no deaths in any group. Food and water consumption of all dose groups increased in a similar fashion to control group. No adverse effects in hematopoietic function or clinical parameters were observed. Absolute and relative increase in liver and kidney weight had no histopathological findings. High dose dogs that exhibited a relative increase in adrenal weight had associated cortical hyperplasia. The NOEL was 300 mg/kg/day.

## 9.3 Genotoxicity

### 9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Fortunato, 1998)

| | |
|---|---|
| *Strains:* | TA98, TA1538, TA1535, TA1537 and TA100 |
| *Concentration range:* | 0.01, 0.05, 0.1, 0.5, 1.0 mg/plate |
| *Test method:* | OECD guideline TG 471 |
| *Comment:* | the test chemical was cytotoxic at 5.0 mg/plate in the preliminary test;<br>positive controls demonstrated the sensitivity of the test and negative controls were within acceptable limits; there was no significant increase in the number of revertants with the test article compared to the negative control for all tester strains; there was no evidence of a dose-dependent response, and the mean reversion frequency following treatment with the test article was less than two times that of the corresponding controls for all tester strains at all concentrations. |
| *Result:* | the notified chemical was considered to be non-mutagenic in the bacterial strains tested with or without metabolic activation. |

### 9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Curry, 1998)

| | |
|---|---|
| *Species/strain:* | mouse/Crl:CD-1®(ICR)BR |
| *Number and sex of animals per dose:* | 6 males per group |
| *Doses/sampling times:* | 6 mice received 0, 500, 1 000 or 2 000 mg/kg notified chemical in distilled water by gavage; bone marrow was sampled 24 and 48 hours after dosing |
| *Test method:* | OECD TG 474 |
| *Result:* | the notified chemical did not induce an increase in the frequency of micronucleated polychromatic erythrocytes; cyclophosphamide, the positive control, demonstrated the sensitivity of the test; there was no statistically significant decrease in the PCE:NCE ratio, demonstrating that the test article was not cytotoxic to the bone marrow. |

## 9.4 Overall Assessment of Toxicological Data

No inhalation or acute dermal toxicity studies have been performed on the notified chemical. The notifier made a claim for variation of schedule data requirements for an acute inhalation toxicity study, on the basis of anticipated low exposure, as the notified chemical is in the form of a slightly volatile liquid (vapour pressure $1.3x10^{-3}$ kPa at 25°C). The notifier also made a claim for variation of schedule data requirements for an acute dermal toxicity study, on the basis of anticipated low exposure, the notified chemical has very low acute oral toxicity, high molecular weight ( > 500) and low water-octanol partition coefficient (log $P_{ow}$ = 1). Both claims for variation were accepted on the basis of anticipated low exposure.

The notified chemical was of low very acute oral toxicity ($LD_{50}$ > 2 000 mg/kg) in rats. However, on the basis of analogue data, the notified chemical is taken to be a severe skin and eye irritant in rabbits. Limited analogue data from patch testing from humans, suggest the notified chemical is not likely to be a skin sensitiser in humans.

A 13 week repeat dose oral study in rats using analogues showed no adverse effects in haematopoietic function or clinical parameters. Growth rate was depressed in high dose animals, however absolute and relative increases in organ weight had no supportive histopathological abnormalities. The NOEL is 530 mg/kg/day. A 15 week repeat dose oral study in dogs using analogues showed no adverse effects in haematopoietic function or clinical parameters. Absolute and relative increases in liver and kidney weights had no supportive histopathological abnormalities. High dose animals that exhibited a relative increase in adrenal weight showed adrenal cortical hyperplasia. The NOEL is 300 mg/kg/day based on this finding.

The notified chemical was non-mutagenic in a bacterial mutation assay. It did not induce a significance increase in the frequency of micronucleated mouse bone marrow polychromatic erythrocytes in an *in vivo* study.

Based on analogue data the notified chemical is determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999), considering the severe and persistent erythema and edema, with the blanching and crust formation in the skin, and severe and persistent effects on the cornea and conjunctiva of the eye.

# 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier supplied limited ecotoxicity data for the notified chemical. Analogue data for a closely related chemical Z were supplied for fish toxicity studies.

*Acute Toxicity Tests*
A 96 hour semi-static acute toxicity study of Z to rainbow trout (*Salmo gairdneri*) was provided.

Groups of 10 fish were exposed to 0, 1, 1,8, 3, 5 and 8 mg/L of the test substance and observed at 24, 48, 72 and 96 hours. The 96 hour NOEC was 1.8 mg/L. The 96 hour $LC_{50}$ of the test chemical was 5.8 mg/L, by the binomial probability method (Stephan, 1979).

| *Conc. (mg/L)* | *Percentage Mortality* | | | |
|---|---|---|---|---|
| | 24 hour | 48 hour | 72 hour | 96 hour |
| Control | 0 | 0 | 0 | 0 |
| 1.0 | 0 | 0 | 0 | 0 |
| 1.8 | 0 | 0 | 0 | 0 |
| 3.0 | 0 | 0 | 0 | 0 |
| 5.0 | 10 | 10 | 20 | 20 |
| 8.0 | 50 | 90 | 100 | 100 |

No data was supplied by the notifier for daphnia or algal toxicity. The relevant environmental information was contained on the Material Safety Data Sheet (MSDS).

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard resulting from the intended use of the notified polymer is low.

No aquatic toxicity data was submitted by the notifier for the notified chemical. Data was supplied for a closely related polymer, Z. Although the polymer is moderately toxic to Rainbow Trout ($LC_{50}$ (96 h) = 5.8 mg/L with a NOEC of 1.8 mg/L), and presumably toxic to other aquatic organisms, the release to the water compartment will be at a very low concentration with the PEC estimated at 0.4 μg/L. Release to the sewer will occur as a result of paint application and subsequent cleaning of equipment.

The notifier indicates that the only release of the notified chemical to the environment as a result of the manufacturing and blending process will be to landfill after on-site treatment. It is estimated that this release will be approximately 490 kg per annum.

The chemical in Q-1549 is not readily biodegradable but not expected to exhibit significant bioaccumulation. It will eventually be broken down through photolysis and slow biological processes.

Despite the moderate toxicity of the notified chemical to aquatic organisms and the lack of measured data relating to its ecotoxicity, environmental release is expected at a low concentration that should not constitute a significant environmental hazard.

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

The toxicological data supplied on the notified chemical and analogues, suggests that the notified chemical is not likely to be acutely toxic or cause systemic toxic effects on repeated or prolonged exposure. However, it is a severe skin and eye irritant. It is unlikely to be a skin sensitiser and is not genotoxic. The notified chemical is determined to be a hazardous substance according to NOHSC Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission, 1999) on the basis of severe skin irritation and severe eye lesion. It would warrant the risk phrases R41, “risk of serious damage eyes” and R36, “irritating to skin.

***Occupational Health and Safety***

*Transport and storage*

Transport and storage workers handling the polymer emulsion and the paint should only be exposed to the notified chemical in the event of accidental spillage.

*Manufacture*

The main group of workers likely to be exposed to the notified chemical on a regular basis are those operating the reactor, and loading and unloading the chemicals. The notifier estimates that exposure is 2 hours/day for 8 days/year. The notified chemical is manufactured in a closed and ventilated reaction vessel. However, workers could be exposed to the notified chemical dermally, by direct contact with spills and liquid aerosols produced by the agitating aqueous medium. The notified chemical is a severe skin and eye irritant and the manufactured product containing 25% notified chemical, is a hazardous substance. Strict controls must be in place to prevent skin and eye contamination. Workers involved in the process should wear impervious gloves, impervious aprons/overalls and safety boots and safety goggles.

*Reformulation*

During manufacture of polymer emulsion, workers involved in operating the reactor have the highest chance of dermal and eye exposure to the notified chemical in the manufactured form (25% and a hazardous substance). Workers involved in other processes, such as quality control testing and equipment maintenance, may also experience dermal and eye exposure to the notified chemical however the duration and frequency of exposure would be less, and after reformulation, the chemical is present at lower concentrations (up to 2% and no longer a hazardous substance). All workers involved in refomulation activities, including quality control and equipment maintenance will need to wear impervious gloves and safety glasses and overalls. Polymer emulsion is manufactured in a closed and ventilated vessel.

*Paint manufacture*

The main group of paint manufacture workers likely to be exposed to the notified chemical on a regular basis are those involved in loading and operating the blender, quality control personnel and personnel involved in paint filling operations. The notified chemical in the polymer emulsion is less than 2% and in the paint is approximately 0.3%. However, the chemical is a severe skin and eye irritant and adequate controls should be in place to prevent dermal or ocular exposure. Paint manufacture is carried out in closed or open mixing vessels with local exhaust ventilation. The notifier states workers involved in paint manufacture, as a minimum should be attired with impervious (neoprene) gloves, coveralls and safety glasses.

*Paint application*

End use of the paint in domestic and commercial situations may potentially result in frequent exposure. Overalls may typically be worn by end uses, however it is unlikely that gloves or goggles would routinely be used. The risk of adverse health effects from the notified chemical is low given that is present below 0.3% and is not a hazardous substance.

***Public Health***

There is potential for public exposure of the notified chemical arising from its use as a surfactant in paints, but the low concentration in the final paint products indicates a negligible risk to public health.

## 13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994a) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994b);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should 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.

## 14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

## 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

## 16. REFERENCES


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

Worgareidge K (1967) Toxicity Study by Oral Administration to FDRL Rats for 13 Weeks Period, Project No. 88029, Food and Drug Research Laboratories, New York USA.

Worgareidge K (1967) Toxicity Study by Oral Administration to Beagle Dogs for 15 Weeks Period, Project No. 88030, Food and Drug Research Laboratories, New York USA.

## Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

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

The Draize scale for evaluation of eye reactions is as follows:

***CORNEA***

| *Opacity* | *Rating* | *Area of Cornea involved* | *Rating* |
|---|---|---|---|
| No opacity | 0 none | 25% or less (not zero) | 1 |
| Diffuse area, details of iris clearly visible | 1 slight | 25% to 50% | 2 |
| Easily visible translucent areas, details of iris slightly obscure | 2 mild | 50% to 75% | 3 |
| Opalescent areas, no details of iris visible, size of pupil barely discernible | 3 moderate | Greater than 75% | 4 |
| Opaque, iris invisible | 4 severe | | |

***CONJUNCTIVAE***

| *Redness* | *Rating* | *Chemosis* | *Rating* | *Discharge* | *Rating* |
|---|---|---|---|---|---|
| Vessels normal | 0 none | No swelling | 0 none | No discharge | 0 none |
| Vessels definitely injected above normal | 1 slight | Any swelling above normal | 1 slight | Any amount different from normal | 1 slight |
| More diffuse, deeper crimson red with individual vessels not easily discernible | 2 mod. | Obvious swelling with partial eversion of lids | 2 mild | Discharge with moistening of lids and adjacent hairs | 2 mod. |
| | | Swelling with lids half-closed | 3 mod. | Discharge with moistening of lids and hairs and considerable area around eye | 3 severe |
| Diffuse beefy red | 3 severe | Swelling with lids half-closed to completely closed | 4 severe | | |

***IRIS***

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