File No: NA/651

January 1999

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**Polymer in Foraperle 225**

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

## Polymer in Foraperle 225

## 1. APPLICANT

Elf Atochem Australia of 270-280 Hammond Rd DANDENONG SOUTH VIC 3175 has submitted a limited notification statement in support of their application for an assessment certificate for Foraperle 225.

## 2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, identities of impurities and details of the polymer have been accepted as exempt from publication in the Full Public Report and the Summary Report.

| | |
|---|---|
| **Trade Name:** | Foraperle 225 |
| **Method of Detection and Determination:** | GPC, IR spectroscopy<br>A report with GPC data and an IR spectrum was submitted for the identification of the notified chemical. |
| **Maximum Percentage of Low Molecular Weight Species** | |
| **Molecular Weight < 1 000:** | 0.48 % |
| **Molecular Weight < 500:** | 0.05 % |

**Additives/Adjuvants:**

| | |
|---|---|
| *Chemical name:* | n-Butyl acetate |
| *CAS No.:* | 123-86-4 |
| *Weight percentage:* | 75 % |

## 3. PHYSICAL AND CHEMICAL PROPERTIES

The imported product, Foraperle 225, is a solution of the notified polymer (25 % (w/w)) in n-butyl acetate (75 % (w/w)). The following physical and chemical properties (unless specified otherwise) are for the product.

| | |
|---|---|
| **Appearance at 20°C and 101.3 kPa:** | Pale yellow transparent liquid |
| **Boiling Point:** | 120 °C |
| **Specific Gravity:** | 0.968 g/mL |
| **Vapour Pressure:** | 1.05 kPa at 20°C |
| **Water Solubility:** | not determined; the notified polymer is hydrophobic |
| **Partition Co-efficient (n-octanol/water):** | not determined |
| **Hydrolysis as a Function of pH:** | The notified polymer does not contain any hydrolysable functional groups |
| **Adsorption/Desorption:** | not determined |
| **Dissociation Constant:** | The notified polymer does not contain any groups which can undergo dissociation |
| **Flash Point:** | 26 °C |
| **Flammability Limits:** | Upper Explosive Limit = 1.7 %<br>Lower Explosive Limit = 7.6 % |
| **Autoignition Temperature:** | not determined |
| **Explosive Properties:** | not explosive |
| **Reactivity/Stability:** | not reactive |

**Comments on Physico-Chemical Properties**

The polymer is stated to be not soluble in water as it exhibits hydrophobic activity that renders it suitable for its main end use as a waterproofing agent. Very low water solubility would be expected on the basis of the presence of a substantial number of very hydrophobic groups.

Partition coefficient could not be obtained due to the surface active properties of the polymer. Adsorption desorption coefficient could not be obtained for the same reason. The notified substance is surface active and is expected to adsorb strongly to soil or sediment organic matter due to the high hydrophobicity of the fluoroalkyl side chain.

## 4. PURITY OF THE CHEMICAL

The following purity data is for the notified polymer; the commercial product Foraperle 225 is a mixture of 25 % (w/w) polymer and 75 % (w/w) n-butyl acetate.

| | |
|---|---|
| **Degree of Purity:** | ≥ 98 % |
| **Toxic or Hazardous Impurities:** | A report including the concentrations and identities of toxic or hazardous impurities was submitted as part of the notification of this chemical. |
| **Non-hazardous Impurities (> 1% by weight):** | none known |
| **Maximum Content of Residual Monomers:** | A report including the concentrations of residual monomers was submitted as part of the notification of this chemical. |

**Additives/Adjuvants:**

| | |
|---|---|
| *Chemical name:* | n-Butyl acetate |
| *CAS No.:* | 123-86-4 |
| *Weight percentage:* | 75 % |

This chemical has an NOHSC exposure standard of 150 ppm (713 mg/m$^3$) TWA and 200 ppm (950 mg/m$^3$) STEL (National Occupational Health and Safety Commission, 1995). No risk phrases are listed, however, in the *List of Designated Hazardous Substances* (National Occupational Health and Safety Commission, 1994c).

## 5. USE, VOLUME AND FORMULATION

The notified polymer confers water and oil repellent properties and will be used for finishing and protection of textiles. Some of the applications for the final textile products may include leather goods, raincoats, tents, tablecloths and carpets.

The notified polymer will not be manufactured in Australia. It will be imported in 40 kg high density polyethylene (HDPE) drums as a component of the product Foraperle 225, containing 25 % notified polymer in n-butyl acetate, at an import volume of 1-2 tonnes per year.

The imported product will be reformulated to form a component of a product which will be sold commercially in 250 mL aerosol cans, for home treatment of textiles. The commercial product will contain 1-3 % notified polymer (4-12 % Foraperle 225).

The polymer will not chemically bond to the textiles as there are no reactive sites in the polymer structure. It is likely that there will be physical intermeshing of the polymer molecule with the textile fibres, but predominantly the polymer will remain with the textile due to the highly hydrophobic nature of the dried polymer.

## 6. OCCUPATIONAL EXPOSURE

At the customer site the aerosol can filling operation is carried out under local exhaust and general ventilation. As aerosols are Dangerous Goods, these processes are carried out in purpose built areas with appropriate fire proofing and bunding. Workers will wear overalls, safety boots, safety glasses and gloves.

Occupational exposure is also possible where textile workers apply the commercial waterproofing product by aerosol on a small scale basis. Such exposure is likely to be more regular than similar public exposure.

The notified chemical will be imported as a component of Foraperle 225 (25 % notified chemical) in 40 kg high density polyethylene (HDPE) drums.

*Transport and Storage*
Exposure to waterside and transport and warehouse workers is unlikely except in case of an accident where the packaging is breached. It is estimated that 2-4 workers will be involved in each of transferring the 40 kg drums at the docks and in transporting the drums to the notifier's warehouse facility, where 3-4 workers will be involved in handling the drums.

*Reformulation*
The imported product Foraperle 225 will be diluted with additional solvents in a batch making machine. The concentrate will be pumped from the import drums into a 1 600 L enclosed stainless steel mixing tank where solvent will be added and the mixture blended and agitated. The diluted mixture will be drained into 200 kg lined steel drums by gravity, for transport to the customer site where the aerosol cans will be packed. One or two workers will be involved in this operation, which will occur on 15-20 days a year. A quality assurance

(QA) sample will be taken by flushing 20 L of mixture into a bucket, then manually sampling 500 mL. The 20 L used for flushing will be returned to the tank, while the sample will be subjected to various laboratory tests. One or two laboratory personnel will be involved each time the batch making is done.

The mixing vessel is supplied with local exhaust ventilation. Dermal exposure to drips and spills could occur during opening of the imported containers and connecting of hoses and pumping equipment. Dermal exposure is also possible during the filling of drums with the diluted product.

The notifier states that all work involving the concentrated material will be performed in areas with general ventilation as well as local exhaust ventilation as required. Workers handling the concentrated material will wear a full face respirator with a solvent filter, PVC gloves and apron, and overalls. The presence of volatile solvents in all of the formulations involving the notified chemical will require that adequate precautions be taken to prevent worker exposure to these formulations.

Cleaning and maintenance personnel will hose out the mixing tank with water which will be drained into a 1 000 L IBC (intermediate bulk container) for waste materials. It is estimated that 2-4 maintenance personnel will be involved each time the batch making is carried out (1-2 hours/day, 15-20 days/year).

*Aerosol Products Manufacture*
The filling of 250 mL aerosol cans will be performed at a customer site, using an automated system. The diluted material supplied by the notifier will be transferred by pump or gravity into a sealed blending tank where other ingredients are added. The mixture is then transferred to a filling and pressurising machine where the 250 mL aerosol cans are filled. No details are given of QA and cleaning and maintenance exposure at the customer site. It is estimated that 80-160 workers may be involved in the aerosol can packing process.

## 7. PUBLIC EXPOSURE

Minimal public exposure is expected through the transport, reformulation or disposal of the notified polymer.

The use pattern of Foraperle 225 suggests that there will be widespread public exposure to the notified polymer. The notified polymer will be supplied to the public in 250 mL pressurised cans at a concentration of 1-3 %, and will be used for home treatment of textiles. Public exposure to the aerosol spray is expected to be infrequent. In addition, the public will be exposed to the polymer in a cured form as a protective coating on textiles.

Likely exposure routes include oral ingestion, inhalation and dermal and ocular contact. However, the notified polymer has a high molecular weight, indicating that it is likely to be poorly absorbed across biological membranes. In addition, it will be either in dilute form (1-3 %) or in a cured form within the textile coating. As such, only limited bioavailability of the notified polymer is expected.

## 8. ENVIRONMENTAL EXPOSURE

### Release

Release to the environment of the notified substance can occur in transport, formulation, mixing and in final application to the textile and leather products. The notifier has estimated the releases that may occur at each site in the preparation and application of formulations containing the notified substance.

| | | |
|---|---|---|
| Releases: | Reformulation: | 20 kg/year |
| | Aerosol formulation: | 10 kg/year |

Waste collected above will be reused where possible or disposed of to landfill by a licensed waste contractor.

Drum recyclers will reclaim the 3% of notified substance that remains in either in the 60 kg or 200 kg drums. Reclaimed material will be removed by a licensed waste contractor.

Release from the application by aerosol in the home will generally be as overspray to masking materials such as old newspapers. The masking materials and empty aerosol containers are expected to join the household solid waste stream.

### Fate

An English summary translation of a French study of biodegradation (Thiebaud, 1996) indicates this was carried out according to OECD test protocol 301B (Organisation for Economic Cooperation and Development, 1993). Under the test conditions the biodegradation of the notified substance was found to be 15% within five days and at the end of the 10 day test window was 12%. The notified substance cannot be claimed to be readily biodegradable but it will degrade over time. However the saturated fluorocarbon chain is known to be strongly resistant to biodegradation.

The notified substance on exposure to the environment as waste or on discarded items of apparel is likely to remain immobile (fixed to the organic matter) and to slowly degrade on exposure to the biota present in landfill.

## 9. EVALUATION OF TOXICOLOGICAL DATA

The notified polymer has been notified under the limited notification category. Although not specifically required under the Act for this notification category the notifier has submitted reports of a number of toxicological tests, which are summarised below. Tests were carried out using the product, Foraperle 225, containing 25 % (w/w) notified polymer, except for the acute inhalation toxicity study, where three formulations containing 2.0 to 4.7 % Foraperle 225 with a variety of solvents and additives were tested. The doses which are quoted here are for Foraperle 225, rather than for the notified polymer.

Foraperle 225 contains 75 % (w/w) n-butyl acetate, which is reported to be a skin, eye and respiratory tract irritant.

## 9.1 Acute Toxicity

**Summary of the acute toxicity of Foraperle 225**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| acute oral toxicity | rat | $LD_{50}$ > 2000 mg/kg | (Miermon, 1994) |
| acute inhalation toxicity | rat | equivalent to $LC_{50}$ > 0.41 mg/L/4 hours | (Arts, 1994) |
| skin irritation | rabbit | slight irritant | (Prod'homme, 1994a) |
| eye irritation | rabbit | moderate irritant | (Prod'homme, 1994b) |
| skin sensitisation | guinea pig | study results are inconclusive due to a high incidence of irritant reactions in the control groups | (Baque, 1994) |

### 9.1.1 Oral Toxicity (Miermon, 1994)

| | |
|---|---|
| *Species/strain:* | rat/albino Sprague Dawley OFA, IFFA-CREDO |
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | gavage, as supplied, dose level 2000 mg/kg |
| *Mortality:* | no deaths occurred during the study |
| *Clinical observations:* | no clinical signs of toxicity were observed during the study |
| *Morphological findings:* | no macroscopic findings were observed at necropsy |
| *Test method:* | limit test, OECD TG 401 (Organisation for Economic Cooperation and Development, 1987b) |
| *$LD_{50}$:* | > 2000 mg/kg |
| *Result:* | Foraperle 225 was of very low acute oral toxicity in rats |

### 9.1.3 Inhalation Toxicity (Arts, 1994)

A report on only one of the three studies of formulations including Foraperle 225 (quoted above) has been supplied by the notifier. The formulation reported here is "Waterproofer E 546-44 with Foraperle 225", which consists of 2 % Foraperle 225 (0.5 % notified chemical) with 2-propanol (50 %) and exxsol-heptane (48 %).

| | |
|---|---|
| *Species/strain:* | rat/Crl:WI(WU)BR |
| *Number/sex of animals:* | 8/sex test group<br>8/sex control group |
| *Observation period:* | 1 day for 4/sex/group<br>14 days for 4/sex/group |
| *Method of administration/dose:* | 4 hours; nose-only inhalation chamber; test material nebulised and mixed with humidified pressurised air; test material concentration 20.6 g/m$^3$; solids 61.7 mg/m$^3$; measured solid particle size: 93 % of particles 1-4.2 μm diameter (respirable)<br><br>control animals were exposed to humidified pressurised air under identical conditions |
| *Mortality:* | no deaths were recorded during the study |
| *Clinical observations:* | irregular breathing in all test animals throughout exposure period; visually decreased breathing frequency during the second half of the exposure period; incoordination in one test group shortly after exposure; no changes in behaviour during the remaining observation period |
| *Lung function:* | decrease in breathing frequency on day of exposure, compensated by increased tidal volume; increased breathing frequency on days 4 and 14 compared with pre-exposure values but not compared with controls; increased tidal volume in males at 1, 4 and 14 days and in females at 1 day; a resultant increase in mean ventilatory flow for males at 1, 4 and 14 days; the study authors stated that the pre-exposure tidal volumes for the male animals were low compared with historical control values |

| | |
|---|---|
| | in the lung function measurements, increased resistance shortly after exposure; decreased inertance and increased compliance (distendability) values one day after exposure although the results were not statistically different to the controls<br><br>mean relative lung weight at 1 and 14 days after exposure was slightly higher in exposed males than controls, but no difference was observed for females |
| *Morphological findings:* | no gross changes were observed; a few small haemorrhages and very slight interstitial pneumonitis comparable in incidence and severity with controls observed at day 1; two test animals showed macrophage accumulations and one a small bone spicule; these were not considered treatment related as these conditions are sometimes also observed in this strain of animals<br><br>at day 14, three out of eight test animals showed changes characterised by very slight peribronchiolar/perivascular inflammatory cell infiltrates (in one animal) and very slight increased septal cellularity in three animals, occasionally accompanied by cuboidal rather than flat epithelium lining the thickened septa; this was stated to be a common response to irritating compounds and considered therefore to be exposure related<br><br>a few small haemorrhages and very slight interstitial pneumonitis was observed; also slight accumulation of macrophages in one male; these were not considered treatment related for reasons described above |
| *Test method:* | according to a protocol pre-agreed by the sponsor and test facility |
| *$LC_{50}$:* | > 0.41 mg/L/4 hours of Foraperle 225<br>(> 0.10 mg/L/4 hours of notified chemical) |

*Result:* due to the limitations of the study caused by the inhalational toxicity of the solvents used, the inhalational toxicity of the notified chemical could not be adequately measured; however, based on the study result of $LC_{50}$ > 20 mg/L/4 hours, the formulation tested was of very low acute inhalational toxicity in rats

### 9.1.4 Skin Irritation (Prod'homme, 1994a)

*Species/strain:* rabbit/New Zealand albino

*Number/sex of animals:* 3 male

*Observation period:* 8 days

*Method of administration:* 0.5 mL of test material as supplied was applied to clipped intact skin of the dorsal flank and secured under a gauze patch for 4 hours; at the end of this time, residual material was removed with an appropriate solvent and paper towels; animals were examined for skin lesions 1, 24, 48 and 72 hours following application of the test substance

*Draize scores (Draize, 1959):*

| ***Time after treatment (days)*** | ***Animal #*** | | |
|---|---|---|---|
| | ***1*** | ***2*** | ***3*** |
| ***Erythema*** | | | |
| 1 | 1[a] | 2 | 1 |
| 2 | 1 | 2 | 1 |
| 3 | 1 | 1 | 1 |
| ***Oedema*** | | | |
| 1 | 2 | 1 | 1 |
| 2 | 1 | 0 | 0 |
| 3 | 1 | 0 | 0 |

[a] see Attachment 1 for Draize scales

| | |
|---|---|
| *Observations:* | very slight to well defined erythema was observed for all animals; this was totally reversible within 7 days; very slight to slight oedema for all animals, visible for 1 day for two animals and for 5 days for one animal; cutaneous dryness in all animals still evident at 8 days |
| *Test method:* | OECD TG 404 (Organisation for Economic Cooperation and Development, 1992a) |
| *Result:* | Foraperle 225 was a slight irritant to the skin of rabbits |

### 9.1.5 Eye Irritation (Prod'homme, 1994b)

| | |
|---|---|
| *Species/strain:* | rabbit/New Zealand albino |
| *Number/sex of animals:* | 3 male |
| *Observation period:* | 12 days |
| *Method of administration:* | 0.1 mL of test material applied as supplied into conjunctival sac of the right eye of each animal; the contralateral eye served as the control; animals were examined for eye lesions 1, 24, 48 and 72 hours after test substance application |

*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 | 2 | 1 | | 1 | 1 | | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| 2 | 2 | 2 | | 2 | 1 | | 2 | 1 | | 1 | 1 | | 0 | 0 | |
| 3 | 1 | 1 | | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| ***Iris*** | | | | | | | | | | | | | | | |
| 1 | | 1 | | | 1 | | | 0 | | | 0 | | | 0 | |
| 2 | | 1 | | | 1 | | | 1 | | | 1 | | | 0 | |
| 3 | | 1 | | | 0 | | | 0 | | | 0 | | | 0 | |
| ***Conjunctiva*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** |
| 1 | 3 | 3 | 2 | 3 | 1 | 1 | 3 | 1 | 1 | 2 | 1 | 0 | 0 | 0 | 0 |
| 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 2 | 1 | 0 |
| 3 | 3 | 3 | 2 | 3 | 1 | 1 | 2 | 1 | 0 | 2 | 1 | 0 | 1 | 0 | 0 |

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness of conjunctiva c = chemosis d = discharge

*Test method:* OECD TG 405 (Organisation for Economic Cooperation and Development, 1987a)

*Observations;* conjunctival redness, chemosis and discharge were observed one hour after installation of the test material; conjunctival redness persisted for 10 days in one animal, chemosis for 8 days and discharge for 6 days

corneal opacity was not observed at one hour but after 24 hours easily discerned areas of opacity and slight obscuration of the iris were observed for two animals and diffuse opacity for the other; iris effects persisted for up to 5 days and corneal opacity for up to 6 days

*Result:* Foraperle 225 was moderately irritating to the eyes of rabbits

### 9.1.6 Skin Sensitisation (Baque, 1994)

| | |
|---|---|
| *Species/strain:* | guinea pig/Hartley |
| *Number of animals:* | test group 20 female<br>control groups 10 females each |
| *Induction procedure:* | day 1: to a clipped area of the scapular dorsal skin, each animal received 3 pairs of 0.1 mL injections as follows – |

test group:

- 1:1 (v/v) mixture of Freund's Complete Adjuvant and distilled water
- the test material diluted to 10% in olive oil
- the test material diluted to 10% with Freund's Complete Adjuvant

control group:

- 1:1 (v/v) mixture of Freund's Complete Adjuvant and distilled water
- olive oil
- 50% (w/v) distilled water in a 1:1 (v/v) mixture of Freund's Complete Adjuvant and distilled water

day 7

test group
local irritation was produced by application of 0.5 mL of a 10% solution of sodium lauryl sulphate in liquid petrolatum
a gauze patch with 0.5 mL of test material was placed over the injection area and kept in contact with the skin by an occlusive patch for 48 hours

control group
as above except using liquid petrolatum in place of the test material

*Challenge procedure:*

day 18
3 compresses; with 0.5 mL 50 % test material in liquid petrolatum, 0.5 mL 25 % test material in petrolatum and liquid petrolatum only applied to region of the dorso-lumbar region which had not previously been used in the sensitising treatment; the compress was held in place for 24 hours under an occlusive patch; the same procedure was used for both test and control groups

day 28
as above, using a fresh group of control animals and an untouched skin region; using 0.5 mL 5 % test material in liquid petrolatum, 0.5 mL 1 % test material in petrolatum and liquid petrolatum only

*Challenge outcome:*

| | ***Test animals*** | | ***Control animals*** | |
|---|---|---|---|---|
| ***Challenge concentration*** | ***24 hours**** | ***48 hours**** | ***24 hours*** | ***48 hours*** |
| 25% | **10/20 | 14/20 | 9/10 | 8/10 |
| 50% | 17/20 | 17/20 | 10/10 | 10/10 |
| | | ***Rechallenge*** | | |
| 1% | 1/20 | 1/20 | 2/10 | 4/10 |
| 5% | 8/20 | 12/20 | 5/10 | 9/10 |

* time after patch removal
** number of animals exhibiting positive response

*Comments:*

a local irritation reaction was observed in all control animals for the 50 % challenge dose, and in 95 % of the control animals for the 25 % challenge dose; a rechallenge was performed 10 days later with lower concentrations; the cutaneous reactions for the test animals were not greater than for the control animals; the reactions were ascribed to an acute irritant property of the test material

*Test method:*

OECD TG 406 (Organisation for Economic Cooperation and Development, 1992b)

*Result:*

from the results of this study, it cannot be determined whether Foraperle 225 is a skin sensitiser or not, due to the high incidence of positive skin reactions in the control animals

## 9.2 Repeated Dose Toxicity

The notified polymer has been notified under the limited notification category. Toxicological tests are not specifically required under the Act for this notification category.

## 9.3 Genotoxicity

The notified polymer has been notified under the limited notification category. Toxicological tests are not specifically required under the Act for this notification category.

## 9.4 Overall Assessment of Toxicological Data

Toxicological reports for acute oral toxicity, acute inhalation toxicity, skin irritation, eye irritation and skin sensitisation have been provided as part of the limited notification provided for Polymer in Foraperle 225. The toxicity studies were performed using Foraperle 225, a product containing 25 % (w/w) notified polymer in n-butyl acetate, or formulations containing this product, and therefore it is not clear to what extent the toxicity results reflect the properties of the notified polymer. The solvent, n-butyl acetate, is reported to be a skin, eye and respiratory system irritant (Sax & Lewis, 1996). As separate toxicity data is not available, the effects are taken as representative of the notified chemical.

Foraperle 225 is of very low acute oral toxicity in rats ($LD_{50}$>2000 mg/kg). There is no available information on dermal toxicity.

The inhalational toxicity of the notified chemical could not be adequately measured, due to the limitations of the study caused by the inhalational toxicity of the solvents used; however, based on the study result of $LC_{50}$ > 20 mg/L/4 hours, the formulation tested was of low acute inhalational toxicity in rats. The limit for Foraperle 225 measured in this test is $LC_{50}$ > 0.41 mg/L/4 hours.

Foraperle 225 was a slight irritant to rabbit skin, but is not classified a skin irritant according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). The irritation effects observed in the skin sensitisation study on guinea pigs appear to be similar to the slight effects observed in the skin irritation study in rabbits.

Foraperle 225 was moderately irritating to the eyes of rabbits. Based on the grades of ocular reaction, in particular the redness of the conjunctiva, and persistence of chemosis to day 9 (one animal) and conjunctival redness to day 11 (one animal), the notified chemical should be classified as 'risk of serious damage to eyes' (R41) according to the NOHSC Approved Criteria for eye contact (National Occupational Health and Safety Commission, 1994a).

No clear conclusions could be drawn from the results of the skin sensitisation study in guinea pigs due to the skin reactions in the control animals. As acrylates tend to be skin sensitisers, further investigation of the skin sensitising potential of the notified chemical is warranted.

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to standardised Test Methods. Summaries only are available in English the full reports being in French.

| *Test* | *Species* | *Results* |
|---|---|---|
| acute immobilisation (Thiebaud, 1997a) | *Daphnia magna* | $EC_{50I}$ between 56 & 100 mg/L |
| bacterial growth inhibition (Thiebaud, 1997b) | *Pseudomonas putida* | $CE_{50}$ >100 mg/L |

A stock solution for both tests was prepared using acetone as the cosolvent and nominal concentrations obtained by dilution were used to conduct the tests and report the results.

The ecotoxicity data for the notified polymer indicate that the notified substance is slightly toxic to daphnia and practically non toxic to sludge bacteria.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified polymer is not likely to present a hazard to the environment when it is transported, stored and used in the proposed manner. Limited amounts of the polymer on release to the environment as waste from the formulation and application process or on discarded items of apparel are likely to remain immobile (fixed to soil or sludge) and slowly degrade on exposure to the biota present in landfill. The polymer is not expected to be exposed to the environment in a form or concentration that could harm the aquatic biota. Tests indicate it is not readily biodegradable, slightly toxic to daphnia and practically non toxic to sludge bacteria. The high molecular weight would also not allow the notified substance to cross biological membranes.

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

No toxicological studies were conducted on the notified polymer. However, studies were conducted on the product Foraperle 225, which contains 25 % (w/w) notified polymer in n-butyl acetate. The toxicity of the notified polymer cannot be directly inferred from the studies.

The acute toxicity of Foraperle 225 is low. It is a slight irritant to the skin of rabbits. It was found to be a moderate irritant to the eyes of rabbits. Based on the results of this study, classification of Foraperle 225 as a persistent eye irritant (R41) is warranted, and therefore the notified polymer also needs to be classified with the risk phrase R41. The skin sensitisation study in guinea pigs was found to be inconclusive due to the skin reactions in the control animals. As acrylates tend to be skin sensitisers, it is recommended that dermal exposure be avoided.

No long term toxicological studies such as repeat dose toxicity studies or a worker health study were provided. Long term inhalation of aerosol sprays containing insoluble polymers may result in impaired lung function. Absorption of the notified polymer through skin and other biological membranes is expected to be low due to the high molecular weight of the notified polymer.

Occupational exposure to the notified chemical can be divided into exposure to the 25 % polymer solution, the 1-3 % polymer solution, and to the treated cloth. Dermal and ocular exposure to drips and splashes is the most probable hazard for workers involved in reformulation and aerosol packing. For workers and the general public using the commercial aerosol product, dermal, ocular and inhalation exposure are probable in the absence of protective measures. Contact with the dried protective coating containing the notified polymer is not likely to be hazardous as the polymer will not be bioavailable.

*Transport and Storage*
The health risk for transport and storage workers is expected to be negligible unless the packaging is breached.

*Reformulation*
The reformulation workers will be exposed to the imported concentrated solution, for which the irritant properties are likely to present the greatest health risk. Workers will also be exposed to the diluted solution. Workers handling the concentrated material should wear a full face respirator with a solvent filter, PVC gloves and apron, and overalls. The reformulation operation is stated to be mechanised and enclosed.

*Aerosol Filling*
The workers involved in filling aerosol cans may be exposed to the diluted (1-3 %) polymer solution. Exposure is likely to be predominantly dermal exposure to drips and spills. Workers in this application are stated to wear overalls, safety boots, safety glasses and gloves. At the low concentration, the risk of adverse health effects due to the notified polymer is expected to be low.

Waterproofing Application
It is likely that the application of the commercial waterproofing product will be a small scale industrial process as well as a home operation. Workers applying the aerosol waterproofing formulation would be exposed to the notified chemical on a much more regular basis than the general public. For workers so engaged, dermal, ocular and inhalation exposure are probable in the absence of protective measures. At the low concentration, the risk of adverse health effects, apart from eye irritation, due to the notified polymer is expected to be low. During aerosol use there is also a risk of skin and eye irritant effects resulting from other ingredients in the product. It is recommended that any workers using the commercial waterproofing product work in a well ventilated area and use gloves and safety glasses for protection.

*Public Health*
Public exposure will occur from the use of pressure packs containing the notified polymer at concentrations of 1-3 %, and from contact with products which have been treated with the notified polymer, such as raincoats, sportsgoods, carpets and tents. The most likely routes of exposure are inhalation, oral ingestion and dermal and ocular contact with the aerosol product, and dermal contact with the cured polymer. However, due to the high molecular weight of the notified polymer, it is expected to be poorly absorbed across the skin and other biological membranes.

Based on the toxicology data, the main acute toxicological hazards are skin and eye irritation, although the skin sensitisation study was inconclusive. As a result of the skin and eye irritation potential of Foraperle 225, the following statement should be incorporated into the label of the aerosol product:

"Avoid contact with the eyes and skin."

## 13. RECOMMENDATIONS

- There is a NOHSC exposure standard for n-butyl acetate of 150 ppm (713 mg/m$^3$) TWA and 200 ppm (950 mg/m$^3$) STEL (National Occupational Health and Safety Commission, 1995). The employer is responsible for ensuring that the exposure standard is not exceeded in the workplace.

- Commercial aerosol products containing the notified polymer should incorporate the following statement into the product label

  "Avoid contact with the eyes and skin"

To minimise occupational exposure to the polymer in Foraperle 225 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);

- Respiratory protection conforming with AS/NZS 1715 (Standards Australia/Standards New Zealand, 1994a) and AS/NZS 1716 (Standards Australia/Standards New Zealand, 1994b) should be use when handling Foraperle 225;

- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990);

- 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, 1994c);

- Occupational users of commercial aerosol products containing the notified chemical should use gloves conforming to AS/NZS 2161.2 and glasses conforming to AS/NZS 1337, and work in a well ventilated area;

- 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.

## 14. MATERIAL SAFETY DATA SHEET

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

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 under Section 64(1) is required if additional skin sensitisation studies or health effects information, including sensitising effects, becomes available for this or other similar perfluoroalkyl acrylate polymer. In addition, 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.

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## Attachment 1

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

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

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

***CORNEA***

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

***CONJUNCTIVAE***

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

***IRIS***

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