File No: NA/672

November 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FR-370/FR-372

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 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9514 FAX (61) (02) 9577-9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FR-370/FR-372

1. APPLICANT

Marchem Australasia Pty Ltd of 19 Somers Rd NORTH SUNSHINE VIC 3019 have submitted a standard notification statement in support of their application for an assessment certificate for FR-370/FR-372.

2. IDENTITY OF THE CHEMICAL

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

Method of Detection and Determination:	UV/visible spectroscopy Infrared spectroscopy nmr spectroscopy (^{1}H and ^{31}P) mass spectroscopy Spectra enabling identification of the notified chemical have been provided by the notifiers.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	off white powder with a slightly sweet, musty odour
Melting Point:	182-184°C
Specific Gravity:	2.35 at 22-23°C
Vapour Pressure:	3×10^{-13} Pa at 25°C
Water Solubility:	~ 0.9 mg/L at 25°C (see comments below)
Partition Co-efficient (n-octanol/water):	log P_{ow} = 3.7 at 25°C (see comments below)

Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	no dissociable groups present
Particle Size:	< 7.1 µm 19.8 % < 10.5 µm 23.1 % < 21.0 µm 30.8 % < 102 µm 73.7 % < 544 µm 99.7 %
Fat Solubility:	1.29 ± 0.08 g/kg at 37°C
Henry's Law Constant:	1×10^{-15} atm/mol/m^3 (at 20°C)
Flash Point:	> 180°C
Flammability Limits:	not flammable
Autoignition Temperature:	602°C
Explosive Properties:	not expected to be explosive
Reactivity/Stability:	expected to be stable

Comments on Physico-Chemical Properties

The Henry's Law Constant was calculated using the formula:

H = (Vapour pressure) × (MW)/(Water solubility)

The water solubility was too low to measure at 20°C. It was determined at 25°C by suspending approximately 100 mg of the chemical in around 30 mL of deionised water in separate polycarbonate tubes, and agitating in a water bath for 1, 2, 5 and 10 days. Particulate matter was then removed from the liquid phase through high G centrifugation at 25,000 rpm. The chemical was extracted from the supernatant liquid with methylene chloride (three 5 mL aliquots used for each sample), and the methylene chloride evaporated off. The residual solid was then redissolved in acetonitrile, and analysed for the new chemical by gas chromatography. The results indicated solubility of between 0.724 and 1.09 mg/L (mean 0.9 ± 0.2 mg/L), and it was apparent that the agitation time had no bearing on the individual results.

No data on hydrolytic degradation as a function of pH was provided. Although the notifier attempted to obtain this data in accordance with the methods of OECD Test Guideline 111, the low solubility of the compound in each of the required aqueous buffers precluded completion of the tests. However, the compound is a phosphate ester, and cleavage of the

ester linkages could be expected under high pH conditions to give the parent brominated alcohol and lower phosphate esters. Progressive hydrolysis would result in phosphate ion and parent alcohol. The parent brominated alcohol contains C-Br bonds which could be expected to be susceptible to hydrolytic cleavage. This could result in the mineralisation of the contained bromine to bromide, and formation of a variety of hydroxylated species. However, this mode of abiotic hydrolysis is speculative, and definitive analytical data would have assisted this assessment.

The n-octanol/water partition coefficient was determined from the ratio of equilibrium concentrations of the compound in water-saturated n-octanol to that in n-octanol-saturated water A summary of the methodology was provided in the notification. Solutions of the compound in water saturated n-octanol were prepared at concentrations between 0.002 mM to 0.2 mM (2-200 mg/L), and aliquots of these solutions were shaken for 30 hours with aliquots of water saturated with n-octanol. The two phases were then separated, with each phase then centrifuged to complete phase separation. The dissolved compound was extracted from the n-octanol phase with methylene chloride, evaporated to dryness, and the residual solid then taken up in acetonitrile and analysed by gas chromatography. Similarly, the compound dissolved in the water phase was extracted with methylene chloride, evaporated to dryness, redissolved in acetonitrile and analysed using gas chromatography. The partition coefficient was calculated as the ratio of the two respective saturation concentrations, and values of Log P_{ow} ranged between 3.5 and 3.83.

Soil adsorption/desorption testing was not conducted due to the very low water solubility of the notified chemical.

The new compound contains no acidic or basic groups, so dissociation constant data are not relevant.

The compound has a modest fat solubility (1.29 g/kg), and this reflects the moderate value for Log P_{ow} of 3.7.

4. PURITY OF THE CHEMICAL

Degree of Purity: The notified chemical will be imported as a neat solid. Details of the purity of the notified chemical and the identity and % weight of impurities have been claimed as exempt by the notifier.

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported at a volume in the range of 10 to 100 tonnes per year over the first five years of importation. The notified chemical will be imported in substantially pure form in 25 kg polyethylene lined paper bags or 500 kg polypropylene bags.

The new chemical will be used as a flame retardant in moulded plastic products such as seating for large sporting venues, and in polypropylene fibres used in carpet production. In these products the new chemical is expected to comprise between 3 and 10 % of the final product weight in polypropylene and up to 12 % in High Impact Polystyrene (HIPS).

The new compound is firstly blended with powdered polypropylene or polystyrene and then extruded and diced into pellets of a masterbatch which may contain up to 25% of the new chemical by weight. The masterbatch pellets are then used for the preparation of the final plastic articles.

It was indicated by the notifier that two masterbatch producers would supply the producers of furniture and mouldings, while another two would supply producers of textile fibres for carpet manufacture. It was not indicated in the notification what percentage of total imports were likely to be used in each of these areas of activity, although initially most of the chemical was expected to be used for polypropylene mouldings. However, it was also indicated that the proportion used in carpet fibre was expected to increase in the future, and also that polymer formulations containing the chemical have many other potential uses, in particular moulded casing for electrical equipment such as power tools and computer cabinets.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in the form of a non-volatile powder, with a particle size distribution such that around 20 % of the particles will be in the respirable size range and another 54 % of the particles will be in the inspirable size range. The notified chemical has water solubility of less than 1 ppm. Potential exposure to the notified chemical would be by skin contact and inhalation.

Transport and Storage
The imported chemical, FR-370/FR-372, will be transported to four sites in Australia for masterbatch preparation. Overall, eight employees would be expected to be involved in storage and handling at these four sites. An unspecified but low number of waterfront and transport workers would also handle the packages containing the notified chemical. The notifier indicates that the packaging is unlikely to be breached in transport or handling incidents.

Drum handlers are expected to wear gloves and eye protection.

Masterbatch Production
The notified chemical will be compounded with the appropriate polymer (polypropylene or polystyrene) to produce a masterbatch containing up to 25 % notified chemical. This will be accomplished by blending the notified chemical with powdered or granulated polymer and extruding the mixture to produce polymer granules with the desired concentration of flame retardant.

On average, two employees at each plant will be potentially exposed to the notified chemical; one colour mixer and one plant operator. The colour mixer will weigh out the flame retardant in a dispensary which is designed for handling fine pigments. Local exhaust ventilation will

be used. The notified chemical is then transferred to a blender, either by a closed transfer system or under local exhaust ventilation. The blended material will be discharged to a collection bin, usually either in an enclosed system or under local exhaust ventilation, and transferred to an extruder. Up until this point in the processing, exposure to the powdered solid is possible.

The most probable forms of exposure are inhalation and ocular exposure to the dust and dermal exposure to the powdered solid, during weighing, transfer (if not enclosed) and equipment cleaning and maintenance. The notifier has indicated that local exhaust ventilation will normally be used where required, and workers will wear overalls, goggles and PVC gloves.

The masterbatch blend is melted in the extruder, and then discharged through a die-cutter to produce the diced masterbatch granules. During this process, the notified chemical will be immobilised by encapsulation in the polymer matrix.

Article Production
At the product manufacturing factory, masterbatch granules will be fed into the hopper of a blender, mixed with the resin and other additives, and extruded, moulded or spun to produce the finished plastic article. The notifier has indicated that it is likely that one worker at each of four factories will handle the notified chemical in the production of articles. The notifier indicated that charging of the mixer with the masterbatch would occur under local exhaust ventilation, and that the plant operator would wear protective equipment. As the notified chemical will be present in encapsulated form, no substantial exposure would be expected.

Cleaning Articles
While the notified chemical is less subject than many other, older generation brominated flame retardant compounds to "blooming" (see below under Environmental Exposure), there will be a slow release of the notified chemical to the surface of the article. The articles containing the notified chemical are likely to be used to a great extent in commercial premises, and there is likely to be occupational exposure of the cleaners in these premises to low levels of the notified chemical over extended time periods.

Recycling
The notifier has indicated that recycling of finished articles containing the notified chemical is likely. As the notified chemical is encapsulated within the polymer matrix, exposure to the notified chemical by workers in the recycling industry is not expected to occur.

7. PUBLIC EXPOSURE

The notified chemical will be used in an industrial environment up to the stage of production of articles, and is not likely to be released to the environment during manufacture. Therefore, public exposure to the pure notified chemical will only occur in the case of accidental spillage during transport. In the finished articles, the notified chemical will be encapsulated in the polymer matrix.

There may be infrequent public exposure to small amounts of the notified chemical as a result of the use of articles where there has been "blooming" of the notified chemical.

8. ENVIRONMENTAL EXPOSURE

Release

Very little release of the chemical is anticipated during preparation of the intermediate masterbatches. Fugitive release of fine powder during blending and extrusion is not expected to be large, and the majority is expected to be collected by vacuum extraction equipment. These measures would be expected to prevent release to the wider environment, and the dust collected in the vacuum extraction equipment filter is periodically removed and probably disposed of into landfill.

The notifier did not indicate the fate of empty polypropylene bags, but it is expected that these would be either incinerated or placed into landfill. Due to the high cost of the new chemical, it is unlikely that large quantities would be disposed of with the empty bags, and it is likely that a maximum of 1 % of import quantities (< 1 tonne per annum) would be disposed of via this route. The notifier has indicated that experience within the industry shows that when properly emptied as little as 5 grams may remain in each bag, and in the present case this would equate to a maximum of 20 kg per annum.

Similarly, release of chemical contained in the primary polymer (either in a masterbatch or in the final polymer blends) would be small and purged polymer from pipes and ducts in the extrusion equipment could be expected to be placed into landfill or most likely added to later production batches.

Initially polymer formulations containing the new chemical are to be used in the manufacture of moulded fittings for large sports venues. However, these formulations have a variety of other applications including the production of polypropylene carpet fibre and flame retardant casings for electrical equipment. Consequently, articles containing the new chemical are likely to have a wide distribution throughout the community which indicates that long term release of the chemical (eg as result of discarding old consumer products or electrical equipment) would be very diffuse.

Some release of the chemical is likely as a result of “blooming” from the manufactured articles during day to day use. This process is effectively the slow diffusion of the chemical from the interior of the plastic article to the surface, and here it may be removed through cleaning processes etc, and released in waste water (presumably mainly to sewer). However, release through this route is expected to be diffuse and at very low levels. The notifier supplied a copy of a report which indicated that blooming of the new chemical from the surface of polypropylene articles is significantly lower than for other, older generation brominated flame retardant compounds and, in this respect, represents an advance over the older products. Specifically, comparative tests conducted over a 28 day period at 100°C between polypropylene containing the new compound, FR-370/FR-372, and polypropylene containing an equivalent percentage of tetrabromobisphenol A bis(2,3-dibromopropyl) ether indicated that the new compound migrated to the polymer surface at less than half the rate of the bisphenol A derivative. It was also indicated that the rate of blooming of the new compound could be further reduced by the incorporation of other technologies (presumed to be addition of certain other compounds) in the formulation or polymer processing. The nature

of the "non blooming technology" was not specified in the report, but its use apparently reduced the extent of blooming of FR-370/FR-372 by a factor of around 3 compared to blooming in polypropylene formulations in which it was not used.

Similarly, carpets made of polypropylene fibre may be subjected to regular cleaning regimes, and it could be expected that some of the new chemical would be released as a result of solubilisation by the detergents used by carpet cleaners. Again, this mode of release would be diffuse and at low levels, and the released chemical would be likely to enter the sewer system.

While recycling of the polypropylene or polystyrene in discarded articles is theoretically possible, this is not anticipated to take place on a large scale (see below in section on Fate). Consequently, the majority of the imported chemical will be discarded with old plastic articles at the end of their useful lives, and these are likely to be either incinerated or placed into landfill.

Material disposed of into landfill will be incorporated in the solid polymer matrix of the plastic article where it will be immobilised. However, the polymer matrix will be slowly degraded through the biological and abiotic processes operative in landfills, and this would release the notified chemical.

Diffusion of the polymer to the surface of broken pieces of plastic (ie "blooming" as discussed above) would contribute to this mode of release.

Fate

A test for biodegradability conducted according to the Modified Sturm Test (European Communities TG A.202-206 test guideline C-4-C) (Scott & Alexander, 1993) indicated between 25 and 32% degradation after 28 days for inoculum containing 33 and 17 mg/L of organic carbon respectively, and approximately 37 % after 39 days, for both organic carbon contents. The compound is therefore not readily biodegradable, but it may be classified as being inherently degradable. The reference compound used during this test was sodium benzoate which was present at a nominal 20 mg/L of organic carbon, and this was degraded more than 72 % over a 28 day test period. While this test established that the new compound is inherently biodegradable, the results give no indication of the nature of the degradation products, and in particular, no indication of the degree to which the bromine content is mineralised to inorganic bromide, or to the rate at which this may occur under typical environmental conditions. Due to the attention being attracted by the possible persistence of brominated flame retardants in the environment, some information on these aspects of the degradation pathways would have been very useful.

While no chemical or analytical data on the biodegradation pathways and products is currently available, it is likely that the products would be similar to those mentioned above in relation to abiotic hydrolysis. It is relevant to note that biodegradation (World Health Organisation, 1995b) of the brominated aliphatic phosphate ester tris(2,3-dibromopropyl) phosphate leads to initial production of bromide ion indicating hydrolysis of C-Br bonds.

The notifiers indicated that polymer incorporating the new chemical as a fire retardant may be recycled many times, and included a scientific conference paper supporting this assertion. However, this is unlikely to be practiced on a large scale due to the lack of adequate

infrastructure for this purpose in Australia for the two main polymers (polypropylene and polystyrene) into which the new chemical will be incorporated. The notifiers pointed out the difficulties involved in tracking individual articles containing the chemical over extended time periods, and unless rigorous labelling and recycling instructions accompanied each article effective recycling of the bulk of the plastics containing the new chemical is unlikely. As mentioned earlier, the eventual fate of the majority of the imported chemical will be strongly linked to that of discarded plastic articles, and this is likely to be either incineration or placement into landfill.

Complete combustion of the chemical in the presence of excess oxygen would be expected to destroy the material with production of water vapour, oxides of carbon, hydrogen bromide and some solid phosphate salts which would become incorporated with the waste incinerator ash. However, it should be noted that incineration of halogenated materials (or materials associated with halogen containing compounds) can potentially produce a great variety of products, including dioxins and furans, both of which are of environmental concern. The formation of these compounds occurs under a wide variety of common furnace operating regimes, and consequently disposal of articles containing the new chemical through incineration should not be encouraged. In the present case, the notifier has pointed out that the absence of aromatic rings in the new compound would preclude dioxin/furan formation, but no supporting analytical data was supplied. It is likely that the aliphatic nature of the compound may lessen the extent of dioxin/furan formation during incineration processes, but would not eliminate their production – see below in "Assessment of Environmental Hazard".

When discarded into landfill, the chemical will be released slowly due to deterioration of the polymer matrix. While no quantitative data for Log K_{oc} was provided in the notification, the measured value for Log P_{ow} of 3.7 indicates that released chemical would most likely become associated with the organic component of soils and sediments. The chemical is inherently biodegradable, and when bound to or otherwise associated with soils and sediments it could be expected to slowly degrade through the agency of biological and abiotic processes operative within landfills.

The modest fat solubility (1.29 g/kg), median value for Log P_{ow} (3.7), relatively low molecular weight (1018 g/mole) and low water solubility (0.9 mg/L) indicate potential for bioaccumulation. Estimations of the bioaccumulation factor from either the partition coefficient or the water solubility may be calculated using equations given by Lyman (1981). These equations are respectively –

$$\text{Log BCF} = 0.76 \times \text{Log } P_{ow} - 0.23$$

and

$$\text{Log BCF} = 2.79 - 0.56 \times \text{Log S}$$ (where S is the water solubility in mg/L).

The bioaccumulation factor from the partition coefficient is 382, while that calculated from the water solubility is 645. Bioconcentration factors in this range indicate the compound to have moderate potential for bioaccumulation (Mensink, 1995). However, since it is expected that the compound will slowly biodegrade, and is in any case unlikely to enter the water compartment in significant volumes, the risks associated with bioaccumulation would be

small.

9. EVALUATION OF TOXICOLOGICAL DATA

The toxicological tests were performed according to OECD guidelines.

9.1 Acute Toxicity

Summary of the acute toxicity of FR-370/FR-372

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(Freeman, 1990b)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(Freeman, 1990a)
acute inhalation toxicity	rat	LD_{50} > 1.81 mg/L	(Mount, 1993)
skin irritation	rabbit	non-irritant	(Freeman, 1990d)
eye irritation	rabbit	minimally irritating	(Freeman, 1990c)
skin sensitisation	guinea pig	non-sensitising	(Freeman, 1990e)

9.1.1 Oral Toxicity (Freeman, 1990b)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Dose Range:	5000 mg/kg
Method of administration:	gavage, 50 % (w/v) in corn oil
Test method:	limit test, OECD TG 401
Clinical observations:	diarrhoea, abdominal staining and pigmented tears and nasal secretions were seen in some animals during the first day after dosing
Mortality:	no deaths were recorded during the observation period
Morphological findings:	no gross internal lesions were observed at necropsy
LD_{50}:	> 5000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Freeman, 1990a)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Dose Range:	2000 mg/kg
Method of administration:	test material moistened with saline was placed on a gauze patch and secured under an occlusive wrap for 24 hours
Test method:	limit test, OECD TG 402
Clinical observations:	diarrhoea, and pigmented tears and nasal secretions were seen in some animals during the first two days after dosing
Mortality:	no deaths were recorded during the observation period
Morphological findings:	no gross internal lesions were observed at necropsy
Comment:	no signs of skin irritation were observed during the study
LD_{50}:	> 2000 mg /kg
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity (Mount, 1993)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Dose Range:	aerosol, 1.81 ± 0.50 mg/L (maximum attainable concentration)
Method of administration:	whole body, 4 hour exposure, dynamically operated chamber
Particle Size:	test material milled to < 3 µm mass median aerodynamic diameter (MMAD) 77 – 87.5 % < 10 µm 17.9 – 26.1% < 1 µm (material largely in respirable range)
Test method:	limit test, OECD TG 403

Clinical observations:	abdominal staining, pigmented nasal secretions, lacrimation and squinting eyes were seen in some animals during and shortly after exposure
Mortality:	no deaths were recorded during the observation period
Morphological findings:	no gross internal lesions were observed at necropsy
LC_{50}:	> 1.81 mg/L
Result:	the notified chemical was of low acute inhalational toxicity in rats

9.1.4 Skin Irritation (Freeman, 1990d)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/sex
Observation period:	72 hours
Method of administration:	0.5 g of test material, moistened with physiological saline, was applied to a clipped intact region of the dorsal skin and secured under a gauze patch with a semi-occlusive dressing for 4 hours; at the end of this time residual material was removed with gauze and methanol; animals were examined for skin reaction 1, 24, 48 and 72 hours following application of the test substance
Test method:	OECD TG 404
Draize scores (Draize, 1959):	all Draize scores were zero
Result:	the notified chemical was not irritating to the skin of rabbits

9.1.5 Eye Irritation (Freeman, 1990c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 male, 4 female
Observation period:	72 hours
Method of administration:	0.1 g of test material applied as supplied into conjunctival sac of the left 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

Test method: OECD TG 405

Draize scores (Draize, 1959) of unirrigated eyes:

	Time after instillation							
Animal	***1 hour***		***1 day***		***2 days***		***3 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1	0[1]	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0
Iris								
1	0		0		0		0	
2	0		0		0		0	
3	0		0		0		0	
4	0		0		0		0	
5	0		0		0		0	
6	0		0		0		0	

Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	2	0	0	0	0	0	0	0	0	0
2	0	0	1	0	0	0	0	0	0	0	0	0
3	0	0	1	0	0	0	0	0	0	0	0	0
4	0	0	1	0	0	0	0	0	0	0	0	0
5	1	0	1	0	0	0	0	0	0	0	0	0
6	1	0	3	0	0	0	0	0	0	0	0	0

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

Result: the notified chemical was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Buehler method) (Freeman, 1990e)

Species/strain: guinea pig/Hartley

Number of animals: 20 test;
10 irritation (challenge) control

Induction procedure:

test group:
days 0, 7 and 14: 0.3 g of test material (100 %), moistened with physiological saline, was applied to a clipped intact region of the left shoulder using an occlusive chamber for 6 hours; at the end of this time residual material was removed with gauze and methanol

control group:
days 0, 7 and 14 no treatment

Challenge procedure:

test group and
control group:
day 28 0.3 g of test material (100 %), moistened with physiological saline, was applied to a clipped intact region of the right shoulder using an occlusive chamber for 6 hours; at the end of this time residual material was removed with gauze and methanol

Test method: OECD TG 406

Observations: no irritation was observed in any animal of either the test or irritation control group (all Draize scores were zero)

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

9.1.7 Acute Delayed Neurotoxicity (Freeman, 1997)

Species/strain: hen/White Leghorn (8-12 months old)

Number/sex of animals: 14 female/group
(test, vehicle control, positive control)

Observation period: 21 days

Dose Range: 2000 mg/kg test substance
500 mg/kg tri-o-tolyl phosphate (positive control)

Method of administration: gavage, gelatin capsule

Test method: limit test, OECD TG 418

Mortality: no deaths were recorded during the observation period

Clinical observations: no clinical signs or abnormal motor activity were noted in test or vehicle control groups; positive control animals behaved as expected

Neurotoxic Esterase (NTE) measurements:	no change in NTE levels was observed in test or vehicle control groups at 24 and 48 hours; positive control animals showed reductions to 93 % and 68 % of normal NTE levels at 24 and 48 hours respectively
Morphological findings:	no neuropathological lesions were observed at necropsy for test or vehicle control animals; axonal degeneration in the spinal cord and peripheral nerves and neuron chromatolysis were observed in positive control hens
Result:	the notified chemical did not cause acute delayed neurotoxicity in hens following a single oral administration of 2000 mg/kg

9.2 Repeated Dose Toxicity

9.2.1 28 Day Feeding Study (Freeman, 1993)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex/group
Method of administration:	test material was mixed with corn oil and blended with rodent diet at the required concentration; the animals were fed the appropriate diet *ad libitum*
Dose/Study duration::	0, 4000, 8000, 20000 ppm; administered for 28 consecutive days
Test method:	OECD TG 407

Clinical observations:

No deaths were recorded and no treatment related clinical signs were observed. One male in the 8000 ppm group was observed to lean to one side, but this was attributed to a middle ear infection on veterinary inspection; the only other signs were various sores on the neck, attributed to the animals scraping on the feed jar lid, and a swollen snout noted in one male of the 20000 ppm group.

Food Consumption/Body Weight:

No statistically significant differences were noted between the treated and control animals either in food consumption or body weights throughout the study. The actual doses determined from food consumption were:

Dose	Males	Females
4000 ppm	313 mg/kg/day	365 mg/kg/day
8000 ppm	631 mg/kg/day	702 mg/kg/day

20000 ppm	1635 mg/kg/day	1858 mg/kg/day

Clinical chemistry/Haematology

The only statistically significant difference in clinical chemistry noted between groups was an increased total bilirubin level for males of the 20000 ppm group. This was not considered treatment related, as the values for all groups were within the normal historical range and there was no dose-response relationship observed.

Females receiving 8000 ppm and greater showed a statistically significant increase in lymphocyte count. Again, this was not considered treatment related, as the values for all groups were within the normal historical range and no consistent dose-response relationship was observed.

Gross Pathology:

A small, soft left testis in one male of the 4000 ppm group and a sore on the right shoulder of one male in the 8000 ppm group were the only gross lesions observed. These were considered isolated, non-dose related findings and were not considered treatment related.

No statistically significant differences in organ weights were noted when comparing treated animals with controls.

Histopathology:

All observations were considered to be spontaneous rather than treatment related, and were considered to be typical of rats of this age and strain. The observations included trace chronic progressive nephropathy in three high dose males, three high dose females, and three control males; microconcretions at the cortico-medullary junction of two high dose females; and mild vacuolar change in the liver of one high dose female. These observations were all considered to be normal spontaneous lesions of rats of this age and strain. Other changes in the liver, granuloma and extramedullary haematopoesis were present to a similar extent in treated and control animals.

Result:

Based on the absence of any significant treatment related findings, a NOEL of 20000 ppm was established in this study (1635 mg/kg/day for males; 1858 mg/kg/day for females).

9.2.2 90 Day Feeding Study (Freeman, 1996)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	10/sex/group
Method of administration:	test material was mixed with corn oil and blended with rodent diet at the required concentration; the animals were fed the appropriate diet *ad libitum*

Dose/Study duration:: 0, 2000, 10000, 20000 ppm; administered for 90 consecutive days

Test method: OECD TG 408

Clinical observations:

No treatment related deaths occurred, and no significant treatment related clinical signs were observed.

A number of symptoms including pigmented tears and nasal secretions, hair loss, red oral discharge, red swollen ears and red-brown staining of the cage pan liner were observed in a non-dose related pattern and were not considered treatment related.

A protruding sternum in one female of the 10000 ppm group was considered a developmental anomaly unrelated to treatment. One male in the 20000 ppm group displayed abdominogenital staining, pigmented nasal secretions, decreased faeces and unthriftiness; these symptoms were attributed to stress following urine collection on the previous day and were not considered treatment related.

There were no significant ophthalmological findings.

Food Consumption/Body Weight:

Statistically significant increases in food consumption were noted among the treated males when compared with the controls. The body weight gains in the males of all the treatment groups were also higher than for the controls. These observations were not considered to be a toxicological effect. No differences in food consumption or body weights were observed among the females. The actual doses determined from food consumption were:

Dose	Males	Females
2000 ppm	137 mg/kg/day	173 mg/kg/day
10000 ppm	682 mg/kg/day	880 mg/kg/day
20000 ppm	1358 mg/kg/day	1685 mg/kg/day

Clinical chemistry/Haematology

No treatment related changes in any of the haematology parameters were noted in comparing the treated groups to the controls.

A decrease in potassium levels in the males of the 20000 ppm group was observed, but no effect was seen in the females. The difference in values was also small, and therefore this was not considered to be biologically significant. A statistically significant decrease in aspartine aminotransferase (AST) was seen in males and females of the 10000 ppm and 20000 ppm groups, although the authors did not consider this to be of toxicological significance as all values were within established reference ranges.

Gross Pathology:

No treatment related findings were noted; all findings were considered spontaneous and unrelated to treatment. No statistically significant differences in organ weights were noted.

Histopathology:

A mild to moderate area of focal liver necrosis was observed in one male at 2000 ppm and two males at 20000 ppm. No similar observations were made among the females, however a minimal focal area of necrosis was noted in a control female. The study authors stated that the character and distribution of the lesion was consistent with a spontaneous lesion which is not uncommon in rats. No treatment related observations were made.

Result:

No NOEL was established in this study, due to the increase in food consumption. In the absence of any adverse treatment related findings, a NOAEL of 20000 ppm was established (1358 mg/kg/day for males; 1685 mg/kg/day for females).

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Batt, 1990)

Strains:	*Salmonella typhimurium*: TA98, TA100, TA1535, TA1537, TA1538
Concentration range:	0, 50, 167, 500, 1667, 5000 µg/plate the test solutions were prepared in DMSO
Metabolic Activation System:	rat liver S9 fraction from animals pretreated with Aroclor 1254
Test method:	OECD TG 471
Positive controls	2-aminoanthracene 4.0 µg/plate – all strains with S9 9-aminoacridine 75 µg/plate – TA 1537, without S9 sodium azide 5 µg/plate – TA100, TA1535 without S9 2-nitrofluorene 5 µg/plate – TA98, TA1538 without S9
Comment:	precipitation occurred for concentrations of test material of 500 µg/plate and higher and this hampered cytotoxicity testing two independent assays were performed using the same concentration range; the first gave negative results while the second showed a 2.3 fold increase in revertants in TA1535 with 5000 µg/plate test material in the presence of metabolic activation and increased revertants for lower doses; an additional test was then performed for TA1535 in the presence of metabolic activation with negative results

	clear positive results were obtained with the positive controls indicating that the test system responded appropriately
Result:	the notified chemical was not considered mutagenic in the bacterial strains tested in the absence or presence of metabolic activation provided by rat liver S9 fraction

9.3.2 Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells *In Vitro* (Putnam & Schadly, 1993)

Cells:	Chinese Hamster Ovary (CHO)
Doses:	initial assay 0.025, 0.075, 0.25, 0.75, 2.5, 7.5, 25, 75, 250 µg/mL repeat assay 31.3, 62.5, 125, 250 µg/mL
Metabolic Activation System:	rat liver S9 fraction from animals pretreated with Aroclor 1254
Treatment Regime:	where metabolic activation was used, test material or positive controls were added to cell cultures in serum free medium for 4 hour incubation with S9 mix; the cells were then washed and incubated in fresh complete medium for the remainder of the incubation time; in the absence of metabolic activation, exposure was continuous up till the time of colcemid treatment; colcemid was added two hours before harvest to arrest cells in metaphase cells were harvested 20 hours after treatment in the initial assay and 20 and 44 hours after treatment in the repeat assay
Test method:	US EPA FIFRA guideline 84-2 (similar to OECD TG 473)
Positive controls	triethylenemelamine 0.5 µg/mL (for cells treated without metabolic activation) cyclophosphamide 50 µg/mL (for cells treated with metabolic activation)
Comment:	precipitation occurred for concentrations of test material of 75 µg/mL and higher two independent assays were performed in the initial assay, the toxicity, by mitotic inhibition, was approximately 48 % at the top dose (250 µg/mL) without S9

and approximately 41 % with S9; no statistically significant increase in chromosome aberrations was observed with and without S9

in the second assay, the toxicity at the top dose (250 μg/mL) was 28 % at 20 hours and 0 % at 44 hours with S9 and 23 % at 20 hours and 18 % at 44 hours without S9

in this assay a statistically significant increase in the percentage of cells with structural aberrations was observed at 62.5 μg/mL without metabolic activation for the 44 hour harvest but not at higher concentrations; as the increase was marginal and there was no dose response, this observation was not considered biologically significant; an increase in the percentage of polyploid cells was seen at 31.3 and 62.5 μg/mL without metabolic activation at the 44 hour harvest but not for higher concentrations

clear positive results were obtained with the positive controls in both assays indicating that the test system responded appropriately

Result:

the notified chemical induced a marginal increase in the percentage of cells with chromosomal aberrations without metabolic activation in the 44 hour harvest, however the response was not dose related and the authors did not attach any biological significance to this result

the notified chemical induced a significant increase in the percentage of numerical aberrations at two dose levels (31.3 and 62.5 μg/mL) without metabolic activation in the 44 hour harvest

no statistically significant increase in chromosome aberrations was observed in the presence of metabolic activation

based on these results, the notified chemical was negative in the induction of structural aberrations but equivocal in the induction of numerical aberrations

9.3.3 Mouse Lymphoma Forward Mutation Assay (Cifone, 1995)

Cells:	mouse lymphoma L5178Y
Doses:	0, 500, 1000, 2000, 3000, 4000, 5000 μg/mL
Metabolic Activation System:	rat liver S9 fraction from animals pretreated with Aroclor 1254

Treatment Regime:	cell culture was treated with test material in the presence or absence of metabolic activation for 4 hours; the cells were washed and resuspended in fresh medium; a fixed number of cells was then suspended in selection medium to selectively recover only TK-/- mutants; then they were seeded into dishes and colonies allowed to grow for 10 to 14 days
Test method:	similar to OECD TG 476
Positive controls	methyl methanesulphonate 10, 15 nL/mL (for cells treated without metabolic activation) 20-methylcholanthrene 2.0, 4.0 μg/mL (for cells treated with metabolic activation)
Comment:	the test material was found to precipitate at concentrations greater than 156 μg/mL little or no cytotoxicity was observed over the entire test range (including the range-finding studies) of 10 – 5000 μg/mL the mutant frequencies observed at the TK locus were below the minimum criteria with and without metabolic activation and the compound was considered to be non-mutagenic the cloning efficiencies and vehicle control mutant frequencies were found to be acceptable; a large increase in mutant frequency was observed for the positive controls indicating that the test system responded appropriately
Result:	the notified chemical did not induce forward mutations in mouse lymphoma L5178Y cells *in vitro* with or without metabolic activation

9.4 Overall Assessment of Toxicological Data

The acute oral toxicity in rats is very low (LD_{50} > 5000 mg/kg) and the acute dermal toxicity in rats is low (LD_{50} > 2000 mg/kg). The limit test for the acute inhalation toxicity used a maximum achievable concentration of notified chemical (1.81 ± 0.50 mg/L) indicating that the inhalation toxicity would be at most moderate, but given the lack of clinical signs, the true LC_{50} is likely to be higher.

The notified chemical is not irritating to rabbit skin. It was found to be a slight irritant to rabbit eyes. It was found not to be a skin sensitiser in a Buehler test.

The notified chemical is a phosphate ester and, and similar to a number of chemicals that have been shown to produce polyneuropathy. For this reason, an acute delayed neurotoxicity study in hens was performed. The notified chemical tested negative at the single dose of 2000

mg/kg.

In a 28 day feeding study in rats, there were no significant treatment related findings, and a NOEL of 20000 ppm (1635 mg/kg/day for males; 1858 mg/kg/day for females) was established.

In a 90 day feeding study in rats, all treated males showed an increase in food consumption relative to the controls, with a corresponding increase in body weight gains. No equivalent observation was made for the females. No other significant treatment related observations were made. The increase in food consumption was not considered to be an adverse effect. Based on these findings, a NOAEL of 20000 ppm (1358 mg/kg/day for males; 1685 mg/kg/day for females) was established.

The notified chemical gave negative results in three *in vitro* genotoxicity tests (*Salmonella typhimurium* reverse mutation assay, chromosomal aberrations in CHO cells and mouse lymphoma forward mutation assay) in the presence and absence of S9 metabolic activation.

The brominated aliphatic phosphate ester tris(2,3-dibromopropyl) phosphate (TBPP) was widely used as a flame retardant (particularly in children's clothing), but was withdrawn due carcinogenic and mutagenic properties (World Health Organisation, 1995b). TBPP gives positive results in a number of genotoxicity tests. The positive results in bacterial mutagenicity tests were more pronounced in the presence of metabolic activation (levels as low as 10 μg/plate). Oxidative metabolism of TBPP was found to produce the potent direct acting mutagens 2,3-dibromopropanal and 2-bromoacrolein (World Health Organisation, 1995b). As the α,β-dibromo structure appears to be needed for this mechanism, and this does not occur in the notified chemical, it is not likely that the same concern will exist for this chemical. In addition, the bacterial mutagenicity results for the notified chemical do not indicate the same mutagenic potential.

Based on the data provided, the notified chemical would not be classed as a hazardous substance according to the National Occupational Health and Safety Commission *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided the following ecotoxicity data, which were performed in accordance with OECD Test Guidelines.

Test	***Species***	***Results***
Acute Toxicity [OECD 203]	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}(96 h) > 100 mg/L
Acute Immobilisation [OECD 202 Part 1]	*Daphnia magna*	EC_{50}(48 h) > 100 mg/L - see notes below.

Chronic Exposure Reproduction [OECD 202 Part 2]	*Daphnia magna*	EC_{50}(16 day) > 3.2 mg/L NOEC(16 day) = 3.2 mg/L
Inhibition of Algal Growth [OECD 201]	*Selanastrum capricornatum*	NOEC(72 h)>100 mg/L
Inhibition of Bacterial Respiration [EU Test Guideline C-4-C]	Activated sludge bacteria	Not inhibitory – see notes below.

* NOEC - no observable effect concentration

The acute test on rainbow trout was a Static Limit Test performed over 96 hours using a water accommodation fraction of the new chemical made up at nominal concentration of 100 mg/L in charcoal filtered dechlorinated tap water (Caley & Knight, 1993b). The test was performed using 5 replicate 25 L glass tanks, each of which contained ten fish, together with a control tank (no test material) which also contained ten fish, a total of 60 test specimens. The nominal concentration of 100 mg/L for the test chemical was very much greater than the measured water solubility (0.9 mg/L), and the presence of undissolved chemical was apparent as a suspension in the water column. The test was conducted over a 96 hour period under static conditions (no replacement of test water) at a controlled temperature of 15 ± 2°C, while the pH was between 8.0 and 8.2, dissolved oxygen between 77 and 92% of the saturation value and water hardness around 68 mg/L as $CaCO_3$.

Apart from one mortality which appeared to be due to aggressive behaviour of the other fish, all test specimens survived over the 96 hour test period. Further, no physical or behavioural anomalies were observed during the test period, and accordingly it was concluded that the new chemical FR-370/FR-372 is non toxic to rainbow trout up to the limits of its water solubility.

The notification summary and the MSDS supplied in the dossier made reference to the acute EC_{50} for *Daphnia magna* as > 100 mg/L (nominal concentration) but no test report accompanied the submission. However, since these tests would have been performed with suspensions of the compound at nominal concentrations well above the water solubility (0.9 mg/L) it is reasonable to deduce that the chemical is not acutely toxic to *Daphnia magna* up to the limits of its solubility. Further, in the chronic study (see below) the initial range finding tests indicated no mortality after 48 hours at exposure to nominal concentrations of the test substance in excess of 1,000 mg/L.

A chronic study on daphnia was reported in the submission (Cunningham, 1995). This study was conducted over a 16 day period at 20 ± 1°C, using a static method with regular renewal of the test medium. Water accommodation fractions of the compound were prepared at nominal loadings of 0 (control), 0.1, 0.2, 0.4, 0.8, 1.6 and 3.2 mg/L, and each test was conducted in quadruplicate using ten daphnia for each test. The water used for the test media had been dechlorinated by passage through activated carbon and re-aerated prior to use. It had a hardness of around 82 mg/L as $CaCO_3$, while over the 16 day test period the pH was between 6.8 and 8.8 and dissolved oxygen between 7.9 and 11.1 mg/L. The test media was renewed three times per week. The media were analysed for dissolved compound using gas chromatography, and the mean measured concentrations of dissolved chemical were between

5 and 43 µg/L, which corresponded to 0.4 to 12 % of the nominal concentrations. The large discrepancy between the nominal and measured concentrations is due to the low water solubility of the chemical, and it was remarked that undissolved chemical was visible in all the test vessels. There was no significant mortality over the 16 day test period, and no reproductive differences between the animals of different generations were observed. Accordingly, based on the nominal concentrations (which are very much larger than those measured), the Lowest Observed Effect Concentration (LOEC) is > 3.2 mg/L. The Maximum Acceptable Toxic Concentration (MATC) could not be calculated.

The tests on *Daphnia magna* indicate that the chemical is not toxic to this species up to the limits of its water solubility.

A limit test on the inhibition of algal growth was also conducted on *Selanastrum capricornutum* over a 72 hour incubation period at 22 ± 1°C with nominal concentration of the test material of 100 mg/L (Caley & Knight, 1993a). Ten replicate tests were conducted in 250 mL Erlenmeyer flasks, together with 6 control flasks containing no chemical. Each flask contained 100 mL of the test medium, and the flasks were continuously agitated to maintain the algal cells in suspension. The pH of the test solutions rose from around 8.2 at the start of the period, to around 10 after 72 hours. Each flask was initially inoculated with 8 X 10^3 cell/mL, and the mean cell concentration determined in test and control samples after 24, 48 and 72 hours. The mean density in the controls was 0.34, 2.36 and 11.37 X 10^5 cells/mL after 24, 48 and 72 hours respectively, while the corresponding densities for the test samples were 0.37, 2.39 and 10.99 X 10^5 cells/mL. These results show the new chemical is non toxic to this species of green algae up to the limits of its water solubility.

No specific test on the inhibition of bacterial respiration was conducted, but it was inferred from the results of the Modified Sturm test employed to test biodegradation (Scott & Alexander, 1993) that the new compound FR-370/FR-372 showed no tendency to inhibit respiration when present (dissolved and suspended) in the test media at nominal concentrations up to 33 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is not expected to be high when it is used for the manufacture of extruded articles and carpet fibre as indicated in the notification. However, some potential hazard may result from slow release of the chemical as a result everyday use (and cleaning) of the polymer articles, and in particular when the articles are disposed of at the end of their useful lives. As indicated above, it is unlikely that much of the polymer containing the new chemical will be effectively recycled, and consequently most is likely to be placed into landfill or incinerated.

If placed into landfill, the compound is likely to be slowly released as a consequence of the slow degradation of the polymer matrix in which it is encapsulated. However, once released in this manner it is expected to associate with the organic component of soils and sediments, and be slowly degraded through the biological and abiotic processes operative in these situations. The material has low water solubility, and little is expected to be released to the water compartment. In any case the chemical is not toxic to those aquatic species against which it has been tested, and consequently release to the water appears to entail low

environmental hazard.

Although more information from the notifier would have been helpful, the new compound is more susceptible to biodegradation than other commonly used brominated flame retardants such as polybrominated diphenyls, bisphenol A and diphenyl ethers. The release and environmental persistence of these classes of chemical has attracted recent literature attention (Organisation for Economic Cooperation and Development, 1994; World Health Organisation, 1995a). The bioaccumulation factor is estimated to be between 100 and 1,000 which indicates the compound to have moderate potential for bioaccumulation (Mensink, 1995). However, since the compound is unlikely to be released to the water compartment in large volume, the risk associated with bioaccumulation is considered to be small.

Incineration of the brominated compound entails the greatest potential hazard due to the possibility for formation of brominated dioxins and furans which could be released in the flue gases or become associated with fly ash or bottom ash. Chlorinated dioxins and furans have attracted a great deal of attention due to their persistence in the environment, and the well documented toxicity of certain of their isomers. The conditions for formation of these compounds and the chemical mechanisms operating during the combustion processes has also attracted a great deal of research and debate. However, there appears to be little doubt that incineration of carbonaceous fuel containing chlorine (even chloride salts) will lead to formation of dioxins and furans over a wide range of furnace operating conditions. In particular (Weber & Hagenmeir, 1998) the temperature, presence of catalytic metals such as copper and of particles of carbon and/or fly ash and other factors influence the extent of formation of these compounds and also the relative ratio of dioxin/furan.

The notifier has pointed out that unlike earlier generations of brominated flame retardants such as those based on brominated bisphenol A and diphenyl ether, the new compound is entirely aliphatic. Consequently, they claim that the absence of aromatic precursor structures for dioxin and furan type compounds precludes formation of these molecules. However, while the absence of aromatic nuclei in the new chemical may lessen the probability for dioxin/furan production, in the light of the work alluded to above, there is no evidence that dioxin/furan production will not occur.

While the literature concerning formation of the brominated dioxin/furan analogues appears to be far less extensive than that for the chlorinated compounds, there is little doubt that incineration of bromine containing compounds does lead to formation of the brominated dioxins and furans (Organisation for Economic Cooperation and Development, 1994), and consequently disposal of old articles via this route should be discouraged.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The acute toxicity of FR-370/FR-372 is low. It is a slight irritant to the eyes of rabbits, however it is not a skin irritant in rabbits. It is not a skin sensitiser to guinea pigs. No signs of systemic toxicity were seen in two longer term feeding studies with rats (28 day and 90 day). Negative results were also obtained in a number of genotoxicity studies and in a neurotoxicity test.

The notified chemical is of low volatility and low water solubility, and will only be handled in solid form, either as the imported chemical or as pellets of a polymer masterbatch containing a high proportion of notified chemical. The imported chemical will be in powder form, with 20 % of the particles in the respirable size range and a further 54 % in the inspirable size range.

Occupational Health and Safety
The greatest occupational exposure to the notified chemical is likely to be in the formulation of polymer masterbatches containing the flame retardant. After the formulation of the masterbatches, the polymer will be encapsulated in the polymer matrix and will only slowly migrate to the surface of the polymer pellets or articles. Therefore the exposure to the notified chemical of workers manufacturing articles containing the notified chemical should be low. Minor exposure to cleaners who handle articles may occur due to slow diffusion of the notified chemical to the surface of the article.

The notifier indicates that the workers who blend the masterbatch will weigh out the notified chemical in a dispensary which is designed for handling fine pigments, and local exhaust ventilation will be used to minimise inhalation exposure. Transfer to the blender and then to the extruder will occur either in a closed system or under local exhaust ventilation. Although inhalation exposure of respirable particles may occur, and some dermal exposure is likely, the risk of adverse health effects in masterbatch preparation is likely to be low due to the low toxicity of the notified chemical. Nevertheless, due to the slight eye irritancy of the notified chemical and the general irritation of nuisance dusts, workers handling the chemical should wear safety gloves, goggles and overalls.

There may be long term exposure to low levels of notified chemical by workers involved in cleaning articles containing the flame retardant, but this is likely to be lower exposure than for the equivalent chemicals currently in use, as the “blooming” of the notified chemical is comparatively low. On the basis of the low acute and subchronic toxicity of the notified chemical and the high molecular weight, which will slow transport through the skin and other biological membranes, the risk for these workers is likely to be very low.

Public Health
Public exposure to the notified chemical is expected to be negligible, as it will be encapsulated in the polymer matrix of plastic articles, and will not be expected to be released to the environment except very slowly through leaching in landfill. The greatest public exposure is expected to be caused by contact with articles where “blooming” has occurred. This is likely to be infrequent and of short duration. Because of the low acute and subchronic toxicity of the notified chemical, it is considered that FR-370/FR-372 will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to FR-370/FR-372 the following guidelines and precautions should be observed:

- Local exhaust ventilation is required while handling the notified chemical in powder form;
- The use of "non blooming technology" should be encouraged in the manufacturing process;
- 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);
- 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, 1994);
- 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, 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 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

Batt KJ (1990) [FR-370/FR-372] *Salmonella*/Mammalian Microsome Plate Incorporation Mutagenicity Assay (Ames Test), Project No. I90-1130, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Caley CY & Knight B (1993a) [FR-370/FR-372] (Ref. No. E8200-58) Alga, Growth Inhibition Test (72 h, Limit Test), Project No. I93-1732, Inveresk Research International, Tranent, Scotland, UK.

Caley CY & Knight B (1993b) [FR-370/FR-372] (Ref. No. E8200-58) Determination of Acute Toxicity to Rainbow Trout (96 h, Static Limit Test), Project No. I93-1730, Inveresk Research International, Tranent, Scotland, UK.

Cifone MA (1995) Mutagenicity Test on [FR-370/FR-372], E8200-58 in the TK+/- Mouse Lymphoma Forward Mutation Assay With a Confirmatory Assay, Project No. I94-1923, Hazleton Washington Inc, Vienna Va, USA.

Cunningham FJ (1995) [FR-370/FR-372]: Chronic Life-Cycle Toxicity to the Water Flea, *Daphnia Magna*, Under Static Renewal Conditions, Project No. I95-2013, Toxikon Environmental Sciences, Jupiter, Fla, USA.

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

Freeman C (1990a) [FR-370/FR-372] Acute Dermal Toxicity in Rats, Project No. I90-1124, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Freeman C (1990b) [FR-370/FR-372] Acute Oral Toxicity in Rats, Project No. I90-1123, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Freeman C (1990c) [FR-370/FR-372] Primary Eye Irritation Study in Rabbits, Project No. I90-1125, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Freeman C (1990d) [FR-370/FR-372] Primary Skin Irritation Study in Rabbits, Project No. I90-1126, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Freeman C (1990e) [FR-370/FR-372] Skin Sensitization Study in Guinea Pigs, Project No. I90-1127, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Freeman C (1993) [FR-370/FR-372] Twenty-Eight Day Feeding Study in Rats, Project No. I92-1707, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Freeman C (1996) [FR-370/FR-372] Ninety Day Feeding Study in Rats, Project No. I95-2016, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Freeman C (1997) [FR-370/FR-372] Acute Delayed Neurotoxicity Study in Hens, Project No. I96-2077, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

Lyman, W. J., Reehl, W. F. and Rosenblatt, D. H. (1981) Handbook of Chemical Property Estimation Methods, McGraw-Hill

Mensink, B. J. W. G. et al (1995) Manual for Summarising and Evaluating the Environmental Aspects of Pesticides"; National Institute of Public Health and Environmental Protection, Bilthoven, Netherlands

Mount E (1993) [FR-370/FR-372] Acute Inhalation Toxicity Study in Rats, Project No. I92-1704, FMC Corporation Toxicology Laboratory, Princeton NJ, USA.

National Occupational Health and Safety Commission (1994a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

Organisation for Economic Cooperation and Development (1994) Selected Brominated Flame Retardants, Paris.

Putnam DL & Schadly EH (1993) [FR-370/FR-372], E8200-58 *In Vitro* Mammalian Cytogenetic Test, Project No. I92-1714, Microbiological Associates, Inc, Rockville Md, USA.

Scott DG & Alexander B (1993) [FR-370/FR-372] Determination of Ready Biodegradability of [FR-370/FR-372] by the Modified Sturm Test, Project No. I93-1733, Inveresk Research International, Tranent, Scotland, UK.

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, Sydney.

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

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, Sydney/Wellington.

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

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

Weber RW & Hagenmeir H (1998) Mechanism of the Production of Polychlorinated Dibenzo-p-dioxins and Dibenzofurans from Chlorophenols in the Gas Phase. Chemosphere, 38 (3): 529.

World Health Organisation (1995a) Environmental Health Criteria 192 Flame Retardants - A General Introduction, Geneva.

World Health Organisation (1995b) Environmental Health Criteria 173 Tris(2,3-dibromopropyl)phosphate and Bis(2,3-dibromopropyl)phosphate, Geneva.

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