

File No: LTD/1058

March 2003

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME  
(NICNAS)**

**FULL PUBLIC REPORT**

**Fluorosurfactant FC-4430**

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**Director  
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**FULL PUBLIC REPORT****Fluorosurfactant FC-4430****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

3M Australia Pty Ltd (ACN 000 100 096) of 2-74 Dunheved Circuit St Marys NSW 2760.

## NOTIFICATION CATEGORY

Limited: Polymer with NAMW  $\geq 1000$  (more than 1 tonne per year).

## EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formula, molecular weight, spectral data, and polymer composition, detailed use.

## VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Data items and details claimed variation: Partition Coefficient.

## PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

## NOTIFICATION IN OTHER COUNTRIES

USA, 2001.

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Fluorosurfactant FC-4430

MOLECULAR WEIGHT        >1 000

**3. COMPOSITION**

## DEGREE OF PURITY

>80%

**4. INTRODUCTION AND USE INFORMATION**

## MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will be transported by ship, road and rail in 3.6 and 18.1 kg drums.

## MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Up to 10 tonnes per annum.

## USE

The notified polymer is a non-ionic polymeric fluorochemical surfactant. It can be used in a variety of waterborne, solvent-borne and high-solids organic polymer coatings.

The notifier states that the notified polymer will be used in non-emissive, permanent industrial coatings such as corrosion resistance coatings on electronic components for computers and telecommunications industry, signage, office furniture and pipes in chemical plants. In addition, product containing the

notified polymer can be used as a surface tension reduction agent (surfactant) in carpet products formulated for protection against water, oil and soil staining.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, Transport and Storage

#### PORT OF ENTRY

Not specified.

#### IDENTITY OF MANUFACTURER/RECIPIENTS

3M Australia Pty Ltd of 2-74 Dunheved Circuit St Marys NSW 2760.

#### TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 3.6 and 18.1 kg drums. Transportation will be by road and/or rail as appropriate.

### 5.2. Operation Description

The imported notified polymer will be formulated in Australia into powder or liquid products. Formulation process will take place at approximately 50 paint/coating manufacturing companies in Australia. The concentration of the notified polymer in the final products will be 0.1-0.5%. These products can be applied by dipping, roller coating, brush painting or spraying. Coatings containing the polymer will be dried and cured, leaving the finished product with a solid coating.

In addition, a formulated carpet protector containing 3% notified polymer will be imported. The carpet protector will be sprayed onto carpet surface during carpet manufacturing process.

### 5.3. Occupational exposure

#### *Number and Category of Workers*

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Warehouse/transport personnel	100	Not stated	Not stated
Formulators	500	Not stated	Not stated
End users/applicators	1 400	Not stated	Not stated

#### *Exposure Details*

##### ***Warehouse/transport personnel***

Warehouse and transport workers are unlikely to be exposed to the notified polymer unless the packaging is breached.

##### ***Formulators***

At the formulation sites, workers will transfer the notified polymer into mixing vessels with other ingredients. The final products could be powder or liquid products with organic solvents, fillers, epoxys or urethanes. The main exposure route is expected to be dermal contact, and inhalation when formulating powder products. The MSDS for the notified polymer states that local exhaust ventilation is fitted at transfer points and when the product is heated. When exposure is likely, vented goggles, appropriate gloves (butyl rubber, neoprene, polyethylene/ethylene vinyl alcohol), apron and respirators will be used. The US PMN provided by the notifier indicated that gloves are used for drain/filter, and packing processes.

##### ***End users/applicators***

Techniques involved during coating application include spraying, roller coating, brushing and dipping. The dipping process can be manual application or automatic using a robot.

The notifier indicates that coil coatings are applied by roller coater. Industrial paints and coatings will be applied by a number of methods, however, automotive coatings are likely to be applied by spray.

The formulated paint or coating will be stirred, thinned and loaded into circulation tanks or spray guns.

These workers will be exposed by skin contact and for inhalation to the finished paint or coating that contains a maximum of 0.5% notified polymer.

Filtered exhaust systems are fitted at the operation sites. Applicators will wear coveralls, safety goggles and impervious gloves. In addition, cartridge type respirators will be used during spray application of the paints or coatings.

The product of Protective Materials Carpet protector containing 3% notified polymer has a milled applied application. It is applied by method of exhaustion (cook carpet fibre and chemical) and spray on the surface or form applied. General dilution ventilation and/or local exhaust ventilation are employed to control airborne exposure at transfer points and if the product is heated. When exposure is likely, workers will wear safety glasses with side shields, vented goggles, neoprene or nitrile rubber gloves, protective clothing, and respirators.

#### 5.4. Release

##### RELEASE OF CHEMICAL AT SITE

During coating production (formulation), there is potential for release. The formulation may take place at around 50 sites. It is estimated that spills may account for 60 kg of waste product per year with any spills contained via bunding. The empty import containers are estimated to contain a further 60 kg per annum. Cleaning of process equipment will account for a further 100 kg of waste product annually. Thus it is likely that up to 220 kg per year of waste product containing the notified polymer will be produced through formulation activities.

##### RELEASE OF CHEMICAL FROM USE

The coatings containing the notified polymer will be used in industrial, automotive and coil applications. The following table summaries the means of application and likely losses for each use group as provided by the notifier.

<i>Usage</i>	<i>Means</i>	<i>Amount of coating released/lost annually via each source</i>		
		<i>Overspray</i>	<i>Equipment cleaning/ Residues Spills</i>	<i>Container</i>
Industrial	60% by brush 40% by spraying	2200 kg	150 kg	50 kg
Automotive	100% by spraying	600 kg	20 kg	20 kg
Coil	100% by roller	none	20 kg	20 kg

The notifier has indicated that some application may occur through dipping, but has not quantified the estimated losses using this method. Dipping is normally a very efficient process, and associated losses are expected to be minimal compared with losses from overspray.

Carpet usage is assumed at 900 kgs per year. The ultimate fate of the notified polymer is as follows:

Loss at carpet mill	7% to waste-water	63 kg
	3% to shear/trim to landfill	27 kg
Loss during installation	5% trim to landfill	45 kg
Loss to environment from steamcleaning/ vacuuming/walk-off during the 12 year average life of a carpet* (over 12 years)	67%**	603 kg
Left on carpet at the end of useful lifetime (at end of 12 years)	18% to landfill	163 kg

\* Assuming 3 steam cleanings over a 12 year period, weekly vacuuming and high foot traffic;

\*\* Steam cleaning removes approximately 30% of the polymer per steam cleaning. Depending on the disposal of the steam cleaning water, some would go to a waste-water treatment facility and

become part of the sludge. Anything vacuumed off would go to landfill. Polymer walked off would go to the environment in general.

### 5.5. Disposal

Import drums containing the notified polymer as waste residue are expected to be landfilled.

The majority of solid waste generated in the formulation and application of the coatings will either be incinerated or disposed of to landfill.

Waste produced during the cleaning on the paint application equipments, such as brushes, rollers and possibly spray equipment will also either be incinerated or sent to landfill.

Ultimately the majority of the notified polymer, as part of the cured coating, will be disposed with the article at the end of its useful life. At this time it may end up in landfill or be incinerated resulting in the release of oxides of carbon, nitrogen and fluoride and water vapour.

### 5.6. Public exposure

It is expected that during transport, storage, and industrial and commercial use, exposure of the general public to the notified polymer will be low, except in the event of an accidental spill.

The notified polymer and products will not be sold to the public. However, there may be public exposure via dermal contact with dried protective coatings containing the notified polymer on such items as office furniture.

The carpet protector will not be sold to public. However, public exposure with treated carpet will occur by dermal contact.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa** Viscous amber coloured liquid.

**Boiling Point** 210°C at 101.3 kPa

Remarks Data from the US PMN.

**Density** 1 147 kg/m<sup>3</sup>

Remarks Data from the US PMN.

**Vapour Pressure** <9.3x10<sup>-3</sup> kPa

Remarks Data from the US PMN.

**Water Solubility** 6 211 mg/L at 22-23°C.

METHOD OECD TG 105 Water Solubility.

REMARKS The water solubility was determined using the shake flask method. Nine replicates of the solubility determination were conducted. The notified polymer (~0.1 g) was weighed into centrifuge tubes to which water (10 g) was added. The centrifuge tubes were then shaken at 30°C for 24, 48 and 72 h followed by equilibration for another 24 h. After equilibration, the samples were centrifuged and an aliquot was analysed for total fluorine content.

It is noted that the product information from the notifier states that the product is

miscible in water at all proportions.

TEST FACILITY Ecotoxicity data indicate a water solubility around 4300 mg/L.  
3M Environmental Laboratory, St Paul, Minnesota (2001).

#### Hydrolysis as a Function of pH

Remarks A comprehensive hydrolysis study report was provided following OECD Guidelines. The polymer was suspended into three sets of buffers containing <1% acetone co-solvent at nominal pH levels 4, 7 and 9 at a nominal concentration of 200 mg/L. Samples were analysed for the primary predicted degradation product fluorochemical alcohol. Four additional possible degradation products were monitored, namely, fluorochemical amide, primary fluorochemical amide, perfluorobutane sulfonate (PFBS), and perfluorobutyric acid (PFBA). The hydrolytic stability of fluorochemical alcohol was separately studied as well in buffered aqueous solutions.

Two methods were used to estimate the hydrolytic half-life of the notified polymer. The first calculated the half-life based on the rate of appearance of the fluorochemical alcohol and two times the standard deviation of triplicate measurements. It resulted in an average half-life of 20.2 years, 0.737 years and 0.19 years at pH 4, 7 and 9 respectively.

The second method calculated the minimum pseudo first order hydrolytic half-life of the notified polymer by calculating how fast it might degrade to generate PFBS. This assumes that PFBS is the only hydrolytic product formed and the method resulted in a hydrolytic half-life of 16.2 years independent of pH.

TEST FACILITY The hydrolytic half-life of fluorochemical alcohol was calculated to be a minimum of 1.7-2.3 years.  
3M Environmental Laboratory (2002).

**Partition Coefficient (n-octanol/water)** Not Determined

Remarks Although no data were provided, the notified polymer is likely to be surface active and therefore expected to partition between the octanol and water layers. The OECD guidelines indicate that surface active chemicals cannot be tested via the shake flask method.

**Adsorption/Desorption** Not determined

Remarks The notifier undertook a sewage sludge adsorption test (see section 8.1.3). Based on the result of this test, it appears that the notified polymer is unlikely to adsorb and will be mobile in the soil or sediments.

**Dissociation Constant** Not determined.

Remarks The notified polymer is not expected to dissociate under normal environmental conditions.

**Particle Size** Not determined for a liquid.

**Flash Point** 100°C

Remarks Closed cup method.

It is likely that the results of this test were influenced by traces of solvent in the polymer.



<b>Flammability Limits</b>	Not determined.
<b>Autoignition Temperature</b>	Not determined.
<b>Explosive Properties</b>	None known.
<b>Reactivity</b>	Not expected to be reactive.

#### Thermal Characterisation

Remarks	A thermal characterisation test report was provided. The decomposition profile suggested that the notifier polymer contains approximately 5% highly volatile matter. This highly volatile component appears to influence the calculation of the kinetics parameters at lower conversion. At higher conversion, a 205 kJ/mole activation energy was calculated.
TEST FACILITY	3M Corporate Analytical Technology Center (2001).

#### Indirect and Direct Photolytic Screening Test

TEST SUBSTANCE	Fluorochemical acrylate copolymer/polyolefin glycol
METHOD	US EPA Toxic Substance Control Act OPPTS 835.5270 & 835.2210
Remarks - Method	GLP & QA.
RESULTS	
Remarks - Results	This is a sanitised report and the test substance was identified only as "Fluorochemical acrylate copolymer/polyolefin glycol".
CONCLUSION	No photolytic degradation by either direct or indirect mechanisms was observed nor detected.
TEST FACILITY	Pace Analytical Services Inc (2001).

## 7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint</i>	<i>Assessment Conclusion</i>
Rat, acute oral	LD50 >2 000 mg/kg bw, low toxicity
Rat, acute dermal	LD50 >2 000 mg/kg bw, low toxicity
Rat, acute inhalation	No data submitted
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation
Rat, oral-gavage repeat dose toxicity - 28 days.	NOAEL = 1 000 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration	non genotoxic
Genotoxicity – in vivo	No data submitted

### 7.1. Acute toxicity – oral

TEST SUBSTANCE	T-7329
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class

Species/Strain                      Method.  
Vehicle                                Rat/Wistar  
Remarks - Method                1% aqueous carboxymethyl cellulose.  
GLP & QA

## RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3/sex	2 000	0

LD50                                      > 2 000 mg/kg bw  
Signs of Toxicity                      On day 1, 5 animals had lethargy, and one female had uncoordinated movements and piloerection.  
Effects in Organs                      None.  
Remarks - Results                    None.

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

TEST FACILITY                        NOTOX (2001a).

**7.2. Acute toxicity - dermal**

TEST SUBSTANCE                      T-7329

METHOD                              OECD TG 402 Acute Dermal Toxicity – Limit Test.  
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.  
Species/Strain                        Rat/Wistar.  
Vehicle                                None.  
Type of dressing                      Occlusive.  
Remarks - Method                    GLP & QA.

## RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5/sex	2 000	0

LD50                                      > 2 000 mg/kg bw  
Signs of Toxicity - Local              All male animals had yellow staining on their treated skin areas. One male had slight erythema during day 2-4.  
  
Signs of Toxicity - Systemic            Four female animals had slight erythema during day 2-6. Two females had scales during day 5-7.  
One male had lethargy and ptosis on day 1.  
Chromodacryorrhoea was observed in 4 animals during day 2-4.  
Effects in Organs                      None.  
Remarks - Results                    All animals had recovered from the symptoms between day 5 and 8.

CONCLUSION                            The notified polymer is of low toxicity via the dermal route.

TEST FACILITY                        NOTOX (2001b).

**7.3. Acute toxicity - inhalation**

No study report was provided for assessment.

**7.4. Irritation – skin**

TEST SUBSTANCE T-7329

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.  
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).  
Species/Strain Rabbit/New Zealand White  
Number of Animals 3  
Vehicle None.  
Observation Period 72 hours  
Type of Dressing Semi-occlusive.  
Remarks - Method GLP & QA.

#### RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0.3	0.3	0.3	2	24 hours	0
<i>Oedema</i>	0	0	0	0		0

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results Primary irritation index (PII) = 0.58

CONCLUSION The notified polymer is slightly irritating to skin.

TEST FACILITY NOTOX (2001c).

### 7.5. Irritation - eye

TEST SUBSTANCE T-7329

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.  
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).  
Species/Strain Rabbit/New Zealand White  
Number of Animals 3  
Observation Period 72 hours  
Remarks - Method GLP & QA.

#### RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0.3	0.3	0.3	2	24 hours	0
<i>Conjunctiva: chemosis</i>	0	0	0	1	1 hour	0
<i>Conjunctiva: discharge</i>	0	0	0	2	1 hour	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results Fluorescein test showed no corneal epithelial damage in animals.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY NOTOX (2001d).

### 7.6. Skin sensitisation

TEST SUBSTANCE	T-7329
METHOD	OECD TG 406 Skin Sensitisation – maximisation test. EC Directive 96/54/EC B.6 Skin Sensitization - maximisation test.
Species/Strain	Guinea pig/Dunkin Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: <0.05% topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
induction phase	Induction Concentration: intradermal injection 0.1% topical application 100%
Signs of Irritation	Well-defined to moderate erythema was observed after intradermal and topical inductions in test animals.
CHALLENGE PHASE	
1 <sup>st</sup> challenge	topical application: 100%
	topical application: vehicle
Remarks - Method	GLP & QA.
	1% aqueous carboxymethyl cellulose was used as the vehicle.

## RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after:</i>			
		<i>1<sup>st</sup> challenge</i>		<i>2<sup>nd</sup> challenge</i>	
		<i>24 h</i>	<i>48 h</i>	<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	100%	0/10	0/10		
	vehicle	0/10	0/10		
<i>Control Group</i>	100%	0/5	0/5		
	vehicle	0/5	0/5		

Remarks - Results	Light yellow staining was observed on the treated skin areas 24 and 48 hours after challenge. This staining did not hamper the scoring of the skin reactions.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	NOTOX (2001e).

**7.7. Repeat dose toxicity-28 day oral**

TEST SUBSTANCE	T-7329
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days.
Vehicle	1% aqueous carboxymethyl cellulose.
Remarks - Method	GLP & QA.
	The dose levels were selected from a 5-day range finding study, where no significant effects were noted at 150 and 1 000 mg/kg/day.

## RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
I (control)	5/sex	0	0
II (low dose)	5/sex	50	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	1 000	0
V (control recovery)	5/sex	0	1
VI (high dose recovery)	5/sex	1 000	0

*Mortality and Time to Death*

One female in the control recovery group died after blood sampling, which was considered to be an accident related to the blood sampling procedure.

*Clinical Observations*

When compared to the control animals, the test animals had no clinical signs of toxicity or behavioural changes, or treatment-related changes in hearing ability, pupillary reflex, static righting reflex and grip strength, ophthalmoscopic examination, bodyweights or food consumption.

Increases in high and/or low sensor reading were observed in 2 animals of group I, 2 females of group III, 1 female of group IV, 1 female of group V and 1 female of group VI. These changes were considered to have occurred by chance without any toxicological relevance.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*

At the end of recovery, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin and mean corpuscular haemoglobin concentration values were decreased among males of group VI. The mean corpuscular volume values were below the historical data in the laboratory.

Bilirubin, sodium and calcium values in blood were decreased in group IV males at the end of treatment. Calcium levels remained low after recovery. Apart from bilirubin, all other values remained within the range of historical control data in the laboratory.

*Effects in Organs*

Kidney/bodyweight ratios in groups III and IV males were increased at the end of treatment.

*Pathology*

There were no macroscopic or microscopic findings recorded which could be attributed to the treatment of the test material.

*Remarks – Results*

The low bilirubin values at the end of treatment in group IV males were not considered toxicologically significant as an opposite effect would be expected in case of target organ toxicity.

Other changes in this study are not considered to be of toxicological importance because either the individual values remained within the range of historical control data in the laboratory, or no supportive evidence was observed microscopically.

## CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1 000 mg/kg bw/day in this study (the highest dose tested).

TEST FACILITY NOTOX (2001f).

**7.8. Genotoxicity - bacteria**

TEST SUBSTANCE T-7329

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2 uvrA.
Metabolic Activation System	S9-mix
Concentration Range in Main Test	a) With metabolic activation: 0-5 000 µg/plate. b) Without metabolic activation: 0-5 000 µg/plate.
Vehicle	DMSO
Remarks - Method	GLP & QA.

## RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	None.	None.	None.	None.
Test 2		None.	None.	None.
<i>Present</i>				
Test 1	None.	None.	None.	None.
Test 2		None.	None.	None.

Remarks - Results      Precipitation in the top agar was observed at 1 mg/plate and upwards. However, precipitation on the plates was not observed.

The values of positive and negative controls were within historical control data ranges.

CONCLUSION      The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY      NOTOX (2001g).

**7.9. Genotoxicity – in vitro**

TEST SUBSTANCE	T-7329
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Human peripheral lymphocytes.
Metabolic Activation System	S9-mix.
Vehicle	DMSO
Remarks - Method	GLP & QA.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	0, 33, 100, 333	3	24
Test 2A	0, 3, 10*, 18, 24*, 33*, 42, 56	24/48	24/48
Test 2B	10*, 24, 33*, 56, 75*, 90, 100	24	24
<i>Present</i>			
Test 1	0, 3, 10, 33, 100, 333	3	24
Test 2A	0, 3, 10, 33*, 100*, 333*	3	48

\*Cultures selected for metaphase analysis.

## RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>			≥333 µg/mL	
Test 1		-	333 µg/mL	None.
Test 2A		-		None.
Test 2B		-		None.
<i>Present</i>				
Test 1		-	333 µg/mL	None.
Test 2A		-	333 µg/mL	None.

## Remarks - Results

The average generation time (AGT) of the human peripheral lymphocytes ranged 15.4-16.4 hours.

Cytotoxicity was observed at 100 µg/mL and higher with 24/48 hour treatment and 24/48 hour fixation in the preliminary test. No inhibition of the mitotic index of 50% was reached in cultures treated for 24 hours with T-7329 in the absence of S9-mix.

Both in the absence and presence of S9-mix, T-7329 did not induce a statistically or biologically significant increase in the number of cells with chromosome aberrations.

The values of positive and negative controls were within historical control data ranges.

## CONCLUSION

The notified polymer was not clastogenic to human peripheral lymphocytes treated in vitro under the conditions of the test.

## TEST FACILITY

NOTOX (2001h).

**7.10. Genotoxicity – in vivo**

No study report was provided for assessment.

**8. ENVIRONMENT****8.1. Environmental fate****8.1.1. Ready biodegradability**

## Remarks – Results

A ready biodegradation test is being performed on the polymer, but the results are not yet available. In general, few studies have been conducted to investigate the biodegradability of perfluorinated or partially fluorinated surfactants. Biodegradation of partially fluorinated surfactants appears to be limited to the nonfluorinated portion of the molecule (Moody and Field, 2000).

**8.1.2. Bioaccumulation**

## RESULTS

Not determined. The size of the molecule indicates it is unlikely to cross biological membranes. However, if the molecule is susceptible to biodegradation, the fluorinated moiety could be isolated and the behaviour of these compounds is not well understood.

In this regard, the company has provided a bioconcentration study of the fluorinated moiety, perfluorobutane sulfonate, potassium salt (PFBS).

The study was conducted following US EPA guidelines using bluegill sunfish (*Lepomis macrochirus*) as the test organism. The test consisted of a 28 day uptake phase followed by a 16 day depuration phase. Two concentrations (0.5 mg/L and 5 mg/L) and a control group were tested.

Concentrations in the negative control were <LOQ (0.125 mg/L), while in the 0.53 mg/L and 0.5 mg/L, concentrations averaged between 106% and 104% of nominal concentrations respectively.

Observations of mortality and clinical signs were undertaken throughout the study. Fish in the negative control appeared normal and healthy throughout while one fish died in the 5 mg/L treatment group on day 23 of the uptake phase of the test. All other fish in the test appeared normal with no treatment-related signs of toxicity.

Concentrations of PFBS in tissues of fish in the 0.53 mg/L test group in edible and nonedible tissues appeared to reach steady state at day 7. The mean measured tissue concentrations during this period of time were 0.113, 0.272 and 0.203 mg/Kg for edible, nonedible and whole fish respectively. During the depuration phase of the test, PFBS was eliminated rapidly with estimates of time to reach 50% clearance of 2.1, 2.9 and 1.3 days for edible, nonedible and whole fish respectively.

Concentrations of PFBS in tissues of fish in the 5 mg/L test group in edible and nonedible tissues appeared to reach steady state at day 3. The mean measured tissue concentrations during this period of time were 0.829, 2.24 and 1.57 mg/Kg for edible, nonedible and whole fish respectively. Steady state bioconcentration factor (BCF) values ranged from 0.16 in edible tissue to 0.43 in nonedible tissue. During the depuration phase of the test, PFBS was eliminated rapidly with estimates of time to reach 50% clearance of 1.9, 2.1 and 2.1 days for edible, nonedible and whole fish respectively.

Based on this low BCF, PFBS is not expected to bioaccumulate in the food chain.

#### TEST FACILITY

Wildlife International Ltd (2001a).

### 8.1.3. Activated Sludge Sorption

#### TEST SUBSTANCE

FC-4430

#### METHOD

US EPA. Fate, transport and transformation test guidelines. OPPTS 835.1110

#### Remarks - Method

The inoculum used was activated sludge.

An oxygen bomb with ion selective electrode method was used to determine the total fluorine in the water and sludge along with a mass balance. The Freundlich sorption isotherm was then calculated.

A preliminary adsorption study (Tier 1) over 48 hours with 6 different sludge/CaCl<sub>2</sub> solution ratios ranging from 1/5 to 1/1000 indicated that the 1/20 ratio (5 g of sludge in 100 mL of 0.01 M CaCl<sub>2</sub> solution) with a concentration of 1000 mg/L should be further investigated (Tier 2) for 24 hours. This was done in triplicate with triplicate controls with no sludge and a single control blank. The study was run for 48 hours with 5 mL aliquots being taken for sampling at 4, 8, 24 and 48 hours. Throughout the study the test sludge solutions were continuously mixed. Each aliquot was centrifuged to separate the aqueous and sludge phases, then analysed for fluorine content and mass balance calculated.



In a tier 3 study, the sorption isotherm was determined using 5 test concentrations (50, 100, 250, 500 and 1000 mg/L) and a sludge/solution ratio of 1/20. The test was done as previously with the fluorine content being determined in the sludge. The sorbed mass per unit mass of sludge was then plotted and the Freundlich sorption isotherm calculated.

## RESULTS

Tier 2 – Sorption constants (K) values were 16.3 and 17.2.  
Mass balance 88.4% average  
Tier 3 –  $K_f$  values was 51.4 with 1/n of 1.208.  
Mass balance 99.8% average

## Remarks - Results

## CONCLUSION

The results indicate that the polymer is very highly mobile and will not adsorb to sewage sludge.

## TEST FACILITY

Centre Analytical Laboratories Ltd (2001).

## 8.2. Environmental Effects

## 8.2.1. Acute toxicity to fish

## TEST SUBSTANCE

FC-4430

## METHOD

OECD TG 203 Fish, Acute Toxicity Test.  
US EPA Series 850 – Ecological Effects Test Guidelines. OPPTS Number 850.1075 (1).  
ASTM Standard E-729-88a. Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.  
Fathead minnow (*Pimephales promelas*)  
Exposure Period 96 hours  
Auxiliary Solvent None  
Water Hardness 131 mg CaCO<sub>3</sub>/L (range 128 – 132)  
Analytical Monitoring None  
Remarks – Method The study was conducted in duplicate with 10 fish for each test vessel (ie 20 fish per concentration).

The test solutions were mixed for one minute after which it was observed that the solutions had a white cloudy colour with foam on the surface. The degree of colour and foam increased with concentration. By the end of the study the appearance of the test solution had not changed.

## RESULTS

Concentration mg/L Nominal	Number of Fish	Mortality				
		2h	24h	48h	72h	96h
0	20	0	0	0	0	0
125	20	0	0	0	0	0
250	20	0	0	0	0	0
500	20	0	1	1	1	1
1000	20	0	14	17	17	17
2000	20	0	20	20	20	20

## LC50

765 mg/L at 96 hours (95% C.I. = 650 – 888).

## NOEC (or LOEC)

250 mg/L at 96 hours.

## Remarks – Results

On day 3 the dissolved oxygen had dropped to 40% saturation (3.6 mg/L), therefore the vessels all received mild aeration.

Sub lethal effects were noticed in the 500 ppm solution with one fish lying at the bottom of the tank. In the 1000 ppm solution, of those fish that were not dead, 2 were lethargic with one appearing normal.

CONCLUSION This LC<sub>50</sub> indicates that the notified polymer is practically non-toxic to fish.

TEST FACILITY Wildlife International Ltd (2001b)

### 8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE FC-4430

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test.  
US EPA Series 850 – Ecological Effects Test Guidelines. OPPTS Number 850.1075.

ASTM Standard E-729-88a. Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent None

Water Hardness 131 mg CaCO<sub>3</sub>/L (range 128 –132)

Analytical Monitoring None

Remarks - Method The study was conducted in duplicate with 10 daphnids for each test vessel (ie 20 daphnids per concentration).

The test solutions were mixed for one minute after which it was observed that the solutions were clear and colourless. By the end of the study the appearance of the test solution had not changed. This is in contrast to the fish experiment described above.

### RESULTS

Concentration mg/L Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
0	20	0	0
47	20	0	0
94	20	0	8
188	20	0	13
375	20	0	20
750	20	9	20
1500	20	14	20

LC50 99 mg/L at 48 hours (*C.I.* = 82 –120 mg/L)

NOEC (or LOEC) 47 mg/L at 48 hours

Remarks - Results

CONCLUSION The results suggest the notified polymer is classed as harmful to aquatic invertebrates.

TEST FACILITY Wildlife International Ltd (2001c)

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE FC-4430

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	US EPA Series 850 – Ecological Effects Test Guidelines. OPPTS Number 850.1075.
Exposure Period	ASTM Standard E-729-88a. Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.
Concentration Range	<i>Selenastrum capricornutum</i>
Nominal	96 hours
Concentration Range	0, 31, 63, 125, 250, 500 and 1000 mg/L
Actual	Not determined
Auxiliary Solvent	None
Water Hardness	131 mg CaCO <sub>3</sub> /L (range 128 –132)
Analytical Monitoring	None
Remarks - Method	Three replicate vessels were used for each concentration with the nominal algal concentration being 1.0 x 10 <sup>4</sup> cells/mL.

## RESULTS

<i>Growth</i>	
<i>EC</i> <sub>50</sub> mg/L at 96 h	<i>NOEC</i> mg/L
763 (95% C.I. = 179 - 1168)	250

Remarks - Results	At the end of the study a visual inspection indicated that algal growth had occurred in all concentrations. This effect was algistatic and not algicidal.
CONCLUSION	This EC <sub>50</sub> indicates that the notified polymer is practically non-toxic to algae.
TEST FACILITY	Wildlife International Ltd (2001d)

**8.2.4. Inhibition of microbial activity**

TEST SUBSTANCE	FC-4430
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 <a href="#">Biodegradation: Activated Sludge Respiration Inhibition Test</a>
Inoculum	Activated sludge (from a treatment plant that takes predominantly domestic effluent).
Exposure Period	3 hours
Concentration Range	0, 1, 3, 10, 30, 100, 300 and 1000 mg of active/L
Nominal	
Remarks – Method	3,5-dichlorophenol was used as the reference material. Nonlinear interpolation statistical analysis was used to calculate the EC <sub>50</sub> values for the reference and test materials.
RESULTS	
EC <sub>50</sub>	786.2 mg/L
NOEC	100 mg/L
Remarks – Results	The reference material had an EC <sub>50</sub> of 28.6 mg/L which lies between 5 and 30 mg/L, thus indicating that the test was valid.
CONCLUSION	The EC <sub>50</sub> indicates that the notified polymer is unlikely to affect the respiration rate of activated sludge.
TEST FACILITY	Wildlife International Ltd (2001e)

## 9. RISK ASSESSMENT

### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

When applied as a coating, the notified polymer should become locked into the coating matrix as it cures and thereby become immobile. The finished product is used as a surfactant or wetting agent to improve or minimise coating defects, it does not participate in the cure.

Assuming 5000 kg of notified polymer is imported each year, and based on some assumptions from company release figures, the following environmental releases may be predicted:

Formulation: assume releases of 0.1% based on industry experience = 5 kg (landfill).

Industrial paints application: Assume around 70% of import volume goes to this end use. Of this, 60% will be by brush application so no overspray will occur. The remaining 40% will be applied through spraying where up to 60% may be lost as overspray. This results in 820 kg per annum released through this manner.

Carpet application: No release estimation has been provided. Application will involve spraying and as a worst case, it will be assumed that 18% of the import volume is used for this purpose. Of this, 60% will be released to the environment over the lifetime of the carpet. This accounts for 540 kg per annum.

Automotive coatings application: Assume around 8% of import volume goes to this end use. Application by spraying will result in approximately 60% loss from overspray which leads to a further 240 kg being released in this manner.

Coil coatings: Assume 5% used in this manner. Application is efficiently performed by roller coating and losses are expected to be minimal and limited to equipment cleaning and spills along with residues in empty containers.

In summary, the bulk of the release where the polymer is not actually associated with the end article amounts to around 1600 kg per annum, or 32% of the import volume. The majority of this is expected to be disposed of to landfill or possibly incinerated. Given the solubility of the notified polymer, there is the chance of discharge to sewer depending on waste collection mechanisms in various industrial facilities. This can be roughly quantified in terms of the fluorinated moiety. Assuming this moiety accounts for around 9% of the weight of the polymer, and an import volume of 5 tonnes, the fluorinated moiety will account for around 450 kg per annum of which 215 kg will be fluorine.

If incinerated, the polymer would be rapidly destroyed and converted to water vapour and oxides of carbon, nitrogen and hydrogen fluoride. On disposal to landfill, the hydrocarbon portion of the polymer is likely to be slowly degraded by biotic and abiotic processes. Any polymer entering receiving waters at a sewage treatment plant is initially unlikely to become associated with either the aqueous or the sludge and sediment compartment given the surface active nature of the chemical. In time, the hydrocarbon moiety may become assimilated with the organic phase, while the fluorinated moiety will rise to the water surface and be subjected to cleavage as a result of exposure to UV radiation. As the polymer has a high molecular weight, it is not expected to cross or react with biological membranes, bioaccumulate or be of toxicological concern in the aquatic environment.

The fluorocarbon moiety is unlikely to be susceptible to biodegradation (Remde and Debus, 1996). This is understandable, in view of the electronegativity of fluorine and the great strength of the carbon-fluorine bond. Perfluorocarbons are more thermally stable than their corresponding hydrocarbon analogues. In particular, perfluorocarboxylic acids and perfluoroalkane sulfonic acids are considered the most thermally stable fluorinated surfactants. In addition to thermal stability, perfluorinated hydrocarbons are stable against degradation by acids, bases, oxidants and reductants (Moody and Field, 2000). Fluorinated carboxylic acids can undergo hydrolytic

defluorination, reductive defluorination, and decarboxylation. To date, however, significant defluorination has only been observed for hydrolytic attack of monofluorinated carboxylic acids, and compounds of more than one fluorine atom per carbon atom are generally recalcitrant (Blake *et al.*, 1997). The notified polymer has a nominal fluorine content of ~9%. Studies have shown that fluorinated compounds with a fluoride content in the order of 50% will not biodegrade over a period of 60 days (Remde and Debus, 1996). Further, fluorocarbons have little affinity for either water or organic phases and ultimately will concentrate near the surface of water bodies, for example when released in sewage treatment plant effluent. Here they are likely to be degraded by abiotic cleavage, with assistance from UV radiation, into smaller fluorocarbon species which will be volatile and partition into the atmosphere. Here further reaction with hydroxyl radicals and action by UV radiation is expected to lead to degradation to hydrogen fluoride and precipitation to the surface in rain.

In the case of the fluorinated building block of the notified polymer, PFBS, the US EPA's PBT profiler predicts the chemical will be found predominantly in soil, but could also be found in water. It is not expected to be found in sediment. The overall persistence in the environment has been calculated by the PBT profiler as 290 days. This allows the persistence of a chemical to be described using a single value and takes into account both the media specific half life and the rate of transport between compartments. However, this parameter can not be measured and should be considered indicative only. The chemical is not expected to bioaccumulate which supports test data (US EPA, 2003).

#### **9.1.2. Environment – effects assessment**

Acute tests of the notified polymer were supplied for a fish species, an invertebrate species and an algal species. The polymer showed very slight toxicity to fish and algae.

However, toxicity was greater to invertebrates with an EC50 determined to be 99 mg/L. The notified polymer may be considered harmful to these species.

A predicted no effect concentration may be determined based on the daphnia result and applying an assessment factor of 100 (justified because acute tests are available on three trophic levels). The resultant PNEC is 0.99 mg/L.

#### **9.1.3. Environment – risk characterisation**

A PEC/PNEC for the aquatic compartment is calculated to be 0.001 indicating an acceptable risk to this compartment with no further testing or exposure refinements being required.

However, there are significant uncertainties surrounding the behaviour of fluorocarbon compounds in general in the environment in areas of partitioning behaviour, degradation, chronic toxicity and bioaccumulation. While these uncertainties make overall risk characterisation difficult to quantify at this time, there is evidence that the fluorinated moiety of the notified polymer will not bioaccumulate. Tests show it to not be greatly concentrating, and rapidly depurate from fish. It is assumed these results can be extrapolated to mammals.

The US EPA has sought additional testing for the ultimate fate product from the notified polymer and placed a Consent Order on the notified polymer and there are consent orders on all subsequent substances involving this chemistry.

### **9.2. Human health**

#### **9.2.1. Occupational health and safety – exposure assessment**

Dermal and ocular exposure may occur during formulation and application processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls in place during formulation and the low concentration of notified polymer in products during application (less than 0.5% in paints and coatings, and 3% in the carpet protection product).

After application and once dried, the paint containing the notified polymer is cured into an inert matrix and is hence unavailable to exposure.

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

#### **9.2.2. Public health – exposure assessment**

Products containing the notified polymer will not be sold to the public. There will be no public exposure arising from industrial and commercial use of the notified polymer in protective coatings. However, there could be dermal contact with dried protective coatings on such items as office furniture. The notified polymer is of low toxicity and is present at <0.5% in paints and coatings, and <3% in carpet protective coatings. Consequently the hazard from public exposure to the notified polymer throughout all phases of its life-cycle is considered to be low.

#### **9.2.3. Human health - effects assessment**

The notified polymer was of low acute oral and dermal toxicity in rats. It was not a skin sensitiser in guinea pigs, but a slight skin and eye irritant in rabbits.

The 28-day repeat dose oral study in rats did not show any treatment related changes in clinical observations, laboratory findings or effects in organs. The NOAEL was established as 1000 mg/kg/day (the highest dose tested) in this study.

The notified polymer was not mutagenic in bacteria strains tested, or clastogenic to human peripheral lymphocytes in vitro.

#### **9.2.4. Occupational health and safety – risk characterisation**

The formulation workers will handle the neat notified polymer, and the painting and coating workers will handle the products containing low concentrations of the notified polymer. The occupational exposure is expected to be low due to the low concentrations of the notified polymer in products, the engineering controls in place and the use of personal protective equipment during formulation and applications. Considering the low occupational exposure and low toxicity profile of the polymer, the OHS risk presented by the notified polymer is considered to be low.

As the notified polymer is a slight eye and skin irritant, dermal and ocular contamination should be prevented to minimise the health risk of irritation. In addition, inhalation exposure should be avoided when handling any powder products and using spray application technique.

#### **9.2.5. Public health – risk characterisation**

The notified polymer will not be available to the public. Members of the public may make dermal contact with coatings containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is present at low concentrations, bound within a matrix and unlikely to be bioavailable.

### **10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS**

#### **10.1. Hazard classification**

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a).

Based on the available data, the notified polymer is classified as “Harmful to aquatic life” under the globally harmonised system of classification and labelling of chemicals (GHS).

#### **10.2. Environmental risk assessment**

The PEC/PNEC ratio indicates the chemical is not considered to pose a risk to the environment

based on its reported use pattern.

### 10.3. Human health risk assessment

#### 10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

#### 10.3.2. Public health

There is No Significant Concern to public health under the conditions described.

## 11. MATERIAL SAFETY DATA SHEET

### 11.1. Material Safety Data Sheet

The MSDS of the notified polymer and products containing the polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

### 11.2. Label

The label for the notified polymer and products containing the polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

## 12. RECOMMENDATIONS

### CONTROL MEASURES

#### Occupational Health and Safety

- Employers should implement the engineering controls and safe work practices in the NOHSC National Guidance Material for Spray Painting to minimise occupational exposure during the spray application of products containing the notified polymer.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Protective clothing
  - Gloves
  - Safety goggles/glasses
  - Respirators (during spray painting).

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

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

#### Environment

- The following control measures should be implemented by end users to minimise environmental exposure of the notified polymer:
  - Where possible, waste (including overspray) should be collected for disposal by

incineration or to landfill.

#### Disposal

- Material should not be discharged to the open environment. Where possible, it is recommended that disposal be through incineration rather than discharge to sewage treatment plants. This material is unlikely to degrade significantly and could pass through the STP. Alternatively, disposal of solid waste to landfill is acceptable.

#### Emergency procedures

- In the event of spillage, cover with absorbent material. Place in a metal container and seal the container. Incinerate in an industrial or commercial facility in the presence of a combustible material. Combustion products will contain hydrogen fluoride. The incinerator should be equipped with suitable controls for combustion of halogenated materials.

### 12.1. Secondary notification

The US EPA has sought additional testing for the ultimate fate product from the notified polymer and placed a Consent Order on the notified polymer. There are US EPA restrictions on the use or manufacture of the substance and there are Consent Orders from the US EPA on all subsequent substances involving this chemistry. These orders link back to completion of the original testing for the ultimate fate product, so when 3M complete the testing, all consent orders should be cleared.

The Director of Chemicals Notification and Assessment must be notified in writing with 28 days by the notifier once testing is complete, and the associated reports forwarded to the Director.

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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