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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Amphoteric Fluoroalkylamide Derivative (5965P)

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Amphoteric Fluoroalkylamide Derivative (5965P)

1. APPLICANT

3M Australia Pty Ltd, of 2-74 Dunheved Circuit ST MARYS NSW 2760 have submitted a standard notification statement in support of their application for an assessment of Amphoteric Fluoroalkylamide Derivative (5965P).

2. IDENTITY OF THE CHEMICAL

Amphoteric Fluoroalkylamide Derivative (5965P) is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae have been exempted from publication in the Full Public Report and the Summary Report

The notified chemical contains no hazardous impurities at levels necessary to classify it as a hazardous substance (1). Therefore, information on the purity of the chemical has been exempted from publication in the Full Public Report and the Summary Report.

Other name:	Amphoteric Fluoroalkylamide Derivative (5965P)
Trade name:	the notified chemical is not marketed as a sole product but as a component in the formulations Acrylic Foamer/Light Water and FC-1100 Fluorad™ Mist Control Agent.

Method of detection and determination:

ultraviolet/visible spectroscopy, nuclear magnetic resonance (NMR) spectroscopy, infrared spectroscopy.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	solid
Odour:	none
Melting Point:	92-131°C

Glass-transition Temperature:	not determined
Density:	D_4^{20}=1.64
Vapour Pressure:	0.0056 mmHg at 25°C
Water Solubility:	450 mg/L at 20°C
Fat Solubility:	< 210 mg/L at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	-0.6 to 0.3 at room temperature
Hydrolysis as a function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant pK_a:	not determined
Flash Point:	not determined
Flammability Limits:	not determined
Combustion Products:	not determined
Pyrolysis Products:	not determined
Decomposition Temperature:	not determined
Decomposition Products:	not determined
Autoignition Temperature:	not auto-flammable
Explosive Properties:	not explosive under influence of flame.
Reactivity/Stability:	not determined
Particle size distribution:	range- > 450 µm - 16% w/w 250-425 µm - 15% w/w 53-250 µm - 39% w/w < 53 µm - 30% w/w

Comments on Physico-chemical data

The water solubility of Amphoteric Fluoroalkylamide Derivative (5965P) could not be determined using the standard methods (column elution or flask) because it formed emulsions in double-distilled water. Therefore, the turbidity of different concentrations of Amphoteric Fluoroalkylamide Derivative (5965P) was measured and then back-extrapolated to give the estimated concentration at which no emulsion occurred.

It is expected no functionalities will hydrolyse under environmental conditions, although some functionalities are expected to confer typical acidity/basicity. Because of its high water solubility and low partition co-efficient, the chemical is not expected to adsorb to any great extent, except by nature of its surface activity.

The partition co-efficient could not be determined by standard guidelines because of the material's surface active nature and complex composition. Therefore, the notifiers determined the co-efficient from its estimated water solubility (see above) and visually estimated n-octanol solubility. Similarly, the material's complex composition prevented development of suitable analytical method to use in determining the fat solubility of Amphoteric Fluoroalkylamide Derivative (5965P). Therefore, the fat solubility was estimated visually. These visual estimation techniques are acceptable for this type of chemical.

4. PURITY OF THE CHEMICAL

Degree of purity: > 95%

5. INDUSTRIAL USE

The chemical will be used in the manufacture of aqueous film forming foam (AFFF) and alcohol type concentrates (ATC) for tests of its effectiveness against fires involving hydrocarbon fuels (Class B fires) (aviation fuel).

The notified chemical will also be used as a surfactant, incorporated at a concentration of 45-55%, in an imported mist control agent (Fluorad™ Mist Control Agent FC-1100). The quantity of the notified chemical to be imported over 5 years will be greater than one tonne.

6. OCCUPATIONAL EXPOSURE

The chemical will be incorporated into the AFFF and ATC by 3M Australia Pty Ltd, and about 20 people may come into contact with the notified chemical. These people would be warehouse personnel, fork-lift drivers, churn operators, foremen, quality assurance personnel, process engineers and managers.

The notified chemical will be incorporated into the fire fighting products at concentrations of 0.5-5% by a churn operator involving pumping the notified chemical into an automated

system for formulation and packaging. A single delivery driver will deliver sealed 20 litre pails of the notified chemical formulated into AFFF and ATC to the fire fighting agencies. Six fire fighters will handle the AFFF and ATC and dilute into an extinguisher such that the concentration of the notified chemical will be less than 0.3%. This mixture will then be applied to Class B fires with a source of AVGAS or AVTUR, after which, the liquid will be pumped from the fire pans to waste drums.

During its application as a mist control agent, the only workers who will be exposed to the notified chemical will be those who are involved in adding the notified chemical at 45-55% in the formulated Fluorad FC-1100. As the number of customers for this product has not yet been determined the number of worker exposed has not been deduced.
Workers will manually dilute the anti-misting agent from 200 litre drums with water before adding it to the incoming electrolyte going into the electrowinning tanks. The notified chemical will be at a concentration of 25-50 ppm within the dilute surfactant when added. This will produce a stable foam blanket to reduce tank house acid mist levels.

7. PUBLIC EXPOSURE

Minor public exposure may result from accidental spillage of the notified chemical during transport, storage, and during reformulation, but any such events are expected to be rare.

The notifier has stated that the fire fighting products, which incorporate the notified chemical, will only be tested for effectiveness, and not used as general fire fighting agents. The efficacy testing will be carried out by fire fighting agencies. During testing, the general public will not be exposed to the products which contain the notified chemical.

The notified chemical will also be used as a surfactant, incorporated at a concentration of 45-55%, in an imported mist control agent FC-1100. The product will only be used in manufacturing processes, and therefore, the general public will not be exposed to the notified chemical at this source.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier claims that there would be no release of the chemical when further processed in Australia, as a process-dedicated transfer system would be used. This would minimise spillage as the imported drums would not have to be shifted from the pallet. The formulated product would be distributed in 1000 L pallecons, with the pallecons reused without rinsing. Any waste or spills would be adsorbed onto adsorbent material, left in 200 L drums and any water allowed to evaporate. The contaminated adsorbent material would be disposed of to landfill.

The finished products typically contain less than 5% of the notified chemical. They are aqueous based and applied to fires with a foam-forming nozzle, with their surfactant properties used to trap fuel vapours of the liquid fuel. This essentially smothers the fire.

The notifier estimates that the dilution achieved is about 3-6% of the finished product, with a final concentration in the foam of about 0.15-0.3%.

Apart from the product's release to fight "real" fires, it will also be used in training fire-fighters in "simulated" situations, or in the testing of equipment.

Release of the chemical when used as a mist-control agent will be limited, as it is used in a closed system to maximise metal recovery. The notifier has indicated that the chemical is renewed because of its sorption to particulate matter and other surfaces in the system, and small losses (<<1 ppm) associated with drag out (product adhering to the metal sheets when removed from the electrolyte bath). It was also claimed that it is non-foaming when used as a mist control agent, and would not be subject to dispersal by wind.

Fate

The fate of Amphoteric Fluoroalkylamide Derivative (5965P) in fighting "real" fires is problematical, as it will depend on the size of the fire and the amount of water and foam needed to control the fire. It is likely, however, that it would enter local waterways via storm water drains, road surfaces, overland flow, etc, unless bunding of the accident scene occurred.

For situations in which the AFFF or ATC products are used in training or testing of equipment, the resultant foam/water mix would likely to be contained in pits, or other types of bunding. One situation that might be less well controlled in on airport tarmacs. In this instance, the chemical may enter airport drains which could lead to storm water drains. It is the Federal Airports Corporation's responsibility to ensure that airport drains conform to local regulations. In effect, this requires an airport to install drains, traps and interceptor pits to prevent the loss of fuels, oils and other contaminants from the airport in any uncontrolled fashion. Such traps would also prevent the chemical from leaving the airport. In any controlled (bunded) situation, the wastes containing Amphoteric Fluoroalkylamide Derivative (5965P) could be released into sewer at appropriate rates, or pumped to storage tanks for possible treatment prior to disposal.

Any chemical trapped by filters in its use as a mist-control agent, will share the fate of the filters and disposed to landfill, while that associated with drag-out will share the fate of the metal and would likely be degraded in further metal refining.

The notified chemical was shown to be not readily biodegradable in a modified Sturm test, with 3% and 6% degradation (measured by CO_2 evolution) only achieved for nominal concentrations of the notified chemical of 20 mg/L and 10 mg/L. However, the notifier claims that some partial degradation of the hydrocarbon part of the notified chemical will occur, although none is expected for the fluorinated part. Also, the notifier expects some of the notified chemical, or its metabolites, to bind to biological solids. While some degradation and adsorption will occur, the degradation rate is likely to be slow because of its demonstrable lack of ready biodegradation. Also its adsorption potential, despite its high surface activity, is unclear because of its high water solubility and low partition co-efficient (log P_{OW} = -0.6 - 0.3).

The bioaccumulation potential of the notified chemical was not investigated. It is noted that it has a very low partition coefficient and fat solubility (<210 mg/L). Also, no bioaccumulation of the notified chemical is expected since its large molecular size range is likely to inhibit membrane permeability and prevent uptake during exposure (2,3).

The Material Safety Data Sheet (MSDS) for the Acrylic Foamer formulation indicates that the chemical could decompose to products of hydrogen fluoride and oxides of carbon, sulphur and nitrogen on thermal degradation. The chemical could partially combust or pyrolyse, but this is not likely to occur to any significant extent because of it requiring some degree of thermal stability to make it useful in fighting fires.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Amphoteric Fluoroalkylamide Derivative (5965P)

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 5000 mg/kg	(4)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(5)
Skin irritation	Rabbit	slight irritant	(6)
Eye irritation	Rabbit	slight irritant	(7)
Skin Sensitisation	Guinea pig	non sensitiser	(8,9,10 11,12)

9.1.1 Oral Toxicity (4)

Wistar rats (5 per sex; 7 weeks old) were administered a single gavage dose of 5000 mg /kg of the notified chemical . The animals were maintained for 14 days. Mortality and clinical signs of toxicity were assessed several times on the day of test compound administration, and twice daily (for mortalities) and daily (for clinical signs of toxicity) thereafter. Body weight was determined on days 1, 8 and 15. An autopsy was performed on all animals at the completion of the study.

No deaths were seen during the 14 day study. On the day of chemical administration, respiratory rales, lethargy, piloerection and/or hunched posture were noted in the majority of animals.

The acute oral LD_{50} of the notified chemical was greater than 5000 mg/kg in male and female rats.

9.1.2 Dermal Toxicity (5)

A dose of 2000 mg/kg of the notified chemical was applied to shaved, intact skin of Wistar rats (5 per sex, 7 weeks old). The area was occluded for 24 hours, after which, the residual chemical was removed using a water moistened tissue. The study was terminated after 14 days. Mortality and clinical signs of toxicity were assessed several

times on the day of test compound application, and twice daily (for mortalities) and daily (for clinical signs of toxicity) thereafter. Body weight was determined on days 1, 8 and 15. An autopsy was performed on all animals at the completion of the study.

No deaths, abnormal clinical signs or evidence of skin irritation was noted during the study.

The acute dermal LD_{50} of the notified chemical was greater than 2000 mg/kg in male and female rats.

9.1.3 Skin Irritation (6)

The fur was removed from the back of 3 female New Zealand White rabbits, and 500 mg of the notified chemical was applied to the intact skin for 4 hours. Residual chemical was then removed. Animals were examined daily for clinical signs of toxicity. Body weight was determined the day of chemical application. Skin reactions were assessed approximately 55 minutes, 24, 48 and 72 hours after chemical removal. The severity of the reactions were determined by the degree of erythema and oedema, as described by Draize.

Very slight erythema (grade 1) which resolved within 24 hours was noted in 2 of 3 animals 55 minutes after chemical application.

The notified chemical was a slight dermal irritant in rabbits.

9.1.4 Eye Irritation (7)

A dose of approximately 94 mg of the notified chemical was instilled into the left conjunctival sac of 3 female New Zealand White rabbits. The study was terminated after 7 days. Clinical signs of toxicity was assessed on a daily basis. Body weight was determined on the day of application. The eyes were examined 1, 24, 48 and 72 hours, and 7 days, after chemical instillation, and the degree of irritation assessed using the Draize method. To assess the presence, and severity, of corneal damage, a 2% fluorescein solution was instilled into the eyes 24 hours after chemical instillation.

Mild conjunctival hyperaemia and chemosis was noted in all animals for a period of 72 hours following chemical installation. Mean total Draize score was 6 after 1 hour, and 2 after 72 hours.

The notified chemical was a slight ocular irritant in rabbits.

9.1.5 Skin Sensitisation (8,9,10,11,12)

Study 1 (8) Five female Himalayan albino guinea-pigs (approximately 11 weeks old) were used in a preliminary induction dose finding study. Subsequently, thirty female Himalayan albino guinea-pigs were divided into a control (n = 10) and a treatment group (n = 20). The hair was removed from a region behind the right shoulder. An induction

dose of 0.2 mL of a 50% w/w suspension of the notified chemical in distilled water was applied to the exposed skin of the treatment group on days 1, 3, 5 and 8. In addition, intradermal injections of 0.1 mL of Freunds Complete Adjuvant were administered either side of the application area to the control and treatment groups, on day 5. Excess test material was removed, and the site assessed for evidence of erythema, on day 10. The control and treatment groups were challenged 2 weeks after the last induction dose. The challenge dose for each animal consisted of 0.05 mL of a 0, 1%, 2% and 5% solution of the notified chemical in distilled water, and was applied to a clipped region of the left flank at four separate sites. The residual test material was removed after 24 hours. The application sites were assessed for redness and swelling 24 and 48 hours after removal of the test material. In addition, animals were examined for clinical signs of toxicity on a daily basis, and body weights were determined at the beginning and end of the study.

A total of 14 of 20 treated animals showed cutaneous red spots (grade 1) 24 hours after removal of the 5% challenge dose. Similarly, 3 of 20 animals and 2 of 20 animals showed grade 1 cutaneous reactions 24 hours after removal of the 2% and 1% challenge dose respectively. Forty eight hours after removal of the 5%, 2% and 1% challenge doses, 9 of 20, 3 of 20 and 2 of 20 animals showed evidence of grade 1 cutaneous reactions respectively. After 48 hours, 2 of 10 animals in the 5% challenge dose control group showed grade 1 reactions. The remainder of the control animals did not react.

The notified chemical caused skin sensitisation in the guinea-pig.

Study 2 (9) Thirty male albino Dunkin/Hartley guinea pigs (4-5 weeks old) were divided into groups of 10 control animals, and 20 treated animals. In the test animals, an area of hair was removed from the scapular region of each animal, and paired intradermal injections containing Freund's Complete Adjuvant (FCA) diluted equally with water, 0.5% Amphoteric Fluoroalkylamide Derivative (5965P) in water or 0.5% Amphoteric Fluoroalkylamide Derivative (5965P) in FCA were given in the area. Six days after injections, the areas were pre-treated with sodium lauryl sulfate, and 0.4 mL of 70% Amphoteric Fluoroalkylamide Derivative (5965P) in water on a patch, was applied and covered with an occlusive dressing. The dressing and patch were removed after 24 hours. Control animals were similarly treated, however, the test compound was deleted. Two weeks after the topical application, hair was removed from the left flank of each animal (control and test), and 0.2 mL of 35% or 70% Amphoteric Fluoroalkylamide Derivative (5965P) in water was applied to two separate sites. The application site was occluded for 24 hours. Clinical signs of toxicity were assessed daily, and body weight was determined at the beginning and conclusion of study. Dermal eschar, erythema and oedema formation were assessed after the induction phase, and 24, 48 and 72 hours after the challenge phase.

No signs of toxicity, or body weight changes were noted during the study. Slight irritation was noted following the induction Amphoteric Fluoroalkylamide Derivative (5965P) intradermal injection. Slight erythema was seen in both control and treated groups following the removal of the induction patches. Slight erythema (grade 1) was noted in 1 of 20 treated animals 24 hours after challenge.

The notified chemical (Amphoteric Fluoroalkylamide Derivative (5965P)) did not cause sensitisation in the guinea pig.

Study 3 (10) Thirty young adult albino Haz:(DH)fBR guinea pigs were divided into groups of 10 control animals, and 20 treated animals. In the test animals, an area of hair was removed from the scapular region of each animal, and paired intradermal injections containing FCA diluted equally with water, 0.1 mL of a 5% w/w formulation (45% Amphoteric Fluoroalkylamide Derivative (5965P); 40% water; 15% diethylene glycol butyl ether) in water or 0.1 mL of 5% of the formulation in FCA were given in the area. Six days after injections, the areas were pre-treated with 10% sodium lauryl sulfate in petroleum. After 24 hours, undiluted test material or water (controls) was applied to a patch and placed over the injection sites and occluded for 48 hours. Two weeks after the topical application, hair was removed from the left flank of each animal (control and test), and undiluted test material or water (controls) was applied to the exposed sites. The application site was occluded for 24 hours. Clinical signs of toxicity were assessed daily, and body weight was determined at the beginning and conclusion of study. Dermal eschar, erythema and oedema formation were assessed after the induction phase, and 24, 48 hours after the challenge phase.

No signs of toxicity, or body weight changes were noted during the study. Scattered mild redness (grade 1) was noted in 1 of 20 tested animals 24 hours after challenge.

The test formulation, 45% Amphoteric Fluoroalkylamide Derivative (5965P), 40% water and 15% diethylene glycol butyl ether, did not cause skin sensitisation in the guinea pig.

Study 4 (11) Thirty young adult albino Haz:(DH)fBR guinea pigs were divided into groups of 10 control animals, and 20 treated animals. In the test animals, an area of hair was removed from the scapular region of each animal, and paired intradermal injections containing 0.1 mL of FCA diluted equally with water, 0.1 mL of a 5% w/w formulation (12% Amphoteric Fluoroalkylamide Derivative (5965P); 84% water; 4% diethylene glycol butyl ether) in water or 0.1 mL of 5% of the formulation in FCA were given in the area. Six days after injections, the areas were pre-treated with 10% sodium lauryl sulfate in petroleum. After 24 hours, undiluted test material or water (controls) was applied to a patch and placed over the injection sites and occluded for 48 hours. Two weeks after the topical application, hair was removed from the left flank of each animal (control and test), and undiluted test material or water (controls) was applied to the exposed sites. The application site was occluded for 24 hours. Clinical signs of toxicity were assessed daily, and body weight was determined at the beginning and conclusion of study. Dermal eschar, erythema and oedema formation were assessed after the induction phase, and 24 and 48 hours after the challenge phase.

No signs of toxicity, body weight changes, or dermal reactions were noted during the study.

The test formulation, 12% Amphoteric Fluoroalkylamide Derivative (5965P); 84% water; 4% diethylene glycol butyl ether, did not cause skin sensitisation in the guinea pig.

Study 5 (12) Thirty young adult albino Haz:(DH)fBR guinea pigs were divided into groups of 10 control animals, and 20 treated animals. In the test animals, an area of hair was removed from the scapular region of each animal, and paired intradermal injections containing 0.1 mL of FCA diluted equally with water, 0.1 mL of a 5% w/w formulation

(2.75% Amphoteric Fluoroalkylamide Derivative (5965P); 96.25% water; 1% diethylene glycol butyl ether) in water or 0.1 mL of 5% of the formulation in FCA were given in the area. Six days after injections, the areas were pre-treated with 10% sodium lauryl sulfate in petroleum. After 24 hours, undiluted test material or water (controls) was applied to a patch and placed over the injection sites and occluded for 48 hours. Two weeks after the topical application, hair was removed from the left flank of each animal (control and test), and undiluted test material or water (controls) was applied to the exposed sites. The application site was occluded for 24 hours. Clinical signs of toxicity were assessed daily, and body weight was determined at the beginning and conclusion of study. Dermal eschar, erythema and oedema formation were assessed after the induction phase, and 24 and 48 hours after the challenge phase.

No signs of toxicity, body weight changes or dermal reactions were noted during the study.

The test formulation, 2.75% Amphoteric Fluoroalkylamide Derivative (5965P); 96.25% water; 1% diethylene glycol butyl ether, did not cause skin sensitisation in the guinea pig.

9.2 Repeated Dose Toxicity (13,14)

Study 1 (13). Groups of 5 Wistar rats per sex (approximately 6 weeks old) were administered 0, 50 mg (LD), 200 mg (MD) or 800 mg (HD) of the notified chemical (Amphoteric Fluoroalkylamide Derivative (5965P); > 95% purity, in distilled water)/kg/day, by gavage, for 28 days. Separate groups (n = 5 per sex) of rats which had been untreated, or had received 800 mg/kg/day for 28 days, were maintained and not treated for an additional 14 day recovery period. Clinical signs of toxicity were assessed daily, animal mortality was determined twice daily, food consumption and body weight was determined weekly, and an ophthalmic examination was carried out prior to study commencement, during the final week of treatment and recovery period. Blood to determine haematological and clinical biochemical parameters was collected at the completion of the study. Autopsies, which included selected organ histopathology, and organ weight determinations, were carried out at study termination.

General lethargy was noted in HD males whilst being treated, and during the recovery phase. Focal areas of alopecia, chromodacryorrhoea, and a foamy appearance to the urine were noted in HD males and females during the treatment and recovery phase. Excess salivation was seen in MD and HD animals, and respiratory rales was noted in HD females, during the treatment period. Body weight gain was reduced in HD and MD animals at the conclusion of the treatment period, and remained marginally depressed in HD animals during the recovery phase.

Red blood cell numbers and haematocrit were increased in HD animals. Red blood cell haemoglobin content and platelet numbers were marginally decreased in all treatment groups. The decrease in platelets was statistically significant in all male dose groups and repeated dosing lower doses. At the end of the recovery period, the haemoglobin concentration remained low in HD males and females. In addition, red blood cell numbers and haematocrit were significantly reduced at the conclusion of the recovery

period in HD females. White blood cell numbers were increased in all treated groups, and were statistically increased in HD males and MD and HD females.

Serum phosphorous was elevated in MD and HD males and females, and urea was increased in MD and HD males, and in HD females. An elevation in creatinine and ALP levels, and a reduction in serum glucose, were noted in HD males and females. At the end of the recovery period ALP remained elevated in HD females. An increase in ALP levels was also noted in MD females following treatment. AST was increased in HD females along with ALT elevations in MD and HD females. Serum cholesterol and triglycerides were reduced, and ALT was elevated, in LD, MD and HD males at the conclusion of the treatment period, and triglycerides remained decreased in HD females after the recovery period. Cholesterol was also reduced in all treated female groups. Serum sodium levels where elevated in LD and HD female groups.

Liver, adrenals and spleen relative weights were increased in MD and HD females, and liver, kidney and adrenals relative weights were increased in MD and HD males. Relative liver weight in HD males and females, and relative kidney and spleen weight in HD females remained elevated at the conclusion of the recovery period. Hepatocyte hypertrophy was noted in all treated males, and in 3 of 5 HD females. Similar pathology was noted at the completion of the recovery period in 2 of 5 HD males and 1 of 5 HD females. Diffuse adrenal cortical vacuolation was noted in all treated males, and in MD and HD females. These changes persisted in HD animals and were present at the end of the recovery period. Slight renal cortical cellular hypertrophy was noted in 4 of 5 HD males at the conclusion of the treatment phase.

Study 2 (14). Because effects considered to be treatment related were noted in the 50 mg/day dose groups, the study was repeated in female medium and high dose groups. Groups of 5 Wistar rats per sex (approximately 6 weeks old) were administered 0, 1 mg (LD), 10 mg (MD) or 25 mg (HD) of the notified chemical (Amphoteric Fluoroalkylamide Derivative (5965P); > 95% purity, in distilled water)/kg/day, by gavage, for 28 days. Separate groups of rats (n = 5 per sex) which had been untreated, or had received 25 mg/kg/day for 28 days, were maintained and not treated for an additional 14 days recovery period. Clinical signs of toxicity were assessed daily, animal mortality was determined twice daily, food consumption and body weight was determined weekly, and an ophthalmic examination was carried out prior to study commencement, and during the final week of the treatment and recovery period. Blood to determine haematological and clinical biochemical parameters was collected at the completion of the study. Autopsies, which included selected organ histopathology, and organ weight determinations, were carried out at study termination.

A statistically significant decrease in the platelet number, and an increase in the prothrombin time, was noted at the completion of the recovery period in the HD male group. Cholesterol was decreased in MD and HD males, and in HD females at the completion of the treatment period, and remained low at the end of the recovery period in HD males. Serum ALT was increased in HD females. Relative liver weight was increased in MD and HD males, and kidney and adrenal weights were marginally increased in HD males. Relative weights of the ovaries were increased in the HD female group at the end of the recovery period. No histological abnormalities were noted. There were no treatment related effects at the lowest dose of 1 mg/kg/day.

9.3 Genotoxicity

9.3.1. *Salmonella typhimurium* Reverse Mutation Assay (15,16)

(15). In the Ames test using *Salmonella typhimurium*, strains TA1535, TA1537, TA98 and TA100 at concentrations of 100 - 3330 µg/plate, and in the presence or absence of metabolic activation, the notified chemical (Amphoteric Fluoroalkylamide Derivative (5965P)), failed to induce a dose-related increase in the number of reverse mutations. The positive controls used without metabolic activation were sodium azide in saline (TA1535), 9-aminoacridine in saline (TA1537), daunomycine in saline (TA98) and methylmethanesulfonate in DMSO (TA100), and, with metabolic activation, 2-aminoanthracene in DMSO (all strains). The positive controls significantly increased the number of revertants and indicated that the assay functioned correctly.

(16). This test was conducted as a duplicate to (13). In the Ames test using *Salmonella typhimurium*, strains TA1535, TA1537, TA98 and TA100, the notified chemical (Amphoteric Fluoroalkylamide Derivative (5965P)), at concentrations of 100 - 5000 µg/plate, and in the presence or absence of metabolic activation, failed to induce reverse mutations. The positive controls used without metabolic activation were sodium azide in saline (TA1535), 9-aminoacridine in saline (TA1537), daunomycine in saline (TA98) and methylmethanesulfonate in DMSO (TA100), and, with metabolic activation, 2-aminoanthracene in DMSO (all strains). The positive controls significantly increased the number of revertants and indicated that the assay functioned correctly.

9.3.2. *Escherichia coli* Reverse Mutation Assay (17)

In the Ames test using *Escherichia coli* bacteria, strain WP_2*uvrA*, the notified chemical (Amphoteric Fluoroalkylamide Derivative (5965P)), at concentrations of 100 - 5000 µg/plate, and in the presence or absence of metabolic activation, failed to induce reverse mutations. The positive controls used without metabolic activation was 4-Nitroquinoline N-oxide in DMSO, and, with metabolic activation was 2-aminoanthracene in DMSO. The positive controls significantly increased the number of revertants and indicated that the assay functioned correctly.

9.3.3. Chromosomal Aberration Assay (18)

The notified chemical (Amphoteric Fluoroalkylamide Derivative (5965P)), when examined at concentrations ranging from 3 to 5000 µg/mL, with or without metabolic activation, did not induce clastogenicity in cultured human lymphocytes after 24 and 48 hours treatment (18). The positive control chemicals, mitomycin C and cyclophosphamide, produced a significant increase in the incidence of cells with chromosomal aberrations.

The notified chemical when examined at concentrations ranging from 10 to 1000 µg/mL (for 24 hours) or 10 to 500 µg/mL (for 48 hours), with or without metabolic activation, did not induce clastogenicity in cultured human lymphocytes (19). The positive control chemical mitomycin C produced a significant increase in the incidence of cells with chromosomal aberrations.

9.4 Overall Assessment of Toxicological Data

The studies demonstrated that the notified chemical has low acute oral, and low acute dermal toxicity in rats, is a slight dermal and ocular irritant in rabbits. Although one sensitisation study indicated that the chemical is a dermal sensitiser, four studies conducted to international recognised standards, indicated that the notified chemical was not a sensitiser. Therefore, on the weight of evidence, it may be concluded that the notified chemical is most probably not a dermal sensitiser. Twenty eight day repeat dose studies indicated that the target organs are the liver, kidney, spleen and adrenals. Alterations in liver structure were detected at, and above, doses of 25 mg/kg/day. The pathology induced in the liver and kidney was not reversible when a dose of 800 mg/kg/day was administered for 28 days. The compound, when assessed in *in vitro* assays, was not mutagenic or clastogenic.

The notified chemical is not classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (20) in relation to the toxicity data provided

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity studies were conducted using Amphoteric Fluoroalkylamide Derivative (5965P) (> 95% purity) dissolved in water. Test details and results are given in Table 2.

In the acute fish test, the LC_{50} was not determined statistically, but was greater than 320 mg/L, indicating that the substance was practically non-toxic. The solubility of the substance is stated to be 450 mg/L, while the concentrations series included treatments greater than this concentration with the test material dissolved by ultra-sonication. This might have led to a concentration response curve where the LC_{50} could not be calculated (see footnote to Table 2), with the test material not remaining in solution at higher concentrations.

Sublethal effects, such as hypoactivity, immobility, snapping at surface, and loss of equilibrium were noted in all treatments (100 - 1000 mg/L nominal concentration range) of the acute fish test. This did not appear to be concentration-dependent.

Two acute studies and one chronic study were performed using the water flea, *Daphnia magna*. The acute test results (Table 2) indicate that Amphoteric Fluoroalkylamide Derivative (5965P) is practically non- toxic to water fleas, but the latter indicates the potential to affect water fleas at lower concentrations if exposed for a much longer period.

The effect of Amphoteric Fluoroalkylamide Derivative (5965P) on algae was tested using *Scenedesmus subspicatus* and *Selenastrum capricornutum*. The results (Table 2) indicated that the notified chemical was only slightly toxic to both algae. *Scenedesmus subspicatus* is considered by the US EPA to be insensitive, although in this instance, it appears to be the more sensitive of the two algal species (21).

The company states that results of testing using *Photobacterium* (Microtox®) are available, but were not included in the submission.

Table 2. Ecotoxicity test results

Species	Test	Nominal Concentrations (mg/L)	Result (mg/L)
Carp (*Cyprinus carpio*)	96 h acute	0, 100, 180, 320, 560, 1000	320< LC_{50} <1000[a]
Water Flea (*Daphnia magna*)	48 h acute	Study A: 0, 100, 180, 320, 560, 1000 Study B: 0, 32, 56, 100, 180, 320	EC_{50} 153 mg/L for study A EC_{50} 186 mg/L for study B
Water Flea (*Daphnia magna*)	21 d	0, 1.6, 5.0, 15, 50, 160[b]	EC_{50} for parental immobility: 18.0 for reproduction: 1.6-5.0
Algae (*Scenedesmus subspicatus*)	72 h growth	0, 1.0, 3.2, 10, 32, 100, 320	For growth inhibition (0-72 h): E_BC_{50} = 10-32 For growth rate reduction (24-72 h): E_RC_{50} = 15.1
Algae (*Selenastrum capricornutum*)	96 h growth	0, 15, 31, 62, 125, 250	For growth rate reduction (0-96 h): E_RC_{50} = 68 mg/L

a. No LC_{50} was calculated. The test report did not state why the LC_{50} was not calculated, although it is noted that such a calculation would be difficult since there was 90% mortality in the 1000 mg/L treatment, then only 20% and 30% mortality in the 560 and 320 mg/L treatments. b. actual concentrations ranged from 69% to 130% of nominal.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The chemical, Amphoteric Fluoroalkylamide Derivative (5965P), will be used as a foaming agent to fight fires that have the aviation fuels, AVGAS or AVTUR, as a fuel source. The main environmental exposure of the chemical will occur when it is used in fire-fighting training or actual use conditions. In the former case, conditions will be controlled, with bunding and traps preventing its release, and the release of the fuel, to the environment. In the latter case, actual use will most likely be in areas where bunding or traps are used to prevent the release of fuel to the environment, such as airports or refineries. At airports, for instance, drains leading from the runway area to storm water will have an interception trap to prevent release of fuel to storm water drains.

An exception to Amphoteric Fluoroalkylamide Derivative (5965P)'s use in the above situations is its use in fire-fighting on actual fires of fuel tankers or trucks carrying aviation fuels. It is unclear how the company intends to market the material in the future, but if it is used in such events, then there is potential for the release of Amphoteric Fluoroalkylamide Derivative (5965P) to the environment. If it is confined to use on fires involving aviation fuels only, then only a few are expected. According to the NSW EPA, these types of accidents might only amount to 3 or 4 per annum at most. Of this, only one accident might involve a petrol tanker - the others would be trucks carrying drums of

aviation fuel. The number of accidents in which other petroleum fuels, such as petrol, were involved would be much greater, with these fuels being recorded as the primary ignition source in more than 1000 instances according to figures from NSW Fire Brigade for 1994.

A realistic, worst case situation would, in any event, appear to be an accident involving a fuel tanker, with runoff from the accident entering a lentic (still) water body with significant wild-life. Figures provided by the ACT Fire Brigade indicate that about 4000 L of water might be used to cool the tanker. Another 4000 L together with the foam might be used to control any fire associated with the tanker (eg from spilt petrol and ignition of cabin material). If the fuel load catches alight, then when the fire can be approached, more than 12000 L of water/foam mix, would be needed to control the fire.

The notifier estimates that Amphoteric Fluoroalkylamide Derivative (5965P) will be used in AFFF concentrates at about 5%. When used, the concentrates are diluted with a foam-forming nozzle by about 3-6%, giving a concentration of about 0.15-0.3% Amphoteric Fluoroalkylamide Derivative (5965P) in the water applied to a fire. In the above situation, the total amount of Amphoteric Fluoroalkylamide Derivative (5965P) applied would be about 0.3% x 20 x 10^4 L, giving 60 L of the chemical. With a density of 1.64 g/mL, this would give 100 x 10^3 g of Amphoteric Fluoroalkylamide Derivative (5965P) potentially available for dispersal. Some of this will be combusted/pyrolysed in the fire leaving the fluorinated residues, although the amount lost expected to be small. Any Amphoteric Fluoroalkylamide Derivative (5965P) left would be associated with run-off from the accident site. Run-off into a reasonably-sized lake of about 1 ha surface area and an average depth of 1 m (giving a volume of about 10^7 L) would give a concentration of 10 mg/L (100 x 10^3 g/10^7 L = 100 x 10^{-4} g/L or 10 mg/L).

The above worst case estimate is the same order of magnitude as the lowest acute effect (growth inhibition (0-72 h) of *Scenedesmus subspicatus*, E_BC_{50} = 10-32), and slightly above the range of the lowest chronic effect (EC_{50} for water flea reproduction = 1.6-5.0). The estimate, however, makes a number of assumptions.

One significant assumption is that all Amphoteric Fluoroalkylamide Derivative (5965P) applied to the fire would be associated with run-off from the accident site. Clearly though, the run-off may not all flow into the lake, with some of the run-off absorbed by road surfaces and soil surrounding the accident site. When and where possible, standard operating procedures of Australian fire brigades would minimise run-off by containment and removal. Also, some losses might be expected through adsorption to sediment and particulate matter because of its surface activity. On entering the surface waters, some Amphoteric Fluoroalkylamide Derivative (5965P) may partition to sediment, with possible (albeit slow) degradation of the hydrocarbon portion of the molecule.

Another assumption is that there would be uniform and complete mixing of the chemical in the receiving surface water. This is not likely to occur, and would lead to localised points (eg the entry point of the run-off) where the concentration of Amphoteric Fluoroalkylamide Derivative (5965P) would be elevated. Although this would undoubtedly have localised impacts on invertebrate and algal species, the effect on fish might be limited as they have the greater ability to avoid contaminated sites. Also, a large proportion of the lake might be left relatively uncontaminated.

The hazard from the chemical's use as a mist control agent is expected to be negligible as it is used within a closed system.

With the amount of Amphoteric Fluoroalkylamide Derivative (5965P) used being potentially quite large, there is clearly a potential hazard posed by the chemical if it is allowed to contaminate surface waters. The situations in which this might occur are, however, a rare event. Several factors would have to be met to for Amphoteric Fluoroalkylamide Derivative (5965P) to have a major environmental impact. These are: 1) a major accident involving a fuel tanker in which the fuel load would catch alight, 2) the run-off from the fire-fighting escaping to a lentic surface water, and 3) the concentration of Amphoteric Fluoroalkylamide Derivative (5965P) remaining near those affecting aquatic organisms for a few days.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is not expected to cause any adverse health effects in humans through acute oral and dermal administration. The notified chemical may cause minor skin and eye irritation but is unlikely to be a skin sensitiser. A twenty eight day repeat oral dose study in rats has indicated that the notified chemical may target the liver, kidney, spleen and adrenals, with injury occurring at doses $\geq$ 200 mg/kg/day. The notified chemical is unlikely to be mutagenic or clastogenic.

The churn operator, quality assurance personnel and process engineers are expected to come into direct contact with the chemical, with the potential for dermal contact to the skin or eyes. To minimise the potential for exposure workers will wear chemical resistant goggles, protective clothing and rubber gloves.

Fire fighters may be exposed to the notified chemical through dermal contact to the skin or eyes by spillage, splashing or spray, and are expected to wear rubber gloves and chemical resistant goggles when decanting to extinguishers and normal fire fighting clothing when fighting a fire. The exposure level of the notified chemical should be around 0.15-0.3% in the foam as applied in a fire.

Workers involved in the dilution of the notified chemical in the mist control agent will potentially be exposed to the notified chemical through dermal exposure due to spillage or splashing. To minimise exposure to the formulated product protective clothing and gloves as well as eye protection should be worn, this also serving to reduce exposure to the notified chemical. Once the chemical is added to the tanks there will be little opportunity for exposure as it will be a closed system.

The notified chemical is a surfactant which will be incorporated into products to be used by fire fighting personnel to control combustible hazards and extinguish fires involving hydrocarbon liquids. The current application states that the notified chemical will be incorporated into fire fighting products which are to be tested by the appropriate agencies to determine their efficacy, and are not to be used for general fire control. In addition, the chemical will be incorporated into a mist control agent to be used only by process

workers. Therefore, excluding accidental spillage during transport, storage and reformulation, the public will not be exposed to the notified chemical. Expected routes of exposure would be through eye or skin contact. Although the notified chemical did cause slight skin and eye irritation, its use is not expected to result in adverse health effects because of the very limited opportunities for public contact.

13. RECOMMENDATIONS

To minimise occupational exposure to Amphoteric Fluoroalkylamide Derivative (5965P) the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to Amphoteric Fluoroalkylamide Derivative (5965P) to a safe level, then the following personal protective equipment which conforms to Australian Standards (AS) or Australian/New Zealand Standards (AS/NZS) should be worn;

  respiratory protection should be selected and fitted in accordance with AS/NZS 1715 (22) and comply with AS/NZS 1716 (23),

  safety goggles should be selected and fitted in accordance with AS 1336 (24) to comply with AS/NZS 1337 (25),

  industrial clothing must conform to the specifications detailed in AS 2919 (26),

  impermeable gloves or mittens conforming to AS 2161 (27),

- spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal to landfill according to local, state or federal regulations;

- good personal hygiene should be practised to minimise the potential for ingestion;

- a copy of the MSDS should be easily accessible to employees.

- it is recommended that the company clearly indicate to users the potentially hazardous nature to aquatic organisms (invertebrates and algae) of their 3M fire foam products containing Amphoteric Fluoroalkylamide Derivative (5965P); also, if the product is used in areas in which control is not present, the company should instruct the user to bund the area to prevent run-off.

14. MATERIAL SAFETY DATA SHEET

These MSDS for Amphoteric Fluoroalkylamide Derivative (5965P) were provided in an acceptable format in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (28).

These MSDS were provided by 3M Australia Pty Ltd as part of the notification statement. The accuracy of this information remains the responsibility of 3M Australia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Amphoteric Fluoroalkylamide Derivative (5965P) shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

Proposals to use Amphoteric Fluoroalkylamide Derivative (5965P) in fire foams to fight fires other than those described in the application will require a secondary notification. Similarly, any proposals to use this chemical other than in controlled evaluation conditions will require a secondary notification. No other specific conditions are prescribed.

16. REFERENCES

1. National Occupational Health and Safety Commission, 1994, *List of Designated Hazardous Substances [NOHSC:10005 (1994)].* AGPS, Canberra

2. Anliker *et al*, 1988, *Chemosphere*, **17**: 1631-1644.

3. Gobas *et al*, 1986, *Environmental Toxicology and Chemistry*, **5**: 637-646.

4. Reijnders, JBJ, 1991, *Assessment of acute oral toxicity with T-2816 in the rat.* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 048026).

5. Reijnders, JBJ, 1991, *Assessment of acute dermal toxicity with T-2816 in the rat.* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 048037).

6. Daamen, PAM, 1991, *Primary skin irritation/corrosion study with T-2816 in the rabbit (4 hour semi-occlusive application).* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 048048)

7. Daamen, PAM, 1991, *Acute eye irritation/corrosion study with T-2816 in the rabbit.* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 048059).

8. Daamen, PAM, 1991, *Assessment of contact hypersensitivity to T-2816 in the albino guinea-pig***.** Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 048061).

9. Huntington Research Centre Ltd, 1995, *T-2816. Skin sensitisation in the guinea pig.* Huntington, Cambridge, England. Report No.: MEU 11/951326/SS.

10. Hazelton Wisconsin, 1993, *Dermal sensitisation study of T-5679 in guinea pigs - Maximization test (EC guidelines).* Madison, Wisconsin, USA. Laboratory No.: 21202562.

11. Hazelton Wisconsin, 1993, *Dermal sensitisation study of T-5680 in guinea pigs - Maximization test (EC guidelines).* Madison, Wisconsin, USA. Laboratory No.: 21202563.

12. Hazelton Wisconsin, 1993, *Dermal sensitisation study of T-5681 in guinea pigs - Maximization test (EC guidelines).* Madison, Wisconsin, USA. Laboratory No.: 21202564.

13. Reijnders, JBJ, 1991, *Subacute 28-day oral toxicity with T-2816 by daily gavage in the rat followed by a 14 day recovery period,* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 048083).

14. Reijnders, JBJ, 1991, *Subacute 28-day oral toxicity with T-2816 by daily gavage in the rat followed by a 14 day recovery period. ,* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no. 059434).

15. Scheres, HME, 1991, *Evaluation of the mutagenic activity of T-2816 in the Ames Salmonella/microsome test.* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 048094).

16. Waart, EJ van de, 1991, *Evaluation of the mutagenic activity of T-2816 in the Ames Salmonella/microsome test*. Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 061278).

17. Scheres, HME, 1991, *Evaluation of the mutagenic activity of T-2816 in the Escherichia coli/microsome test.* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.:048105),

18. Scheres, HME, 1991, *Evaluation of the ability of T-2816 to induce chromosome aberrations in cultured peripheral human lymphocytes.* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 048116).

19. Waart**,** EJ van de, 1991, *Evaluation of the ability of T-2816 to induce chromosome aberrations in cultured peripheral human lymphocytes.* Report to 3M Pty Ltd (RCC NOTOX BV, The Netherlands. Report no.: 061289).

20. National Occupational Health and Safety Commission, 1994, *Approved Criteria For Classifying Hazardous Substances [NOHSC:1008 (1994)].* AGPS, Canberra.

21. USEPA, 1982, *Algal acute toxicity test, EG-8,* Environmental Effects Test Guideline.

22. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

23. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

24. Standards Australia, 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia.

25. Standards Australia, 1992, *Australian Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia.

26. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.

27. Standards Australia, 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney, Australia.

28. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Labelling of Workplace Substances* [NOHSC:2012(1994)], Australian Government Publishing Service, Canberra.