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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Perfluoroamphiphile in Dynax DX 5011

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

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Perfluoroamphiphile in Dynax DX 5011

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Kidde Australia Pty Ltd (ABN 68 006 252 428) of 314 Boundary Road, Dingley, VIC, 3172.

NOTIFICATION CATEGORY

Limited: Polymer with NAMW \geq 1000.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Identity

Molecular Weight

Spectral Data

Purity and identity and % weight of impurities

Import volume

Identity of customer and site where product will be used

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Molecular Weight Determination, including Low Molecular Weight Species

Melting Point

Boiling Point

Density

Vapour Pressure

Water Solubility

Hydrolysis as a function of pH

Partition Coefficient

Adsorption/Desorption

Flash Point

Flammability Limits

Autoignition Temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (1995)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Perfluoropolyamphipile

Fluorochemical Foam Stabilizer

Anionic Fluorochemical Foam Stabilizer of Perfluoroalkyl type

MARKETING NAME(S)

DYNAX® DX 5011 (Imported product containing 44% notified polymer)

METHODS OF DETECTION AND DETERMINATION

METHOD Infrared (IR) Spectroscopy

Remarks A reference infrared spectra was provided. IR spectroscopy is used to track the reaction.

3. COMPOSITION

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

All hazardous impurities are present at below the relevant cut offs for classification of the notified polymer as a hazardous substance. Perfluorooctanoic acid was not detectable ($<0.05 \mu g/mL$) in an analysis of one batch of DYNAX DX 5011 by LC/MS (Exygen, 2006). Residual levels of the perfluorinated monomer in the notified polymer are stated to be <0.1%.

ADDITIVES/ADJUVANTS

None

DEGRADATION PRODUCTS

Under fire-fighting conditions the notified polymer may be exposed to extreme temperature conditions. Thermal decomposition products expected are oxides of carbon, nitrogen and sulphur, together with the release of low molecular weight fluorocarbon compounds, and possibly hydrogen fluoride.

Potential degradation products formed in the environment are discussed in section 8.1.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The notified polymer contains trace levels of residual monomers/impurities which may be lost during use.

4. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years

The notified polymer is not manufactured in Australia. It will be imported into Australia by sea as a 44% aqueous solution of the notified polymer. The notified polymer may also be imported (concentration $\sim 0.3\%$) in fire extinguishers.

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

Year	1	2	3	4	5
Tonnes	< 1	< 1	< 1	< 1	< 1

USE

The notified polymer will be used as an additive for improving foam stability in aqueous fire fighting foam concentrates for hydrocarbon fuels. Typical end-users are fire brigades, industrial fire services and foam fire extinguisher manufacturers. Fire extinguishers will not be used in home or office environments.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY Melbourne, Victoria

IDENTITY OF RECIPIENTS

The reformulation site is Kidde Australia Pty Ltd in Dingley, VIC. The aqueous fire fighting foam concentrates will be distributed to customer sites, e.g. fire brigades, industrial fire services, foam fire extinguisher manufacturers.

TRANSPORTATION AND PACKAGING

DYNAX® DX 5011 is transported into Australia by ship in 200 kg plastic drums. The finished fire

fighting foam concentrates are packaged into 20 L or 200 L drums and 1000 L intermediate bulk containers (IBCs). If imported in a fire extinguisher the notified polymer is packaged in an 800 mL cartridge within the extinguisher.

5.2. Operation description

During the formulation of the fire fighting foam concentrates, the aqueous solution containing the notified polymer will be first warmed and then pumped into a bulk mixing tank (typical volume is 8000 L). Other ingredients are added (water, surfactants, corrosion inhibitors) and mixed for approximately one hour. The notified polymer makes up approximately 0.3% of the final fire fighting foam concentrate.

Samples of the finished product are tested by Quality Assurance Laboratory before being filled into the final packaging (20L or 200L drums and 1000L IBCs), using automated lines.

The final packaged product is sold to fire brigades, industrial fire services organisations and foam fire extinguisher manufacturers.

Fire brigade personnel and industrial fire service personnel would store the containers of finished product until required for use. It is expected they will drain off the required amount of concentrate into smaller containers for taking on to service vehicles. During fire fighting, it is expected the notified polymer will be further diluted (even to as low as 0.03%) in stream use. A hose and nozzle is connected to the drum or containing the reformulated product and the water draws the product containing the notified polymer and forms a foam spray.

Fire extinguishers are checked every 5 years. Service technicians will load the cartridge with foam concentrate and replace back in the extinguisher.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	Number	Exposure Duration	Exposure Frequency
Transporting from dock to	1 - 2	1 hour per trip	5 times per year
manufacturer's site for reformulation			
(loading/unloading trucks) (sealed			
product only)			
Handling and Storage Operators	2 - 3	20 mins per day	5 days per year
Fire brigade fire fighters	>5,000	Up to 2 hours per	< 20 days per year
		day	
Industrial fire service personnel	>500	Up to 2 hours per	50 – 100 days per year
		day	
Foam fire extinguishing manufacturer	50 - 100	Up to 8 hours per	50 - 100 days per year
personnel		day	

Exposure Details

Transport and storage

Transport and storage workers are not expected to be exposed to DYNAX® DX 5011 (containing 44% notified polymer) as they are handling closed containers. DYNAX® DX 5011 is supplied in robust 200 Kg drums and transported on secure pallets. Exposure is possible in the event of an accident where the packaging is breached.

Formulation of foam fire fighting concentrate

The batching and mixing areas are all equipped with local exhaust ventilation and opening doors to allow for natural local ventilation. However, dermal and limited ocular exposure to DYNAX® DX 5011 (containing 44% notified polymer) may occur when opening and closing the 200 Kg drums and when pumping the solution containing the notified polymer to the mixing vessel, and connecting and disconnecting transfer and filling lines. Inhalation exposure is not expected as the notified polymer is in solution form and the processes are not expected to generate aerosols.

Dermal exposure to the foam fire fighting concentrate containing 0.3% of the notified polymer may

also occur due to drips and spills and if containers are overfilled at the drumming area. Skin contamination may occur when maintenance workers are cleaning equipment and during maintenance of equipment. Workers involved in the above activities wear personal protective equipment such as overalls, safety glasses, safety boots and gloves.

End Use

Fire brigade personnel and industrial fire service personnel have the potential to be exposed to the notified polymer (approximately 0.3%) when transferring the fire fighting concentrate to smaller containers. Fire extinguisher service technicians have the potential to be exposed to the notified polymer (approximately 0.3%) when filling the cartridge with the fire fighting concentrate. Dermal contact is likely to be the main route of exposure. Dermal and inhalation exposure could occur to the notified polymer (0.03-0.3%) during the application of the foam spray. Contact may be prolonged depending on the end use circumstances. Fire personnel are expected to wear extensive PPE when using the foam.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Reformulation of the notified polymer will occur at one site in Victoria. It is estimated that a maximum of 1% of the imported product will remain in the import drums (corresponding to less than 10 kg of the notified polymer per annum). This residue will be disposed of by a waste disposal contractor. Residues of the formulation equipment will be used in the following batch wherever possible. If the mixing tank is cleaned at the end of an extended batch run of different products, the amount of notified polymer to be disposed via waste disposal contractor is expected to be less than 1 kg per batch run.

RELEASE OF CHEMICAL FROM USE

The greatest potential for release of the chemical is through the use in fire fighting foams. Such fires would include those in flammable liquid stores, vehicle accidents involving flammable liquid tankers or water insoluble products of a flammable or combustible nature. The finished foam concentrate will typically contain approx. 0.3% of the notified polymer. The action of the foam based concentrate combined with water spray is to smother the fire – this level of notified polymer delivered could be as low as 0.03%. In cases where flammable liquid storage areas have foam fire fighting facilities containing the new polymer, it is expected these areas will have fire water containment such as bunding, sumps and onsite water treatment plants. The fire water would only be released to the sewer with prior consent from the local water authority. If consent is not granted, the waste is to be disposed of at a liquid waste facility.

The fate of the chemical in fighting "real" fires (such as a tanker accident) is problematic, 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 that it could enter local waterways via storm water drains, road surfaces and over land surface flow unless bunding of the accident scene occurred.

High temperature incineration would destroy the polymer with evolution of water and oxides of carbon, nitrogen and sulphur, together with the release of low molecular weight fluorocarbon compounds, and possibly hydrogen fluoride.

5.5. Disposal

The empty containers will be collected by a licensed waste contractor and cleaned out for re-use or disposal to secure landfill.

5.6. Public exposure

The formulated fire fighting foam is for industrial use only and as such negligible direct public exposure to the notified polymer is expected. The public could be exposed to low levels of the notified polymer and/or its breakdown products via environmental routes

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is introduced as an aqueous solution. Limited data has been provided for Dynax DX 5011, an aqueous solution containing 44% notified polymer.

Appearance at 20°C and 101.3 kPa

Amber, viscous liquid (Dynax DX 5011)

Melting Point/Freezing Point Not determined

Remarks The notified polymer is introduced as an aqueous solution. The melting point of

the product Dynax DX 5011 is estimated to be similar to water (0 °C).

Boiling Point Not determined

Remarks The notified polymer is introduced as an aqueous solution. The boiling point of the

product Dynax DX 5011 is estimated to be similar to water (100 °C).

Density Not determined

Remarks The notified polymer is introduced as an aqueous solution. The density of the

product Dynax DX 5011 was reported in the MSDS to be 1140 kg/m³.

TEST FACILITY

Vapour Pressure Not determined

Remarks By comparison to similar polymers, the vapour pressure of the polymer is

expected to be very low.

Water Solubility Soluble

Remarks The product Dynax DX 5011 is an aqueous solution (approx. 48% water). The

notified polymer in this product is water soluble.

TEST FACILITY

Hydrolysis as a Function of pH Not determined.

Remarks The notified polymer contains a hydrolysable linkage but this is unlikely to occur

at ambient environmental conditions.

Partition Coefficient (n-octanol/water) Not determined.

Remarks No test conducted. The notified polymer is water soluble, but insoluble in alcohol

and therefore, partition into n-octanol is expected to be small.

Adsorption/Desorption Not determined

Remarks The high water solubility and the expected low log Pow may indicate that the

notified polymer can be highly mobile in soil. However, the cationic and the anionic functionalities may help sorption to the mineral or other components of

soil.

Dissociation Constant Not determined

Remarks The polymer contains both acidic and basic functionalities which would be

expected to display the typical pKa dependant behaviour.

Particle Size Not determined

Remarks The notified polymer is introduced in solution

Flash Point Not determined

Remarks

The notified polymer is introduced as an aqueous solution. The flashpoint of the product Dynax DX 5011 was reported in the MSDS to be > 66 °C determined by the closed cup method. Given the estimated low vapour pressure and the use of the notified polymer it is not considered that the polymer would evolve sufficient vapour for a flammable vapour/air mixture upon heating.

Flammability Limits

Not determined

Remarks The notified polymer is introduced as an aqueous solution. The notified polymer is

not expected to be highly flammable.

Autoignition Temperature

Not determined

Remarks The notified polymer is introduced as an aqueous solution. The notified polymer is

not expected to autoignite under conditions of use.

Explosive Properties

Not determined

Remarks From examination of the structure, there are no chemical groups that would infer

explosive properties.

Thermal Stability

Remarks Thermogravimetric analysis of the product Dynax DX 5011 showed 42% weight

loss up to 150°C (considered to be due to water loss) and then a further 20%

weight loss up to 250°C

Reactivity

Remarks The notified polymer is considered to be stable up to 135°C. Under fire-fighting

conditions the notified polymer may be exposed to extreme temperature conditions. Thermal decomposition products expected are oxides of carbon, nitrogen and sulphur, together with the release of low molecular weight

fluorocarbon compounds, and possibly hydrogen fluoride.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicity data was provided for the product Dynax DX 5011. The batch tested was stated to contain 30% notified polymer.

Endpoint and Result	Assessment Conclusion
Rat, acute oral	low toxicity, LD50 > 5000mg/kg bw
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating

7.1. Acute toxicity – oral

TEST SUBSTANCE Dynax DX 5011 (30% notified polymer)

METHOD US EPA Guidelines for Test Procedures, Subsection F., Series 81-1

Species/Strain Rat/Wistar Albino

Vehicle Test substance administered as supplied.

Remarks - Method No significant deviations from OECD TG 401 Acute Oral Toxicity -

Limit Test.

RESULTS

Group	Number and Sex	Dose	Mortality		
	of Animals	mg/kg bw			
I	5 male	5000	0		
II	5 female	5000	0		
LD50	> 5000 mg/kg bw (1 > 1500 mg/kg bw (1				
Signs of Toxicity	Instances of anoge	Instances of anogenital soiling was noted in one male. Body we changes were normal.			
Effects in Organs	There were no rema	rkable necropsy findings.			

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY MB Research Laboratories (1995a)

7.2. Irritation – skin

TEST SUBSTANCE Dynax DX 5011 (30% notified polymer)

METHOD 40 CFR 158 Guideline Reference #81-5

Species/Strain Rabbit/New Zealand White

Number of Animals 6 females

Vehicle Test substance administered as supplied.

Observation Period 72 hours Type of Dressing Semi-occlusive.

Remarks - Method No significant protocol deviations from OECD TG 404 Acute Dermal

Irritation/Corrosion.

RESULTS

Lesion	Mean Score*	Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
Erythema/Eschar	0.11	1	< 48 hours	0
Oedema	0	0	n/a	0

^{*}Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

cleared within 48 hours

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY MB Research Laboratories (1995b)

7.3. Irritation – eye

TEST SUBSTANCE Dynax DX 5011 (30% notified polymer)

METHOD 40 CFR 158 Guideline Reference #81-4

Species/Strain Rabbit/New Zealand White

Number of Animals 6 males Observation Period 72 hours

Remarks - Method No significant protocol deviations from OECD TG 405 Acute Eye

Irritation/Corrosion.

RESULTS

Lesion	Mean Score*	Maximum	Maximum Duration	Maximum Value at End
		Value	of Any Effect	of Observation Period
Conjunctiva: redness	0	2	< 24 hours	0
Conjunctiva: chemosis	0	2	< 24 hours	0
Conjunctiva: discharge	0	2	< 24 hours	0
Corneal opacity	0	0	n/a	0
Iridial inflammation	0	0	n/a	0

^{*}Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results Four of six eyes appeared normal at each observation period.

Conjunctival irritation, noted in 2/6 eyes, cleared by day 1. Abnormal physical signs of diarrhoea and soiling of the anogenital area were noted

during the study.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY MB Research Laboratories (1995c)

7.4. Toxicity profile of potential breakdown products

No degradation products or pathways of the notified polymer have been identified, perfluorocarboxylic acids and fluorotelomer sulfonates are potential breakdown products (see section 8.1. for more details).

Perfluorocarboxylic acids

The notified polymer has the potential to degrade to perfluorohexanoic acid (PFHxA) and perfluoroheptanoic acid (PFHPA) and trace amounts of perfluorooctanoic acid (PFOA) and perfluorononanoic acid (PFNA) (NICNAS, 2006). In the absence of toxicological information for these breakdown products hazard information for PFOA will be used (NICNAS, 2006). The primary health effects of concern for PFOA are liver toxicity and developmental toxicity. A summary of the conclusions from the US EPA preliminary risk assessment of the developmental toxicity associated with exposure to PFOA and its salts (US EPA, 2003) are provided below. Other systemic effects such as hepatooxic effects and carcinogenicity associated with PFOA are not covered by this risk assessment. A detailed review by NICNAS of the source data for this summary has not been conducted, the summary has been provided to give a brief overview of the toxicity profile of the potential breakdown products.

Pharmacokinetics

Little information is available concerning the pharmacokinetics of PFOA. An ongoing half-life study in retired workers suggests a serum half-life of years. Animal studies have shown that the ammonium salt of PFOA (APFO) is well absorbed following oral and inhalation exposure, and to a lesser extent following dermal

exposure. PFOA distributes primarily to the liver, plasma and kidney. It does not partition to the lipid fraction or adipose tissue. PFOA is not metabolized and there is evidence of enterohepatic circulation of the compound. The urine is the major route of excretion of PFOA in the female rat, while the urine and faeces are both main routes of excretion in male rats.

Developmental effects

In a two-generation reproductive toxicity study of APFO, the LOAEL for developmental effects from the study was 10 mg/kg/day and the NOAEL was 3 mg/kg/day based on effects in the F1 males. The endpoints that were considered relevant for assessing developmental toxicity included the significant reduction in F1 mean body weight during lactation (sexes combined). In addition, for F1 females, postweaning mortality and delayed sexual maturation were noted at 30 mg/kg/day APFO; the NOAEL for developmental effects for F1 females was 10 mg/kg/day. Postweaning mortality, delayed sexual maturation and a significant reduction in postweaning body weights were noted in F1 males at 30 mg/kg/day, and a significant reduction in postweaning body weight was noted at 10 mg/kg/day. It is not known whether the effects on postweaning mortality, body weight, or age of sexual maturation were due to prenatal exposures, lactational exposures, postweaning exposures, or a combination of one or more of these exposure periods.

Perfluorotelomer sulfonates

The following summary of toxicity data for a product 'Zonyl FS-62' containing the potential breakdown product 6:2 fluorotelomer sulfonate was provided by the notifier (Dupont, 2004). A detailed review by NICNAS of the source data for this summary has not been conducted, the summary has been provided to give a brief overview of the toxicity profile of the potential breakdown products.

Endpoint	Assessment Conclusion	Comment
Rat, acute oral	Low toxicity, Approximate lethal dose 2300 mg/kg in males	Doses up to 3400 mg/kg
Rat, repeat dose oral toxicity 28 days.	NOEL 15 mg/kg bw/day (males/females)	Doses were 0, 15, 50 and 150 mg/kg bw/day. No mortality seen; target kidney
Genotoxicity – bacterial reverse mutation	non mutagenic	
Genotoxicity – in vivo chromosome aberration test	No evidence of chromosome damage or bone marrow cell toxicity	Treated by intraperitoneal injection at doses of 0, 50, 100 and 200 mg/kg bw.
Developmental and reproductive effects via inhalation	NOEL 25 ppm	Inhalation concentrations were 0, 25, 125 and 600 ppm. No fetal resorptions or external malformations at any dose.

The presentation states that Zonyl FS-62 is largely F(CF2CF2)nCH2CH2SO3X, where n=3, and X is a counterion. The following composition information was taken from an MSDS for 'Zonyl FS-62' (Dupont, 2000):

Perfluorohexylethylsulfonic Acid (27619-97-2) 12-18 % Ammonium Perfluorohexylethylsulfonate (59587-39-2) 6-9 % Perfluorooctylethylsulphonic Acid (39108-34-4) 1-3 WT% Ammoniumperfluorooctylethylsulphonate (149724-40-3) 1-3 WT% Acetic Acid (64-19-7) 1-3 % Water (7732-18-5) 60-85 %

8. ENVIRONMENT

8.1. Environmental fate

Environmental fate data for the notified polymer was not available.

The molecule has a perfluoroalkyl side chain (99% CF₃(CF₂)₅-CH₂CH₂-) attached through a thio functional group which is linked by the alkyl amide functional group. In the environment the notified polymer could undergo cleavage at the R-S-R₁ bond (or the oxidized sulphoxide or sulphone) and at the amide bond under both biotic and abiotic conditions. Depending on where the cleavage takes place a mixture of different products or a dominant product could be formed. In the case of cleavage at the R-S-R₁ bond these include perfluoroalkylCH₂CH₂SH (or the oxidized forms), perfluoroalkylCH₂CH₂X (where X may be OH – ie a fluorotelomer alcohol or perhaps another nucleophile), perfluoroalkylCH=CH₂ or perfluoroalkylCH₂CH₃ (if formed under reducing conditions). With cleavage at the amide bond, perfluoroalkylCH₂CH₂-S-CH₂CO₂H and its subsequent degradation products could be formed. Each molecule will have different reactivity, but their environmental fate will be determined by the perfluorinated side chain.

Literature evidence by Schultz et al (2004) has suggested that the ultimate breakdown products of $C_6F_{13}CH_2CH_2SCH_2CH_2CONHC(CH_3)_2CH_2SO_3^-$ are fluorotelomer sulfonates $C_6F_{13}CH_2CH_2SO_3^-$. The fluorotelomer sulfonates were detected at sites where the polymer had been used as a fluorosurfactant in AFFF fire fighting foam. the high levels found particularly at one site, would seem to rule out the presence of fluorotelomer sulfonates due to impurities in the parent polymer. The notifier therefore expects the notified polymer to similarly degrade to $C_6F_{13}CH_2CH_2SO_3^-$, which is one of the possibilities mentioned above.

While there are some differences in structure, this pathway is possible. Whether the fluorotelomer sulfonate breaks down further is unclear, noting that perfluoroalkyl carboxylates were also detected at these sites though apparently there was no correlation between their concentrations (Schultz et al; 2004). Interestingly the parent compound could not be detected, possibly due to the need to develop additional analytical methodology.

Evidence to show that this fluorotelomer sulfonate is persistent is its recent detection in sewage effluent at relatively high levels (Shultz et.al, 2006).

The notifier has provided biodegradability data on a product, Forafac 1157 where the backbone is $F(CF_2CF_2)nCH_2CH_2SO_2Y$, where n=3 predominantly, and Y are various organic functional groups or appendages. A summary the inherent biodegradability for Forafac 1157 is as follows (a detailed review of the source data for this summary has not been conducted):

OECD 302B – Modified Zahn-Wellens/EMPA test Main study conclusions

- Analysis by GC/MS: No biodegradation products were observed
- LC/MS Forafac®1157: No detectable degradation over the 28-day study was observed
- GC/MS: No fluorinated species were observed in the cartridge samples (gaseous products)
- Fluoride analysis of the samples indicated that no additional fluoride was produced (No C-F degradation)
- Levels measured were at background and did not change
- Test substance was not toxic to the microorganism and the system remained aerobic

The above seem to be the only results available, though tests of Forafac 1157 on soil samples under aerobic and anaerobic conditions are said to be in progress. This is also said to show no degradation.

Whatever the initial products of degradation, noting that a significant proportion of the notified polymer consists of the perfluoroalkyl group monomer, perfluoroalkyl containing functional groups such as sulphoxide, alcohol, carboxylates or similar products could be slowly formed. Recent literature indicates that fluorotelomer alcohols (FTOHs, a possible degradation product) are both sufficiently volatile (Stock *et al*, 2004a) and stable enough (Ellis *et al*, 2003) to be transported for long distances downwind from their points of emission. Stock *et al* (2004b) have recently reported that FTOHs are widely distributed throughout the North American troposphere. Most recently Wallington *et al* (2006) have demonstrated conversion of perfluorotelomer alcohols to PFOA and other perfluorocarboxylic acids. Given the persistence and lack of degradation pathways for the perfluorocarboxylic acids, it is reasonable to assume that, over prolonged times, it is possible for the initial degradation products to eventually degrade to perfluorocarboxylic acids. The expected end product from the

6:2 FTOH and related substances likely to be released from the notified polymer are PFHxA and PFHpA. The notified polymer contains 1% CF₃(CF₂)₇-CH₂CH₂- perfluoroalkyl side chain which may result in the release of trace amounts of PFOA and PFNA. Based on polymer composition information provided and assuming that the entire quantity imported per annum is released in that year, the estimated amount of perfluorocarboxylic acid that could be released per annum is 175 kg.

Perfluorinated compounds are the subject of reviews by the US EPA and the OECD and NICNAS has issued alerts for perfluorocatanyl sulfonate (PFOS) and perfluorocatanoate (PFOA) in Australia. Perfluorinated compounds are known to be persistent and some of them are bioaccumulating.

While perfluoroalkylcarboxylic acids have been detected in arctic seals, whales and birds, these have largely been the 9-15 carbon chain length acids. PFHxA and PFHpA have either not to date been found in biota or have not been found to be a major contaminant. PFOA has also not been found to be a major contaminant. The lack of detection of the lower homologues is attributed by Verreault *et al* (2005) to "a comparable high depuration and excretion rate, and perhaps also low bioavailablity, bioaccumulation potential and exposure, as a result of low environmental concentrations". Similarly the possible degradation product C₆F₁₃CH₂CH₂SO₃- may not bioaccumulate.

A summary of a bioconcentration study for Forafac 1157 is as follows (a detailed review of the source data for this summary has not been conducted):

Endpoint	Results	Comment
Bioconcentration in Carp,	For main active ingredient	Whole fish test
Cyprinus carpio, via OECD 305	> 97.5% of substance:	
	At 5 μ g/L, BCF = < 5.1	
	At 50 μ g/L, BCF = < 51	

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Dynax DX 5011

METHOD EPS 1/RM/13 2nd Edition Dec.2000.

Species Fingerling Rainbow Trout

Exposure Period 96 h Auxiliary Solvent Well water

Water Hardness Not given

Analytical Monitoring

Remarks – Method Temperature (°C) 14.0-16.0, DO (mg/L) 9.3-9.6, pH 7.4-8.0, specific conductivity (ms/cm):0.21-0.83.Only a one page tabulated summary was

available with only initial and final values. Stephen's Binomial test was

used to calculate the LC50.

RESULTS

Concentration mg/L		Number of Fish		Ì	Mortalit	y	
Nominal	Actual	•	1 h	24 h	48 h	72 h	96 h
50000		10					10
25000		10					10
12500		10					0
6250		10					0
3125		10					0
Ctl		10					0

LC50 17678 mg/L at 96 h (95% C.L. 25000-50000 mg/L)

NOEC 25000 mg/L at 96 h LOEC 50000 mg/L at 96 h

Remarks – Results At 50,000 mg/L 10 fish were dead by 22 h whereas 7 fish were dead at

this time with 3 stressed at 25,000 mg/L. After 47 h all the fish were dead

at 25,000 mg/L.

CONCLUSION The notified polymer is not harmful to Rainbow trout

TEST FACILITY Harris Industrial Testing Service Ltd (2006)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Dynax DX 5011

METHOD EPS 1/RM/14 2nd Edition Dec. 2000.

Species Daphnia magna

Exposure Period 48 h
Auxiliary Solvent Well water
Water Hardness 105 mg CaCO₃/L

Analytical Monitoring

Remarks - Method Temperature: (°C) 19.5-21.5, DO (mg/L) 8.6-9.2, pH 7.3-8.2 specific

conductivity (ms/cm): 0.2-1.46. Only a one page tabulated summary was available with only initial and final values. Toxstat 3.5 Probit method was

used to calculate EC50.

RESULTS

Concentration mg/L		Concentration mg/L Number of D. magna		nmobilised
Nominal	Actual		24 h	48 h
100,000		10		10
50,000		10		10
25,000		10		10
12,500		10		10
6250		10		10
3125		10		7
1600		10		3
800		10		0
Control		10		0

LC50 2236 mg/L at 48 h (95% confidence limit 1728-2894 mg/L)

NOEC 1728 mg/L at 48 h LOEC 2894 mg/L at 48 h

Remarks - Results After 48 hours 3 Daphnia were sluggish at 3125 mg/L and 1 was

immobile at 1600 mg/L

CONCLUSION The notified polymer is not harmful to *Daphnia magna*.

TEST FACILITY Harris Industrial Testing Service Ltd (2006)

8.2.3. Summary of Ecotoxicity for two fluorotelomer sulfonates

The notifier has also provided some toxicity data on two fluorotelomer sulfonates Forafac 1157 and Zonyl FS-62 (identity details are provided in sections 7.4 and 8.1). A detailed review by NICNAS of the source data for this summary has not been conducted.

Forafac 1157

Endpoint	Results	Comment
Acute fish toxicity with killfish,	96 h $LC_{50} > 35 \text{ mg/L}$	No greater than
Oryzias latipes		low-moderate toxicity
Invertebrates toxicity	$24 \text{ h EC}_{50} = 1.5-2 \text{ g/L}$	Low toxicity
with Daphnia magna	_	•

Zonyl FS-62

Endpoint	Results	Comment
Acute fish toxicity	$96 \text{ h LC}_{50} = 316 \text{ mg/L}$	Slight toxicity
With Fathead minnow,		
Pimephalus promelas		
Acute fish toxicity	96 h LC $_{50} > 94.1 \text{ mg/L}$	Slight toxicity
With Rainbow trout,		
Oncorhychus mykiss		
Invertebrate toxicity with	$48 \text{ h EC}_{50} > 85.9 \text{ mg/L}$	Slight toxicity
Daphnia magna		
Green Algae toxicity with	$72 \text{ h } E_b C_{50} \text{ and } E_r C_{50}$	Slight toxicity
Seleanstrum capricornutum	> 199 mg/L	

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be primarily used as a stabilizer in fire fighting foam to fight fires that have flammable or combustible liquids as a fuel source. The main environmental exposure of the polymer will occur when it is used in fire-fighting training or use conditions. In the former case, conditions will be controlled, with bunding and traps preventing the release of both chemical and fuel, to the environment. Actual use may occur in areas where bunding or traps are used to prevent the release of the flammable or combustible liquids to the environment, such as storage areas or refineries or in uncontrolled situations such as tankers carrying flammable liquids.

The notifier indicated that for a fire in a flammable liquid store, the water/foam is contained and may be released to the sewer if approval is granted from the local water authority. The concentration of the polymer leaving the foam-forming nozzle is less than 3000 ppm (0.3%) and may be as low as 300 ppm (0.03%). The release of the water/foam mixture to a metropolitan sewer will lead to a concentration in receiving waters of less than 30 ppm (assuming a 10X dilution on entering the sewer with a further 10X dilution on leaving the sewage treatment plant and no adsorption or degradation of the polymer). Lower dilution factors are likely in country areas and a maximum concentration of 300 ppm in receiving waters is possible, depending on sewage volume, flow of receiving water and concentration of the foam.

Should the chemical be used in fire-fighting on tankers or trucks carrying flammable liquids, there is potential for release of the chemical to the environment.

A realistic, worst case situation would, be an accident involving a fuel tanker, with run-off from the accident entering a lentic (still) body of water with significant wild-life. Information provided indicates that up to 12000 L of water/foam may be needed to control the fire if a fuel load catches alight. There is also the possibility 4000 L may be needed to cool the tanker and 4000 L to control any fire associated with the tanker.

In the situation where the fluid load catches alight, the total amount of the polymer applied would be about 48 L ($0.3\% \times 16 [12 + 4] \times 10^3 L$). The density of 1.14 g/mL, gives 54.72 kg of the notified polymer potentially requiring dispersal. Some of this will be combusted/pyrolysed in the fire leaving the fluorinated residues, although the amount lost is expected to be small. Any notified polymer left would be associated with run-off from the accident site. Run-off into a pond of about 1 ha surface area and an average depth of 15 cm (volume of about 1.5 x $10^6 L$) would give a maximum concentration of 36.4 mg/L.

The above worst case estimate is an order of magnitude below the lowest measured acute effect. However, this estimate makes a number of assumptions.

One important assumption is that all of the polymer applied to the fire would be associated with run-off from the accident site. The run-off may not all flow into the lake, with some of the run-off adsorbed by road surfaces and soil surrounding the accident site. Where possible, standard operating procedures of Australian fire brigades should operate to minimise run-off by containment and removal. Also, some losses might be expected through adsorption to sediment and particulate matter because of the surface activity. On entering the surface waters, some of the chemical may partition to sediment due to its expected surface activity.

Another assumption is that there would be uniform and complete mixing of the chemical in the receiving surface water. This may not occur, and would lead to localised points (e.g. entry point of the run-off) where the concentration of the polymer would be elevated. This could have localised impacts on invertebrate and algal species, but the effect on fish might be limited as they have the greater ability to avoid contaminated sites. Additionally, the situations in which release to surface waters might occur are likely to be rare. Several factors would have to be met for the chemical to have a major environmental impact. These are:

- 1.) A major accident involving a flammable liquid tanker in which the load would catch alight;
- 2.) The run-off from the fire-fighting escaping to a lentic surface water; and
- 3.) The concentration of the polymer remaining near those affecting aquatic organisms for a few days.

As none of these potentially mitigated circumstances can be quantified, for example there are no soil adsorption data, it is not possible to estimate a refined PEC.

9.1.2. Environment – effects assessment

Under the proposed use pattern as a fire fighting agent, practically all the notified polymer could potentially in run-off into the water compartment. The notified polymer is said to be highly water soluble and is potentially amphoteric where its cationic form may be highly toxic to aquatic organisms. However, the ecotoxicity studies conducted on Rainbow trout and *Daphnia magna* indicates that the notified polymer is expected to be practically non toxic to these organisms.

The following table is a summary of the available data for the notified polymer.

Test	Species	Results
Acute Toxicity	Rainbow trout	LC50 (96 h) = 17,678 mg/L (nominal)
Fish	Oncorhynchus mykiss	
Acute Immobilisation Daphnia	Daphnia magna	LC50 (48 h) = 2236 mg/L (nominal)

The notified polymer is practically non toxic to Rainbow trout and *Daphnia magna*. The Predicted No Effect Concentration (PNEC) is derived from the EC50 of *Daphnia magna* divided by an uncertainty safety factor of 1000 is calculated as 2.236 mg/L. This factor is used as there are results for only two trophic levels and toxicity to algae may be expected to be highest.(Nabholz et al; 1993)

9.1.3. Environment – risk characterisation

The worst case PEC/PNEC calculation for a fuel tanker fire gives a risk quotient of 16.3 (36.4/2.236) which indicates a potential unacceptable risk to the environment. Based on the worst case for a country liquid store fire estimated maximum concentration of 300 ppm in country receiving waters above, the Q of 134 also indicates a potential unacceptable risk.

As noted above it is difficult to further mitigate this risk even semi-quantitatively. It is acknowledged this would be a rare event and in most cases, the relevant authorities would erect bunding to prevent releases in this situation. This all demonstrates the need for further information in areas such as algae toxicity (which would allow use of an assessment factor of

100), and adsorption/desorption, and it is recommended this be provided if import levels exceed one tonne per annum. This is particularly relevant in country liquid store fire situations where sewage and receiving water flow may be limited.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage

Transport and storage workers are not expected to be exposed to the notified polymer except in the event of an accident.

Formulation of foam fire fighting concentrate

Although dermal and possibly ocular exposure to the notified polymer (up to 44%) may occur during formulation activities exposure is limited due to the largely automated process, the presence of local exhaust ventilation and the use of PPE.

Following formulation, although exposure to the notified polymer could occur if a container overfills, during sample and analysis and during maintenance and cleaning of equipment, exposure is expected to be low due to the incidental contact expected and the low concentration of the notified polymer (0.3%).

End Use

Although exposure to the notified polymer could occur when transferring the fire fighting concentrate to smaller containers or when filling the cartridge with the fire fighting concentrate exposure is expected to be low due to expected volumes involved and the low concentration of the notified polymer (0.3%).

Prolonged dermal and inhalation exposure to the notified polymer and thermal decomposition products could occur during the application of the foam spray. Exposure would be limited by the low concentration of the notified polymer (0.03-0.3%) in the foam and the expected wearing of extensive PPE.

9.2.2. Public health – exposure assessment

The formulated fire fighting foam is for industrial use only and as such negligible direct public exposure to the notified polymer is expected.

Once released to the environment the notified polymer will be subject to biotic and abiotic mechanisms which will overtime, breakdown the polymer. No degradation products or pathways of the notified polymer have been identified. Perfluorocarboxylic acids and fluorotelomer sulfonates are potential breakdown products (see section 8.1. for more details). The pathways of human exposure to the perfluorocarboxylic acid PFOA are unknown (US EPA, 2003) however as PFOA has been detected in the serum on non-occupational populations it cannot be ruled out that the public could be exposed to low levels of the notified polymer's breakdown products via environmental routes.

9.2.3. Human health – effects assessment

Toxicokinetics, metabolism and distribution.

The notified polymer has a high molecular weight (> 1000) and as such is not expected to cross biological membranes. However low molecular weight species of the notified polymer may be bioavailable.

Acute toxicity.

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

Irritation and Sensitisation.

Based on studies in rabbits the notified polymer is considered to be slightly-irritating to skin and eyes.

Hazard classification for health effects.

Based on the available data, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

Health effects of potential breakdown products

Once released to the environment the notified polymer will be subject to biotic and abiotic mechanisms which will overtime, breakdown the polymer. No degradation products or pathways of the notified polymer have been identified. Perfluorocarboxylic acids and fluorotelomer sulfonates are potential breakdown products (see section 8.1. for more details).

Based on the behaviour of PFOA, the potential breakdown products perfluorohexanoic acid/perfluoroheptanoic acid will bind to protein, distribute primarily to the liver, plasma and kidney and have a long half life in humans (US EPA, 2003). Based on its structure the potential breakdown product fluorotelomer sulfonate may also bind to proteins.

In the absence of data on the potential breakdown products perfluorohexanoic acid/perfluoroheptanoic acid, it is considered that these breakdown products could have a number of systemic toxic effects including developmental effects. Based on the limited data available the potential breakdown product 6:2 fluorotelomer sulfonate is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). However, it is noted that the full toxicological profile of this breakdown product has not been investigated e.g. carcinogenicity.

9.2.4. Occupational health and safety – risk characterisation

Formulation of foam fire fighting concentrate

The risk to workers involved in formulation activities is considered to be low due to the limited exposure predicted and the expected low toxicity of the notified polymer itself. The notified polymer is a slight skin and eye irritant and as such workers involved in the transfer of the notified polymer as introduced (concentration 44%) should wear gloves and eye protection to minimise the risk of an irritation effect.

End Use

The risk to workers transferring the fire fighting concentrate to smaller containers or filling the cartridge with the fire fighting concentrate exposure is expected to be low due to the limited exposure predicted and the expected low toxicity of the notified polymer itself. The risk of irritation effects is considered to be low due to the low concentration of the notified polymer (0.3%).

Prolonged dermal and inhalation exposure could occur to the notified polymer and thermal decomposition products during the application of the foam spray. The risk of adverse effects from exposure to toxic decomposition products would be limited by the low concentrations and the expected wearing of extensive PPE.

9.2.5. Public health – risk characterisation

The risk to the public from direct exposure to the notified polymer is considered to be negligible based on the negligible exposure predicted and the expected low toxicity of the notified polymer itself

Although indirect exposure of the general population to the polymers degradation products is expected to be low, long-term potential adverse health effects cannot be ruled out. Although, the pathways of human exposure are unknown limiting the release of the notified polymer into the environment would limit the risk of long-tem potential health effects. Therefore, it is recommended that the notified polymer only be used in essential situations such as fighting real fires, where no suitable and less hazardous alternatives are available.

9.3. Comparison with Persistent Organic Pollutant (POP) Criteria

The Stockholm Convention on Persistent Organic Pollutants (POPs) is a global treaty to protect human health and the environment. The convention contains criteria which address persistence,

bioaccumulation potential, long-range transport and toxicity concerns. These criteria are used to identify substances that may be candidates for inclusion in the treaty. The Stockholm Convention on Persistent Organic Pollutants (POPs) entered into force on 17 May 2004. Australia ratified the Convention on 20 May 2004, and obligations of the POPs Convention entered into force for Australia on 18 August 2004. The Stockholm Convention requires parties under the Convention to take into account POPS characteristics when conducting assessments on new and existing chemicals.

The POPs characteristics of the notified polymer and its theoretical potential breakdown products are as follows:

Persistence

No data has been provided on the biodegradation of the notified polymer. The notifier indicates that the notified polymer will not biodegrade in the environment for which there is some literature or other evidence. Thus the notified polymer would meet the criterion for POP chemicals. Based on data for PFOA and the information provided, the potential breakdown products perfluorohexanoic acid/perfluorohexanoic acid/fe:2 fluorotelomer sulfonate would be persistent in the environment (US EPA, 2003).

Bioaccumulation

No data has been provided on the bioaccumulation of the notified polymer. The notified polymer has a number average molecular weight in excess of 1000 and it is therefore unlikely that it will cross biological membranes and be able to bioaccumulate. The notified polymer does not meet this criterion for POP chemicals. The potential breakdown products may bioaccumulate however there is evidence that the bioaccumulation potential appears to be proportional to the length of the chain.

Potential for long-range environmental transport

The low volatility and bioaccumulation potential of the notified polymer would suggest that it is unlikely to undergo long range environmental transport through air, water or migratory species. Hence the notified polymer would not meet this criterion for a POP chemical. The potential breakdown products are expected to have some potential for long range environmental transport.

Adverse environmental effects

Ecotoxicity data provided for the notified polymer indicates that it is non toxic to fish and Daphnia. However, until the potential higher toxicity to algae has been clarified it is not possible to rule the notified polymer does not meet this criterion for POP chemicals. Note that the potential breakdown product $C_6F_{13}CH_2CH_2SO_3^-$ is at most slightly toxic to fish, daphnia and algae.

Adverse health effects

No specific criteria for health endpoints are provided, however based on the available toxicity data the notified polymer itself is not expected to cause serious damage to health by prolonged exposure. Therefore, the notified polymer are not considered to meet the toxicity criteria for POP chemicals. The potential breakdown products may cause adverse health effects including developmental effects or prolonged exposure effects. Therefore, although sufficient information is not available, the notified polymer's potential breakdown product may meet the toxicity criteria for POP chemicals.

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*.

and

As a comparison only, the notified polymer is not classified as hazardous using the Globally

Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the notified polymer may pose an unacceptable risk to the environment. However, it is acknowledged this would be a rare event and in most cases the relevant authorities would erect bunding to prevent releases in this situation. Breakdown products of the notified polymer are persistent and may build-up and be distributed widely in the environment.

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 Negligible Concern to public health due to direct exposure to the notified polymer. Although indirect exposure of the general population to the polymers degradation products is expected to be low, long-term potential adverse health effects cannot be ruled out.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is 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 product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

AICS

- When the notified polymer is added to the Australian Inventory of Chemical Substances (AICS), it should be annotated with the following condition of use:
 - For use only as a class B fire fighting foam for which no suitable and less hazardous alternatives are available.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
 - Avoid contact with skin and eyes
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Impervious gloves
 - Eye protection

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer/thermal decomposition products during fire fighting activities.
 - Breathing apparatus

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.

Public Health

- The following measures should be taken to minimise public exposure to the notified polymer and its potential breakdown products:
 - Use of the fire fighting foam concentrate containing the notified polymer should be restricted to only essential uses, for which no suitable and less hazardous alternatives are available.
 - Fire fighting foam concentrate containing the notified polymer should not be used for fire training purposes to limit environmental release.

Environment

The following control measures should be implemented to minimise environmental exposure during fire fighting activities with foam concentrate containing the notified polymer:

- Minimise run-off by containment (e.g. bunding) and removal
- If any polymer does reach natural waters, ensure sufficient dilution with water occurs (up to 100 fold the volume of the lost foam may be needed if this occurs in a country sewer).

Disposal

• The notified polymer should be disposed of in accordance with the relevant local, state and federal government regulations and undertaken by a registered chemical disposal company. Disposal to landfill is acceptable.

Emergency procedures

- Spills/release of the notified polymer should be handled by containing the spill / stopping the leak if possible (for example, turn the leaking containers leak-side up) or by bunding for a large spill.
- Place inert absorbent material such as vermiculite, sand or dirt onto spilled material and recover by vacuuming, shovelling or sweeping and place into a suitable labelled container for disposal.
- Wash the floor with plenty of water and recover the cleaning water for disposal.
- If large quantities of the polymer enter waterways, contact the Environmental Protection Authority and the local waste management authority

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if

- the importation volume exceeds one tonne per annum notified polymer; or
- the polymer has a number-average molecular weight of less than 1000; or
- further information becomes available about the breakdown of the polymer to perfluoroalkyl moieties and/or their toxicity.

or

- (2) Under Section 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. If the importation volume exceeds one tonne per annum a result for toxicity to algae and information on potential adsorption to soil should be provided. Data on the biodegradability of the notified polymer similar to that discussed for Forafac 1157 in section 8.1 should also be provided.

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