File No: LTD/1945

December 2016

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

## **PUBLIC REPORT**

2-Propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl-, chloride (1:1), polymer with 2-propenamide, decarbonylated, hydrochlorides

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, 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 Energy.

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**Director NICNAS** 

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## **SUMMARY**

The following details will be published in the NICNAS Chemical Gazette:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1945	SNF Australia Pty Ltd	2-Propen-1-aminium, <i>N</i> , <i>N</i> -dimethyl- <i>N</i> -2-propen-1-yl-,	ND*	≤ 425 tonnes per annum	An additive in paper
	,	chloride (1:1), polymer with 2- propenamide, decarbonylated, hydrochlorides		•	manufacturing

<sup>\*</sup>ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

#### **Hazard classification**

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	Hazard statement	
Acute Category 2	H401 – Toxic to aquatic life	
Chronic Category 2	H411 – Toxic to aquatic life with long lasting effects	

#### Human health risk assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is considered to pose/not considered to pose an unreasonable risk to public health.

#### **Environmental risk assessment**

On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment

#### Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - Closed and automated equipment
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid skin and eye contact
  - Avoid generation of aerosols

• A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:

- Impervious gloves
- Safety glasses
- Coveralls
- Respirator if ventilation is inadequate

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

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

## Disposal

• Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

## Emergency procedures

• Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

#### **Regulatory Obligations**

## Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS 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 polymer has a number-average molecular weight of less than 1,000;

or

- (2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from an additive in paper manufacturing, or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

## (Material) Safety Data Sheet

The (M)SDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

## **ASSESSMENT DETAILS**

#### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

SNF (Australia) Pty Ltd (ABN: 32 050 056 267)

98 Broderick Road LARA VIC 3212

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn  $\geq$  1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: molecular and structural formulae, molecular weight, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and manufacture/import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada and USA

#### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

FLORET HF 31 (containing the notified polymer at < 10% concentration)

CAS NUMBER

913068-94-7

CHEMICAL NAME

2-Propen-1-aminium, *N,N*-dimethyl-*N*-2-propen-1-yl-, chloride (1:1), polymer with 2-propenamide, decarbonylated, hydrochlorides

OTHER NAME(S)

Copolymer of vinylamine and dimethyldiallylammonium chloride

MOLECULAR WEIGHT

> 10,000 Da

ANALYTICAL DATA

Reference GPC spectra was provided.

## 3. COMPOSITION

DEGREE OF PURITY

> 75%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Loss of monomers is not expected during storage or normal conditions of use.

DEGRADATION PRODUCTS

The degradation of the polymer from combustion leads to the formation of oxides of carbon, oxides of nitrogen and hydrogen chloride.

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish viscous liquid<sup>1</sup>

Property	Value	Data Source/Justification
Boiling Point	> 100 °C at 101.3 kPa	(M)SDS <sup>1</sup> (the notified polymer is
		expected to decompose at $> 150$ °C).
Relative Density	$1,050-1,250 \text{ kg/m}^3$	$(M)SDS^1$
Vapour Pressure	2.3 kPa at 20 °C	$(M)SDS^1$
Water Solubility	Miscible	(M)SDS
Hydrolysis as a Function of	$t_{1/2} > 240$ days at 20 °C at pH 4	Measured
pН	$t_{1/2} > 365$ days at 25 °C at pH 7	
	$t_{1/2} > 365$ days at 25 °C at pH 9	
Partition Coefficient (n-octanol/water)	log Pow = -2	Measured
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment
1		based on high molecular weight and
		positive charges
Dissociation Constant	Not determined	The notified polymer is a salt and is
		expected to be ionised at the
		environmental pH range of 4–9
Flash Point	Not determined	(M)SDS <sup>1</sup> (the notified polymer is
		imported in aqueous solution and is not
		expected to flash).
Flammability	Not determined	(M)SDS <sup>1</sup> (the notified polymer is
		imported in aqueous solution and is not
		expected to be flammable).
Autoignition Temperature	Not determined	$(M)SDS^1$
Explosive Properties	Not determined	The notified polymer contains no
		functional groups that would imply
		explosive properties.
Oxidising Properties	Not determined	The notified polymer contains no
		functional groups that would imply
		oxidising properties.

<sup>&</sup>lt;sup>1</sup> Polymer aqueous solution (at < 10% concentration)

## DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

#### Reactivity

The notified polymer is expected to be stable under normal conditions of use. Depolymerisation, hydrolysis, photodegradation and thermal degradation are not expected under normal conditions of use.

## Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

## 5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported into Australia as an aqueous solution at < 10% concentration in 1,000 L intermediate bulk containers (IBCs) or 5,000 L Flexitanks.

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

Year	1	2	3	4	5
Tonnes	10–100	10–100	100-425	100-425	100-425

PORT OF ENTRY Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS SNF Australia Pty Ltd

#### TRANSPORTATION AND PACKAGING

The imported containers containing the notified polymer at < 10% concentration will be transported to the notifier's warehouse then distributed to the customer sites for use. There will be no reformulation or repackaging in Australia.

#### USE

The notified polymer will be used as a processing aid in paper manufacturing. It will be used in the manufacture of paperboard which some may have food contact uses.

#### OPERATION DESCRIPTION

There will be no reformulation or repackaging in Australia. At customer sites (paper manufacture), the imported products containing the notified polymer will be pumped via pipeline (flexible or rigid) to a dilution device. The notified polymer may be diluted with water prior to addition into the thick stock system. Typically, the dilution is done via a static in-line mixer. The notified polymer will be added to paper at a rate up to 5 kg/tonne (0.5%) of finished paper on a dry weight basis.

#### 6. HUMAN HEALTH IMPLICATIONS

#### **6.1.** Exposure Assessment

## 6.1.1. Occupational Exposure

#### CATEGORY OF WORKERS

Category of Worker	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport and warehouse workers	2–6	12–30
Process workers	8	50–100

## EXPOSURE DETAILS

Transport and warehouse workers may come into contact with the notified polymer (at < 10% concentration) only in the event of accident.

Dermal, ocular and inhalation exposure of the process workers to the notified polymer at < 10% concentration may occur during transfer operations, connecting and disconnection of hoses/transfer lines from import containers to the machine reservoir tank, during cleaning up and during machine maintenance operations. Exposure to the notified polymer at other operations is expected to be negligible given the paper manufacturing process will be largely automated and enclosed. Exposure to the notified polymer is expected to be minimised by the use of the PPE (including overalls, safety boots, safety glasses, impervious gloves and hard hat and respirator if ventilation is inadequate).

#### **6.1.2.** Public Exposure

The imported solution containing the notified polymer will only be used for industrial applications and will not be sold to the general public. The public may come into contact with finished paper products containing the notified polymer (at up to 0.5% concentration). However, in this finished form the notified polymer will be relatively immobile as it is strongly adsorbed onto paper fibres. Exposure to the notified polymer in this form is not considered to be significant.

#### 6.2. Human Health Effects Assessment

An acute oral toxicity study on the product containing the notified polymer indicated an LD50 of > 2,000 mg/kg bw and is summarised in the following table. For full details of the study, refer to Appendix B.

 Endpoint	Result and Assessment Conclusion
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity

Considering its high molecular weight (>10,000 Da), high water solubility and low partition coefficient, the notified polymer is not expected to be absorbed by the dermal route.

#### Health hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

#### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety

There is limited information available on the hazards of the notified polymer. The highest potential for worker exposure to the product containing the notified polymer at < 10% would occur during the paper manufacturing processes including exposure from spills and drips which may occur during handling, transfer operations, connection and disconnection of hoses from the import containers to the paper manufacturing system. Potential inhalation exposure may also occur during these processes; however, the risk is expected to be low as water-soluble high molecular weight polymers are not expected to exhibit lung toxicity because they are usually rapidly cleared by the respiratory tract and not cause lung overloading effects. The use of enclosed and automated systems, safe work practices and PPE will further reduce worker exposure.

Therefore, provided that adequate control measures are in place to minimise worker exposure, the risk to workers from the use of the notified polymer is not considered to be unreasonable.

#### 6.3.2. Public Health

The notified polymer will not be available to the general public. Public exposure is not expected during transport or use of the polymer in the manufacturing of paper. Dermal exposure of the public can occur to the paper containing the notified polymer at < 0.5%. However, in finished paper the notified polymer is expected to be bound within the paper matrix, and not likely to transfer or leach.

Therefore, the risk to the public health from exposure to paper containing the notified polymer is not considered to be unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

## 7.1. Environmental Exposure & Fate Assessment

## 7.1.1. Environmental Exposure

#### RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia and releases of the notified polymer to the environment are not expected from manufacture and reformulation. Accidental spills of the notified polymer during import, transport or storage are expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations. Small amounts of the notified polymer may remain as residues in empty containers, which are expected to be disposed of in accordance with local regulations.

#### RELEASE OF CHEMICAL FROM USE

The notified polymer will be used by a number of paper mills as a processing aid. The notified polymer will be used in a completely automated system and will be incorporated in the finished paper products. Based on the cationic nature of the notified polymer, strong binding is expected to occur between the polymer and the paper fibres. No significant release of the notified polymer is expected from the aqueous stream during paper manufacturing. Small spills and leaks may occur and these are to be collected using a suitable adsorbent for

disposal to landfill. Some residual polymer may remain in the empty import containers. These will be rinsed and the reinstate will be added to the process stream.

#### RELEASE OF CHEMICAL FROM DISPOSAL

No release is expected to occur from the paper manufacturing process. Any spilt material will be collected using a suitable absorbent and will be disposed to landfill.

It is assumed that 50% of waste paper to which the notified polymer is applied will end up in landfill and the remainder will undergo paper recycling processes. The notified polymer may be desorbed from the paper during the recycling process. As the notified polymer is a cationic polymer with a high molecular weight, it is expected to flocculate out of the aqueous water stream and will be bound to sludge. The sludge will be collected periodically and disposed of to landfill.

#### 7.1.2. Environmental Fate

The notified polymer is not expected to be readily biodegradable based on hydrolysis results and its structure. However, the notified polymer is not expected to bioaccumulate in aquatic life given its molecular weight is greater than 10,000 Da and it contains no significant percentage of low molecular weight constituents.

Most of the notified polymer is expected to share the fate of the paper on which it applied to, to be either disposed of to landfill or subject for paper recycling. The notified polymer disposed of to landfill along with used paper is not expected to be mobile, based on its cationic properties, or bioavailable, based on its high molecular weight. It is assumed that 50% of the waste paper treated with the notified polymer will be recycled domestically. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. Notified polymer discharged to waste water from paper recycling processes is expected to be efficiently removed through adsorption of the cationic polymer to sludge or by flocculation at waste water treatment plants (Boethling and Nabholz, 1997).

Sludge containing the notified polymer will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil or sludge due to its cationic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). The notified polymer is expected to undergo slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

#### 7.1.3. Predicted Environmental Concentration (PEC)

It is assumed that that 50% of the used paper containing the notified polymer would be recycled and be released to sewers. The predicted environmental concentration (PEC) has been calculated assuming 97% removal of the notified polymer from influent during sewage treatment plants (STPs) processes through partitioning to sediment or sludge, which is based on expert information provided by the notifier. As paper recycling is to be processed at facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume. The resultant PEC in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment				
Total Annual Import/Manufactured Volume	425,000	kg/year		
Proportion expected to be released to sewer	50%			
Annual quantity of chemical released to sewer	212,500	kg/year		
Days per year where release occurs	260	days/year		
Daily chemical release:	817.31	kg/day		
Water use	200.0	L/person/day		
Population of Australia (Millions)	22.613	million		
Removal within STP	97%	Mitigation		
Daily effluent production:	4,523	ML		
Dilution Factor – River	1.0			
Dilution Factor – Ocean	10.0			
PEC - River:	5.42	$\mu g/L$		
PEC - Ocean:	0.54	μg/L		

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m³). Using these assumptions, irrigation with a

concentration of  $5.42~\mu g/L$  may potentially result in a soil concentration of approximately  $36.14~\mu g/kg$ . Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 0.18~mg/kg and 0.36~mg/kg, respectively.

#### 7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	Result	Assessment Conclusion
Fish Toxicity (96 h)	LC50 = 1.4  mg/L	Toxic to fish
Daphnia Toxicity (48 h)	EC50 = 50.4  mg/L	Harmful to aquatic invertebrates

Under the Globally Harmonised System of Classification and Labeling of Chemicals (United Nations, 2009) the notified polymer is expected to be toxic to fish. Therefore, the notified polymer is formally classified as 'Acute Category 2; Toxic to aquatic life' under the GHS. Based on the acute toxicity and lack of biodegradation, the notified polymer is formally classified as 'Chronic Category 2; Toxic to aquatic life with long lasting effects' under the GHS.

#### 7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated based on the acute endpoint for fish. A safety factor of 250 was used given acute endpoints for two trophic levels are available and fish appears to be the more sensitive aquatic species affected by the notified polymer.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, 96h)	1.4	mg/L
Assessment Factor	250	
Mitigation Factor	1.00	
PNEC:	5.6	μg/L

## 7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk□Assessment	PEC μg/L	PNEC μg/L	Q
Q – River	5.42	5.6	0.97
Q – Ocean	0.54	5.6	0.1

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its maximum annual importation quantity. The notified polymer is hydrolytically stable and is not expected to rapidly biodegrade based on its structure. Due to the cationicity and high molecular weight, the notified polymer is not expected to be bioaccumulative.

Therefore, on the basis of the PEC/PNEC ratio, the maximum annual importation volume and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

## **APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**

**Hydrolysis as a Function of pH**  $t_{1/2} > 240$  days at 20 °C at pH 4

 $t_{1/2}$  > 365 days at 25 °C at pH 7  $t_{1/2}$  > 365 days at 25 °C at pH 9

Method OECD TG 111 Hydrolysis as a Function of pH.

EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as

a Function of pH.

Remarks At pH 7 and 9, less than 10% of degradation was observed after 5 days at 50 °C,

corresponding half life greater than 1 year at 25 °C.

At pH 4, the observed degradation is not a pseudo-first order reaction and the half-life could not be calculated. A graphical estimation of the half-life > 240 days at 20 °C was provided

in the test.

Test Facility DEFITRACES (2012a)

## Partition Coefficient (n-octanol/water) $\log Pow = -2$

Method OECD TG 107 Partition Coefficient (n-octanol/water).

EC Council Regulation No 440/2008 A.8 Partition Coefficient.

Remarks Flask method.

Test Facility DEFITRACES (2012b)

## **APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**

## **B.1.** Acute toxicity – oral

TEST SUBSTANCE Notified polymer

METHOD OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.

Species/Strain Rat/Female CD(SD)

Vehicle Water

Remarks - Method No deviations from protocol

RESULTS

TEST FACILITY

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw	
1	5F	2,000	2/5
LD50	> 2,000 mg/kg bw		
Signs of Toxicity	Reduced motility, animals and dysp administration of th	noea in 2 animals at e test substance. One anim	tele tone were noted in all 5 minutes after the last all died prematurely 6 hours nee and another animal died
Effects in Organs	All surviving anima	ls gained the expected wei	ght.
Remarks - Results		dings were noted at necrop	
Conclusion	The notified polyme	er is of low toxicity via the	oral route.

LPT (2012)

## **APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS**

## **C.1.** Ecotoxicological Investigations

#### C.2.1. Acute toxicity to fish

TEST SUBSTANCE FLORET HF 31 (product containing the notified polymer at 2.88%

concentration)

METHOD OECD TG 203 Fish, Acute Toxicity Test – Static

Species Oncorhynchus mykiss

Exposure Period 96 hours
Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring None

Remarks – Method A stock solution of 1 g/L in active component was prepared by dissolving

17.36 g of test substance into 500 mL of river water. The test solutions were then prepared by diluting convenient volumes of the stock solution

with river water into the different testing vessels.

The test was conducted in accordance with the test guidelines above, and

in compliance with GLP standards and principles.

#### RESULTS

Concentration mg/L		Number of Fish	Mortality (%)			
Nominal	Measured	•	24 h	48 h	72 h	96 h
0	ND	8	0	0	0	0
1.1	ND	8	0	0	0	0
1.9	ND	8	100	100	100	100
3.3	ND	8	100	100	100	100
5.7	ND	8	100	100	100	100
10	ND	8	100	100	100	100

\*ND: Not determined

LC50 1.4 mg/L at 96 hours. NOEC 1.1 mg/L at 96 hours.

Remarks – Results All validity criteria for the test were satisfied. The results are based on

nominal concentrations of the active component.

CONCLUSION The notified polymer is toxic to fish

TEST FACILITY GRL (2012)

## C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE FLORET HF 31 (product containing the notified polymer at 9.7%

concentration)

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction

Test-Static

Species Daphnia magna
Exposure Period 48 hours

Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring None

Remarks - Method Conducted in accordance with the test guidelines above, and in

compliance with GLP standards and principles.

RESULTS

Concentration mg/L (based on active component)		Number of D. magna	Number Immobilised (%)	
Nominal	Measured		24 h	48 h
0	ND*	20	0	0
4.87	ND	20	0	0
8.91	ND	20	0	5
16.32	ND	20	0	25
29.87	ND	20	0	35
54.65	ND	20	0	50
100	ND	20	15	70

<sup>\*</sup>ND: Not determined

LC50 50.4 mg/L at 48 hours NOEC 16.3 mg/L at 48 hours

Remarks - Results All validity criteria for the test were satisfied. The test concentrations

were 1031, 563.4, 307.9, 168.2, 91.9 and 50.2 mg/L, corresponding to the nominal concentrations of 100, 54.65, 29.87, 16.32, 8.91 and 4.87 mg/L,

respectively, for the active component.

CONCLUSION The notified polymer is harmful to aquatic invertebrates

TEST FACILITY GRL (2011)

## **BIBLIOGRAPHY**

- Boethling, RS & Nabholz VJ (1997) Environmental Assessment of polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1<sup>st</sup> ed. New York, Van Nostrand Reinhold, pp 187-234.
- DEFITRACES (2012a) Abiotic degradation of FLORET HF 31 pH dependent hydrolysis (Study No. 11-919001-007, May 2012) Brindas, France, DEFITRACES (Unpublished report submitted by notifier).
- DEFITRACES (2012b) Octanol / Water Coefficient of FLORET HF 31 (Study No. 11-919001-008, March 2012) Brindas, France, DEFITRACES (Unpublished report submitted by notifier).
- GRL (2011) FLORET HF 31 (2.88%) FLORET HF 31 Acute toxicity (inhibition of mobility to *Dahnia magna* Straus (Study No. 0042/11/A, October 2011) Lacq, France, GROUPEMENT DE RECHERCHES DE LACQ (GRL) (Unpublished report submitted by notifier).
- GRL (2012) FLORET HF 31 (2.88%) Fish (*Oncorhynchus mykiss*), acute toxicity test under static conditions (Study No. 0009/12/A, March 2012) Lacq, France, GROUPEMENT DE RECHERCHES DE LACQ (GRL) (Unpublished report submitted by notifier).
- LPT (2012). Acute Oral Toxicity Study of Floret HF 31 in Rats. LPT Laboratory of Pharmacology and Toxicology GmbH & Co. Hamburg, Germany, Report No. 27475, 15 February 2012, pp 1-39. (Unpublished report provided by the notifier).
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <a href="http://www.unece.org/trans/danger/publi/ghs/ghs\_rev03/03files\_e.html">http://www.unece.org/trans/danger/publi/ghs/ghs\_rev03/03files\_e.html</a> >.