File No: LTD/1559

May 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1-difluoroethene and 1,1,2-trifluoro-2-(trifluoromethoxy)ethene

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 Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

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/1559	Polymers International Australia Pty Ltd DuPont (Australia) Pty Ltd	Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1-difluoroethene and 1,1,2-trifluoro-2-(trifluoromethoxy)ethene	ND*	≤ 20 tonnes per annum	Rubber parts

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
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 not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable short-term risk to the environment. However, due to the potential release and persistence of perfluorinated compounds of varying chain length, the long-term environmental implications are unknown.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- 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 for the 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

- The notified chemical should be disposed of to landfill.

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 polymer 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 polymer, 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 1000;
- new information becomes available on the potential for the notified polymer to degrade, in the long term, to perfluorinated compounds;
- new information becomes available on the long-term environmental implications associated with the potential release and persistence of perfluorinated degradation products of the notified polymer.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from rubber parts, or is likely to change significantly;
- the amount of polymer being introduced has increased from 20 tonnes per annum, 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 notified polymer 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)
Polymers International Australia Pty Ltd (ABN: 92 069 883 825)
17-19 Endeavour Way
Braeside VIC 3195

DuPont (Australia) Pty Ltd (ABN: 59 000 716 469)
7 Eden Park Drive
Macquarie Park NSW 2113

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: structural formula, molecular weight, degree of purity, polymer constituents, residual monomers, use details, import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints except

water solubility

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada, EU, Japan, Korea

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Viton polymer GFLT-600S

CAS NUMBER
56357-87-0

CHEMICAL NAME
Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1-difluoroethene and 1,1,2-trifluoro-2-(trifluoromethoxy)ethene

OTHER NAME(S)
1,1-Difluoroethylene-1,1,2-trifluoro-2-(trifluoromethoxy)ethylene-tetrafluoroethylene polymer

MOLECULAR FORMULA
$(C_3F_6O.C_2H_2F_2.C_2F_4)_x$

MOLECULAR WEIGHT
>10,000 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, GC, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 98%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: white to tan rubber-like sheets

Property	Value	Data Source/Justification
Glass Transition Temperature	-25 °C	Measured
Density	1860 kg/m^3 at 20 °C	SDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight of the notified polymer
Water Solubility	0.0 mg/L at 100 °C	Measured water extractability
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse under environmental conditions (pH 4-9) due to a lack of hydrolysable functionality.
Partition Coefficient (n-octanol/water)	Not determined	Not expected to bioaccumulate based on its high molecular weight and limited bioavailability. The notified polymer is not soluble in water and

		hexane therefore the partition coefficient is not measureable.
Adsorption/Desorption	Not determined	Not expected to be mobile in soils and sediments based on its low water solubility and high molecular weight
Dissociation Constant	Not determined	Does not contain dissociable functionality that is likely to dissociate under environmental conditions (pH 4-9)
Particle Size	Not determined	Rubber-like substance that is not expected to form dust particles during processing and use
Flash Point	> 204 °C at 101 kPa	SDS
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not expected to autoignite
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

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.

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 for the 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 product containing the notified polymer will be imported as large sheets (> 98% notified polymer) wrapped in polyethylene and contained within 25 kg cartons.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 5	< 20	< 20	< 20	< 20

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
DuPont (Australia) Ltd
Polymers International Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported neat in 25 kg cartons containing sheets of products and then transported by road.

USE
The notified polymer will be used in the manufacture of aeronautical, automotive, and general engineering parts.

OPERATION DESCRIPTION

Sheets of the neat notified polymer may have additives incorporated into it using roll milling. The resulting sheets will then be extruded or compression moulded into moulds. The moulds will then be heated to crosslink and cure the notified polymer. Following cooling, excess material may be trimmed and the resulting articles automatically packaged.

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	0.5 - 1	12 – 24
Milling	4 - 8	200
Moulding	4 - 8	200
Packaging	4 - 8	200

EXPOSURE DETAILS

Dermal exposure of workers to the neat notified polymer may occur when removing the polymer from its packaging, feeding/removing from the mill rolls and extruder/compression moulding equipment. Inhalation exposure of workers to the notified polymer is not expected, given its low vapour pressure and that it is in rubber-like sheets. Exposure is expected to be lowered by the use of gloves, overalls, safety boots, and safety glasses. Local exhaust ventilation will be used when operating the compression moulding equipment, further reducing exposure. Following curing and cross-linking, the notified polymer is not expected to be available for exposure.

6.1.2. Public Exposure

The notified polymer will not be sold to the public. Members of the public are not expected to come into contact with articles containing the notified polymer. However, if such exposure were to occur the notified polymer will be cured and cross-linked and unavailable for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

Based on its high molecular weight (> 1000 Da), the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion, or to be dermally absorbed after exposure is expected to be limited. Based on the currently available information, the notified polymer is expected to be of low hazard.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the 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

The notified polymer is expected to be of low hazard. The main route of worker exposure to the neat notified polymer is expected to be dermal. Engineering controls and personal protective equipment will be used by workers during handling of the notified polymer, acting to minimise exposure.

Overall, the risk to workers from handling of the notified polymer at neat concentrations is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer will not be available to the public. Therefore, when used in the proposed manner, the risk to the public 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 not be manufactured or reformulated in Australia. Therefore no release to the environment is expected from these activities. The notified polymer will be imported neat in sheets. Releases to the environment may occur following accidents during import, transport or storage; however, the notified polymer is expected to be collected and re-used or disposed of in accordance with local regulations.

Sheets of neat notified polymer will be reworked at sites across the country using roll milling followed by moulding to form the desired articles. During the reworking process, material lost from trimming moulded articles is expected to be recycled into the reworking process. The notified polymer that is not recycled is expected to be disposed of to landfill. Therefore, less than 0.5% of the total import volume of the notified polymer is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

Release of the notified polymer from use is expected to be limited. Up to 2% of the total import volume of the notified polymer may be released during use as a result of mechanical wear of the rubber articles. This release is expected to be dispersive with the majority of the released notified polymer ending up in the soil compartment.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to share the fate of the article into which it is incorporated. These articles are expected to be disposed of to landfill. Aeronautical, automotive, and general engineering parts containing the notified polymer may be thermally decomposed during reclamation processes.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. The notified polymer will be incorporated into moulded articles where it is expected to remain within the inert polymer matrix. The cross-linked and cured notified polymer is not expected to be bioavailable in this form. The notified polymer is expected to be stable based on its structure and use. The notified polymer is expected to be resistant to biotic degradation mechanisms due to its exceptionally high molecular weight and based on it being in its cross-linked and cured form.

The majority of the notified polymer is expected to be disposed of to landfill at the end of its useful life. The notified polymer is not expected to leach from the polymer matrix and is therefore not expected to be mobile in landfill. However, in landfill the notified polymer is expected to eventually degrade to form water, fluorinated compounds and oxides of carbon. These degradation products are also expected during thermal decomposition processes, as well as hydrogen fluoride. The notified polymer contains functionality that, over extended periods of time, may eventually degrade to form potentially persistent perfluorinated degradation products of varying chain length. Degradation of the notified polymer to form perfluorinated degradation products of varying chain length may occur over the short-term; however this is only likely under extreme temperatures and conditions.

Predictions of the environmental partitioning behaviour of polyfluorinated compounds remains uncertain based on current knowledge, because of limited data and their unique properties. In particular, the usual predictive models for partitioning during sewage treatment are inapplicable for chemicals containing perfluorinated functionality as they assume lipophilicity for hydrophobic functionality, whereas the perfluorinated functionality is both hydrophobic and lipophobic. Therefore, perfluorinated degradation products have the potential to enter surface waters, even following wastewater treatment. These degradation products are expected to be very persistent in the environment.

Any notified polymer that may be released during use is expected to remain in the soil compartment with a potential for some of the article containing the notified polymer to be washed to surface waters. In the soil and water compartments, the notified polymer is expected to remain incorporated in the inert polymer matrix. Over significant periods of time the notified polymer in the soil and water compartments is expected to eventually degrade to form water, oxides of carbon and potentially persistent perfluorinated compounds of varying chain length.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment. The notified polymer is also not expected to be bioavailable based on its very high molecular weight and being cross-linked into a cured and inert polymer matrix.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment, in ecotoxicologically significant quantities, is not expected based on its reported use pattern. The majority of the notified polymer will eventually be disposed to landfill. The notified polymer is expected to remain in an inert matrix and is unlikely to leach or be bioavailable. The notified polymer contains functionality that may slowly degrade over extended periods of time to form potentially persistent perfluorinated degradation products of varying chain length. However, based on the incorporation of the notified polymer into a cross-linked inert polymer matrix and the expected limited environmental exposure and mobility of the articles formed using the notified polymer, the potential release of perfluorinated degradation products of varying chain length is expected to be limited. Degradation of the notified polymer in the short term may only occur under extreme conditions. Therefore, on the basis of the assessed use pattern and assumed low hazard, the notified polymer is not considered to pose an unreasonable short-term risk to the environment. However, due to the potential release and persistence of perfluorinated compounds of varying chain length, the long-term environmental implications are unknown.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility Water extractability of 0.0 mg/L at 100 °C

Method	Articles Intended for Repeated Use, 21 CFR 177.2600
Remarks	A water extractability test was conducted on an analogue polymer that differed only in molecular weight. The analogue polymer had a lower molecular weight and is therefore considered suitable for determination of the water extractability of the notified polymer. The test article (43.8 in^2 of rubber sheet) was extracted into 150 mL refluxing sterile water for 7 hours followed by an additional 2 hours. The test was also conducted in 150mL n-hexane. The extraction water was evaporated to dryness and the resulting residue was weighed. No residue was detected and the reported extraction is 0.0 mg/in^2 (0.0 mg/L) in both water and hexane.
Test Facility	Toxikon (2004)

BIBLIOGRAPHY

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

Toxikon (2004) Rubber Articles Intended for Repeated Use (Study No. 04-1494-G1, April, 2004). Bedford, Massachusetts, United States, Toxikon Coporation (Unpublished report submitted by the notifier).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.