

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

### POLYMER OF LOW CONCERN PUBLIC REPORT

#### Tilamar Fix A1000

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government 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:

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**Director  
NICNAS**

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### Table of Contents

SUMMARY .....	2
CONCLUSIONS AND REGULATORY OBLIGATIONS.....	2
ASSESSMENT DETAILS.....	4
1. APPLICANT AND NOTIFICATION DETAILS.....	4
2. IDENTITY OF POLYMER .....	4
3. PLC CRITERIA JUSTIFICATION .....	5
4. PHYSICAL AND CHEMICAL PROPERTIES.....	5
5. INTRODUCTION AND USE INFORMATION .....	5
6. HUMAN HEALTH RISK ASSESSMENT.....	6
7. ENVIRONMENTAL RISK ASSESSMENT .....	7

## SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1015	DSM Nutritional Products Australia Pty Limited	Tilamar Fix A1000	No	≤ 6 tonnes per annum	Component of hair care products

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Human Health Risk Assessment**

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

### **Environmental Risk Assessment**

Based on the PEC/PNEC ratio, the import volume and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

### **Health and Safety Recommendations**

- Employers should implement the following engineering controls to minimise occupational exposure during aerosol spray applications of products containing the notified polymer:
  - Ventilation system
- Employers should implement the following safe work practices to minimise occupational exposure during aerosol spray applications of products containing the notified polymer:
  - Avoid inhalation of aerosol
- 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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

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

- Aerosol spray products containing the notified polymer should carry the following safety directions (or similar) on the label:
  - Spray only in well ventilated areas
  - Avoid inhalation of aerosol

### **Environmental Recommendations**

- No specific control measures are required to minimise release of the notified polymer to the environment.

**Disposal**

- The notified polymer should be disposed to landfill.

**Storage**

- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Store in a segregated and approved area.
  - Store in original container protected from direct sunlight in a dry, cool and well ventilated area, away from incompatible materials (oxidising substances, strong acids, strong bases).

**Emergency Procedures**

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

**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 notified polymer is introduced in a chemical form that does not meet the PLC criteria;
  - the notified polymer is intended for use in aerosol hair spray products at > 10% concentrationor
- (2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from a component in hair care products, or is likely to change significantly;
  - the amount of notified polymer being introduced has increased per annum, or is likely to increase, significantly;
  - the notified polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the notified 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 MSDS of the notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

## ASSESSMENT DETAILS

### 1. APPLICANT AND NOTIFICATION DETAILS

#### Applicants

DSM Nutritional Products Australia Pty Limited (ABN 36 000 991 793)  
9 Moorebank Avenue  
Moorebank NSW 2170

#### Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: polymer constituents and residual monomers/impurities

### 2. IDENTITY OF POLYMER

#### Marketing Name(s)

Tilamar Fix A1000

#### Chemical Name

2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate

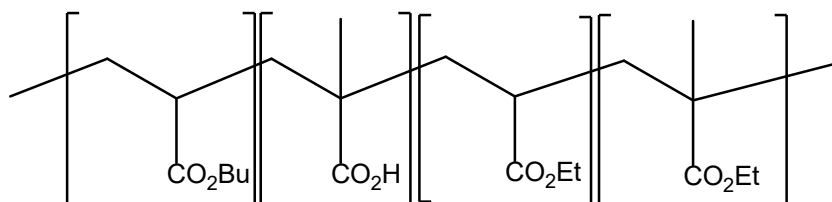
#### CAS Number

1070166-98-1

#### Molecular Formula

$(C_8H_{14}O_2.C_6H_{10}O_2.C_5H_8O_2.C_4H_6O_2)_x$

#### Structural Formula



#### Molecular Weight

Number Average Molecular Weight (Mn)	80,000 Da
Weight Average Molecular Weight (Mw)	100,000 Da
Polydispersity Index (Mw/Mn)	1.25
% of Low MW Species < 1000 Da	0 %
% of Low MW Species < 500 Da	0 %

#### Reactive Functional Groups

The notified polymer contains only low concern functional groups.

### 3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

### 4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White beads
Melting Point/Glass Transition Temp	198-208 °C
Density	650 kg/m <sup>3</sup> at 20 °C
Water Solubility	≥ 50 g/L (based on turbidity of a solution with 5% solids in water)
Dissociation Constant	Not determined. Contains functionality with an estimated pKa ~ 4.
Particle Size	Surface weighted mean 144 µm Inhalable fraction (< 100 µm): < 6.46% Respirable fraction (< 10 µm): 0%
Reactivity	Stable under normal environmental conditions. The notified polymer contains functional groups that are expected to hydrolyse very slowly in the environmental pH range (4-9).
Degradation Products	None under normal conditions of use

### 5. INTRODUCTION AND USE INFORMATION

#### Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	3	4	5	6	6

#### Use

The notified polymer will not be manufactured in Australia. The notified polymer will be imported neat (> 99% purity) into Australia as solid beads. Products containing the notified polymer will be reformulated in Australia. The notified polymer will be used as a component of hair care products at a concentration of ≤ 10%.

## 6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints for the notified polymer and an acceptable analogue of the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD TG 423
Rabbit, skin irritation	non-irritating	no	OECD TG 404
Rabbit, eye irritation	slightly irritating	yes	OECD TG 405
Skin sensitisation - LLNA	no evidence of sensitisation.	no	OECD TG 429
Rat, repeat dose inhalation toxicity – 90 days (analogue)	NOEL = 30 mg/m <sup>3</sup>	no	Similar to OECD 413
Genotoxicity - bacterial reverse mutation	non-mutagenic	no	OECD TG 471
Genotoxicity – in vitro mouse lymphoma cell mutation assay*	non-genotoxic	no	OECD TG 476

\*Study reports not provided.

All results were indicative of low hazard.

In an eye irritation study in young adult New Zealand White Rabbits, mild to moderate, early-onset and transient ocular changes, such as reddening of the conjunctivae and sclerae, discharge and chemosis were observed. These effects were reversible and were no longer evident at the end of the observation period (7 days). The notified polymer is therefore slightly irritating to the eye but the effects observed do not warrant classification as an eye irritant.

In a 90-day repeat dose inhalation toxicity study on a similar acrylate copolymer in rats the following effects were observed: Increased lung weights were found in males and females at 300 mg/m<sup>3</sup> and in the 100 and 300 mg/m<sup>3</sup> recovery groups. Histopathological effects including alveolar histiocytosis and lymphadenitis in the mediastinal lymph nodes in the 100 and 300 mg/m<sup>3</sup> exposure groups for males and females, while alveolar histiocytosis, intraalveolar cellular debris, lymphadenitis in the mediastinal lymph nodes, and/or interstitial pneumonitis were noted in these two exposure groups of the females after the 6-wk recovery period. However, no effects were observed in the 30 mg/m<sup>3</sup> exposure group, which thus represents a no-observable-effect level (NOEL) in this 90-day study.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008 (2004)]. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

The notified polymer is intended to be used in a range of hairstyling products at ≤ 10% concentration, including aerosol hair sprays. The primary risk to human health associated with use of products containing the notified polymer will be due to the potential for lung overloading effects following inhalation of aerosols from hairsprays. The potential for the formation of respirable particles is considered to be lower for pump hairsprays and inhalation exposure is not expected during use of non-spray products.

The notified polymer although of high molecular weight ( $> 80,000$  Da) is water soluble and therefore if inhaled at low levels is likely to be cleared from the upper respiratory tract readily through mucociliary action. Small proportions of the notified polymer may reach the lower respiratory tract, but it should still be readily cleared from the lungs unless high levels are inhaled. When high concentrations of the notified polymer are inhaled, it is likely to be cleared from the lungs, but this may be slower and temporary respiratory impairment is possible. This is supported from the results of a 90-day repeat dose inhalation toxicity in rats which showed lung overloading effects at high doses (i.e. at  $> 100 \text{ mg/m}^3$ ). The NOEL was determined to be  $30\text{-mg/m}^3$  in this study.

The notifier has also provided an expert statement on the assessment of the toxicological potential of the notified polymer after inhalative exposure to hairsprays during spray application by consumers in private households and by professional application in hairdressing saloons. Using conservative safety factors this assessment concluded that exposure to the notified polymer under the proposed use scenario was within the acceptable level.

Therefore, the risk to the health of workers and the public is not considered to be unreasonable provided that measures to minimise exposure during aerosol spray applications are in place. Such measures include that users be directed to only apply hairsprays in well ventilated areas and to avoid inhalation of the spray contents.

## 7. ENVIRONMENTAL RISK ASSESSMENT

The notified polymer meets the PLC criteria and can therefore be assumed to be of low hazard to the aquatic environment. This is supported by environmental endpoints observed in testing conducted on the notified polymer.

<i>Endpoint</i>	<i>Test Method</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Daphnia Toxicity	OCED TG 202	48 h EL50 $> 100 \text{ mg/L}$ (WAF)	Not harmful to aquatic invertebrates
Inhibition of microbial activity	OECD TG 301F	Passed toxicity validity criteria at $150 \text{ mg/L}$ in biodegradation test	Not assumed inhibitory

All results were indicative of low hazard to the aquatic environment.

The toxicity of the notified polymer to daphnia was investigated in a limit test using the filtered water accommodated fraction (WAF) of the test item at a loading rate of  $100 \text{ mg/L}$ . The reported endpoint, EL50, is the calculated loading rate of the test item which results in 50% immobilisation. No effects were observed during the test period (48 h) up to limit of solubility of the test item in the test media at a loading rate of  $100 \text{ mg/L}$ .

Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. Additionally, the toxicity to algae is likely to be further reduced due to the presence of calcium ions in the aquatic compartment which will bind to the acid functional groups.

The lower limit of the daphnia endpoint was used to calculate the Predicted No-Effect Concentration (PNEC). An assessment factor of 1000 was used as an acute toxicity endpoint is only available for aquatic species from one trophic level which is not considered to represent the most sensitive species. The resultant PNEC is  $> 100 \text{ } \mu\text{g/L}$  (i.e.  $> 100 \text{ mg/L} \div 1000$ ).

The majority of the notified polymer will be released to sewer as a result of its use in haircare products that will be washed off hair. Release is assumed to occur daily and to be diffuse in nature. A predicted environmental concentration in rivers ( $PEC_{\text{river}}$ ) can be calculated on the worst-case assumptions that 100% of the total annual import volume is released to sewer nationwide and none of the notified polymer is removed by sewage treatment plant (STP) processes. The  $PEC_{\text{river}}$  is 3.63  $\mu\text{g/L}$  if the daily chemical release ( $6000 \text{ kg}/365 = 16.44 \text{ kg}$ ) is diluted by the daily effluent production ( $200 \text{ L/person/day} \times 22.613 \text{ million people} = 4,523 \text{ ML}$ ). The  $PEC_{\text{ocean}}$  is 0.363  $\mu\text{g/L}$  based on a dilution factor of 10.

Although no removal of the notified polymer in STPs was assumed in the worst case calculation above, based on its very high molecular weight, up to 90% of the notified polymer may be removed in STPs by partitioning to biosolids (Boethling & Nabholz, 1997). Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 32.7 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m<sup>3</sup> and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.218 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 1.09 mg/kg and 2.18 mg/kg, respectively.

The notified polymer is expected to be hydrolytically stable in the environmental pH range and is not expected to be rapidly biodegradable based on a ready biodegradability test (OECD TG 301F; 1% biodegradation after 28 days). Based on its high molecular weight, the notified polymer is not anticipated to cross biological membranes and is therefore not expected to bioaccumulate. The notified polymer is expected to disperse and eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

Based on the above PEC and PNEC values, the Risk Quotients ( $Q = PEC/PNEC$ ) have been calculated for riverine and marine waters as  $Q_{\text{river}} = 0.036$  and  $Q_{\text{ocean}} = 0.004$ , respectively. The resultant risk quotients for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations. The notified polymer has a low potential for bioaccumulation. Therefore, on the basis of the PEC/PNEC ratio, annual importation volume and assessed use pattern in haircare products, the notified chemical is not expected to pose an unreasonable risk to the environment.

### **Bibliography**

Boethling RS & Nabholz JV (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. New York, Van Nostrand Reinhold, pp 187–234.