

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

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

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 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 the Environment.

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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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/1014	DSM Nutritional Products Ltd.	2-Propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate and ethyl 2-propenoate	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 its low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure during aerosol spray applications of products containing the notified polymer:
 - Ventilation system
- A person conducting a business or undertaking at a workplace 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 (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.

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

- Aerosol spray products intended for professional use 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 of 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% concentration;
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of hair care products, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, 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 (M)SDS of the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

DSM Nutritional Products Ltd. (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 A140

Chemical Name

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

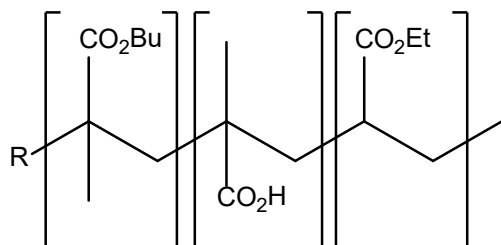
CAS Number

26715-43-5

Molecular Formula

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

Structural Formula



Molecular Weight

Number Average Molecular Weight (Mn)	132,000 Da
Weight Average Molecular Weight (Mw)	130,000 Da
Polydispersity Index (Mw/Mn)	0.98
% of Low MW Species < 1000 Da	< 2%
% of Low MW Species < 500 Da	< 1%

Reactive Functional Groups

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion

Criterion met

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 solid at 100% concentration; Milky white liquid at 40% concentration
Melting Point/Glass Transition Temp	82-92 °C
Density	1050 kg/m ³ at 20°C
Water Solubility	Expected to be dispersible in water
Dissociation Constant	Not determined. The notified polymer contains acid functionality with an estimated pKa ~4 – 5.
Particle Size	90-120 nm
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 Polymer (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 into Australia as an aqueous dispersion at a concentration of approximately 40% for use in hair care products at < 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.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD 423
Rat, acute dermal	LD50 > 2000 mg/kg bw	no	OECD 402
Rat, repeat dose inhalation toxicity – 90 days (analogue)	NOEL = 30 mg/m ³	no	Similar to OECD 413
Rabbit, skin irritation	slightly irritating	Yes	OECD 404
Rabbit, eye irritation	slightly irritating	Yes	OECD 405
Skin sensitisation - LLNA	no evidence of sensitisation	no	OECD 429
Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD 471

Genotoxicity – in vitro mouse
lymphoma cell mutation assay

non genotoxic

no

OECD 476

All results were indicative of low hazard.

In a skin irritation study in young adult New Zealand White Rabbits, mild signs of irritation including very slight erythema and scaling were observed. These effects were no longer evident 72 hours after exposure. No corrosive effects or clinical signs were observed.

In an eye irritation study in young adult New Zealand White Rabbits, mild, early-onset and transient ocular changes, including reddening of the conjunctivae and sclerae were observed. These effects were reversible and no longer evident 48 hours after treatment. No abnormal findings were observed in the cornea or iris of any animal at any of the examinations. No corrosion was observed at any of the measuring intervals. No staining of the treated eyes by the notified polymer was observed and no clinical signs were observed.

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/m³ and in the 100 and 300 mg/m³ recovery groups. Histopathological effects including alveolar histiocytosis and lymphadenitis in the mediastinal lymph nodes in the 100 and 300 mg/m³ 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 2 exposure groups of the females after the 6-wk recovery period. However, no effects were observed in the 30 mg/m³ 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 particle size of the notified polymer indicates that a portion will be respirable (< 10 µm). The notified polymer 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 the 90-day repeat dose inhalation toxicity study in rats which showed lung overloading effects at high doses (i.e. at > 100 mg/m³). However, the notified polymer will be imported in a 39-41% aqueous dispersion which is expected to result in minimal inhalation exposure to reformulation workers. Should the polymer be imported in a concentrated solid form, the use of dust masks and local exhaust ventilation is recommended to reduce reformulation worker inhalation exposure levels and hence lower the risk of temporary lung overloading.

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 notifier has also provided an expert statement on the assessment of the toxicological potential of an analogue 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

Hazard characterisation

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard to fish and was shown to be of low hazard to aquatic invertebrates. Anionic polymers may be toxic to algae. However no toxicity to algae was observed in testing conducted on the notified polymer. A summary of the ecotoxicological endpoints obtained from two studies on the notified polymer is outlined in the table below.

<i>Endpoint</i>	<i>Test Guideline</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Daphnia Toxicity	OECD TG 202	EC ₅₀ (48 h) > 100 mg/L	Not Harmful
Algal Toxicity	OECD TG 201	E _r EC ₅₀ (72 h) > 100 mg/L	Not Harmful

The lower limit of the endpoints from the results of the ecotoxicological studies summarised above was used to calculate the Predicted No-Effect Concentration (PNEC). An assessment factor of 100 was used as although acute toxicity endpoints are available for the effects of the notified polymer on aquatic species from only two trophic levels, algae is considered to represent the most sensitive species. The resultant PNEC is > 1,000 µg/L (i.e. > 100 mg/L ÷ 100).

Environmental Risk Assessment

The majority of the notified polymer will be released to sewer as a result of its use in cosmetic 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_{river}) can be calculated on the worst-case assumption 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_{river} is 3.63 µg/L if the daily chemical release (6000 kg/365 = 16.44 kg) is diluted by the daily effluent production (200 L/person/day × 22.613 million people = 4,523 ML). The PEC_{ocean} is 0.363 µg/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/m³ 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 an inherent biodegradability test conducted on the notified polymer (OECD TG 302C; 0% 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.

The worst case PEC_{river} and PEC_{ocean} are well below the PNEC and therefore the riverine and marine Risk Quotients, $Q (= PEC/PNEC)$ are both $\ll 1$. Based on its low hazard and assessed use pattern, the notified polymer is not considered 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.