File No: LTD/1709

April 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Acetic acid ethenyl ester, polymer with 2,5-furandione, hydrolyzed, sodium salts

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 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.

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

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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/1709	Filterfab Pty Ltd	Acetic acid ethenyl ester, polymer with 2,5-furandione, hydrolyzed, sodium salts	ND*	≤ 1000 tonne/s per annum	Component of pouches for detergents

*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 PEC/PNEC ratio and the reported 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 safe work practices to minimise occupational exposure during handling of products containing the notified polymer:
  - Avoid skin and eye contact

- 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 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 1000;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of pouches for detergents, 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.

No additional secondary notification conditions are stipulated.

(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)
Filterfab Pty Ltd (ABN: 65 005 247 647)
16 Leanne Crescent
LAWNTON QLD 4501

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: other names, structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, 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.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA (2012) and Canada (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Modified polyvinyl alcohol

CAS NUMBER
1428741-30-3

CHEMICAL NAME
Acetic acid ethenyl ester, polymer with 2,5-furandione, hydrolyzed, sodium salts

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 50%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear film

Property	Value	Data Source/Justification
Melting Point	180–230 °C	(M)SDS
Boiling Point	Not determined	Introduced only in formulated products
Density	1,310 kg/m^3 at 20 °C	Analogue data
Vapour Pressure	< 1.3 × 10^{-9} kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013).
Water Solubility	~ 250 g/L at 20 °C	Measured
Hydrolysis as a Function of	Not determined	Contains functionalities that may slowly

pH		hydrolyse under normal environmental conditions of pH 4–9.
Partition Coefficient (n-octanol/water)	Not determined	Not expected to significantly partition to n-octanol based on its high water solubility.
Adsorption/Desorption	Not determined	Expected to have low mobility in soil based on its high molecular weight.
Dissociation Constant	Not determined	The notified polymer is a salt and is expected to be ionised under environmental conditions (pH 4–9).
Flash Point	Not determined	Introduced only in formulated products.
Autoignition Temperature	Not determined	Introduced only in formulated products. Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Does not contain any functional groups that imply explosive properties.
Oxidising Properties	Not determined	Does not contain any functional groups that imply oxidising 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 notified polymer will not be manufactured in Australia. The notified polymer will be imported as a component (>50%) of an outer film pouch that will be filled with a detergent.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100–1000	100–1000	100–1000	100–1000	100–1000

TRANSPORTATION AND PACKAGING
The finished pouches containing the notified polymer will be individually wrapped in plastic and packed ready for retail distribution throughout Australia.

USE
The notified polymer will be imported as a component of soluble film pouches to be filled with detergent and cleaning products for a range of applications such as laundry and dishwasher detergents. The notified polymer will be present in the soluble film pouch at a concentration of >50% and will be available for commercial and consumer use.

OPERATION DESCRIPTION
The notified polymer will not be manufactured, reformulated or repackaged within Australia.

The notified polymer will be imported as a component (>50%) of soluble film pouches that will be filled with detergent or other cleaning products for various applications for commercial and consumer use.

Consumers will take one pouch, which contains the cleaning product or detergent, from an outer packaging and place it into the appropriate equipment (e.g. washing machine or dishwasher) prior to the commencement of the wash. Once in the equipment the water soluble pouch containing the notified polymer is designed to rapidly dissolve, releasing the contents.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Transport and storage
Transport and storage workers are expected to only be exposed to the notified polymer in the unlikely event of an accident. In this case, dermal exposure may occur; however, standard clean-up procedures would be in place to minimise worker exposure to the notified polymer.

Retail workers
Retail workers are not expected to have potential for exposure to the notified polymer except in the event of an accidental package breach. In this case, dermal exposure may occur; however, exposure is expected to be minimised by the use of appropriate PPE including gloves and protective clothing during clean-up of any spills.

End use
Workers in professions using commercial cleaning equipment may be exposed to the notified polymer (>50%) when using pouches for cleaning. Dermal exposure is expected when removing the pouch, which is filled with a cleaning product or detergent, from an outer packaging and placing it into the equipment (e.g. washing machine or dishwasher). Dermal contact with the pouch will be brief with exposure expected to be less than 1 minute per day and only to the fingers. The notified polymer is bound in the film pouch and transfer to the skin during dermal exposure is expected to be low. The pouches are designed to be added to cleaning equipment and are not designed to be dissolved in water for hand washing of items such as dishes or clothes. However, if used in this manner, potential dermal exposure is expected on the hands and wrists (which are expected to be rinsed after washing). Dermal exposure may be minimised if workers are using PPE such as gloves. The notified polymer is expected to dissolve in contact with water, and be rinsed away with waste water; therefore, exposure from residual polymer left on items after a cleaning cycle is expected to be low.

The water-soluble packaging is designed to reduce public exposure to the concentrated cleaning and washing chemicals contained in the pouch which are potentially classified as hazardous. Contact with the pouch with wet hands will rapidly dissolve the film containing the notified polymer, rupturing the pouch, and potentially expose the user to the contents of the pouch.

6.1.2. Public Exposure
Consumers will have similar but less frequent potential than workers for exposure to the notified polymer at > 50% in pouches filled with detergent (exposure discussed above).

6.2. Human Health Effects Assessment
No toxicity data were submitted on the notified polymer. Although the notified polymer has moderate water solubility, due to its high molecular weight (> 10,000 Da) it is not expected to be absorbed following oral or dermal exposure. Inhalation exposure is not expected as dusts are unlikely to be created. Furthermore, it contains no detectable low molecular weight species.

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
Dermal exposure to the notified polymer at > 50% is expected during normal use such as removing the pouch and placing it into equipment (e.g. dishwashers), as well as during any potential spills and may be reduced by the use of PPE. There was no toxicity data available on the notified polymer. However, the high molecular weight suggests that absorption across biological membranes is unlikely and hence systemic toxicity from

exposure to the notified polymer is not expected. Based on the predicted low toxicity and the assessed use pattern, the risk of the notified polymer to workers is not considered to be unreasonable.

6.3.2. Public Health

Consumers are expected to have similar but less frequent potential than workers for exposure to the notified polymer at > 50% in pouches filled with detergent (risk characterisation discussed above). Use of PPE when handling the pouches is not expected; however, this will not significantly increase the risk to the public, as the polymer is bound in the film pouch. Therefore, the risk to the public from the use of the notified polymer is not expected 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, reformulated or repackaged in Australia; therefore there will be no release of the notified polymer to the environment from these activities.

RELEASE OF CHEMICAL FROM USE

The notified polymer dissolves in contact with water during use as a component of film pouches containing detergents placed in dishwashers and washing machines. Therefore, the majority of the notified polymer is expected to be released in wastewaters to sewer nationwide following use.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer dissolves during use and majority is expected to be disposed of to sewer. Some of the notified polymer may be disposed of to landfill as domestic waste when unused pouches are discarded.

7.1.2. Environmental Fate

The notified polymer is not readily biodegradable based on the environmental fate study as there was only 44.4% biodegradation during the biodegradation test. This is expected as the notified polymer is a modified polyvinyl alcohol (PVA) resin, and PVA polymers are known to be biodegradable. For the details of the environmental fate studies please refer to Appendix C. The notified polymer is not expected to be significantly hydrolysed in the aquatic environment under normal environmental conditions based on structural considerations.

The majority of the notified polymer is expected to be released to sewage treatment plants (STPs) via domestic wastewater. As the notified polymer is a water soluble anionic polymer of moderately high molecular weight, up to 75% removal of the notified polymer from STP effluent is anticipated via partitioning to sludge (Boethling & Nabholz, 1997). Notified polymer in treated sewage effluent may be released to surface waters or applied to land when used for irrigation. Notified polymer in sewage sludge may be disposed of to landfill or applied to land when sludge is used for soil remediation. The notified polymer is not expected to be bioaccumulative due to its high molecular weight. Despite its high water solubility, notified polymer applied to soils or in landfill is expected to have low mobility due to its high molecular weight. In landfill, the notified polymer is expected to undergo degradation by both biotic and abiotic processes to form oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use of dissolvable pouches containing detergents, it is assumed that 100% of the total import volume of the notified polymer is released to the sewer. The release is assumed to be nationwide over 365 days per year. Since the notified polymer is an anionic polymer with high molecular weight, it is assumed that 75% of the notified polymer is expected to be removed during sewage treatment processes (Boethling & Nabholz, 1997).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2739.73	kg/day

Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	75%	mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	151.45	µg/L
PEC - Ocean:	15.14	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 4543.5 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^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 30.3 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 151.5 mg/kg and 302.9 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/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 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 151.5 µg/L may potentially result in a soil concentration of approximately 1010 µg/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 5.05 mg/kg and 10.1 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer.

Anionic polymers are generally of low toxicity to fish and daphnia, however they 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. The result from an ecotoxicological investigation conducted on a similar polyanionic polymer was available in Boethling & Nabholz (1997), and is presented in the table below. The endpoint presented below is likely to reflect the worst case ecotoxicity of the notified polymer as the analogue had a greater proportion of acid groups. Furthermore, the indirect 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 functional groups the notified polymer.

Endpoint	Result	Assessment Conclusion
Algal Toxicity (96 h)	EC50 = 560 mg/L	Not expected to be harmful to algae

On the basis of the toxicity data used for the notified polymer, the notified polymer is not expected to be harmful to algae in the aquatic environment. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified polymer has not been formally classified.
The notified polymer is not readily degradable and is not considered to have potential for bioaccumulation. On the basis of its acute toxicity, the notified polymer has not been classified for long-term aquatic hazard under the GHS.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has been calculated from the acute toxicity data (algae) and an assessment factor of 1000. A conservative assessment factor of 1000 was used as acute toxicity endpoint for only one trophic level was available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	560	mg/L
Assessment Factor	1,000	
PNEC:	560	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotients (RQ) have been calculated for the aquatic compartment:

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	151.45	560	0.270
Q - Ocean:	15.14	560	0.027

The risk quotients for discharge of treated effluents containing the notified polymer to the aquatic environment indicate that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual introduction volume. The notified polymer has potential for biodegradation in the environment. The notified polymer is considered to have low potential for bioaccumulation and is expected to be of low hazard to aquatic organisms. Therefore, on the basis of the PEC/PNEC ratio and the assessed use pattern the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility ~ 250 g/L at 20 °C

Method	In house method.
Remarks	At room temperature, approximately 300 g of water was added to a 600 mL beaker. Under constant agitation, 76.94 g of film containing the notified polymer was added to the water. The opacity and viscosity of the mixture were used as indication of the solubility endpoint (saturated level). The solubility of the notified polymer was approximately 0.25 g/L in water. This approximate solubility endpoint was determined due to significant opacity of the solution stemming from its high viscosity, which inhibited proper degassing of air bubbles from the mixture. It was also noticed that partially dissolved film adhering to the mixing blade near the surface of the solution during agitation indicated that the solubility endpoint of the mixture was reached.
Test Facility	MonoSol (2012)

Partition Coefficient (n-octanol/water) Not determined

Method	In-house method
Remarks	A determination of the concentration of the notified polymer in the aqueous phase of the partition experiment could not be performed. Due to negligible solubility of the notified polymer in 1-octanol, and abundant solubility in water, the log Pow value for the notified polymer was not found to be a meaningful value.
Test Facility	MonoSol (2011)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	TOC-V-CSH Carbon Analyzer
Remarks - Method	The test was conducted according to the guidelines above. No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	3.1	3	43.6
6	5.8	7	61.6
14	8.3	14	80.9
28	44.4	28	86.6

Remarks - Results	All validity criteria for the test were satisfied. The reference compound, sodium benzoate, reached the 60% pass level by day 6 indicating the suitability of the inoculum. The toxicity control exceeded 25% biodegradation (required by guideline) within 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the notified polymer after the cultivation period was 44.4%. Therefore, the test substance cannot be classified as readily biodegradable according to the OECD (301 B) guideline.
CONCLUSION	The notified polymer is not readily biodegradable
TEST FACILITY	RespirTek (2013)

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