File No: LTD/1720

April 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Modified polyvinyl alcohol AP-17

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.

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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1720	Cintox Australia Pty Ltd	Modified Polyvinyl alcohol AP-17	ND*	< 20 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 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 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 polymer 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.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer provided by the notifier were 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)
Cintox Australia Pty Ltd (ABN: 63 122 874 613)
Suite 1, Level 2, 38-40 George Street
Parramatta NSW 2124

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, impurities, use details and 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
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Modified polyvinyl alcohol AP-17

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Transparent film

Property	Value	Data Source/Justification
Melting Point/Freezing Point	180–200 °C	(M)SDS
Boiling Point	> 200 °C at 101.3 kPa	(M)SDS
Specific gravity	1.19–1.31at 20 °C	(M)SDS
Vapour Pressure	< 0.134 kPa at 25 °C	Estimated
Water Solubility	Not determined	Expected to be highly water soluble based on the presence of hydrophilic functional groups in the chemical structure and use in water soluble films
Hydrolysis as a Function of pH	Not determined	Contains functionalities that may slowly 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 expected 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 ionised under normal environmental conditions (pH 4–9)
Flash Point	Not determined	Introduced only in formulated products. Not expected to be flammable under normal conditions of use
Autoignition Temperature	Not determined	Imported 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

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 of a polymer film either on a roll or as pre-formed pouches for local filling and repackaging.

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

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

PORT OF ENTRY
Melbourne, Sydney

TRANSPORTATION AND PACKAGING
The imported film containing the notified polymer will be packed in plastic bags which will be further packaged into cardboard boxes.

USE
The notified polymer will be imported as a component of a water soluble film that will be used to form pouches into which detergent and cleaning products will be added for a range of applications such as laundry and dishwasher detergents. The notified polymer will be present in the final products at < 10% and will be available for commercial and consumer use.

OPERATION DESCRIPTION
Repackaging
The unfilled pouches will be filled with detergent using specially designed machinery. The two layers of film will be loaded onto the filling machine. Within a moulding chamber the detergent liquid is injected between the two layers. The edges are sealed using a hot bar, impulse or sonic sealers (to temperatures of 120–200°C). The unit doses are then cut to separate them and put into secondary packaging.

End 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. dishwasher or washing machine), 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 cleaning product or detergent.

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 and ocular exposure may occur; however, standard clean-up procedures would be in place to minimise worker exposure to the notified polymer.

Repackaging
Workers involved in repackaging the finished films and maintenance of machinery may come into dermal contact with the notified polymer (at < 10% concentration) when unpacking and loading the film containing the notified polymer onto the filling machine. The packaging process for filling the pouches is largely automated. The notifier states that exposure is expected to be minimised by the use of appropriate PPE including gloves and protective clothing.

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 and ocular exposure may occur. However, the notifier states that 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 come into contact with the notified polymer when using pouches for cleaning (at < 10% concentration). 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. dishwasher or washing machine). Dermal contact with the pouch will be brief with exposure expected to be less than 1 minute per day and usually to the fingers. The notified polymer is bound in the 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). The notifier states 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.

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	2–4	24
Plant operators	8	200
Maintenance	1–2	12

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

6.2. Human Health Risk Assessment

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by the test submitted on the following toxicological endpoint.

Endpoint	*Result*	*Effects Observed*	*Test Guideline*
1. Rat, acute oral	LD50 > 2,000 mg/kg bw	no	OECD TG 401

The notified polymer was of low acute toxicity by the oral route. Although the notified polymer has moderate water solubility, due to its high molecular weight (> 1,000 Da), and very low percent of low molecular weight species, absorption across biological membranes is unlikely. Systemic toxicity from exposure to the notified polymer is not expected.

6.2.1. Occupational Health and Safety Risk Assessment

Repackaging

During packaging operations dermal exposure is expected. Inhalation exposure is not expected as dusts are unlikely to be generated. Exposure is expected to be minimised by the use of appropriate PPE including gloves and protective clothing.

Retail and End-use

Dermal exposure to the notified polymer (at < 10% concentration) is expected during normal use such as removing the pouch and placing it into equipment (e.g. dishwashers or washing machines), as well as during any potential spills and may be reduced by the use of PPE.

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

6.2.2. Public Health and Safety Risk Assessment

Consumers are expected to have similar but less frequent potential than workers for exposure to the notified polymer at < 10% concentration in pouches filled with detergent (risk assessment 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 from these activities. It will be imported as a film and will be moulded into containers for unit doses of liquid. During the production of unit doses, it is likely that film waste will be produced (2% of the total import volume) from cut-off edges and residues remaining with the moulding machinery. The waste film is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer dissolves on use as a component in film containers 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 the majority is expected to be disposed of to sewer. Some of the notified polymer may be disposed of to landfill when film waste is discarded. There is some domestic waste expected to be disposed of to landfill when unused detergents in film containers are discarded.

7.1.2. Environmental Fate

The notified polymer has potential for biodegradation based on the environmental fate study. The notified polymer showed 82.2% of biodegradation during the 33-day 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 study 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 containers 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. It is conservatively assumed that 0% of the notified polymer will be removed during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	20,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	20,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	54.79	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	12.12	µg/L
PEC - Ocean:	1.21	µg/L

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 chemical 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 12.1 µg/L may potentially result in a soil concentration of approximately 80.8 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 403.9 µg/kg and 807.7 µg/kg, respectively.

7.2. Environmental Effects Assessment

The result from an ecotoxicological investigation conducted on the notified polymer is summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish	LC50 (96 h) > 1,000 mg/L	Not harmful to fish

The notified polymer is an anionic polymer. Anionic polymers are generally of low toxicity to fish and aquatic invertebrates but 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, which is unlikely to apply to the notified polymer due to the addition of non-chelating functionality. Further, the indirect toxicity to algae is likely to be mitigated due to the presence of calcium ions in the aquatic compartment, which can bind to the functional groups of the notified polymer.

The notified polymer is not expected to be harmful to fish. Therefore, the notified polymer has not been formally classified for acute aquatic hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009). The notified polymer is expected to degrade in the environment and is not considered to have potential for bioaccumulation. On the basis of its acute toxicity, the notified polymer is not 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 (fish) and an assessment factor of 1000. A conservative assessment factor of 1000 was used as one acute toxicity endpoint for an aquatic species from only one trophic level is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Fish).	> 1,000	mg/L
Assessment Factor	1,000	
PNEC:	> 1,000	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:	12.12	> 1,000	< 0.012
Q - Ocean:	1.21	> 1,000	< 0.001

The risk quotients for discharge of 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 is expected to be biodegradable in the environment. It is thus unlikely to persist in surface waters or soils. 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

Partition Coefficient (n-octanol/water) Not determined

Method	OECD TG 107 Partition Coefficient (n-octanol/water): Shake Flask 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, the log Pow value for the notified polymer was not found to be a meaningful value.
Test Facility	Japan (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/ Crj:CD(SD)
Vehicle	Water
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6M, 6F	2,000	0/12

LD50	>2,000 mg/kg bw
Signs of Toxicity	No signs of toxicity were reported during the study period.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	Surviving animals showed expected gains in bodyweight over the study period.
CONCLUSION	The notified chemical was found to be of low toxicity via the oral route.
TEST FACILITY	Life Science Laboratories (2003)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	ISO-14851/JIS-K6950: Degree of Biological Decomposition from Oxygen Demand (BOD)
Inoculum	Activated sludge
Exposure Period	33 days
Auxiliary Solvent	None reported
Analytical Monitoring	Closed system oxygen consumption measuring equipment/COULOMETER OM3100A
Remarks - Method	The test was conducted according to the guidelines above, which are similar to OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.

RESULTS

Test substance		*Cellulose*	
Day	*% Degradation*	*Day*	*% Degradation*
33	82.2	33	79.7

Remarks - Results	The percent degradation of the reference compound in 14 days during the 33-day test period was not reported. Therefore, it cannot be recommended that the test satisfy the validity criteria. The reference compound, cellulose, reached the 60% pass level at the end of the 33-day test. However, it was not mentioned in the study report that the 60% pass level was reached in a 10-d window within the 28-d period of the test. The degree of degradation of the notified polymer at the end of the 33-day test was 82.2%. Therefore, the test substance cannot be classified as readily biodegradable according to the OECD (301 B) guideline. However, based on the available information, the notified polymer has potential for biodegradation.
CONCLUSION	The notified polymer has potential for biodegradation.
TEST FACILITY	Mitsui (2003)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	Semi-static Acute Toxicity Test with Medaka
Species	Medaka (*Oryzias latipes*)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks – Method	The test was conducted using a non-standard method, which is similar to OECD TG 203. The ecotoxicity test consisted of only one treatment and a control without any replication. The test solution was renewed after 48-hour exposure. This test was a limit test.

RESULTS

Nominal Concentration (mg/L)	*Number of Fish*	*Mortality (96 h) (%)*
Control	10	0
1000	10	0

LC50	>1,000 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. There was no mortality of fish observed for the concentration tested.

CONCLUSION The notified polymer is not harmful to fish.

TEST FACILITY Mitsubishi (2003)

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