File No: LTD/1710

May 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Gohsenol KX-315L

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:

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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/1710	M&A Trading Pty Ltd	Gohsenol KX-315L	ND*	≤ 150 tonnes per annum	Agent for polymer manufacture

*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

- Based on the information provided, no specific engineering controls or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

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

- 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 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 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 an agent for polymer manufacture, 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 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)
M&A Trading Pty Ltd (ABN: 17 000 704 450)
Suite 134/438 Forest Rd
HURSTVILLE NSW 2220

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 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, degree of purity, polymer constituents, residual monomers, impurities, and import volume.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Gohsenol KX-315L

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 94%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White to slightly yellowish powder/granules

Property	Value	Data Source/Justification
Melting Point	140-210 °C	SDS
Boiling Point	Not determined	Expected to be high based on high molecular weight
Density	1,190-1,310 kg/m^3 at 20 °C	SDS
Vapour Pressure	Not determined	Expected to have a low vapour pressure based on high molecular weight.
Water Solubility	≥ 1% (w/w) at 25 °C	Measured. Expected to be highly water soluble based on the presence of hydrophilic moieties in the chemical structure
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functionality that may slowly hydrolyse under normal environmental conditions of

		pH 4 – 9
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to have potential to partition to water phase based on the presence of hydrophilic moieties in the chemical structure
Adsorption/Desorption	Not determined	Expected to have low mobility in soil based on its high molecular weight
Dissociation Constant	Not determined	The notified polymer contains no readily dissociable functional groups and is not expected to be ionised in the environment
Particle Size	Inhalable fraction (< 100 μm): 0%	Measured
Flash Point	> 300 °C at 101 kPa	SDS
Flammability	Not determined	Not expected to be flammable based on flash point
Autoignition Temperature	200 °C	SDS
Explosive Properties	Not explosive	SDS
Oxidising Properties	Not determined	Not expected to have 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
Imported neat (> 94% purity) in powder/granule form.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 150	< 150	< 150	< 150	< 150

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 20 kg lined paper bags.

USE
The notified polymer will be used as a dispersing stabiliser for the suspension polymerisation of vinyl chloride monomer.

OPERATION DESCRIPTION
No reformulation of the notified polymer will occur in Australia.

At the end use site the notified polymer will be manually added via a port to a dissolution tank where it will be dissolved in water through heating. The resulting polymer solution (containing the notified polymer at 20-100 g/L) will then be dosed into a sealed, heated and pressurised polymerisation reactor to achieve a concentration of 100-200 ppm of the notified polymer in the reactor. Liquefied vinyl chloride monomer will be added to the reactor, which after addition of the initiator and other agents undergoes polymerisation to give polyvinyl chloride (PVC). The PVC will be isolated and the supernatant recovered and recycled via an on-site water

purification/recycling plant using membrane filtration. The notified polymer is expected to be removed during the supernatant recycling process and will be collected as sludge and disposed of to landfill.

The operation, with the exception of the manual addition of the notified polymer to the dissolution tank, will be fully automated and sealed.

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 Storage	2-4	12
PVC manufacture	2-6	200

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. Safety glasses, gloves and dust masks will be worn during any clean-up operation.

PVC Manufacture
Operators may be exposed to the notified polymer (at > 94% concentration) through the manual addition of the notified polymer to the dissolution tank. Exposure to the notified polymer may occur by dermal, inhalation and/or ocular routes. Exposure should be minimised by the stated use of PPE (coveralls, safety glasses, impervious gloves and a respirator) and local exhaust ventilation to remove any dusts and aerosols. Exposure at other times is not expected as the operation is fully automated and sealed.

6.1.2. Public Exposure
The notified polymer will be used in an industrial process and the majority will be removed from the PVC stream during the manufacturing process. The public may come into contact with the finished manufactured PVC articles. However exposure to the notified polymer is not expected as the notified polymer will not be present at significant levels in the manufactured articles and if present will be trapped within the PVC matrix and not available for exposure.

6.2. Human Health Effects Assessment
No toxicological data were submitted for the notified polymer.

The notified polymer is a modified polyvinyl alcohol (PVA). PVA polymers have been shown to have low oral toxicity after both acute and repeated exposure (DeMerlis et al, 2003) as well as low dermal toxicity, slight to no eye or skin irritation, to be non-sensitising, and not genotoxic (Nair, 1998). Furthermore, a study provided by the notifier on partially saponified PVA was found to be non-irritating to the eye (see Appendix B for details).

The notified polymer is expected to have very similar properties to PVA, as the additional monomer present in the notified polymer is not expected to significantly affect the polymer's toxicity. As such, PVA is considered to be suitable analogue to estimate the toxicity of the notified polymer.

The notified polymer has a high molecular weight (> 10,000 Da) with a low percentage of low molecular weight species and is highly water soluble; hence it is not expected to be absorbed following oral, dermal or inhalation exposure. Lung overloading effects are also not expected given the high water solubility.

Health hazard classification
As no toxicity data on the notified polymer 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

Based on the results of analogous polymers and the absence of structural alerts of concern, the notified polymer is expected to be of low hazard.

Workers may be exposed to dusts of the notified polymer when manually adding the polymer to the dissolution tank. The notified polymer does not contain particles in the respirable or inhalable size range hence inhalation exposure is not expected. Furthermore, the expected use of dust masks and local exhaust ventilation when handling the powdered notified polymer by workers should reduce any potential for inhalation exposure. If inhalation were to occur, lung overloading effects would not be expected as the notified polymer is highly water soluble and would be expected to be readily cleared from the lungs.

Overall, based on the expected low hazardous nature of the notified polymer, the risk to workers is not considered unreasonable.

6.3.2. Public Health

The public are not expected to be exposed to the notified polymer, hence the risk to the public is not considered to be unreasonable under the proposed use of the notified polymer.

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/repackaged in Australia; therefore there is no release of the notified polymer to the environment from these activities.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used as a dispersing stabiliser for the suspension polymerisation of vinyl chloride monomer. Residues of the notified polymer in the empty containers are expected to be disposed of to landfill along with the empty containers. Accidental spills are expected to be collected and disposed of to landfill. Almost the entire notified polymer is expected to be recovered in the on-site recycling plant. The notified polymer is expected to be efficiently removed during the recycling process by filtration using membrane technology. The notified polymer collected as sludge from the on-site recycling plant is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer is expected to be disposed of to landfill either from residues in empty containers and spills or when associated with sludge from the on-site recycling plant.

7.1.2. Environmental Fate

The notified polymer has potential for biodegradation based on the environmental fate study conducted on an analogue (PVA) submitted by the notifier. The analogue showed 90% biodegradation within 14 days when exposed to a selected strain of sewage bacteria. 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 an on-site recycling plant as industrial effluent. The majority of the notified polymer is expected to be removed from the wastewater at the on-site recycling plant by membrane filtration. The treated wastewater is then expected to be released to the sewer. During wastewater treatment processes in sewage treatment plants (STPs), a further 90% of notified polymer is expected to be removed from wastewaters due to its high molecular weight (Boethling and Nabholz, 1997). Notified polymer in treated sewage effluent may be released to surface waters or applied to land when used for irrigation. Notified polymer bound to 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 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 water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use for the notified polymer as a dispersing stabilizer for polymerization, it is conservatively assumed that 100% of the total import volume of the notified polymer will be released to the sewer. It is expected that 90% of the notified polymer will be removed to sludge during sewerage treatment plant (STP) processes (Boethling and Nabholz, 1997). As the notified polymer is to be processed at a polymerization facility, it is anticipated that such releases will occur one day per week into a local metropolitan STP (456 ML capacity). The resultant estimate for the predicted environmental concentration (PEC) in sewage effluent from individual STP is summarised in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	150,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	150,000	kg/year
Days per year where release occurs	52	days/year
Daily chemical release:	2884.6	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	456	ML/day
Removal within STP	90%	**Mitigation**
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	632.59	µg/L
PEC - Ocean:	63.26	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 56.93 g/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 polymer may approximate 379.6 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 1.9 g/kg and 3.8 g/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 632.6 µg/L may potentially result in a soil concentration of approximately 4.2 mg/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 21.1 mg/kg and 42.2 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified polymer. The result from an ecotoxicological investigation conducted on an analogue (PVA), which is a constituent in the notified polymer, is summarised in the table below. Details of the study of the analogue can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (48 h)	LC50 > 1000 mg/L	Not expected to be harmful to fish

On the basis of the acute toxicity data of the analogue, the notified polymer is not expected to be harmful to aquatic organisms. The notified polymer is a non-ionic polymer which is generally of low concern to the 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 for its acute and long-term hazard.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has been calculated from the acute toxicity data (fish) for the analogue 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 (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 (Q) have been calculated for the aquatic compartment:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	632.59	1000	0.633
Q - Ocean:	63.26	1000	0.063

The risk quotients for the worst case 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 ≥ 1% (w/w) at 25 °C

Method In-house method
Remarks Water solubility of the notified polymer was determined using two concentrations (weight percent) of 0.1% and 1.0%. After the test solutions were prepared (8-hour stirring period), the solutions were observed. Both solutions were clear and undissolved residue was not observed.
Test Facility Not reported (2013)

Particle Size

Method In-house analytical method – test material is sieved using different-sized standard sieves (JIS Z 8801) and the weight of each test material on each different sieve is measured.

Range (μm)	*Mass (%)*
106-150	0.9
150-300	3.5
300-500	12.1
500-710	20.0
710-1000	34.2
> 1000	29.3

Remarks The proportion of particles in the inhalable fraction (< 100 μm) was 0.0%
Test Facility Not reported (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – eye

TEST SUBSTANCE	Analogue (partially hydrolysed PVA; degree of saponification 88.2 %)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	Three (male)
Observation Period	72 h
Remarks - Method	Partially hydrolysed polyvinyl alcohol (100 mg) as a white crystalline solid was instilled into the eyes of three New Zealand White rabbits. Observations were made at 1, 24, 48 and 72 h post instillation with signs of irritation noted at each time point.
RESULTS	
Remarks - Results	Slight conjunctival redness (grade 1) was noted in all animals at 1 h post instillation which was fully resolved by the 24 h observation period. No corneal or iridial effects were observed. The study author suggests that the reactions noted were possibly caused by mechanical damage due to the granular test material rather than chemical damage.
CONCLUSION	The notified polymer is non-irritating to the eye.
TEST FACILITY	Inveresk Research International (1992)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue (PVA; degree of saponification 88-99.3%)
METHOD	In-house method
Inoculum	*Pseudomonas* Bacteria cultured on PVA
Exposure Period	144 days
Auxiliary Solvent	Not reported
Analytical Monitoring	Total Organic Carbon (TOC) analysis
Remarks - Method	The decomposition and assimilation of PVA was studied using the *Pseudomonas* bacteria. It was conducted by the standard microorganism screening technique to isolate microorganisms that decompose and assimilate polyvinyl alcohol (PVA), and search for microorganisms that would grow on culture media containing PVA as the only carbon compound. It was reported in the study that bacteria (colonies) that grew on agar culture media containing PVA were selected and pure bacteria were obtained. Among the selected colonies, which assimilate PVA, the bacteria belonged to the *Pseudomonas* family was chosen as it was considered the most well suited to decompose and assimilate PVA. The bacteria were exposed to PVA in wastewater to determine the level of degradation of PVA. TOC analysis was carried out to measure TOC removal rate (% degradation).

RESULTS

Test substance	
Day	*% Degradation*
14	90.0
28	87.8
42	96.1
144	96.0

Remarks - Results	It was found that the bacteria generated protein that apparently looked like the residue of the initial TOC concentration. The bacteria almost completely decomposed and assimilated PVA. The properties of PVA were examined and used for the experiment.
CONCLUSION	The TOC removal rate for PVA wastewater at the on-side recycling/treatment plant was 90% on day 14.
TEST FACILITY	Not reported (1975)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue (PVA; degree of saponification not reported)
METHOD	A Testing Method for Industrial Wastewater and Acute Toxicity for Fish Specified by 7.1 of K 0102-1986
Species	Japanese Killifish (*Oryzias latipes*)
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks – Method	The test was a limit test. Only one treatment concentration was used and inclusion of a control was not reported. The test method was similar to OECD TG 203 Fish, Acute Toxicity Test. No significant deviation from the test guidelines was reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*		
Nominal	*Actual*		*1 h*	*24 h*	*48 h*
Control	-	Not reported			
1000	Not detected	0	0	0	0

LC50	> 1000 mg/L at 48 hours.
NOEC (or LOEC)	> 1000 mg/L at 48 hours.
Remarks – Results	Validity criteria for the test were not satisfied as the mortality for controls were not reported.
CONCLUSION	The analogue and, by inference, the notified polymer are not harmful to fish.
TEST FACILITY	Japan (1992)

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