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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Aquatreat® HP 250

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
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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/1847	Akzo Nobel Pty Limited	Polymer in Aquatreat® HP 250	ND*	≤ 50 tonnes per annum	Scale inhibitor in water cooling towers

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of 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 its limited aquatic exposure 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

- No specific engineering controls, work practices 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 of 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

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical 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 scale inhibitor in water cooling towers, 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

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Akzo Nobel Pty Limited (ABN: 59 000 119 424)
8 Kellaway Place
WETHERILL PARK NSW 2164

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, site of manufacture/reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints except water solubility and hydrolysis as a function of pH.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/814, CER/47

NOTIFICATION IN OTHER COUNTRIES
Canada (2011)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Aquatreat® HP 250 (product containing the notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference GPC and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Amber colour liquid (product)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer will be imported in an aqueous solution
Boiling Point	Not determined	The notified polymer will be imported in an aqueous solution
Density	1,050 kg/m^3 at 25 °C	(M)SDS (product)
Vapour Pressure	< 1.3 × 10^{-9} kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)

Water Solubility	Expected to be fully water soluble	Component of an aqueous solution
Hydrolysis as a Function of pH	$t_{½}$ > 1 year at pH 4, 7, and 9	Measured
Partition Coefficient (n-octanol/water)	log Pow = -2.95 at 21 °C	Measured
Adsorption/Desorption	Not determined	Expected to partially adsorb to soil and sediment based on molecular weight, water solubility, and anionic properties
Dissociation Constant	pKa = -3.4 ± 0.4 (strongest acid)	Calculated using ACD I-Lab
Flash Point	Not determined	Imported in aqueous solution
Autoignition Temperature	Not determined	Imported in aqueous solution
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES
The notified polymer is synthesized in solution and is not isolated. The final product contains 50-75%.

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 of 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 and/or reformulated in Australia. The notified polymer will be imported in a product at up to 50% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	< 50	< 50	< 50

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The product containing the notified polymer will be imported in 200 L drums or 1,000 L intermediate bulk containers. The containers will be transported from dock to the site of use by road and stored there until required for use.

USE
The notified polymer will be used as a scale inhibitor in water cooling towers.

OPERATION DESCRIPTION
The notified polymer will be imported as an aqueous solution at ≤ 50% concentration in bulk containers. At the site of use the notified polymer will be pumped directly from storage containers into the process stream via an automated dosing system. The process will be automated with the workers involved in coupling and decoupling of the transfer hose to the bulk containers. Once empty, the containers will be disposed by licensed waste contractor. The final concentration of the notified polymer in the cooling mixture will be < 10 part per million (ppm). The cooling water will be recirculated, and the level of the notified polymer in the cooling water will be replenished when needed. Periodically the water treatment plant may undergo maintenance during which cooling

water containing the notified polymer will be released to an on-site wastewater treatment plant prior to discharge into the environment.

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	0.5	2-4
Dispensing workers	0.5	2-4
Plant operators	8-12	260

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified polymer (at ≤ 50 % concentration) except in the unlikely event of an accidental release due to container breach or spill.

Dermal and ocular exposure of workers to the notified polymer at up 50% concentration may occur during opening and closing of containers and coupling/decoupling of transfer hoses. The dispensing process itself is automated. At this stage of the process, inhalation exposure is not expected due to the high molecular weight and estimated low vapour pressure ($< 1.3 \times 10^{-9}$ kPa).

Plant operators may be indirectly exposed to the notified polymer at very low concentrations (< 10ppm) from aerosol originating from the top of the cooling towers. The main route of exposure will be dermal, however inhalation exposure may also occur.

6.1.2. Public Exposure
The notified polymer is intended for use in industry only. Public exposure to the notified polymer is not expected except in the unlikely event of an accident occurring during road transport. Direct exposure to the public is therefore expected to be negligible. However there is a potential for indirect exposure from the environment from cooling tower drift at concentrations of up to 10 ppm. Such an exposure is expected to be very low as the site of use is not close to heavily populated areas, the polymer would not partition readily into air, and the emissions contain a very low concentration of the notified polymer.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. Dosing was adjusted to take account of the concentration of the polymer in the test substance. Information on other endpoints is not available.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 300 mg/kg bw
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non genotoxic

Acute toxicity
The notified polymer exhibited low acute oral toxicity in female rats with an estimated LD50 of greater than 2,000 mg/kg bw. No deaths or abnormal changes in body weight were observed in Wistar rats (females only) following oral gavage exposure to a single limit dose of 2,000 mg test substance/kg bw. Initially, 1 animal was dosed at 300 mg/kg bw as a test dose, followed by 4 animals dosed at 2,000 mg/kg bw and 1 dosed at 2,292 mg/kg bw (due to a dosing error). During the 14-day observation period, no systemic toxicity was observed in any of the animals. No abnormal macroscopic observations were made at terminal necropsy on day 14.

Repeated Dose Toxicity
A 28-day oral repeated dose toxicity test was conducted using the notified polymer. Groups of 5 male and 5 female Wistar rats were administered the test substance orally via gavage for 28 days at concentrations of 100, 300, and 1,000 mg/kg/day. All animals survived until the scheduled necropsy and no test substance related

clinical behavioural changes were noted. At 300 mg/kg/day, males were noted to have increased blood glucose and phospholipid levels. Bilirubin levels were seen to be decreased in males. T3 levels were significantly increased in both sexes at the 300 mg/kg/day group however this was not dose related and is considered incidental. Males at this dose were also noted to have absolute liver and liver/body weight and liver/brain weight increase as well as decreased absolute and relative adrenal weight. There was minimal to slight hepatocellular hypertrophy in males as well as increased glycogen. At the 1,000 mg/kg dose males were noted to have increased blood glucose, triglyceride and phospholipid levels. Bilirubin was seen to be decreased in both males and females. Males at this dose were also noted to have absolute liver and liver/body weight and liver/brain weight increase as well as decreased absolute and relative adrenal weight. There was minimal to slight hepatocellular hypertrophy in males as well as minimal to slight follicular cell hypertrophy in the thyroid gland.

These observations were considered to be indicative of increased metabolism in the liver and an adaptive response. Based on the various effects observed, a NOAEL of 300 mg/kg/day was established by the study author. The notified substance is considered to have low - moderate repeated dose oral toxicity.

Mutagenicity/Genotoxicity
In vitro Ames test was conducted on the notified polymer. No substantial increases in the number of revertant colonies were observed in *S. typhimurium* strains TA98, TA100, TA1535, or TA1537, or in *E. Coli* strain WP2uvrA when plated with the test substance at dose levels up to 5,000 µg/plate, either in the presence or absence of exogenous metabolic activation. The notified polymer is considered to be non-mutagenic in this test system.

In Vitro Chromosomal Aberrations was also conducted on the notified polymer. No evidence of clastogenic activity was observed after cultured human lymphocyte cells were exposed to concentrations of the notified substance up to 5,000 µg/mL, either in the presence or absence of exogenous metabolic activation.

Based on the study results, the notified polymer is considered to have low hazard potential in *in vitro* genotoxicity.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of 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
The notified polymer is of high molecular weight and based on available information is not classified as hazardous. It will be used as a scale inhibitor in water cooling towers and will be added periodically to the tower, when dermal and accidental ocular exposure to the notified polymer at up to 50% concentration may occur. Inhalation exposure is not expected during this process but may occur at very low levels (< 10 ppm) from aerosol originating from the top of the cooling towers.

Overall the notified polymer is not expected to pose an unreasonable risk to workers.

6.3.2. Public Health
The notified polymer is for industrial use only and as such no public exposure is expected. Indirect exposure through the environment may occur, at very low levels only.

Overall considering the use pattern and expected hazard of the notified polymer, the risk to the public is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported as a finished aqueous solution for scale inhibition in water cooling towers. The notified polymer will not be manufactured or reformulated in Australia. Therefore, the release of the notified

polymer to the environment is expected to be limited to accidental spills and leaks, which are expected to be disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The notified polymer is not expected to be released to the environment during use under normal operating conditions as a scale inhibitor in water cooling towers. The notified polymer will be dosed directly from import containers into the cooling tower water circuit, with continual dosing and discharge of the treated water to maintain the concentration of the notified polymer in the system. It is estimated by the notifier that approximately 0.5% (or 250 kg) of the notified polymer may be released to the environment as a result from accidental spills and leaks during coupling and decoupling of containers to the dosing system.

The majority of the notified polymer will be removed from the system during service maintenance operations through manual system blowdown. Wastewater from normal operations and service maintenance will be discharged into an on-site dam before release to a local sewage treatment plant (STP). A negligible amount of the notified polymer may also be released into the environment in the form of condensation on the water cooling towers (estimated by the notifier to be 0.002%, or 1 kg).

RELEASE OF CHEMICAL FROM DISPOSAL
The notified polymer in wastewater is expected to be discharged into an on-site dam before being released to a local STP. It is expected that up to 100% of the import volume of the notified polymer will eventually be released to undergo wastewater treatment. It is estimated by the notifier that approximately 1% (or 500 kg) of the notified polymer will remain as residue in import containers, which are expected to be collected and disposed of to landfill by licensed waste disposal contractors.

7.1.2. Environmental Fate
Following its use, the majority of the notified polymer is expected to be released into an on-site dam, before undergoing wastewater treatment processes. A negligible amount of the notified polymer may also be released through condensation on the water cooling towers; however, based on its expected low vapour pressure, high molecular weight and high water solubility, the notified polymer is unlikely to partition to the air compartment and is expected to remain as residue on cooling tower surfaces. The notified polymer is not considered readily biodegradable, but shows inherent biodegradability (30% in 28 days). For details of the environmental fate study, please refer to Appendix C. Based on its water solubility, molecular weight and anionic properties, release to surface waters may occur as only partial partitioning to sludge (50%) is expected (Boethling and Nabholz, 1997).

The notified polymer is not expected to bioaccumulate due to its high water solubility, low n-octanol/water partition coefficient (log P_{OW} = -2.95) and inherent biodegradability. Therefore, in surface waters and in landfill, the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)
The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified polymer to a local sewage treatment plant (STP). Based on its molecular weight, water solubility and anionic properties, 50% removal in STP processes was predicted (Boethling and Nabholz, 1997) and used in the following calculations. A flow rate of 456 ML/day over 260 working days per year was used for a local STP according to the notifier's information of a single usage site.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	50,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	192.308	kg/day
Individual Sewage Treatment Plant Average Daily Flow	456	ML/day
Removal within STP	50%	**Mitigation**
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	210.864	µg/L
PEC - Ocean:	21.086	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 210.864 µg/L may potentially result in a soil concentration of approximately 1.406 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 7.03 mg/kg and 14.06 mg/kg, respectively.

7.2. Environmental Effects Assessment

Several study reports were submitted on ecotoxicological investigations conducted on the notified polymer in seawater, and one study conducted in freshwater. The studies in seawater indicated low toxicity to marine organisms of three trophic levels, and marine sediment dwellers. As the notified polymer is not expected to be released directly to marine waters, only the results from the ecotoxicological investigation conducted in freshwater are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful to *Daphnia*

Based on the above ecotoxicological endpoint for the notified polymer, it is not expected to be harmful to daphnids. Therefore, the notified polymer is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated, since the notified polymer is not considered to be harmful to aquatic organisms, and no significant release of the notified polymer to the aquatic environment is expected.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) of the notified polymer has not been calculated, due to its low potential for release to the aquatic compartment and low toxicity to aquatic organisms. The majority of the notified polymer will be contained within an on-site dam following use as a scale inhibitor in water cooling towers, before undergoing STP processes. Based on its high water solubility, high molecular weight and low log P_{OW}, the notified polymer is not expected to be bioaccumulative. On the basis of its limited aquatic exposure and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Hydrolysis as a Function of pH $t_{½}$ > 1 year at pH 4, 7, and 9

Method EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ (years)*
4	25	> 1
7	25	> 1
9	25	> 1

Remarks The test was conducted under accelerated conditions of 50 °C for 5 days at pH 4, 7, and 9. The amount of degradation of the notified polymer was determined to be < 10% after 5 days, which equates to $t_{½}$ > 1 year at 25 °C.
Test Facility Harlan (2010a)

Partition Coefficient (n-octanol/water) log Pow = -2.95 at 21 °C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks Shake Flask Method
Test Facility SafePharm (2008)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test..
Inoculum	Secondary activated sludge
Exposure Period	28 days (extended to 84 days)
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Oxygen Demand (ThOD)
Remarks - Method	Ammonium chloride was omitted from the test medium to prevent oxygen consumption due to nitrification. The deviation from protocol was not deemed to have had a significant impact on the validity or integrity of the study. All other validity criteria were met and satisfied.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
7	13	7	63
14	22	14	76
21	27		
28	30		
42	33		
56	38		
84	40		

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium acetate, surpassed the threshold level of 60% by 7 days (63%), and achieved 76% degradation by 14 days. Therefore, the test indicates the suitability of the inoculum. The notified polymer attained 30% degradation by 28 days. The rate of degradation had slowed after 20 days, although a degradation plateau was not achieved by 28 days. Therefore, the notified polymer cannot be classified as readily biodegradable according to the OECD (301 D) guideline. However, the notified polymer exhibited inherent biodegradability.
CONCLUSION	The notified polymer is not readily biodegradable.
TEST FACILITY	Akzo Nobel (2008)

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