File No: STD/1609

September 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in 031556

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 and Energy.

This Public Report is 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

TABLE OF CONTENTS

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
STD/1609	Cintox Australia Pty Ltd	Polymer in 031556	Yes	≤ 5000 tonnes per annum	Component of marine engine lubricants

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

Human health risk assessment
Provided that the recommended controls are being adhered to, 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 reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Skin Sensitisation (Category 1): H317 – May cause an allergic skin reaction

The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

Health Surveillance

- As the notified polymer is a sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation:
  - Enclosed, automated processes, where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with skin and eyes
  - Avoid generation of mists or aerosols during reformulation

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Impervious gloves, coveralls and goggles

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

- A copy of the 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 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
  - products containing the notified polymer are made available to the public for DIY use;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of marine engine lubricants, 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.

Safety Data Sheet

The SDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Cintox Australia Pty Ltd (ABN: 63 122 874 613)
Suite 1, Level 2, 38-40 George Street
PARRAMATTA NSW 2150

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year) – Similar to a chemical that has been previously assessed by NICNAS as STD/1251.

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 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 except melting point, density, vapour pressure and water solubility, and all endpoints for human health and environmental effects.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
031556 (product containing the notified polymer at < 60% concentration)

MOLECULAR WEIGHT
> 400 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC and GPC data were provided.

3. COMPOSITION

DEGREE OF PURITY
60-80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point*	-14 °C	Measured (summary only supplied)
Boiling Point	Not determined	Expected to decompose before boiling
Density*	995 kg/m^3 at 20 °C	Measured (summary only supplied)
Vapour Pressure	2.3× 10^{-7} kPa at 20 °C	Calculated
Water Solubility*	< 1.3 × 10^{-4} g/L	Measured
Hydrolysis as a Function of pH	Not determined	Does not contain any readily hydrolysable functional groups and is expected to be stable at the environmental pH range (4-9)
Partition Coefficient* (n-octanol/water)	21.4	Measured. Expected to partition to phase boundaries based on its expected surface

Property	Value	Data Source/Justification
		activity
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on its low water solubility and surface activity
Dissociation Constant	Not determined	The notified polymer is a salt and expected to be ionised under environmental conditions
Flash Point*	180 °C at 101.3 kPa	Measured
Flammability	Not determined	-
Autoignition Temperature	Not determined	-
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

* For the product containing < 60% notified polymer.

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 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 in Australia. It will be imported as a component of lubricant additive packages at ≤ 25% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1,000-5,000	1,000-5,000	1,000-5,000	1,000-5,000	1,000-5,000

PORT OF ENTRY
Brisbane, Melbourne, Perth, Sydney

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in containers of various sizes, either 205 L drums or larger bulk containers. At the port of entry the lubricant additive packages containing the notified polymer at ≤ 25% concentration will be offloaded to tank trucks or rail cars for distribution. Around 70% will be delivered using tank trucks and rail cars and 30% delivered in 205 L drums.

USE
The notified polymer will be used as a component of lubricants at ≤ 10% concentration for marine engines.

OPERATION DESCRIPTION
Reformulation
At blending sites, the lubricant additive packages containing the notified polymer at ≤ 25% concentration will be transferred into storage tanks via 10 cm hose using pumping equipment. From the storage tanks, the product will be pumped to blend tanks through a computer-controlled automated valve process and fixed lines. After blending with other components, the final product (lubricant oil) containing the notified polymer at ≤ 10% concentration will be transferred back to storage tanks and later to 205 L drums or isotainers for distribution to customers. The process will be automated and occur in an enclosed system. Samples will be collected at various stages for quality control testing.

End-use
Lubricant engine oils containing the notified polymer at ≤ 10% concentration will be used to lubricate marine engines. When used in stationary engines, routine lubrication is likely to use dedicated lubricating oil reservoirs and piping to add fluids directly. When used in non-stationary marine applications, workers are likely to manually check the engine lubricant levels and additional fluid will be added using pneumatic delivery equipment.

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)*
Unloading isotanks and drums of additive package	0.5	30
Sampling and analysing additive package	0.2	220
Unloading isotanks and drums of finished oil	0.5	30
Sampling and analysing finished oil	0.2	220
Loading oil in tank trucks	0.5	220
Distribution to service stations	0.5	220
Mechanics/engineers	8	12

EXPOSURE DETAILS
Transport and storage
Transport and storage workers are not expected to be exposed to the notified polymer except in an event of spills or leaks. They may experience dermal and perhaps ocular exposure during clean-up of spills. Workers are expected to wear personal protective equipment (PPE) such as coveralls, goggles and impervious gloves to reduce exposure.

Reformulation
Reformulation is expected to be largely enclosed and automated, therefore limited exposure is expected. Dermal and accidental ocular exposure may occur to the notified polymer at ≤ 25% concentration during transfer processes and quality control testing. The notifier advised that proper control measures along with PPE such as impervious gloves, coveralls and goggles will be employed to reduce exposure.

End-use
Mechanics/engineers may experience dermal and perhaps ocular exposure to the notified polymer at ≤ 10% concentration when adding the lubricants manually or when changing containers and coupling/decoupling of transfer hoses for automated addition. Workers are expected to receive training on handling of oils and to wear PPE such as coveralls, impervious gloves, and goggles to reduce exposure.

6.1.2. Public Exposure
The notified polymer is intended for industrial use only and will not be available to the public. Public exposure to the notified polymer may occur in the unlikely event of a transport accident or a spillage/loss of lubricant product from a marine engine.

6.2. Human Health Effects Assessment
No toxicity data were provided for the notified polymer. The results from toxicological investigations conducted on an analogue chemical (chemical previously assessed by NICNAS (STD/1251)) have been used to estimate the hazard profile of the notified polymer and are summarised in the following table.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	moderately irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation –non-adjuvant test	evidence of sensitisation

Rat, repeat dose oral toxicity – 28 days	NOEL = 160 mg/kg bw/day NOAEL = 400 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic
Genotoxicity – in vivo mammalian erythrocyte micronucleus test	non genotoxic

Toxicokinetics
Based on the relatively low molecular weight (> 400 Da) the notified polymer may have the potential to cross biological membranes.

Acute toxicity
The analogue chemical was found to be of low acute oral toxicity in rats.

Irritation and sensitisation
The analogue chemical was found to be moderately irritating to skin and slightly irritating to eyes based on studies conducted in rabbits according to OECD test guidelines.

The analogue chemical was found to be a skin sensitiser in a Guinea pig non-adjuvant test (Buehler) conducted according to the OECD test guideline.

Repeated dose toxicity
In a 28-day repeated dose oral toxicity study conducted according to the OECD test guideline on the analogue chemical at exposure doses of 160, 400 and 1000 mg/kg bw/day, a No Observed Effect Level (NOEL) of 160 mg/kg bw/day was established by the study authors on the basis of clinical observations and serum chemistry at 400 and 1000 mg/kg bw/day, and body weight and coagulation parameter effects at 1000 mg/kg bw/day. A No Observed Adverse Effect Level (NOAEL) of 400 mg/kg bw/day was established by the study authors based on the absence of related microscopic changes for the clinical observations and serum chemistry level effects.

Mutagenicity/Genotoxicity
The analogue chemical tested negative both in a bacterial reverse mutation assay and in an *in vitro* mammalian chromosomal aberration test. The analogue chemical also tested negative in an *in vivo* mouse micronucleus test. All studies were conducted according to OECD test guidelines.

Health hazard classification
Based on the available information on a close analogue, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

6.3. Human Health Risk Characterisation
Based on toxicological data provided on an analogue chemical, the critical health effect of the notified polymer is as a skin sensitiser. The notified polymer is also expected to be moderately irritating to the skin and slightly irritating to eyes.

6.3.1. Occupational Health and Safety
Reformulation workers and professional end-users may be exposed to the notified polymer at ≤ 25% concentration during reformulation, packaging and end-use. The proposed use of PPE including impervious gloves, coveralls and goggles and largely enclosed, automated processes during reformulation is expected to minimise dermal and accidental ocular exposure.

Provided that the stipulated control measures are in place and the proposed PPE is employed, the risk to workers from use of the notified polymer is not considered unreasonable.

6.3.2. Public Health

The notified polymer is only intended for use in industrial settings, and hence public exposure is not expected. Therefore, when used in the proposed manner, the risk to public health from the notified polymer is not considered 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 be used as a component of lubricant oils for marine vessel engines.

The notified polymer will be imported into Australia as a component of lubricating oil additive packages for reformulation into lubricant oils for marine vessel engines. Significant release of the notified polymer to the environment is not expected during transport and storage except in the unlikely event of an accidental spillage or leakage. Accidental leaks and spills of the product containing the notified polymer is expected to be collected by inert absorbent material and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that are expected to occur within a fully automated controlled enclosed system. Therefore, significant release of the notified polymer from this process to the environment is not expected. After reformulation, empty import drums containing residual notified polymer are expected to be steam cleaned, with the residual waste sent to on-site wastewater treatment facilities or collected for disposal by licensed waste management services. It is estimated by the notifier that 0.1% of the annual import volume (5000 kg) of the notified polymer may be sent to the waste water treatment facilities.

RELEASE OF CHEMICAL FROM USE

The finished lubricants containing the notified polymer will be used for lubricating marine vessel engines by professionals. Release during use may arise from spills when pouring lubricants into engines or from engine leaks, and is expected to be very low.

RELEASE OF CHEMICAL FROM DISPOSAL

Any spent or waste product containing the notified polymer is expected to be recycled, re-refined or used as low grade burner fuel, or disposed of by approved waste management. It is likely that the notified polymer will be degraded into simpler compounds during refining, with any residue partitioning to the heavy fractions such as lubricating oils or asphalt.

7.1.2. Environmental Fate

Biodegradation studies conducted on an analogue of the notified polymer indicate the notified polymer is not expected to be readily biodegradable. The acceptable analogue (chemical previously assessed by NICNAS (STD/1251)) and the notified polymer are members of a similar class of chemicals. There is a difference in alkyl chain length and branching between them, however this is not expected to significantly alter their physical-chemical properties. Therefore, the environmental fate for the notified polymer is considered to be well represented by the analogue data.

The majority of the notified polymer in engine oils will be either thermally decomposed during use or recycled. A small proportion of the notified polymer may be released to sewer from the steam cleaning of empty import drums. Notified polymer released to sewers is likely to partition to sludge based on its low water solubility and surface active properties. Notified polymer disposed of to landfill is not expected to be mobile, bioavailable or bioaccumulative based on its low water solubility and surfactant properties. In landfill, the notified polymer is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

It is assumed by the notifier that 0.1 % of the total import volume of the notified polymer may be released to the waste water treatment facilities. Under the worst-case scenario it is assumed that the waste water will be treated at a sewage treatment plant (STP) with a daily flow of 40 ML and there is no removal of the notified polymer during STP processes. Assuming the release occurs 260 days per year, corresponding to working days, the calculated PEC is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5000,000	kg/year
Proportion expected to be released to sewer	0.1%	
Annual quantity of chemical released to sewer	5000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	19.231	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	40.000	ML/day
Removal within STP	0%	
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	480.77	µg/L
PEC - Ocean:	48.08	µg/L

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on water accommodated fractions (WAF) of the analogue chemical is summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL50 (96 h) > 1000 mg/L WAF	Not harmful to fish
Daphnia Toxicity	EL50 (48 h) > 1000 mg/L WAF	Not harmful to aquatic invertebrates
Algal Toxicity	EL50 (96 h) > 1000 mg/L WAF	Not harmful to algae
Inhibition of bacterial respiration	IC50 > 1000 mg/L	Non-inhibitory to microbial respiration

The above ecotoxicological endpoints for the analogue chemical are found to be not harmful to aquatic life. Therefore, the analogue and, by inference, 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 expected to be harmful to aquatic life up to the limit of its solubility in water. There is also no significant release of the notified polymer to the aquatic environment.

7.3. Environmental Risk Assessment

A Risk Quotient (RQ = PEC/PNEC) has not been calculated based on assumed low hazard of the notified polymer. Although the notified polymer is not considered readily biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the assessed use pattern as a component of engine lubricant oils and the expected limited aquatic release, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

The following physico-chemical endpoints were obtained on the product containing the notified polymer at < 60% concentration.

Vapour Pressure 2.3×10^{-7} kPa at 20 °C

Method	OECD TG 104 Vapour Pressure.
Remarks	Directly measured properties (specific gravity and high temperature simulated distillation) were used to calculate the vapour pressure by the Maxwell-Bonwell method.
Test Facility	Confidential

Water Solubility $< 1.3 \times 10^{-4}$ g/L

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. The limit of detection for the analytical method was used to determine the limit of water solubility of the notified polymer.
Test Facility	Confidential

Partition Coefficient (n-octanol/water) $\log P_{ow} = 21.4$ at 35 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method
Test Facility	Confidential

BIBLIOGRAPHY

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.