

File No: EX/218 (LTD/1942)

September 2018

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Polymer in X-17801

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**

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This assessment report is for an extension of original assessment certificate for Polymer in X-17801. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading '*Extension Application*' in the respective sections.

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
EX/218 (LTD/1942)	Total Oil Australia Pty Ltd	Polymer in X-17801	ND*	≤ 1,000 tonnes per annum	Component of engine lubricant

*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 the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

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

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 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 1,000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of engine lubricant, 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 and products containing 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.

Extension Application:

Applicant for the extension application has provided SDS for the product containing the notified polymer. The accuracy of the information on the SDS remains the responsibility of the extension 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

APPLICANTS

Holder of Original Assessment Certificate (LTD/1942):

Afton Chemical Asia Pacific LLC (ABN: 99 109 644 288)

Level 12, 20 Berry Street

NORTH SYDNEY NSW 2060

Applicant for an Extension of the Original Assessment Certificate:

Total Oil Australia Pty Ltd (ABN: 15 149 501 922)

Level 2, 415 Riversdale Road

HAWTHORN EAST VIC 3123

NOTIFICATION CATEGORY

Limited (Reduced fee notification): Synthetic polymer with $M_n \geq 1,000$ Da (approved foreign scheme)

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 and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for density, boiling point, vapour pressure, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, flash point, flammability, autoignition temperature, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT

None

NOTIFICATION IN OTHER COUNTRIES

USA (2012)

Canada (2012)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

X-17801 (product containing the notified polymer at < 60% concentration)

MOLECULAR WEIGHT

Number average molecular weight > 1,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

Extension Application

No new information on physical and chemical properties of the notified polymer was submitted. This section of the assessment report is not modified from the original report.

APPEARANCE AT 20 °C AND 101.3 kPa: brown viscous liquid*

Property	Value	Data Source/Justification
Freezing Point	< -48 °C	Measured
Boiling Point	> 240 °C	Estimated based on thermal analysis results
Specific gravity	0.93 – 0.94 at 15.6/15.6 °C (equivalent to a density of 930 – 940 kg/m ³ at 15.6 °C)	(M)SDS*
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Extractability	0.02 %	Measured
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functionality. However, the notified polymer is not expected to be significantly hydrolysed in the environmental pH range (4 – 9).
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surface activity
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based low water solubility and surface activity
Dissociation Constant	Not determined	Expected to be ionised under environmental conditions (pH 4-9)
Flash Point	> 200 °C (closed cup)	(M)SDS*
Flammability	Not determined	Not a flammable liquid based on flash point
Autoignition Temperature	Not determined	Expected to be high based on flash point
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 the notified polymer at < 60% concentration

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties that were not assessed by Canada, 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

Extension Application

No increase of introduction volume, no change of use details and no change of operation description was proposed for the notified polymer. This section of the assessment report is not modified from the original report.

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 package products at ≤ 18% concentration or formulated lubricants at < 5% concentration.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 1,000	1,000	1,000	1,000	1,000

PORT OF ENTRY

Sydney, Melbourne, Brisbane and Perth

TRANSPORTATION AND PACKAGING

Lubricant additive package products containing the notified polymer at $\leq 18\%$ concentration will be imported in 205 L drums, 2,500-14,500 L iso-tanks and 1,000 kg IBC totes. The containers will be transported by road or rail for distribution.

Formulated finished engine lubricants containing the notified polymer at $< 5\%$ concentration will be packaged in containers typically in the size of 1, 4 and 20 L, or 205 L drums, and distributed by road or rail.

USE

The notified polymer will be used as a component in automotive lubricants for industrial, commercial and personal vehicles. The finished lubricants will contain the notified polymer at $< 5\%$ concentration.

OPERATION DESCRIPTION

Reformulation

At the blending sites, the additive package products containing the notified polymer at $\leq 18\%$ concentration will be transferred using a transfer hose from the shipping container to a storage tank or blending tank, where it will be mixed with base oils and possibly other additives to produce the finished lubricants. A special air back flush system will be used to prevent fluid leakage/spillage during transfer. The blending process will occur in a closed system and will be fully automated. After blending, the finished lubricant products containing the notified polymer at $< 5\%$ concentration will be packed into containers using fully automated equipment. Workers will also take samples from each production batch of the finished lubricant for quality control purposes.

End use

At original equipment manufacturer (OEM) sites, the finished lubricant containing notified polymer at $< 5\%$ concentration will be pumped into dedicated lubricating oil reservoirs for installation directly into crankcases of vehicles as part of the vehicle assembly processes.

A portion of finished lubricant products containing the notified polymer will be sent to service providers. At service sites, the finished lubricant may be transferred from the container via automated valves or manually decanted into vehicle's crankcases. Used lubricant will be collected for recycling or appropriate disposal.

6. HUMAN HEALTH IMPLICATIONS*Extension Application*

No additional information on human health effects of the notified polymer was provided. This section of the assessment report is not modified from the original report.

6.1. Exposure Assessment**6.1.1. Occupational Exposure**

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Receiving quality control	0.30	90
Storage and transport	2	90
Transferring and blending	8	200
Product quality control	< 0.50	200
Filling and packaging	4	200
Maintenance	4	4
Service provider	8	220

EXPOSURE DETAILS

Reformulation

Dermal and ocular exposure of workers to the notified polymer (at $\leq 18\%$ concentration) may occur when connecting/disconnecting transfer hoses and during quality control processes. Exposure at other times during reformulation and packaging off is expected to be limited as these processes will be enclosed and automated.

Dermal and ocular exposure to workers should be further mitigated through the use of appropriate PPE including protective clothing, impervious gloves, and goggles, as anticipated by the notifier. Inhalation of vapour from the notified polymer is unlikely given the estimated low vapour pressure. Although oil mists may be generated during blending, exposure to the mist is expected to be limited due to enclosed nature of the blending operation. Significant formation of oil mist outside blending tank is not expected due to the presence of adequate general ventilation and local exhaust ventilation.

End-use

At automotive OEM or service sites, workers may experience dermal or ocular exposure to the engine lubricant products containing the notified polymer at $< 5\%$ concentration when filling engine lubricants to vehicles. The potential for dermal and ocular exposure may be mitigated through the use of appropriate PPE. Inhalation exposure is not expected given that aerosols are not likely to be generated and the notified polymer has a low vapour pressure.

6.1.2. Public Exposure

Additive package products containing the notified polymer will not be made available to the general public.

Finished lubricant products containing the notified polymer are primarily intended for use by industrial and commercial users and are not intended for consumer use at this time. In future instance, consumers may perform DIY oil changes for their vehicles, and dermal and potential ocular exposure to the notified polymer at $< 5\%$ concentration may occur. Inhalation exposure to the notified polymer for consumer users is not expected under normal use conditions. Dermal and potential ocular exposure is expected to be minimized by following the safe handling precautions on product labels.

6.2. Human Health Effects Assessment

The molecular weight of the notified polymer is $> 1,000$ Da with $< 10\%$ of the molecules below 500 Da. The notified polymer contains surface active functional groups that may enhance dermal absorption through skin contact. However, based on the high molecular weight, dermal absorption is expected to be limited.

An acute oral toxicity study performed on rats indicated an $LD_{50} > 2,000$ mg/kg bw for a product containing 50% notified polymer, corresponding to low to moderate acute toxicity (Harlan, 2012). No other toxicological study reports on the notified polymer were provided.

The notified polymer contains amine groups, which are functional groups of concern for corrosion/skin irritation (Hulzebos *et al.*, 2005). However, the potential for irritation is likely to be reduced by the high molecular weight of the notified polymer and low levels of low molecular weight species.

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

Based on structural alerts, the notified polymer may have potential to cause skin irritation effects. Workers may be at risk of slight irritation effects when handling the notified polymer at $\leq 18\%$ concentration during reformulation. However, potential for dermal and ocular exposure of workers during reformulation should be minimised by the stated use of enclosed/automated processes and PPE, including protective clothing, impervious gloves and goggles.

Workers handling engine lubricants containing the notified polymer may come into contact with the polymer at < 5% concentration during OEM applications and engine servicing. At this low use concentration, skin irritation effects of the notified polymer are not expected.

Given the assessed use pattern, the risk to workers is not considered unreasonable.

6.3.2. Public Health

The notifier stated in the submission that in the future finished lubricants containing the notified polymer at < 5% concentration may be made available to the public. DIY users performing oil changes for their vehicles may come into contact with the notified polymer at < 5% concentration. At this low use concentration, skin irritation effects of the notified polymer are not expected.

Given the assessed use pattern, the risk to public health from the use of the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

Extension Application

No additional information on environmental effects of the notified polymer was provided. This section of the assessment report is not modified from the original report.

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a component of lubricant additive packages for reformulation into engine lubricant oils, or as a component of finished engine lubricant oils. No significant release of the notified polymer is expected from transportation and storage, except in the unlikely event of accidental spills and leaks.

Local blending and repackaging of the additive containing the notified polymer into engine oils is expected to occur within enclosed automated systems. Blending tanks and equipment are expected to be cleaned with mineral oil, which is expected to be recycled during subsequent blending, or collected for disposal by licensed waste management services. Accidental spills and leaks during transport and normal blending and packaging procedures is expected to be contained and collected for recycling where appropriate, or disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The finished products containing the notified polymer will be used as a component of automotive engine oils in industrial and commercial settings. 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

Waste from industrial and commercial applications is expected to be collected for disposal by accredited waste management companies. Empty containers containing the residue of the notified polymer are expected to be recycled by accredited waste management companies or disposed of according to local regulations. Products containing the notified polymer including waste oils are expected to be collected for disposal by licensed waste management facilities. Consequently, the notified polymer in engine oils is expected to be recycled or incinerated.

7.1.2. Environmental Fate

No environmental fate studies were submitted. The notified polymer, however, is not expected to be bioaccumulative based on its high molecular weight and surfactant properties. The majority of the notified polymer in engine oils will be either thermally decomposed during use or recycling. It is also expected to have limited release to the aquatic environment based on the assessed use pattern. The notified polymer disposed of to landfill is not expected to be mobile nor bioavailable based on its high molecular weight, 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 nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated, as significant release of the notified polymer to the aquatic environment is not expected based on its reported use pattern.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer using a water accommodated fraction (WAF) are summarised in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Algal Toxicity [#]	72 h EL50 >100 mg/L (WAF*)	Not harmful to algae up to water solubility limit

[#] Maxxam (2012b)

* Water Accommodated Fraction

Based on the above ecotoxicological endpoints for the notified polymer, it is not expected to be harmful to algae up to the limit of its solubility in water. Therefore, the notified chemical 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

The predicted no-effects concentration (PNEC) has not been calculated, as the notified polymer is not expected to be harmful to algae up to the limit of its solubility in water, and no significant aquatic release is expected from the reported use pattern.

7.3. Environmental Risk Assessment

A Risk Quotient ($RQ = PEC/PNEC$) has not been calculated, as no significant release of the notified polymer to the environment is expected from the proposed use pattern. The notified polymer has the potential to persist in the aquatic compartments; however it has low toxicity to algae and is not expected to bioaccumulate based on its high molecular weight and low water solubility. On the basis of the assessed use pattern and the expected limited aquatic release, the notified polymer is not expected to pose an unreasonable risk to the environment.

8. RISK ASSESSMENT RELATING TO EXTENSION APPLICATION

There are no changes proposed for the notified polymer to the use, introduction volume, or the occupational and environmental exposure. The circumstances in the extension application are not expected to impact on the original human health and environment risk assessment and recommendations.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Freezing Point** < -48 °C

Method	Expert statement based on preliminary thermal analysis
Remarks	The test substance X-17801 is a polymer containing molecules covering a relatively wide molecular weight range. It is not amenable to the use of hot-stage apparatus recommended in OECD guideline 102 for determining melting point due to its tar-like properties. Preliminary thermal analysis data indicated that X-17801 did not exhibit a melting point over a temperature range of -48 to 240 °C.
Test Facility	Maxxam (2012a)

BIBLIOGRAPHY

- Hulzebos *et al.*, (2005) Use of structural alerts to develop rules for identifying chemical substances with skin irritation or skin corrosion potential. *QSAR Combinatorial Science*. 24:332-342.
- Harlan (2012) X-17801: Acute Oral Toxicity in the Rat – Fixed Dose Method (Project Number: 41203722, October 2012) UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).
- Maxxam (2012a) Expert Statement/Request for Test Exemption: Melting Point (Study No. AFTO921-120023, May, 2012). Burnaby, Canada, Maxxam Analytics (Unpublished report submitted by the notifier).
- Maxxam (2012b) 72-H Growth Inhibition Test of X-17801 Using *Pseudokirchneriella Subcapitata* (OECD Guideline 201) (Study No. TOX1207, May, 2012). Burnaby, Canada, Maxxam Analytics (Unpublished report submitted by the notifier).
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