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

PUBLIC REPORT

Polymer in SP1863

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/1694	Cintox Australia Pty Ltd	Polymer in SP1863	ND*	≤ 200 tonnes per annum	A component of automotive engine lubricant oils

*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

Provided that the recommended occupational health and safety control measures 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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation processes:
 - 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
- 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:
 - Coveralls, goggles, impervious gloves

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 in accordance with local regulations for recycling, re-use or recovery.

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 polymer, 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;
 - the polymer is proposed to exceed 2.5% concentration in automotive engine lubricant oils;
 - additional information becomes available on the sensitisation potential of the notified polymer;
 - additional information becomes available on the genotoxicity potential of the notified polymer;
- or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of automotive engine lubricant oils, 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 a product containing 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)

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

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ 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 and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

None

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2013)

Canada (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

SP1863 (contains the notified polymer at ~60% concentration)

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference NMR, IR, and GPC spectra and elemental analysis data were provided.

3. COMPOSITION

DEGREE OF PURITY

> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Pour Point	-12 °C	Measured
Boiling Point	342 – 450 °C at 101.3 kPa	Measured
Density	918 kg/m ³ at 20 °C	Measured
	917.3 kg/m ³ at 20 °C	Measured
Vapour Pressure	5.16×10^{-7} kPa at 20 °C	Measured
Water Solubility	$< 2.5 \times 10^{-5}$ g/L at 25 °C	Measured
Hydrolysis as a Function of pH	$t_{1/2} > 1$ year at 25 °C, pH 4 – 9	Measured
Partition Coefficient (n-octanol/water)	log Pow = 10 – 14	Measured
Surface Tension	35.95 mN/m	Measured

Adsorption/Desorption	Not determined.	The notified polymer has potential cationicity, therefore, it is expected to partition to sludge and soil.
Dissociation Constant	Not determined	Contains potentially ionisable functionalities and hence it may ionise under normal environmental conditions (pH 4 – 9).
Flash Point	217 °C at 101.3 kPa 196 °C at 101.3 kPa	Measured Measured
Flammability	Not expected to be highly flammable	Based on measured flash point
Autoignition Temperature	390 °C	Measured
Explosive Properties	Predicted negative based on chemical structure	Measured
Oxidising Properties	Stable under ambient conditions	(M)SDS

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

The notified polymer will be imported into Australia as a component of lubricant additive packages containing the notified polymer at < 16% concentration and in finished lubricant oil products containing the notified polymer at < 2.5% concentration.

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

Year	1	2	3	4	5
Tonnes	100-200	100-200	100-200	100-200	100-200

PORT OF ENTRY

Various ports

TRANSPORTATION AND PACKAGING

The lubricant additive packages containing the notified polymer at < 16% concentration will be imported by ship, contained in either 20,000 L isotanks or in 205 L steel drums. The isotanks will be offloaded to tank trucks or rail cars at the port for distribution to lubricant manufacturing customers while the 205 L steel drums will be shipped directly. The finished blended oils containing the notified polymer at < 2.5% concentration will then be packaged and distributed in 205 L drums and small containers (e.g. 1 L and 4 L) to service stations and end-use customers.

The imported finished lubricant oil products containing the notified polymer at < 2.5% concentration will be imported in 205 L drums and small containers (e.g. 1 L and 4 L) and distributed directly to service stations and end-use customers.

USE

The notified polymer will be used as a component of lubricating oils for automotive engines at < 2.5% concentration in finished products.

OPERATION DESCRIPTION

The notified polymer will be imported into Australia as part of finished lubricating oils for automotive engines at < 2.5% concentration.

The notified polymer will also be imported as a component of lubricant additive packages at < 16% concentration for reformulation into lubricant oils.

Formulation of lubricant oils

The imported lubricant additive packages containing the notified polymer at < 16% concentration will be distributed to oil lubricant manufacturers for formulation of finished lubricant oils. At the blending sites, the notified polymer will be transferred using pumps into storage tanks. From these tanks the notified polymer will be transferred into blending tanks through computer-controlled and fully automated valves. The notified polymer will be blended at < 2.5% concentration with other components in a fully closed and automated system. The finished oil product will then be returned to the storage tanks via an automated process. Samples may also be taken by laboratory staff prior and after reformulation for quality testing. The finished oils will then be packed off into drums or small containers, or transferred through hard piping to tank trucks or rail cars for distribution to end-use customers (service stations or retail outlets).

End-use

At end-use sites, the finished lubricant oils containing the notified polymer at < 2.5% concentration will be transferred (by automated or manual means) to automobile engines.

6. HUMAN HEALTH IMPLICATIONS**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>
Unloading of isotanks and drums	0.5	30
Sampling and analysis of finished oil	0.2	220
Distribution	0.5	220
Commercial automotive and industrial engine service workers	7	250

EXPOSURE DETAILS

Transport and Storage

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Formulation of products

Dermal and ocular exposure of workers to the notified polymer at < 16% concentration may occur during formulation when connecting and disconnecting hoses and during sample testing. Inhalation exposure is not expected due to the low vapour pressure of the notified polymer. Exposure is expected to be minimised through the use of enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves.

End-use

Workers may be exposed to engine oils containing the notified polymer at < 2.5% concentration during use, for example, at automobile manufacturing sites, car dealerships or automotive service centres during transfer, charging or top-up activities.

At car manufacturing sites, the finished engine oil containing the notified polymer (< 2.5% concentration) will likely be added to engines using automated systems and exposure is unlikely. However, dermal and ocular exposure from drips, spills and splashes as well as from handling equipment contaminated with engine oil is possible. The potential for dermal and ocular exposure is expected to be reduced by the wearing of PPE, e.g. gloves, protective clothing and goggles.

At automotive service centres, professional users such as mechanics may experience dermal or ocular exposure to the engine oil products containing the notified polymer (< 2.5% concentration) when transferring engine oil to cars. The potential for dermal and ocular exposure may be mitigated through the use of PPE (e.g. gloves, protective clothing and goggles).

Overall, workers exposure to the notified polymer (< 2.5% concentration in finished engine oils) is not expected to be significant.

6.1.2. Public Exposure

The finished oil products containing the notified polymer at up to 2.5% concentration will be available to the general public. DIY users may experience inadvertent dermal and ocular exposure to final products containing up to 2.5% of the notified polymer when adding and/or replacing engine oil of their vehicles. However, once engine oil containing the notified polymer is added to the engine, the general public will not be exposed to the notified polymer in the engine oil.

Overall, public exposure is expected to be limited due to the infrequent use and the low concentration of the notified polymer in finished engine oil.

6.2. Human Health Effects Assessment

No toxicity data was submitted for the notified polymer. Information on the expected health effects of the notified polymer are based on two acceptable analogues of the notified polymer. These (analogues 1 and 2) have a highly similar structure and molecular weight to the notified polymer and are therefore considered acceptable for read-across.

The results from toxicological investigations conducted on Analogue 1 are summarised in the following table.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – <i>in vivo</i> mouse micronucleus assay	genotoxic
Rat, reproductive and developmental toxicity	NOAEL = 1000 mg/kg bw/day

Toxicokinetics.

The notified polymer is not expected to be absorbed across biological membranes to a significant extent based on its high molecular weight ($M_n > 1,000$ Da) and low level (< 1%) of low molecular weight species (< 1000 Da). Similarly, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed is limited. Hence systemic toxicity is not expected. This is supported by the absence of toxic effects in acute toxicity studies and in a repeated dose oral toxicity study in rats with Analogue 1.

Acute toxicity

Analogue 1 was found to be of low acute oral and dermal toxicity in studies conducted in rats (HPV, 2012). Based on the result of these studies, the notified polymer is not expected to be acutely toxic by the oral and dermal routes.

Irritation and sensitisation.

The notifier has provided results of irritation and sensitisation studies for Analogue 2. However, no study details were provided. The results of these studies indicate that Analogue 2 is slightly irritating to the eye and skin and is not a skin sensitiser. No data on these endpoints were submitted for Analogue 1. However, Analogue 1 has been classified by a number of notifiers on ECHA's C&L Inventory database as an eye irritant and skin sensitiser.

The notified polymer contains a functional group that is associated with irritation/corrosion and sensitisation. While the potential for these effects may be limited by the high molecular weight of the notified polymer, sensitisation and/or irritant effects cannot be ruled out.

Repeated dose toxicity.

In a 28-day repeated dose oral toxicity study in rats with Analogue 1, no remarkable findings were noted for any of the endpoints evaluated (HPV, 2012). The NOAEL was established as 1000 mg/kg bw/day.

Mutagenicity/Genotoxicity.

Analogue 1 was not mutagenic in a bacterial reverse mutation assay (HPV, 2012). However, Analogue 1 did induce micronuclei formation in mice *in vivo* (HPV, 2012). In this study, mice were administered Analogue 1 in peanut oil via the intraperitoneal route at 0, 1250, 2500 or 5000 mg/kg. The results from the study showed a statistically significant increase in micro nucleated polychromatic erythrocytes in the 5000 mg/kg males at 24 hours. The study authors attributed this increase to the low number of micronucleated PCEs in the concurrent control group in addition to the value being within the historical control range for the laboratory (HPV, 2002). However, given the positive finding in the *in vivo* study and in the absence of further supporting data, the genotoxicity potential of the notified polymer cannot be ruled out.

Toxicity for reproduction.

In a reproduction/development oral toxicity screening test in rats with Analogue 1, no remarkable findings were noted for any of the endpoints evaluated (HPV, 2012). The NOAEL was established as 1000 mg/kg bw/day.

Health 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).

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety**

Based on the available information, the notified polymer may be irritating to the eyes and skin and may have the potential to be a skin sensitiser. Furthermore, the genotoxicity potential of the notified polymer cannot be ruled out but may be limited by the high molecular weight of the notified polymer. Toxicity by the inhalation route is not known. However, based on the low vapour pressure, and the high viscosity of the formulation, inhalation exposure is not expected.

Reformulation

Reformulation workers may potentially be at risk of irritating and skin sensitising effects and genotoxicity when handling the imported additive packages containing the notified polymer at < 16% concentration. However, the risk is expected to be minimised by the use of largely enclosed and automated processes, and use of appropriate PPE including coveralls, impervious gloves, and eye protection.

Provided the stated control measures are in place to limit exposure, the risk to the health of reformulation workers is not considered to be unreasonable.

End-use

End users (e.g. mechanics in automotive centres) will be exposed to the notified polymer at < 2.5% concentration when transferring engine oil to cars. At this end-use concentration, the main risk posed by the notified polymer is as a potential skin sensitiser. Furthermore, the potential risk of genotoxicity cannot be ruled out. However, given the low concentration and expected use of PPE, exposure and hence the risk of skin sensitisation and genotoxicity should be low.

Therefore, the risk to professional end users from use of the notified polymer at < 2.5% concentration in engine oil products is not considered unreasonable.

6.3.2. Public Health

The public will be exposed to the notified polymer at < 2.5% concentration during DIY engine oil change/top-up activities. At this end-use concentration, the main risk posed by the notified polymer is as a potential skin sensitiser. Furthermore, the potential risk of genotoxicity cannot be ruled out. Given the low concentration and expected infrequent use of engine oils by the public, exposure and hence the potential risk of skin sensitisation and genotoxicity should be low. Therefore, the risk to the public from use of the notified polymer at < 2.5% concentration in engine oil products 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 imported into Australia as products for reformulation into lubricant oils. Significant release of the notified polymer to the environment is not expected during transport and storage except in the unlikely event of accidental spills or leaks.

Any notified polymer spilled during reformulation is expected to be sent to on-site waste treatment facilities. At the on-site waste treatment facilities, residues of the notified polymer will be separated from the aqueous waste stream. The aqueous waste undergoes further treatment involving pond aeration and biological treatment before being released to the sewage system. The remaining non-aqueous waste is expected to be disposed of according to local regulations. As a result of these treatments, greater than 90% removal of the notified polymer is estimated by the notifier. Therefore, the accidental release from reformulation of the notified polymer and finished oils is unlikely to be significant.

RELEASE OF CHEMICAL FROM USE

The finished products containing the notified polymer will be used as a lubricating oil additive in automotive engines. The only release during its use may come from spills when pouring lubricant into automotive engines or leaks from the engines, which is expected to be negligible.

RELEASE OF CHEMICAL FROM DISPOSAL

After reformulation, empty import drums containing residues of the notified polymer (0.1% of the total import volume) are expected to be steam cleaned, with the residual waste sent to on-site wastewater treatment facilities. Assuming 0.1% of the notified polymer remains in the empty drums after use, 200 kg/yr ($200 \text{ tonnes/yr} \times 0.1\%$) of the notified polymer will be sent to the on-site waste treatment. It is estimated by the notifier that up to 98% of the notified polymer may be removed during waste treatment processes. Therefore, the amount of the notified polymer released to sewer from the cleaning of empty drums is estimated to be 4 kg/yr ($= 200 \text{ kg/year} \times 2\%$). The wastewater will be further treated at the sewage treatment plants. Therefore, the release of the notified polymer to surface waters is expected to be limited from the cleaning of empty drums.

The major release of the notified polymer to the environment will come from inappropriate disposal of waste or used oils. Oil products containing the notified polymer will be poured into automotive engines by service station workers or by do-it-yourself (DIY) consumers. A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the annual sales of engine oils in Australia, 60% of oils are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly (e.g. oil recycling or incineration). Assuming this is the case, negligible release of the notified polymer should result from these professional activities. The remaining 14% of oil is removed by DIY consumers. In these cases, some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill.

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997), only approximately 20% of used oil removed by DIY consumers is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. In a worst case scenario involving the 14% of used oil removed by DIY consumers, up to 0.7% of the total import volume of the notified polymer may enter the aquatic environment via disposal to stormwater drains ($= 14\% \times 5\%$). Therefore, the amount of the notified polymer released to the aquatic environment from disposal of used oil due to DIY consumers is expected to be 1.4 tonnes/yr ($= 200 \text{ tonnes/year} \times 0.7\%$). In addition to this, considering the unknown fate of some of the oil used by DIY consumers, a small proportion may also be disposed of to sewer. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified polymer in neat concentrations is unlikely except as a result of transport accidents.

7.1.2. Environmental Fate

No environmental fate data were submitted. An analogue substance (Analogue 1) is considered appropriate to support general assumptions for the notified polymer with regards to biodegradability as it has a highly similar

chemical structure. The analogue is considered not readily biodegradable (16% biodegraded after 28 days (HPV, 2006)). Hence, the notified polymer is not expected to be readily biodegradable.

Most of the notified polymer will be either thermally decomposed during use, recycled or re-refined. A very small amount of the notified polymer from cleaning of empty drums is expected to be released to sewer. In Sewage Treatment Plants (STPs), up to 90% of the notified polymer is expected to partition to sludge due to its potential cationicity (Boethling and Nabholz, 1997). Sludge from the wastewater treatment plants containing the notified polymer is expected to be disposed of to landfill or applied to agricultural soils. Notified polymer released to surface water is expected to partition to sediment based on its limited water solubility and potential cationicity. The notified polymer is not expected to be bioaccumulative due to its high molecular weight. It is also not expected to be bioavailable as it has low water solubility and anticipated limited release to the aquatic environment. Notified polymer sent to landfill or spilt on the ground is expected to sorb strongly to soil and sediment due to its potential cationicity. It is anticipated to ultimately be degraded into water and oxides of carbon and nitrogen by thermal decomposition or by natural processes in landfill.

7.1.3. Predicted Environmental Concentration (PEC)

For the worst case scenario, the percentage of the imported quantity of notified polymer inappropriately disposed to stormwater drains is estimated to be 0.7%. That is, 14% (fraction collected by DIY users) \times 5% (fraction disposed to stormwater). The release of the notified polymer may be up to 1.4 tonnes/yr (= 200 tonnes/year \times 0.7%). In this worst case scenario, it is assumed that the release goes into stormwater drains in a single metropolitan area with a geographical footprint of 500 km² and an average annual rainfall of 500 mm, all of which drains to stormwater. With a maximum annual release into this localised stormwater system of 1.4 tonnes and the annual volume of water drained from this region estimated to be 250×10^6 m³, the calculated PEC will be up to 5.6 µg/L. This result reflects a worst-case scenario upper limit, as in reality releases of the notified polymer will be distributed over multiple areas. Moreover, the concentrations of the notified polymer will be further diluted if it reaches the ocean.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. The ecotoxicological results for an analogue substance (Analogue 1) are summarised in the table below (HPV, 2006). The analogue substance is used as read across to the notified polymer as it has a highly similar chemical structure to the notified polymer.

Endpoint	Result	Assessment Conclusion
Fish	LL50 (96 h) > 1000 mg/L*	Not expected to be harmful to fish at its solubility limit
Daphnia	EL50 (48 h) > 1000 mg/L*	Not expected to be harmful aquatic invertebrates at its solubility limit
Algae	EL50 (72 h) = 270 mg/L*	Not expected to be harmful to algae

*WAF (Water Accommodated Fraction)

Based on the analogue data, the notified polymer is not expected to be harmful to aquatic organisms. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is not expected to be harmful to fish, aquatic invertebrates and algae on an acute basis and is not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using the toxicity endpoints of the analogue substance and the assessment factor of 1,000. The most conservative assessment factor of 1,000 was appropriate to use as whilst ecotoxicological endpoints for three trophic levels are available for an analogue substance, they are in lieu of measured data for the notified polymer.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>		
E _r C50 (Algae)	270	mg/L
Assessment Factor	1000	
PNEC:	270	µg/L

7.3. Environmental Risk Assessment

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	5.6	270	0.02
Q - Ocean:	0.56	270	0.002

The Risk Quotients ($Q = PEC/PNEC$) for the notified polymer have been calculated to be less than 1 for both the riverine and marine compartments. Release of the notified polymer to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. The notified polymer is not expected to either be significantly bioavailable or bioaccumulative. Therefore, based on the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour Point -12 °C

Method OECD TG 102 Melting Point/Melting Range.
 Remarks An automatic apparatus, ASTM D 5950 was used. The apparatus detects the lowest temperature at which movement of the sample occurs.
 Test Facility Integrated (2013a)

Boiling Point 342 – 450 °C at 101.3 kPa

Method Thermogravimetric analysis
 Remarks A thermogravimetric analysis was used to determine the weight change as a function of temperature.
 Test Facility Integrated (2013a)

Density 918 kg/m³ at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
 Remarks The density was determined using a pycnometer.
 Test Facility Harlan (2013a)

Density 917.3 kg/m³ at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
 Remarks The density was determined using an oscillating densitometer.
 Test Facility Integrated (2013a)

Vapour Pressure 5.161 x 10⁻⁷ kPa at 20 °C

Method Maxwell-Bonnell method
 Remarks The vapour pressure was computed using the Maxwell-Bonnell calculation in conjunction with a correlation from distillation data (software by Simulation Sciences ProVision, v.10).
 Test Facility Integrated (2013a)

Solubility < 2.5 × 10⁻⁵ g/L

Method OECD TG 105 Water Solubility
 Remarks A turbidity measurement technique was used to determine the water solubility of the test substance. The test substance was dissolved in tetrahydrofuran, and various amounts were spiked into water. As the concentration of the test substance reached its solubility limit, the insoluble material caused turbidity and was measured by an ultraviolet-visible (UV-Vis) spectrophotometer.
 Test Facility Integrated (2013a)

Partition Coefficient log Pow = 10 – 14 (n-octanol/water)

Method OECD TG 117 Partition Coefficient (n-octanol/water).
 Remarks A high performance liquid chromatography (HPLC) was used for reverse phase analysis using a Zorbax XDB-C18 column, a UV detector for the calibrants, and an evaporative light scattering detector for the test material. A mobile phase of 75% tetrahydrofuran/25% water was used at a flow rate of 1.0 mL/min. Four reference substances with known log Kow values (cited from literature sources) ranging from 4.9 to 10.2 were used to generate a calibration curve.
 Test Facility Integrated (2013a)

Surface Tension 36.95 mN/m

Method ASTM D971, Interfacial Tension of Oil Against Water by the Ring Method

Remarks A platinum wire ring was mounted on a tensiometer and the force required to detach the ring from the surface of the distilled water/test substance layered sample was measured in duplicate.

Test Facility Integrated (2013a)

Hydrolysis as a Function of pH $t_{1/2} > 1$ year

Method OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> (°C)	<i>t</i> _{1/2}
4	25 °C	> 1 year
7	25 °C	> 1 year
9	25 °C	> 1 year

Remarks The molecular weight distribution does not change significantly for any of the pH levels tested. A comparison of the IR spectra obtained shows that the test substance functional groups did not significantly change under any of the pH levels tested.

Test Facility Integrated (2013b)

Flash Point 217 °C at 101.3 kPa

Method EC Council Regulation No 440/2008 A.9 Flash Point.

Remarks Closed cup

Test Facility Harlan (2013b)

Flash Point 196 °C at 101.3 kPa

Method Pensky-Martens Closed Cup Tester

Test Facility Integrated (2013a)

Autoignition Temperature 390 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks The test determined the lowest temperature at which the notified polymer underwent ignition in a heated flask.

Test Facility Harlan (2013b)

Explosive Properties Predicted to be negative

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.

Remarks The notified polymer was assessed for chemical groups that imply explosive properties according to Bretherick's Handbook on Reactive Chemical Hazards, 7th Edition, Academic Press, 2007.

Test Facility Harlan (2013b)

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