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May 2015

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

PUBLIC REPORT

Polymer in CP 4078

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
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/1810	Cintox Australia Pty Ltd	Polymer in CP 4078	ND*	≤ 100 tonnes per annum	Component of engine oils

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of its assessed use pattern and potential low hazard to the environment, 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 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 of calorific content.

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 polymer 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.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of engine 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 products 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 $M_n \geq 1,000$ 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 and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, adsorption/desorption, dissociation constant, partition coefficient and flammability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2014)

Canada (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

CP 4078 (contains 50-60% notified polymer in mineral oil)

MOLECULAR WEIGHT

> 10,000 Da

ANALYTICAL DATA

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

3. COMPOSITION

DEGREE OF PURITY

90-100%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown viscous liquid

Property	Value	Data Source/Justification
Pour Point	- 15 °C	Measured*
Boiling Point	150 - 520 °C at 101.3 kPa	Measured*
Density	913 kg/m ³ at 20 °C 915.2 kg/m ³ at 15 °C	Measured*
Vapour Pressure	3.296×10^{-7} kPa at 20 °C	Calculated*
Water Solubility	$< 6 \times 10^{-4}$ g/L at 20 °C	Measured*
Hydrolysis as a Function of pH	Not determined	The notified polymer does not contain any readily hydrolysable groups and is therefore expected to be hydrolytically stable under the environmental pH range of 4 – 9.

Partition Coefficient (n-octanol/water)	log Kow > 7.4 (extrapolated value > 16)	Measured*
Adsorption/Desorption	Not determined	The notified polymer is expected to sorb strongly to soil sediment and sludge based on its amphoteric structure
Dissociation Constant	Not determined	The notified polymer is a salt. Therefore, it will be ionised under normal environmental conditions (pH 4 – 9).
Flash Point	194 ± 2 °C at 101.3 kPa	Measured (closed cup)*
	220 °C at 101.3 kPa	Measured (open cup)*
Flammability	Not determined	The notified polymer will be imported and used as a mixture in highly refined mineral oil at 50-60% concentration. The mixture is not expected to be flammable based on its measured flash point.
Autoignition Temperature	364 ± 5 °C	Measured*
Explosive Properties	Predicted negative	Based on the chemical structure
Oxidising Properties	Predicted negative	Based on the chemical structure

* Test substance was CP 4078 (contains 50-60% notified polymer in mineral oil)

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

As only limited physico-chemical 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.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be introduced into Australia as a component of additive packages for engine oils (at ≤ 20% concentration) or as a component of finished engine oils (at < 1.5% concentration).

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

Year	1	2	3	4	5
Tonnes	1-10	1-10	1-10	1-10	10-100

PORT OF ENTRY

Typical ports of entry include Sydney, Melbourne, Perth and Brisbane

TRANSPORTATION AND PACKAGING

The additive packages containing the notified polymer at ≤ 20% 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 < 1.5% 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 < 1.5% concentration will be imported in 205 L drums and distributed directly to service stations and end-use customers.

USE

The notified polymer will be used as a component of engine oils at < 1.5% concentration for automotive use.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia, but the additive packages will be reformulated after importation.

Reformulation

After importation additive packages containing the notified polymer (at $\leq 20\%$) will be transferred into storage tanks through hoses with an air back flush system to prevent spillage, before being transferred into the blending facilities and formulated into engine oil products by mixing with oil and other additives. Transfer from the storage tanks to the blending facilities and the blending process itself is expected to involve automated and enclosed systems. The resulting engine oil products containing the notified polymer ($< 1.5\%$) will be filled into 205 L drums and smaller containers (such as 1 L and 4 L plastic bottles) which will be distributed to consumers. Samples will be taken during the blending process for quality control testing.

End use

Engine oil products containing $< 1.5\%$ of the notified polymer will primarily be used by vehicle manufacturers and service stations and to a limited extent by do-it-yourself (DIY) users. Use by the public will involve the engine oils being manually decanted into automobile engines, while at industrial sites the engine oils will be pumped from the drums.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Transport and Storage

Transport and storage workers may come into contact with the notified polymer ($\leq 20\%$) only in the event of accidental rupture of containers.

Formulation of products

The blending process is expected to be automated in a closed system; however, plant operators may be exposed (dermal and ocular) to the notified polymer at up to 20% concentration during opening of containers, connection and disconnection of hoses when pumping into blending or storage tanks. Workers may also come into contact with the notified polymer during maintenance, cleaning, and sampling.

Dermal and ocular exposure to workers should be mitigated through engineering controls such as the use of a special air back flush system to prevent spillage during transfer and the use of notified anticipated personal protective equipment (PPE) including protective clothing, gloves and goggles. Inhalation exposure is not expected given the low vapour pressure and high viscosity of the notified polymer.

End-use

Workers may be exposed to engine oils containing the notified polymer at $< 1.5\%$ 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 ($< 1.5\%$ 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 ($< 1.5\%$ 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 ($< 1.5\%$ 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 < 1.5% concentration will be available to the general public. DIY users may experience inadvertent dermal and ocular exposure to final products containing < 1.5% 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

The results from toxicological investigations conducted on the product CP 4078 containing the notified polymer are summarised in the following table. For full details of the study, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Mutagenicity – bacterial reverse mutation	non mutagenic

The notified polymer has a high molecular weight (> 10,000 Da) with a low proportion (< 1%) of low molecular weight species (< 1000 Da); hence absorption across biological membranes is not expected.

The product CP 4078 containing the notified polymer was negative in a bacterial reverse mutation assay. As the concentrations tested were adjusted to factor the concentration of the notified polymer in the product, it could be concluded that the notified polymer was not mutagenic in the study.

The notified polymer contains functional groups associated with irritation; however, given the high molecular weight and low proportion of low molecular weight species irritation effects are expected to be limited.

Health hazard classification

As only limited 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

The notified polymer is expected to be of low hazard, presenting at most only as a slight skin and eye irritant. Given workers will only be exposed to the notified polymer at up to 20% concentration, the risk of irritation effects is expected to be low. Therefore, the risk of the notified polymer to occupational health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

6.3.2. Public Health

The public (mainly do-it-yourself users) may have dermal or ocular exposure to products containing the notified polymer at < 1.5% concentration while servicing their own automotive engines. However, given the infrequent use of the products containing the notified polymer by the public and the low concentration of the notified polymer in the products, the risk to the general public 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 for repackaging and reformulation into engine 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.

Reformulation of the notified polymer is expected to take place in fully enclosed automated systems. Blending tanks are expected to be cleaned with lubricating oil, which is expected to be recycled during subsequent blending. Any notified polymer spilled during reformulation is expected to be contained with concrete bunds and

either reclaimed or 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 by the American Petroleum Industry (API) process. As a result of this treatment, greater than 90% removal of the notified polymer is estimated by the notifier. The aqueous waste undergoes further treatment involving biological treatment and biodisk filtration before being released to the sewage system. The remaining non-aqueous waste is expected to be disposed of according to local regulations. Therefore, the accidental release of the notified polymer from reformulation 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 component of engine oils. Release during its use may come from spills when pouring lubricants into engines or leaks from the engines, which is expected to be negligible.

RELEASE OF CHEMICAL FROM DISPOSAL

After reformulation, empty import drums containing the residues of the notified polymer (0.1% of the total import volume) are expected to be steam cleaned and the residual waste sent to on-site wastewater treatment facilities. Assuming 0.1% of the notified polymer remains in the empty drums after use, 100 kg/yr (100 tonnes/yr \times 0.1%) of the notified substance will be sent to the on-site waste treatment. It is estimated by the notifier that greater than 90% 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 10 kg/yr ($= 100 \text{ kg/yr} \times 10\%$). The wastewater will be further treated at 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 engines by automotive service centres 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. It was estimated that DIY activities account for 7 - 10% of the unaccounted used oil (Meinhardt, 2002).

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. 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 0.7 tonnes/yr ($= 100 \text{ tonnes/yr} \times 0.7\%$). 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 the sewer. Since the use of the engine 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 for the notified polymer. The notified polymer is expected to be hydrolytically stable under environmental conditions.

Most of the notified polymer will be 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 amphoteric structure. 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 amphoteric structure. 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 0.7 tonnes /yr (= 100 tonnes/yr \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 700 kg and the annual volume of water drained from this region estimated to be 250×10^6 m³, the calculated PEC will be up to 2.8 µg/L. This result reflects a worst-case scenario upper limit, as in reality releases of the notified polymer will be distributed over multiple regional/farming areas and it will be further diluted if it reaches the ocean.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified polymer. The notified polymer contains an amphoteric structure. The potential cationicity of the notified polymer may contribute ecotoxicity to aquatic life. Therefore, ecotoxicological endpoints for the notified polymer were calculated based on Structure Activity Relationships (SARs) equations. For amphoteric polymers, the predicted toxicity based on % A-N (amine nitrogen) is corrected by multiplying the predicted toxicity values by a toxicity reduction factor (TRF) to get final toxicity endpoints. The endpoints are summarised in the table below. As worst case scenarios, the toxicity values predicted by SARs have not been modified by mitigation factors to reflect the actual toxicity in the natural aquatic environments to account for the anticipated binding of the polymer with organic carbon in surface waters.

<i>Endpoint</i>	<i>Results</i>	<i>Assessment conclusion</i>
<i>Acute toxicity</i>		
Fish	LC50 (96 h) = 56.8 mg/L	Predicted to be not harmful to fish at saturation
Daphnia	LC50 (48 h) = 3356.1 mg/L	Predicted to be not harmful to aquatic invertebrates at saturation
Algae	EC50 (96 h) = 48.5 mg/L	Predicted to be not harmful to algae at saturation

The SARs estimation endpoints indicate that the notified polymer is potentially not harmful to fish, aquatic invertebrates, and algae at saturation in the aquatic environment. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

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 up to the limit of its solubility in water.

7.3. Environmental Risk Assessment

The risk quotient (RQ = PEC/PNEC) has not been calculated. The notified polymer is not harmful up to its solubility limit. The notified polymer is not expected to be bioaccumulative. Based on its reported use pattern, the notified polymer is not expected to reach the aquatic environment at environmentally significant concentrations. 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	-15 °C
Method	An automatic apparatus, ASTM D 5950 was used. The apparatus detects the lowest temperature at which movement of the sample occurs.
Test Facility	Chevron (2013)
Boiling Point	150-520 °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	Chevron (2013)
Density	913 kg/m ³ at 20 ± 0.5 °C
Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Pycnometer method
Test Facility	Harlan (2013a)
Density	915.2 kg/m ³ at 15 °C
Method	OECD TG 109 Density of Liquids and Solids.
Remarks	The density was determined using an oscillating densitometer.
Test Facility	Chevron (2013)
Vapour Pressure	3.296 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	Chevron (2013)
Water Solubility	< 6 × 10 ⁻⁴ g/L at 20 °C
Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask Method
Test Facility	Chevron (2013)
Partition Coefficient (n-octanol/water)	log K _{ow} > 7.4 (extrapolated value > 16)
Method	OECD TG 117 Partition Coefficient (n-octanol/water) EC Council Regulation No 440/2008 A.8 Partition Coefficient
Remarks	HPLC Method. Five reference substances with known log K _{ow} values ranging from 1.4 to 7.4 were used to generate a calibration plot. An elution time of 5 minutes is equivalent to 0.95 on the log K scale and to 16 on the log K _{ow} scale. Therefore, any compounds eluting after 5 minutes may be extrapolated to a log K _{ow} value of >16. The column retention time for the notified chemical was longer than that for the standard (chemical) with the longest retention time. The log K _{ow} value of the notified polymer was determined to be greater than the highest reference standard, 7.4, however, the log K _{ow} value can be extrapolated to greater than 16 based on its elution time.
Test Facility	Chevron (2013)
Flash Point	194 ± 2 °C at 101.3 kPa
Method	EC Council Regulation No 440/2008 A.9 Flash Point.

Remarks Closed cup equilibrium method
Test Facility Harlan (2013b)

Flash Point 220 °C at 101.3 kPa

Method Cleveland Open Cup Tester
Test Facility Chevron (2013)

Autoignition Temperature 364 ± 5 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility Harlan (2013b)

Explosive Properties Predicted negative

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks Predicted negative based on the chemical structure
Test Facility Harlan (2013b)

Oxidizing Properties Predicted negative

Method EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks Predicted negative based on the chemical structure.
Test Facility Harlan (2013b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – bacteria

TEST SUBSTANCE	CP 4078 (contains 50-60% notified polymer)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 15, 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 15, 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Tetrahydrofuran
Remarks - Method	The concentrations tested were adjusted to factor the concentration of the notified polymer in the test substance.

A pre-test for toxicity was conducted on TA100 and WP2uvrA at concentrations up to 5000 µg/plate. The concentrations used in the main study were determined in a preliminary study.

The negative control was the vehicle and positive controls were 9-aminoacridine, 4-nitroquinoline-1-oxide and N-ethyl-N-nitrosoguanidine in the absence of S9 mix and 2-aminoanthracene and benzo[a]pyrene in the presence of S9 mix.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in pre/Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	> 5000	> 5000	≥ 1500	negative
Test 2		> 5000	≥ 1500	negative
<i>Present</i>				
Test 1	> 5000	> 5000	≥ 1500	negative
Test 2		> 5000	≥ 1500	negative

Remarks - Results	There were no toxicologically significant increases in the frequency of revertant colonies recorded for any of the bacterial strains, at any test dose, with or without metabolic activation.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan (2014)

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