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

PUBLIC REPORT

BPL 4639

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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1639	BP Australia Pty Ltd	BPL 4639	No	≤ 120 tonnes per annum	A component of engine oil products

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 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 the PEC/PNEC ratio and 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 and/or repackaging 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 when handling the notified polymer during reformulation and/or repackaging processes:
 - 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 during reformulation and/or repackaging processes:
 - Gloves
 - Goggles
 - Coveralls

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 chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of engine oil products, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 120 tonnes per annum, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet

The (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

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

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

BP Australia Pty Ltd (ABN 53 004 085 616)

132 McCredie Road
Guildford, NSW 2161

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, import volume and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada, Japan, Korea, Philippines, USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

BPL 4639

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference FTIR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Glass Transition Temperature	-71 °C	Measured
Boiling Point	Decomposes at ≥ 400 °C	Measured
Density	871.9 kg/m ³ at 20 °C	Measured
Vapour Pressure	$< 1.33 \times 10^{-11}$ kPa at 20 °C	Measured
Water Solubility	$< 3 \times 10^{-4}$ g/L at 20 °C	Measured (water extractability was < 2%)
Hydrolysis as a Function of pH	Not determined	The test for hydrolysis was not required as the notified polymer has low water solubility/extractability.
<i>n</i> -Octanol Solubility	≥ 1060 g/L	Measured
Partition Coefficient (n-octanol/water)	log Pow > 6.55 at 20 °C	Measured
Adsorption/Desorption	log K _{oc} > 5.4	Calculated
Dissociation Constant	Not determined	The notified polymer contains potential cationic functionalities which are expected to be ionised in the environmental pH range (4 - 9). However, the notified polymer is not expected to be significantly ionised under environmental conditions due to

Flash Point	136 °C at 101.3 kPa	its limited water solubility. Measured
Flammability	Not highly flammable in contact with water; not pyrophoric	Measured
Autoignition Temperature	440 °C at 101.31-102.75 kPa	Measured
Explosive Properties	Predicted negative	Not expected to have explosive properties, based on the chemical structure.
Oxidising Properties	Predicted negative	Not expected to have oxidising properties, based on the chemical structure.

DISCUSSION OF PROPERTIES

For full details of tests on some of the physical and chemical properties (including those that were not assessed in 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 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 at 100% concentration or as a component (< 1%) of automotive engine lubricants.

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

Year	1	2	3	4	5
Tonnes	10 - 50	70 -120	70 - 120	70 -120	70 - 120

PORT OF ENTRY

Sydney, Melbourne, Brisbane, Perth

IDENTITY OF MANUFACTURER/RECIPIENTS

BP Australia Pty Ltd (and other recipient(s) in Lytton, QLD; Newport, VIC; Spotswood VIC; North Fremantle, WA; and Guildford, NSW)

TRANSPORTATION AND PACKAGING

The notified polymer will be imported (at 100% concentration) in 200 L drums and transported by road to the blending facilities for formulation into the finished engine oil products. Alternatively, the notified polymer will be imported by sea in 1 or 5 L plastic containers, 20 L tins, or 205/209 L steel drums as a component of finished engine oil products at < 1% and transported by road to storage and/or repackaging facilities.

USE

The notified polymer will be used as a component of engine oil products at < 1% concentration in automobiles.

OPERATION DESCRIPTION

Formulation of the notified polymer into engine oil products

During formulation, the drums containing the notified polymer (100%) will be transferred onto a pallet by forklift from the warehouse area to the blending area. The drums will be emptied into a blending vessel by a controlled, automated system that will weigh and measure the notified polymer and other ingredients. The ingredients will be blended in a closed system. The finished engine oils will be transferred from blending vessels by hard piping to automated filling machines that will fill various size containers such as: 1 L, 5 L, 20 L and 205 L. These containers will be placed into cartons and then, if appropriate, onto pallets for distribution to

distribution centres, retail outlets and automotive service centres.

Repackaging of imported engine oil products

Engine oil products containing the notified polymer at < 1% will be imported in package sizes of 1 L, 5 L, 20 L, 205 L and 209 L. Some repackaging of the imported engine oil products may take place in Australia. The repackaging operations (if applicable) are expected to take place using controlled automated systems and the products may then be warehoused prior to transport to distributors, commercial customers and consumers around Australia.

End Use

At end-use sites, the finished engine oils containing the notified polymer 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>
Transport and storage	2-4	40-60
Blending		
Blending Operator	2	50
Filling Operator	8	50
Quality Control	1-2	≤ 60
Import and use of finished products		
Decant Operator	1-2	15-20
Warehouse Operator	4-6	150-200
Pack driver	4-6	150-200
Product Disposal Operator	1-2	40-60
End use – Commercial	2-3	150-200

EXPOSURE DETAILS

Transport and storage

Transport and storage workers on the docks and in the storage warehouses are not likely to be exposed to the notified polymer except in the case of an accident involving damage to the containers.

Formulation of the notified polymer into engine oil products

Exposure to the notified polymer (at ≤ 100% concentration) may be experienced by workers during transfer processes, quality control analysis, cleaning and maintenance tasks and occasionally from leaks and spills. Blending of the notified polymer is expected to take place in a closed, fully automated system equipped with ventilation, which is expected to result in limited potential for exposure. The main route of exposure is expected to be dermal, although some ocular exposure is also possible (inhalation exposure is not expected). Personal protective equipment (PPE; e.g. gloves, goggles and protective clothing) is expected to be worn by workers to minimise exposure to the notified polymer.

Repackaging of imported engine oil products

Workers involved in the repackaging of the finished engine oils containing the notified polymer (< 1%) from 205 or 209 L drums into smaller containers are not expected to experience significant exposure given the automated systems in place and that work will be conducted in ventilated areas. Similarly to workers involved in the formulation of engine oil products, workers involved in the repackaging of engine oil products are expected to wear PPE, such as gloves, goggles and protective clothing, to minimise dermal and ocular exposure to the notified polymer (inhalation exposure is not expected).

End use

Workers may be exposed to engine oils containing the notified polymer (< 1%) 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%) 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%) 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, worker exposure to the notified polymer (< 1% concentration in finished engine oils) is not expected to be significant.

6.1.2. Public Exposure

The notified polymer will be used as a component of engine oils at < 1% concentration. Once engine oil containing the notified polymer is added to the engine, the general public is not expected to be exposed to the notified polymer during its use in the engine. DIY users may experience limited dermal and accidental ocular exposure to engine oils containing < 1% of the notified polymer when changing/topping-up the engine oil in their vehicles. However, such activities are expected to occur infrequently.

Overall, public exposure to the notified polymer is expected to be low, and further limited by the infrequent use of the finished engine oils (containing < 1% notified polymer).

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>	<i>Test Method</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity	OECD TG 423
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity	OECD TG 402
Rabbit, skin irritation	slightly irritating	OECD TG 404
Rabbit, eye irritation	slightly irritating	OECD TG 405
Mouse, local lymph node assay	no evidence of sensitisation	OECD TG 429
Rat, repeat dose oral toxicity – 28 days	NOAEL = 250 mg/kg bw/day	OECD TG 407
Mutagenicity – bacterial reverse mutation	non-mutagenic	OECD TG 471
Genotoxicity – <i>in vitro</i> chromosome aberration (cultured human lymphocytes)	non-genotoxic	OECD TG 473

Toxicokinetics, metabolism and distribution

While the notified polymer may be absorbed across biological membranes (gastrointestinal tract and skin), the extent of absorption is expected to be limited by the high molecular weight (> 1,000 Da), the low water solubility (< 3×10^{-4} g/L at 20 °C) and high partition coefficient (log Pow > 6.55 at 20 °C) of the notified polymer. However, the notified polymer contains a proportion of low molecular weight species (< 1,000 Da) that may be absorbed.

Acute toxicity

Three female Wistar rats were administered 2000 mg/kg body weight of the notified polymer in corn oil, by gavage. When the animals were observed to have survived for two days, three more female rats were administered the notified polymer. No test substance-related mortalities occurred. Signs of toxicity following administration were hunched posture and/or piloerection, on day 1 only. All animals gained weight between days 1-8 and 5/6 animals gained weight between days 8-15 of the study (one animal lost weight slightly, 1g, during this period). On day 15 post-administration, the animals were sacrificed. Post-mortem examination did not reveal any abnormalities in either of the groups. The notified polymer showed low acute oral toxicity, with the LD50 > 2000 mg/kg bw.

The notified polymer was applied on Wistar rats (5 males, 5 females), diluted in corn oil, under an occlusive dressing to a shaved area on the back of the animals, comprising about 10% of the total body surface. The

occlusive patch was left in place for 24 hours, then removed and the area cleaned using tap water. No test substance-related mortalities occurred. Clinical signs of toxicity were flat posture, ptosis and/or chromodacryorrhea in 2/5 males and 4/5 females on days 1 or 2. The signs had resolved in the animals by day 3. Scales on the treated skin were noted in one male and one female between days 7-13. Regarding body weights, while only 4/5 male and 4/5 female rats gained weight in the first week of observation, all male rats and all female rats gained weight in the second week of the study. Following sacrifice on day 15, necroscopic examination did not reveal any abnormalities. The notified polymer showed low acute dermal toxicity in rats, with the LD50 > 2000 mg/kg bw.

No acute inhalation toxicity data were provided.

Irritation

Skin irritation was assessed on three male New Zealand white rabbits. 0.5 mL of undiluted notified polymer was applied under a semi-occlusive dressing to a 10 × 15 cm patch of shaved dorsal skin. The exposure time was four hours, after which the bandage was removed and the skin washed with water and watery ethanol. A sticky residue was noted to have persisted (time point 1 hour post patch-removal) and brown staining of the skin was noted up to 72 hours post patch-removal. No mortalities occurred, no signs of toxicity were evident in the test animals and all animals gained weight during the study. Grade 1 erythema was observed at 1 hour (2/3 animals) and at 24 hours (1/3 animals) following patch-removal. The scores for edema and all other time point erythema scores were zero up until 72 hours. The results of this study indicate that the notified polymer was slightly irritating to the skin.

Eye irritation was tested on one male and two female New Zealand white rabbits. 0.1 mL of undiluted notified polymer was instilled into the conjunctival sac of one eye, with the other eye serving as the untreated control. Animals were observed at 1, 24, 48 and 72 hours. No signs of systemic toxicity were observed and all animals survived until the end of the study. No corneal or iridial irritation was evident. Conjunctival irritation ranged from grade 1 to 2 and included redness and discharge only. All signs had resolved by 24 hours in all animals. The results of this study indicate that the notified polymer was slightly irritating to the eyes.

Sensitisation

The notified polymer in a toluene/olive oil vehicle (2:1) was tested in an LLNA study in mice (5 animals/group; CBA/J mice). Additional mice were treated with 25% α -hexylcinnamaldehyde in the same vehicle as a positive control. Based on a preliminary study, 100% notified polymer, which caused slight irritation only, was chosen as the maximum concentration. Dilutions of 0, 25, 50 and 100% notified polymer were used. No mortalities occurred. Animals treated with the notified polymer were noted to have squeaked and appear very restless after application. No other signs of systemic toxicity were noted. Erythema was noted in all treated and positive control animals. The auricular lymph nodes from the treated animals were not assessed as being larger than the vehicle control animals (those from the positive control animals appeared larger than the vehicle control animals). Following administration of ^3H -methyl thymidine, the stimulation indices (SI) were determined for the treatment groups, and were 1.75, 1.04 and 1.32 at 25, 50 and 100% concentration, respectively. The positive control induced a SI of 3.16. The results of this study indicate that there was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.

Repeated dose toxicity

The notified polymer was administered by oral gavage to Wistar rats, using corn oil as a vehicle. Groups of five animals/sex received 0, 60, 250 or 1000 mg/kg bw/day notified polymer (five additional animals/sex/group received 0 or 1000 mg/kg bw/day notified polymer, and following the 28 day administration period, these animals were allowed to recover for 14 days prior to terminal sacrifice). No clinical signs (except for scabs on the cheek and throat of one rat for a few days), or signs of systemic toxicity were recorded, at any dose level, during the study. Functional observations and body weight gain were not significantly different from the control animals. No toxicologically relevant changes occurred in treatment groups relative to the control animals, for hematology and clinical chemistry. Necropsy did not show any unusual findings in the treatment groups, relative to the control animals. Sporadic observations were present in all dosed groups, including control, and these were not considered to be treatment-related. Generally, organ weights did not differ between the control and treatment groups, and where slight differences were observed, these were not carried through to the recovery groups or were not supported by histopathological examination of the tissues. Histopathology revealed a papilliform, multifocal, hyperplasia of the urothelium of the urinary bladder in one high-dose male. Since this is not a usual finding for this strain, the possibility of dose-relationship could not be excluded. The NOAEL was established as 250 mg/kg bw/day.

Mutagenicity/genotoxicity

The potential for the notified polymer to induce bacterial reverse mutations was tested on four strains of *S. typhimurium* (TA98, TA100, TA1535 and TA 1537) and *E. coli* strain WP2uvrA. Two separate experiments were performed using the plate incorporation method. The first experiment used concentrations ranging from 10-5000 µg/plate, in the absence and presence of metabolic activation (S9 mix; added at 5% v/v). The second experiment used fewer dose groups (with the highest being 1000 µg/plate) in the absence and presence of metabolic activation (S9 added at 10% v/v). Precipitate of the notified polymer was observed at ≥ 1000 µg/plate. No apparent cytotoxicity of the notified polymer was observed, either as a change in the background lawn or a decrease in the number of revertant colonies. No toxicologically relevant increase in the number of revertant colonies was observed at any concentration, for any strain. The positive controls induced statistically significant increases in revertant colony numbers. The results of this study indicate that the notified polymer was not mutagenic to bacteria under the conditions of the test.

The potential for the notified polymer to induce chromosomal aberrations was tested in cultured human lymphocytes. Following an initial experiment, the notified polymer was observed to precipitate at concentrations ≥ 33 µg/mL. Therefore, the test concentrations used for the main experiment were 0.3, 10 and 33 µg/mL of culture medium. Incubation/fixation times were 3/48 hours (with metabolic activation – S9); 24/24 hours and 48/48 hours (without metabolic activation). Assays were performed in duplicate. No statistically significant increase in the number of chromosomal aberrations was observed for any dose level, compared to the solvent control value. The positive controls showed chromosomal aberration counts that were significantly elevated, compared to the solvent controls. The results of this study indicate that the notified polymer did not induce chromosomal aberrations in cultured human lymphocytes under the conditions of the test.

Health hazard classification

Based on the available information, the notified polymer is not recommended for classification 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 results of studies conducted on the notified polymer indicate that it is slightly irritating to the skin and eyes. In addition, an adverse effect was considered to have occurred in a repeated dose oral toxicity study in rats.

The workers expected to experience the highest exposure are those handling the notified polymer as imported ($\leq 100\%$) at reformulation (and/or repackaging sites). Workers involved in reformulation processes may experience dermal and ocular exposure to the notified polymer during transfer of the notified polymer to blending vessels, quality control analysis, packaging, cleaning and maintenance tasks and occasionally from leaks and spills. The blending process is expected to be largely enclosed and automated, and therefore significant exposure is not expected to occur. Exposure of workers is expected to be further minimised by the use of PPE such as protective clothing, gloves and goggles. Given the use of automated and enclosed systems and the appropriate use of PPE during handling of the notified polymer as imported, the potential for adverse health effects is not considered unreasonable.

Engine oil products containing the notified polymer at $< 1\%$ concentration will be used by workers at car manufacturing sites, car dealerships and automotive service centres. Exposure to these workers may occur frequently during oil changes. While workers may use some PPE to minimise exposure, the potential for adverse health effects from use of the notified polymer is not considered to be unreasonable due to the low concentration of the notified polymer in the engine oils ($< 1\%$).

Overall, the potential for adverse health effects in workers exposed to the notified polymer ($\leq 100\%$) is not considered to be unreasonable, given the use of appropriate engineering control measures to minimise exposure during reformulation and/or repackaging processes ($\leq 100\%$ notified polymer) and the low concentration of the notified polymer in the engine oil products ($< 1\%$).

6.3.2. Public Health

Engine oil products containing $< 1\%$ notified polymer will be available to the public for DIY use. During engine oil changes, limited dermal and accidental ocular exposure is possible, as members of the public are not likely to use PPE. The potential for limited/accidental exposure to the notified polymer is expected to be

further reduced by the infrequent nature of DIY engine oil change/top-up activities. Therefore, the risk to the public from use of the notified polymer at < 1% 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 an additive for automotive engine oil. Further blending with other ingredients may be required at customer's blending facilities. At the blending facilities, release during the highly automated blending process is not expected. The equipment used will typically be cleaned with oil, with these washings used in the formulation of the next batch or another oil blend. In these situations release would occur through accidental spills, which would be recycled or collected for proper disposal, which will most likely be to landfill. Any of the notified polymer remaining in the import containers (expected to be < 0.1% of the contents), would be washed out and recycled or collected for proper disposal, which will most likely be to landfill.

RELEASE OF CHEMICAL FROM USE

The formulated engine oils will be used by automobile manufacturer facilities, automotive service centres and by do-it-yourself (DIY) consumers. Some minor, diffuse exposure will result from spills during the addition and removal of oil from machines. It is estimated by the notifier that 45% of oil changes will take place in specialised automotive service centres, where release of the notified polymer from professional activities should be disposed of appropriately. The remaining 55% will be removed by DIY users. Of the engine oil containing the notified polymer disposed of by DIY users, approximately 20% will be collected for recycling, 25% will be buried or disposed of in landfill, 5% (i.e. 2.75% of the total annual import volume) may be disposed of inappropriately into storm water drains and the remaining 50% will be used in treating fence posts, killing grass and weeds or disposed of in other ways (Snow, 1997).

RELEASE OF CHEMICAL FROM DISPOSAL

Empty containers should be sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies are typically passed to an onsite waste treatment facility and any waste sludge may be sent to landfill.

7.1.2. Environmental Fate

The notified polymer is likely to be mainly disposed of by thermal decomposition as part of the process to recover the calorific value of used lubricants. Smaller amounts of the notified polymer may be consigned to landfill, or disposed of inappropriately to land or stormwater. On land or in landfill, the notified polymer is expected to associate strongly with the organic compartment based on its high soil adsorption coefficient and partition coefficient. The low water solubility, along with a very high log K_{oc} , suggests that the notified polymer will not be environmentally mobile. The notified polymer is not expected to be bioavailable or bioaccumulative to aquatic organisms due to its high molecular weight. Since the substance is not readily biodegradable (0-12% over 28 days; OECD 301B), removal of the notified polymer through biodegradation processes is expected to be minimal. Either in landfill or through thermal decomposition, the notified polymer will finally be decomposed into water, oxides of carbon and nitrogen, and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The percentage of the imported quantity of notified polymer inappropriately disposed to stormwater drains is estimated to be 2.75%. That is, 55% (fraction collected by DIY users) \times 5% (fraction disposed to stormwater). The release of the notified polymer may be up to 3300 kg/year (120 tonnes/year \times 2.75%). For a 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 3300 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 13.2 µg/L. This result reflects a worst-case scenario upper limit, as in reality releases of the notified polymer will be distributed over multiple urban areas. Moreover, the notified polymer will be further diluted if it reaches the ocean.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on water soluble fractions (WSF) of the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Results</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LL50 (96 h) > 100 mg/L (WSF)	Not harmful to fish up to limit of solubility in water
Daphnia Toxicity	EL50 (48 h) > 100 mg/L (WSF)	Not harmful to aquatic invertebrates up to limit of solubility in water
Algal Toxicity	EL50 (72 h) > 100 mg/L (WSF) NOELR = 100 mg/L (WSF)	Not harmful to algae up to limit of solubility in water

Under the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS, United Nations, 2009), the notified polymer is considered not harmful to fish, aquatic invertebrates and algae. Based on this toxicity, the notified polymer is not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

The endpoint for fish, daphnia or algae of E(L)L50 > 100 mg/L from the reported results was used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 100 was used as the endpoints for three trophic levels are available.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>			
EL50		> 100	mg/L
Assessment Factor		100	
PNEC:		> 1,000	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:	< 13.2	> 1000	< 0.013
Q - Ocean:	< 1.32	> 1000	< 0.001

The Risk Quotients ($Q = PEC/PNEC$) for the worst case scenario have been calculated to be < 1 for the river and ocean compartments. Although the notified polymer may be released into waterways, it is unlikely to pose a risk to the aquatic environment due to the notified polymer's low ecotoxicity. Therefore, on the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Water Solubility** $< 3 \times 10^{-4}$ g/L at 20 °C

Method Modified OECD TG 105

Remarks This study was done based on the metal content of the notified substance. The test was performed at a nominal concentration of 2.38 mg/L and then compared to standards made (0.1 – 100 µg metal/L). The solubility was then calculated based on the metal content and the dilution factor.

Water Extractability – The water extractability has been calculated. A study to determine the solubility of the substance in five different solvents (including water) was provided by the notifier. To determine its solubility in water, two sample solutions at a concentration of ~2.0 g/L were prepared. After heating at 35-40 °C, stirring and equilibration, the aqueous layers were analysed by total organic carbon (TOC) analysis. Since the result obtained (6.2 mg/L) is the TOC content, it is not the true water solubility of the notified substance. The following equation and assumption were used for the calculation of the water extractability:

%TOC: 83.38% (from Ready Biodegradation study)

Initial Concentration: 2.000 g/L

Measured TOC Concentration: 0.0062 g/L

$$\%WE = \frac{\text{Measured_TOC_Concentration} / \%_TOC}{\text{Initial_Concentration}} \times = \frac{0.0273 \text{ g/L} / 0.8443}{2.000 \text{ g/L}} \times 100 = 1.62\%$$

Test Facility NOTOX B.V. (2010a)

Partition Coefficient (n-octanol/water) log Pow > 6.55 at 20 °C

Method Calculated

Remarks The notifier estimated the log K_{ow} to be > 6.55 using the ratio of the solubility of the substance in n-octanol (1060 g/L) to its solubility in water (0.3 mg/L). Since the n-octanol value was a minimum and the water solubility value was a maximum, the calculated log K_{ow} is a minimum value.

Test Facility NOTOX B.V. (2010a)

Adsorption/Desorption log K_{oc} > 5.4
– screening test

Method Calculated using quantitative structure activity relationships (QSAR's)

Remarks The log K_{oc} was calculated using the QSAR's given in the Technical Guidance document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances and Commission Regulation (EC) 1488/94 on Risk Assessment of existing substances. Since the substance is a hydrophobic compound, the following equation was used: log K_{oc} = (0.81)log K_{ow} + 0.10. The notifier obtained a log K_{oc} value of greater than 5.4 using a log K_{ow} value of 6.55.

Test Facility NOTOX B.V. (2010a)

Flash Point 136 °C at 101.3 kPa

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

Remarks A model APM-7 Pensky-Martens closed cup automatic flash-point tester was used.

Test Facility NOTOX B.V. (2010a)

Flammability Not highly flammable in contact with water
Not pyrophoric

Method	EC Council Regulation No 440/2008 A.12 Flammability (Contact with Water).
Remarks	EC Council Regulation No 440/2008 A.13 Pyrophoric properties of Solids and Liquids. In contact with water, the test substance did not spontaneously ignite or give off flammable gas in excess of 1 L/kg/h. The test substance did not ignite within 5 minutes of coming in contact with air.
Test Facility	NOTOX B.V. (2010a)

Autoignition Temperature 440 °C at 101.31-102.75 kPa

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Determined using a commercially available auto-ignition temperature apparatus.
Test Facility	NOTOX B.V. (2010a)

Explosive Properties Predicted negative

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	Determined by the observation of functional groups that are associated with explosive properties.
Test Facility	NOTOX B.V. (2010a)

Oxidizing Properties Predicted negative

Method	EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks	Determined by the observation of functional groups that are associated with oxidising properties.
Test Facility	NOTOX B.V. (2010a)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS**B.1 Environmental Fate****B.1.1 Ready biodegradability**

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Remarks - Method	<p>The validity of the test was determined using five criteria:</p> <ol style="list-style-type: none"> 1) The difference in extreme of replicate values of the removal of the test chemical at the plateau, at the end of the test or at the end of the 10 day window, as appropriate, is less than 20%. The difference in duplicate values for percent degradation was never greater than 11%. 2) The percentage degradation of the reference compound (positive control) must reach the pass level by day 14. The reference compound achieved 86% degradation by day 14. 3) In the toxicity control, containing both the test substance and a reference compound, greater than 25% degradation (based on total ThOD or ThCO₂) must occur within 14 days. If not, the substance is considered inhibitory. In the toxicity control, 32% degradation was achieved in 14 days. 4) The inorganic carbon content of the test substance suspension in the mineral medium at the beginning of the test must be less than 5% of the total carbon content. The test medium was prepared in tap water purified by reverse osmosis (carbon levels < 500 ppb) and the total carbon content is mainly from the test substance (12 mg TOC/L). 5) The total CO₂ evolution in the inoculum blank at the end of the test should not normally exceed 40 mg/L medium. The total CO₂ evolution in the inoculum blank was 48.1 mg per 2 litres of medium, which corresponds to 24.1 mg/L. <p>The study was considered valid since all five criteria for acceptability of the test were met.</p>
RESULTS	0-12% degradation in 28 days
CONCLUSION	The notified polymer is not readily biodegradable
TEST FACILITY	NOTOX B.V. (2010b)

B.2 Ecotoxicological Investigations**B.2.1 Acute toxicity to fish**

TEST SUBSTANCE:	Notified polymer
TEST METHOD:	OECD TG 203
SPECIES:	Carp
EXPOSURE PERIOD:	96 h
REMARKS METHOD:	The water soluble fraction (WSF) solution was prepared by stirring the substance in water for 48 h, followed by 67 min equilibration. Clear and colourless WSF solution was taken for testing. The highest concentration tested was 100 mg/L WSF.
RESULTS:	

Concentration		Number of Fish	Mortality			
Nominal (mg/L)	Correlated polymer concentration (mg/L)*		24 h	48 h	72 h	96 h

Concentration		Number of Fish	Mortality			
Control		7	0	0	0	0
100	9	7	0	0	0	0

* Polymer concentration calculated based on measured concentration of metal and theoretical concentration of metal at 100 mg/L of polymer or 907 µg/L.

96 h LL₅₀:

> 100 mg/L (WSF)

Remarks – Results:

The substance did not display acute toxicity towards fish at saturation. The No Observed Effect Loading Rate (NOELR) is 100 mg/L.

The concentration of the substance was monitored through Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The theoretical metal concentration at 100 mg/L of polymer would be 907 µg/L. The reported polymer concentrations, as per the analytical report, for 100 mg/L (WSF) at time = 0 h, 24 h and 96 h are 9.01 mg/L, 9.61 mg/L and 9.43 mg/L, respectively. However, the average concentration is reported as 9.0 mg/L in the actual study report.

CONCLUSION

The notified polymer is not harmful to fish up to the limit of its solubility in water.

TEST FACILITY

NOTOX B.V. (2011c)

B.2.2 Acute toxicity to aquatic invertebrates

TEST SUBSTANCE:

Notified polymer

TEST METHOD:

OECD TG 202

SPECIES:

Daphnia Magna

EXPOSURE PERIOD:

48 h

REMARKS – METHOD:

The water soluble fraction (WSF) solution was prepared by stirring the substance in water for 48h, followed by 100 min equilibration. Clear and colourless WSF solution was taken for testing. The highest concentration tested was 100 mg/L WSF. The 100 mg/L WSF solutions was diluted to lower concentrations for toxicity testing. During the combined preliminary and final test, daphnia trapping on the surface was observed. The trapped daphnia was reimmersed into water prior to recording of immobility/immortality.

RESULTS:

Concentration			Number of Daphnia	Mortality **		
Nominal (mg/L)	Correlated concentration (mg/L)*	polymer		24h	48h	Average %
Control	A		5	0	0	10
	B			1	1	
	C			0	0	
	D			1	1	
0.1	A	Not reported		0	0	0
	B			0	0	
1.0	A	Not reported		0	0	0
	B			0	0 (1)	
10	A	0.3		0	0 (5)	0
	B			0	0 (4)	
100	A	2.8		0 (5)	1 (2)	30
	B			0 (5)	2 (3)	
	C			0 (5)	2 (1)	
	D			0 (5)	1 (3)	

* Polymer concentration calculated based on measured concentration of metal and theoretical concentration of metal at 100 mg/L of polymer or 907 µg/L.

** Mortality/immobility recorded after daphnia were immersed into test solution. Values in () indicate observed surface trapped daphnia.

48 h EL₅₀:

> 100 mg/L (WSF)

Remarks – Results:

The lower concentration WSF test solutions were prepared by diluting from 100 mg/L solution. It is not recommended that lower concentration WSF test solution be prepared through dilution, as different molecular weight fractions will have different water solubility. Therefore, the soluble fraction at each concentration would change, and simple dilution would not account for the soluble fraction at that concentration. For the four control tests, an average of 10% of the daphnia was reported to be immobilised, which is within the acceptable limits of the test requirement.

In the final test, some surface trapping of daphnia was reported for solutions at 10 mg/L and 100 mg/L. The daphnia were reimmersed prior to recording of mortality/immobility. At 100 mg/L WSF, 30% immobility/mortality was recorded. The author proposed that the 48 h EL₅₀ > 100 mg/L (WSF) was due partly to presences of floating layers and that the 50% mortality/immobility was not reached.

The concentration of the substance was monitored through Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The theoretical metal concentration at 100 mg/L of polymer would be 907 µg/L. The reported polymer concentration for 100 mg/L (WSF) at time = 0 h and 48 h are 3.11 mg/L and 2.57 mg/L, respectively. The average concentration reported is 2.8 mg/L.

CONCLUSION:

The notified polymer is not harmful to aquatic invertebrates up to the limit of its solubility in water.

TEST FACILITY:

NOTOX B. V. (2010d)

B.2.3 Algal growth inhibition test

TEST SUBSTANCE:

Notified polymer

TEST METHOD:

OECD TG 201

SPECIES:

Pseudokirchneriella subcapitata

EXPOSURE PERIOD:

72 h

REMARKS - METHOD:

The water soluble fraction (WSF) solution was prepared by stirring the substance in water for 48 h, followed by 75 min equilibration. Clear and colourless WSF solution was taken for testing. The highest concentration tested was 100 mg/L WSF. The 100 mg/L WSF solutions was diluted to lower concentrations for toxicity testing. The preliminary and final tests were combined into one test.

RESULTS:

Yield			Growth		Correlated polymer concentration (mg/L) *
72h (mg/L)	E _y L ₅₀	NOELR (mg/L)	72h E _r L ₅₀ (mg/L)	NOELR (mg/L)	
> 100		100	> 100	100	7.2

* Polymer concentration calculated based on measured concentration of metal and theoretical concentration of metal at 100 mg/L of polymer or 907 µg/L.

Remarks – results:

In the combined test, the substance did not display acute toxicity towards algae at saturation. The No Observed Effect Loading Rate (NOELR) is 100 mg/L.

The concentration of the substance was monitored through Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The theoretical metal concentration at 100 mg/L of polymer would be 907 µg/L. The reported polymer concentration, as per the analytical report, for 100 mg/L (WSF) at time = 0 h, 24 h and 72 h are 7.25 mg/L, 7.58 mg/L and 7.86 mg/L, respectively. However, the average concentration is reported as 7.2 mg/L

in the actual study report.

CONCLUSION: The notified polymer is not harmful to algae up to the limit of its solubility in water.

TEST FACILITY: NOTOX B.V. (2010e)

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