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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in OLOA 13300

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 the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Oronite Australia Pty Ltd (ABN 16 101 548 716)
Level 10, 45 William Street
Melbourne, Victoria 3000

NOTIFICATION CATEGORY
Limited: Synthetic Polymer with NAMW > 1000 (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical Name
- CAS Number
- Molecular Formula
- Structural Formula
- Molecular Weight
- Spectral Data
- Purity
- Identity of Toxic or Hazardous Impurities
- % Weight toxic or hazardous impurities
- Non-hazardous impurities
- Identity of additives
- % Weight of additives
- Manufacture/Import volume
- Identity of manufacturing site

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Flammability
- Auto ignition temperature
- Dissociation
- Adsorption/Desorption
- Hydrolysis

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
United States (2006), Canada (2006)

2. IDENTITY OF CHEMICAL

OTEHRNAME(S)
SP 1600; XC 1600; CP 1600

MARKETING NAME(S)
OLOA 13300 (containing typically 50% of the notified polymer and 50% neutral oil)

ANALYTICAL DATA
Reference GPC, FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>90%
The notified polymer contains a hazardous residual monomer (a skin sensitiser) at <1%.

DEGRADATION PRODUCTS
The notified polymer is not designed nor expected to degrade, decompose, or depolymerize.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None expected during use.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Dark amber viscous liquid

Property	Value	Data Source/Justification
Pour Point	2°C	Measured
Boiling Point	≥329°C	Measured
Density	921 kg/m^3 at 20°C	Measured
Vapour Pressure	2.32 x 10^{-7} kPa at 20°C	Calculated
Water Solubility	≤ 0.001 g/L at 20°C	Estimated
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functional groups. However, due to the low water solubility, hydrolysis is not expected.
Partition Coefficient (n-octanol/water)	log Pow = > 7.4	Measured
Adsorption/Desorption	Not determined	The notified polymer has a high Pow and is therefore likely to adsorb strongly to organic carbon soil.
Dissociation Constant	Contains potentially cationic groups. Based on the functional group the pKa is expected to be approximately 9.	Estimated
Particle Size	Not applicable	Introduced in solution
Flash Point	>180 °C	MSDS for the imported product
Flammability	Not determined	Based on its flash point, the notified polymer would be expected to have limited flammability.
Autoignition Temperature	Not determined	The notified polymer is not expected to autoignite under normal condition of use.
Explosive Properties	The polymer will not detonate as a result of heat, shock or friction.	The notified polymer does not contain nitro group, peroxides or any other functional group known to be explosive.

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity
The notified polymer is expected to be stable under normal condition of use. May react with strong oxidizing agents, such as chlorates, nitrates, and peroxides. Hazardous polymerization will not occur.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. It is imported into Australia as part of a lubricant additive package. Typically the additive package will contain 50% of the notified polymer and 50% neutral oil.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	300-600	300-600	300-600	300-600	300-600

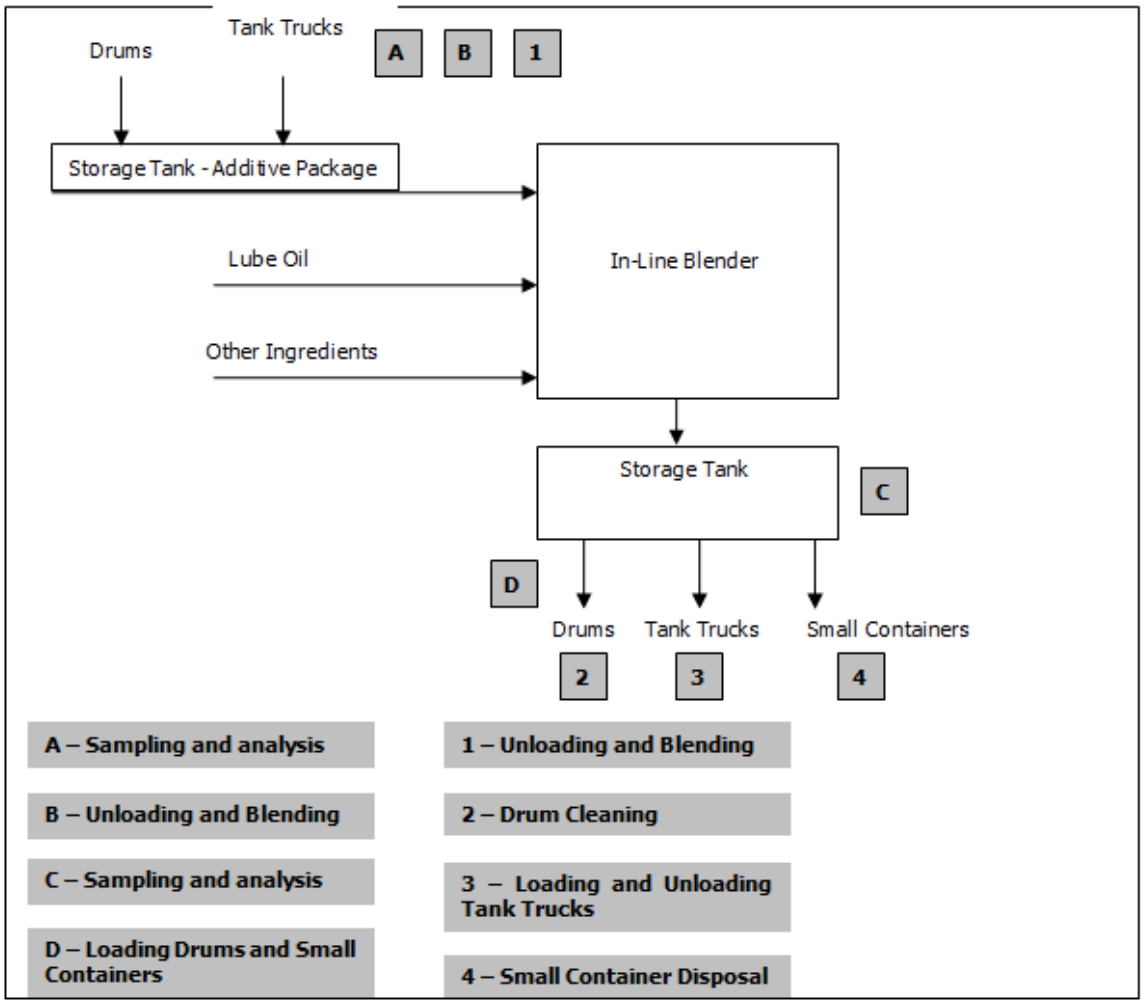
PORT OF ENTRY
Varies

IDENTITY OF MANUFACTURER/RECIPIENTS
Lubricant oil manufacturers

TRANSPORTATION AND PACKAGING
The imported additive package containing typically 50% of the notified polymer will be imported in 200kg drums or tank trucks (typically 20 000 kg) or rail cars and transported to the formulators directly, mainly by road. The formulated finished oils are packaged in tank trucks or rail cars, drums, and smaller containers.

USE
The imported additive package will be used to manufacture finished automotive diesel and gasoline crankcase engine oils/lubricants.

OPERATION DESCRIPTION
Typically, the additive package will be blended at 5 – 10% in the finished oils (equivalent to 2.5 – 5% of the notified polymer in the finished oil). The operation description is illustrated in the flow chart below.



Reformulation

Upon arrival of the additive package to the formulation site, laboratory staff will take samples of the additive package to ensure quality before it is transferred from drums and tank trucks into storage tanks. The transfer process from the tank truck occurs by use of a 10 cm hosing. Connection of the hose takes 10 minutes. A special air back flush system is used to prevent spillage during transfer. Transfer from storage tanks to blending tank will be automated, using computer controlled valves. The blending process occurs in a closed system at 60 °C and is computer controlled. The blended lubricant (containing a maximum of 5% notified polymer) is transferred automatically (computer controlled) to a storage tank and laboratory staff will take samples of the finished oil to ensure quality. Then the finished lubricants are packaged for shipment in bulk tanks, drums, or small containers. Bulk tank truck or rail car filling is performed by a transfer hose. The drumming facility uses automated weight scales to fill the drums. The small container packaging machine is a fully-automated machine and will fill quarts. The repackaging facility uses automated weight scales to fill the containers.

The finished oils containing < 5% of the notified polymer will be sold to high volume industrial end users, commercial automotive engine service outlets, and consumer users.

End use

Industrial and Commercial end users

High volume industrial and commercial end users, such as truck and taxi fleets and commercial automotive engine service outlets, will use the finished oils to lubricate gasoline and diesel engines. In many cases, any stationary engines involved will be routinely lubricated using dedicated lubricating oil reservoirs and piping to add lubricants directly without human intervention. For non-stationary automotive applications, workers will check lubricant levels in the engine manually and top-off as

needed using lubricants added via pneumatic delivery equipment. Commercial automotive engine service outlets will also receive roughly 10% of the small containers.

Consumer users
Consumer users will be automotive do-it-yourselfers, farmers, or anyone who changes their own oil. Consumers will top-off or change the motor oil in their cars, lawn mowers, etc.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Laboratory Staff	40	1 hour/day	4 days/year
Unloading/Blending/Loading	40	2 hours/day	4 days/year
Industrial/Commercial Users	>1000	7 hours/day	250 days/year

Exposure Details
The major route of exposure to workers is via dermal and/or ocular, as exposure by ingestion is unlikely at workplace. Potential for inhalation exposure is low due to low vapour pressure of the notified polymer.

Reformulation
During sampling and analysis of the additive package and finished oil there may be skin contact. However, workers' exposure is expected to be low since it will occur only a few minutes per batch.

During unloading, incidental skin and eye contact to the additive package (containing typically 50% of the notified polymer) from splashes, drips, and spills is possible during connection and disconnection of transfer lines. Workers' exposure is not expected during transfer from storage tanks to blending tanks and during blending due to the computer-controlled process, except during equipment cleaning and maintenance. Dermal and ocular exposure to drips and spills of finished oils (containing <5% of the notified polymer) is possible during the connection and disconnection of transfer hoses for filling of bulk containers. Workers' exposure is expected to be minimal during drum and small container filling due to the automated process.

The blending facilities are typically well ventilated and with control systems for accidental spills such as the special air back flush system. Workers involved in the above-mentioned activities typically receive training in handling the additive packages and finished oils, and wear personal protective equipment (PPE) such as gloves, eye protection, protective clothing and hard hats. In addition, duration of the activities where potential exposure occurs, such as connection and disconnection of transfer lines, is short. Therefore, workers' exposure during reformulation is expected to be low.

End use by high volume industrial and commercial end users
Use of lubricants containing the notified polymer in stationary engines results in limited exposure to workers as the process typically uses dedicated lubricating oil reservoirs and piping to add lubricants directly without human intervention, although accidental splashes, spills and drips could occur during connection and disconnection. In addition, in the industrial or commercial environment, engines are maintained by highly trained professional mechanics. Most likely these mechanics will have access to engineering controls and PPE.

Dermal and ocular exposure is possible during non-stationary automotive applications when workers check lubricant levels in the engine manually and top-off lubricants using pneumatic delivery equipment. Manual top-off is also possible using the small containers. Based on an EASE model using reasonable worst case defaults for the exposure scenario 'manual addition of liquids' (European Commission, 2003), the estimated dermal exposure for this use scenario is 21 mg/day considering the notified polymer is present at concentration of 5%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 0.3 mg/kg bw/day. It should be noted that this

estimate is considered to be conservative due to a number of assumptions. Workers' exposure would be further reduced by the use of engineering controls and PPE.

6.1.2. Public exposure

Consumer users of the lubricants containing the notified polymer are unlikely to take precautions to minimise exposure. Thus, they will have intermittent dermal exposure, and possibly accidental ocular and oral exposure, to the notified polymer. However, public exposure will be limited due to short use duration and generally infrequent uses. In addition, the high molecular weight of the notified polymer and its low solubility will prevent it from passing through biological membranes.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2000 mg/kg bw, low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw, low toxicity
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Irritating
Guinea pig, skin sensitisation – non-adjuvant test	Evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOAEL 1000 mg/kg/day NOEL 1000 mg/kg/day (females) 250 mg/kg/day (males)
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosomal Aberration Test	non genotoxic
Genotoxicity – in vivo Mammalian Erythrocyte Micronucleus Test	non genotoxic

The notified polymer is of low acute toxicity via oral and dermal exposure. It is slightly irritating to the skin and irritating to the eyes. However, the severity of the irritation does not meet the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

A Bueluer test indicates that the notified polymer is a skin sensitiser. The notified polymer contains a hazardous residual monomer which is a skin sensitiser. However, due to its low concentration in the polymer (<1%), the skin sensitising property should be attributed to the notified polymer.

A 28-day oral repeated study found that there were no treatment-related effects, except an isolated statistically significant increase in activated partial thromboplastin time (APTT) in the 1000 mg/kg/day male group. Therefore, the No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day (the highest dose tested). The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day for females and 250 mg/kg/day for males.

A series of genotoxicity studies indicates that the notified polymer is not mutagen.

Based on the skin sensitisation result the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Potential risks arising from acute exposure

The notified polymer is of low acute toxicity via oral and dermal exposure. However, it is slightly irritating to the skin and irritating to the eyes in animals, although these effects are not severe enough to meet the hazard classification criteria.

The risk of skin and eye irritation during handling the additive package (typically containing 50% of the notified polymer) at the formulation site is expected to be acceptable due to limited dermal and

eye exposure during unloading processes based on the short duration, use of engineering controls and PPE. This risk is considered acceptable during handling the finished oils by workers at both the formulation and end use sites as the concentration of the notified polymer in lubricants is low (5%).

Potential risks arising from repeated exposure

Skin sensitisation

The risk of skin sensitisation exists during handling both the additive package and finished oils containing the notified polymer. The risk will be mitigated during the formulation and end use of lubricants for the stationary engines due to minimal human interventions and use of PPE. However, skin sensitisation could occur from the manual application of lubricants for the non-stationary engines, especially if appropriate PPEs are not used. Therefore, use of appropriate PPEs and automated process wherever possible will be recommended for this use scenario to reduce workers' exposure.

Systemic effects

The risk of systemic effects is expected to be low during handling products containing the notified polymer at the formulation site and end use of lubricants for the stationary engines due to minimal human interventions and limited repeated exposure as well as use of PPE.

Based on a NOEL of 250 mg/kg bw/day, derived from a 28-day rat oral study and the reasonable worst-case worker exposure estimation during end uses of lubricants for non-stationary engines, the margin of exposure (MOE) is 833 (250/0.3). MOEs greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects based on the modelled data is acceptable for workers who handle products containing up to 5% of the notified polymer during end uses of lubricants for non-stationary engines.

6.3.2. Public health

The maximum concentration of the notified polymer in the lubricant is 5%. The risk of dermal and eye irritation due to acute exposure will be limited by the low concentration of the notified polymer within the lubricants.

However, there is a risk of dermal sensitisation for persons using the lubricants containing up to 5% of the notified polymer without PPE. Users should wear protective gloves and avoid skin contact. Therefore, advice to consumers needs to be highlighted on the label.

The risk of systemic effects to the general public is expected to be insignificant due to the limited repeated exposure and the expected poor absorption of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Unloading and blending the imported additive package

The area around and under the rail car/tank truck is cement with an open drain that has a steel grate on top. After the rail car/tank truck is unloaded, the hose is automatically pigged to the rail car or tank truck. Using ISO 9001 procedures, spills and leaks are less than 50 grams of additive package or 25 grams of the notified substance per bulk shipment. It is expected that 90% (<540 tonnes per annum) of the additive package will be shipped by tank truck or rail car. Tank trucks and rail cars are expected to have approximately 40 m^3 (~ 40 tonnes) capacity. Each rail or tank truck therefore contains approximately 20 tonnes of notified polymer of which up to 25 g are spilled per bulk shipment. This translates to < 700 g/year of the notified substance which will be sent to waste water treatment. The hose end is kept on an oily drain when not in use. Any spills or leaks are sent to the storm water system. The storm water system is an on-site chemical waste water system that includes an American Petroleum Industry (API) water and oil separator to separate the oil waste from the water. Approximately 90% of the spilled additive package will be removed from the waste water by the API. The waste oil containing the notified substance is sent to a used oil recycler who re-refines

the waste oil into fresh lubricant base stock using hydrocracking technology. The bottoms product containing the notified substance from the re-refining process becomes asphalt. The waste water is then sent to a pond where it is further treated by induced air floatation and biological treatment. The waste biological sludge from the biological treatment is sent off site for incineration. After biological treatment, the waste water is sent through a biodisk filter, then sand filtration before the treated water is released. This additional process will remove another 80% of the spilled additive package. Altogether < 20 g/year of the notified substance will be released.

The blending operations will take place at specially constructed sites owned and operated by the major lubricant manufacturers. It is anticipated that there will be minimal release of the notified polymer during transfer from the storage containers to the blending tanks, as a special air back flush system prevents any spillage. Blending occurs in fully enclosed automated systems. Blending tanks will be cleaned with lube oil, which will typically be recycled during subsequent blending, or incinerated. Any spills incurred in the blending operations will be contained within concrete bunds and either reclaimed or sent to on-site waste-water treatment facilities where residual hydrocarbon based products will be separated from the aqueous stream by API process, with a claimed removal of greater than 95%. Before being released to the sewage system, the aqueous waste undergoes further treatment involving pond aeration and sand filtration. The remaining oily waste will be incinerated.

Loading and unloading tank trucks with finished products
It is expected that 10% (<60 tonnes per annum) of the notified polymer in the finished product will be shipped by tank truck. Using the assumptions detailed above then approximately 2.5 g will be spilled per 4 tonnes of notified polymer per handling of a bulk shipment. Assuming two handlings (loading and unloading) it is expected that less than 80 g per annum, of notified polymer will be spilled. Of this approximately 2 g will be released to the environment after water treatment.

Typically, the tank trucks used to distribute lubricant products are dedicated trucks and are rarely cleaned. If cleaning is required this will be performed by licensed contractor.

Drum cleaning
Empty drums which distribute the finished lubricant containing residual notified polymer would be steam cleaned, with the resultant aqueous waste sent to on-site waste-water treatment facilities. Assuming 50% (<300 tonnes per annum) of the volume is delivered by drum, and that 0.1% (300 kg per annum) of the finished product remains in the container after use then with waste water treatment as described above the environmental release will be less than 6 kg per annum.

Small container disposal
It is estimated that 40% (240 tonnes) of the finished product is distributed in small containers. Assuming 0.1 wt% (240 kg) of the finished product remains in the bottle. This is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
Approximately 70% (< 420 tonnes) of the notified polymer is expected to be supplied to commercial end users such as taxi and truck fleets. Virtually all of the used oil containing the notified polymer is expected to be handled by professional mechanics.

The remaining 30% (< 180 tonnes per annum) will be sold to consumers.

A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (ie not burnt in the engines during use). This figure is likely to have increased as oil consumption in modern engines has tended to decrease. This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases could be expected to be disposed of responsibly - either to oil recycling or incineration. The remaining 14% are removed by “do it yourself” (DIY) enthusiasts, and 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. A recent report estimated that DIY activities account for between 7 to 10% of the unaccounted used oil (Meinhardt, 2002).

According to a survey tracing the fate of used lubricating oil in Australia (Snow, 1997) only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed to landfill, 5% is disposed of into stormwater drains and the remaining 50% unaccounted for.

Consequently, assuming that oil removed by professional mechanics is disposed of appropriately (ie sent for recycling or incineration; or possibly burning as workshop heating oil), negligible release of the notified polymer should result from these professional activities. During recycling it is expected that most of the polymer will decompose and any remainder will be associated with the asphalt portion.

Assuming that 14% of the consumer product (<25 tonnes per annum) of the used oil is removed by the DIY enthusiasts it is possible that of the oil removed by DIY enthusiasts, 20% (<5 tonnes per annum; ~1% of total import volume) is collected for recycling, 25% (< 6 tonnes ~1% of total import volume) is buried or disposed to landfill, 5% (< 1300 kg per annum; 0.2 % of total import volume) is disposed into stormwater drains and 50% (13 tonnes per annum; ~2% of total import volume) is unaccounted for.

RELEASE OF CHEMICAL FROM DISPOSAL

Drums are sent to drum recyclers where they are steam cleaned and water is sent to wastewater treatment. Empty quart and gallon containers are expected to be disposed of to landfill.

7.1.2 Environmental fate

The notified polymer will be imported and reformulated into lubricant oils at the blending facilities. Waste from reformulation is likely to go to oil recyclers or possibly be incinerated. Similarly most of the waste oil containing the notified polymer is expected to be recycled, where most of the notified polymer is expected to be decomposed to simpler organic molecules, with any remainder being associated with the oil or asphalt components. Some of the notified polymer is expected to enter the environment by incorrect disposal of oil by DIY enthusiasts. The notified polymer released into the aquatic environment would be expected to become associated with the sediments due to its estimated low water solubility. The notified polymer is not readily biodegradable, but is expected to eventually degrade by biotic and abiotic process to methane, ammonia, oxides of carbon and nitrogen; and water vapour (refer to Appendix C for the details of the environmental fate studies).

7.1.3 Predicted Environmental Concentration (PEC)

The likely route of exposure of the notified polymer to the aquatic environment is through incorrect disposal of waste oil products containing the notified polymer. It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified polymer released into the stormwater drains, which have the potential to directly enter the aquatic environment. However, it is expected that approximately 1% of the notified polymer may be released to the aquatic environment from direct and indirect release to stormwater from incorrect disposal of used oil containing the notified polymer. Assuming a worst case estimated PEC where 1% of the notified polymer is released into the stormwater (i.e. 6 tonne) and drains into a single metropolitan area with a geographical footprint of 500 square kilometres and an average annual rainfall of 500 mm, then a maximum annual release into this localised stormwater system of 6000 kg and the annual volume of water drained from this region estimated to be approximately 250 X 10^6 m^3, the resultant PEC is approximately 24 μg/L. It should be stressed that this result is very much a worst case scenario, and that in reality releases of the polymer would be very much more diffuse than indicated here, and also at significantly reduced levels.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 >1000 mg/L	Practically non-toxic
Daphnia Toxicity	EC50 >1000 mg/L	Practically non-toxic
Algal Toxicity	EC50 >1000 mg/L	Practically non-inhibitory
Inhibition of Bacterial Respiration	EC50 >1000 mg/L	Practically non-inhibitory

7.2.1 Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Lowest Endpoint	> 1000	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	10000	µg/L

All of the endpoints were above the 1000 mg/L WAF. The notified polymer is not toxic to the limits of its water solubility. An assessment factor of 100 was used as tests were performed on three trophic levels. 1000 mg/L was nominally chosen as the lowest endpoint and divided by the assessment factor.

7.3. Environmental risk assessment

From the PEC/PNEC (24 µg/L÷10 000 µg/L) ratio, a value of <0.01 is calculated for the risk quotient for the aquatic environment. The notified polymer is therefore not expected to pose an unacceptable risk the aquatic environment. However, as the notified polymer forms a component of an oil based product, which in itself poses a risk to the aquatic environment, the product should be prevented from entering waterways.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

Based on the available data the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). The classification and labelling details are:
R43 – May cause sensitisation by skin contact

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard Category	Hazard statement
Skin Sensitisation	1	May cause an allergic skin reaction

8.2. Human health risk assessment

8.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable given appropriate control measures in place to minimise dermal exposure.

8.2.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable provided appropriate warning statements on product labels.

8.3. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

The MSDS of the product OLOA 13300 containing the notified polymer provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of

the information on the MSDS remains the responsibility of the applicant.

10. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following hazard classification for the notified polymer:
  - R43 May cause sensitisation by skin contact

- The following risk phrase for products/mixtures containing the notified polymer applies:
  - ≥ 1% R43 May cause sensitisation by skin contact

- Products containing ≥1% notified polymer should carry the following warning on the label:
  - S2 Keep out of reach of children
  - S24 Avoid contact with skin
  - S36 Wear suitable protective clothing
  - S37 Wear suitable gloves

- The National Drugs and Poisons Standing Committee (NDPSC) should consider the notified polymer for listing on the SUSDP.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe practices to minimise occupational exposure during handling of products containing the notified polymer:
  - Minimise spills and drips
  - Where possible, automated processes should be used to reduce workers' exposure, especially for the use of lubricants for non-stationary engines
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to products containing the notified polymer:
  - Chemical resistant gloves
  - Protective clothing
  - Safety goggles

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The manufacturers of lubricants containing 1% or more of the notified polymer should indicate on the product label that the product may cause skin sensitisation (allergic skin reaction) and that skin contact should be avoided.

Environment

- The notified polymer should be disposed of by authorised incineration or oil recycling.

- Spills or accidental release of the notified polymer should be handled by preventing spills entering waterways, using physical containment, followed by absorption onto inert material (vermiculite, sand etc) and placed into suitable containers for disposal.

11. REGULATORY OBLIGATIONS

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 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 lubricant oils, or is likely to change significantly;
- the amount of polymer being introduced has increased from 600 tonnes, or is likely to increase, significantly;
- if the polymer has begun to be manufactured in Australia; and
- 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.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Melting Point/Freezing Point 2°C

METHOD ASTM D5950 (Internal Guidelines)
Remarks Pour point method. The sample is heated then inserted into the automatic pour point apparatus. The sample is cooled according to the cooling profile listed in ASTM D5950 and examined at 1°C intervals. The lowest temperature at which movement of the sample is detected by the automatic equipment is displayed as the pour point.
TEST FACILITY Chevron (2006)

Boiling Point 329 – 735°C (for 52.9% of recovered mass, the remaining 47.1% had boiling points > 735 °C)

METHOD ILT Test Code 59128, High Temperature simulated Distillation, similar to ASTM D 6352 (Internal Guidelines)
Remarks Gas chromatography is used to simulate the boiling point range distribution determination by distillation. The sample is diluted with carbon disulfide and injected onto a non-polar capillary column. The column oven temperature is raised and the sample's hydrocarbon components elute in order of increasing boiling point. The components are quantitatively measured by a flame ionisation detector. Retention times of known normal paraffinic hydrocarbons are used to determine boiling point temperatures. An external standard calculation method is used to quantify total percent recovery and mass percent by boiling point. Carbon-based components volatile to 735°C are recovered. Non-volatile hydrocarbons with boiling points above 735°C and inorganic compounds are not recovered by this method.
TEST FACILITY Chevron (2006)

Density 921 kg/m^3 @ 20 °C

METHOD ASTM D 4052 (Internal Guidelines)
Remarks Oscillating densitometer was used. The U-shaped sample cell, housed in a thermostatically-controlled chamber, is electromagnetically excited to oscillate at its natural frequency. When a sample is introduced into the cell, the mass of the sample changes the frequency of the cell's oscillation and a microprocessor calculates the density from this change.
TEST FACILITY Chevron (2006)

Vapour Pressure 2.32 x 10^{-7} kPa at 20°C

METHOD Calculated using the Maxwell-Bonnell method (Alternative method to ASTM D 323 and D5191, Internal Guidelines)
REMARKS Calculations were performed using the density and boiling point.
TEST FACILITY Chevron (2006)

Water Solubility ≤ 0.001 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
Remarks A preliminary test showed water solubility of less than 1×10^{-2} g/L. Indicating that the HPLC method is suitable. However, similar polymers have shown poor elution from the column. Further the functional groups detectable by UV detector would be below the limits of quantification. The solubility was therefore estimated on the basis of polymer fragments.
TEST FACILITY Chevron (2006)

Partition Coefficient (n-octanol/water) log Pow = > 7.4

METHOD	OECD TG 117 Partition Coefficient (n-octanol/water)
Remarks	HPLC Method. Reverse phase analysis was used with the mobile phase being 90% methanol and 10% water. Reference substances with Kow values between 3.6 and 7.4 were used. Peaks for the notified polymer were detected at Kow values of 4.8-13.1. The weighted average of 8.6 was calculated, which was above the calibration range.
TEST FACILITY	Chevron (2006)

Flash Point >180ºC

Remarks	Cleveland open cup (from MSDS for OLOA 133000)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Hsd: Sprague Dawley SD
Vehicle	Corn oil
Remarks - Method	The test substance was administered at 50% concentration in corn oil. No significant protocol deviations.

RESULTS

Number and Sex of Animals	*Dose mg/kg bw*	*Mortality*
3 females	2000	0
3 females	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	No clinical abnormalities were observed during the study.
Effects in Organs	No abnormal gross necropsy findings were observed during the study.
Remarks - Results	Body weight gain were noted for all test animals during the study.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Charles River (2006a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Hsd: Sprague Dawley SD
Vehicle	None
Type of dressing	Occlusive
Remarks - Method	The test substance was administered undiluted. No significant protocol deviations.

RESULTS

Number and Sex of Animals	*Dose mg/kg bw*	*Mortality*
5/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Transient dark material around the facial area was observed in 9/10 animals at the initial observation, but disappeared by day 1.
Signs of Toxicity - Systemic	Slight body weight loss was noted in 2 female rats during day 0 and 7 period. However, all animals exceeded their initial body weight by day 14.
Effects in Organs	A small kidney with associated small ureter in one female rat was noted, but was considered to be a pre-existing condition.
CONCLUSION	The notified polymer is of low toxicity via the dermal route.

TEST FACILITY Charles River (2006b)

B.3. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 males
- Vehicle: None
- Observation Period: 72 h
- Type of Dressing: Semi-occlusive.
- Remarks - Method: The test substance was administered undiluted. No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0.67	0.67	1	< 72h	0
Oedema	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results: Very slight erythema was observed on 3/3 test animals at 1 hour, which resolved completely on one animal by 24 hours and remaining animals by 72 hours.

No results on clinical observations were reported.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Charles River (2006c)

B.4. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 (1 male and 2 females)
- Observation Period: 96h
- Remarks - Method: The test substance was administered undiluted. No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.33	1.00	1.33	2	< 72h	0
Conjunctiva: chemosis	0.67	1	0.67	2	< 72h	0
Conjunctiva: discharge	0	0	0	1	< 24h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Conjunctivitis in 3/3 test eyes was observed at 1 hour, which resolved completely by 72 hours. Soughing of the corneal epithelium was noted in 1/3 test eyes, but the duration of this effect was not reported. No results on clinical observations were reported.
CONCLUSION	The notified polymer is irritating to the eye.
TEST FACILITY	Charles River (2006d)

B.5. Skin sensitisation

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 406 Skin Sensitisation – Buehler Test
Species/Strain	Guinea pig/Hartley-derived albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10/sex/group Control Group: 5/sex/group
INDUCTION PHASE	Induction Concentration: topical: undiluted
Signs of Irritation	Slightly patchy erythema was noted in up to 3/20 test animals in the first (day 0) and second induction (day 7) administrations at both 24 and 48 hours scoring interval. After the third induction (day 14), 14/20 and 5/20 animals showed slightly patchy erythema at the 24 and 48 hours scoring interval, respectively. In addition, moderate patchy erythema with very slight oedema was noted in 2 males and 1 female animals at the 24 and 48 hours scoring interval.
CHALLENGE PHASE	
1st challenge	topical: undiluted
2nd challenge	topical: undiluted
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	undiluted	10/20	9/20	6/20	5/20
Control Group	undiluted	0/20	0/20	0/20	0/20

Remarks - Results	Following the 1st and 2nd challenge, the maximum dermal reaction was grade 1 (slight but confluent erythema) noted at both 24 and 48 hours scoring interval. One male also showed very slight oedema at 24 hours following the 1st challenge. All test animals generally appeared in good health and gained weight as expected during the study.
CONCLUSION	There was evidence of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	Charles River (2006e)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Crl:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Olive oil
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	60	0
III (mid dose)	5/sex	250	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death

One female in the control group died during blood collection on day 28 and was considered an accidental death. All other animals survived to the scheduled necropsies.

Clinical Observations

All clinical findings noted in the test groups were either with similar incidence to the control group, or limited to single animals, or not dose-related, except dry yellow material around anogenital area was observed in 4/10 males rats at 1000 mg/kg/day.

Although some dose related body weight changes (decreased body weight, body weight gain, and cumulative body weight gain in males, increased cumulative body weight gain in females) were observed, there were no statistically significant differences when compared with the control groups.

In the open field observation, dose-related decrease in mean rearing count was observed in females, together with statistically significantly lower counts in the high dose group. However, the authors indicated that the mean rearing count in the control group (14.8 counts) was remarkably higher than the historical control mean of this testing laboratory (6.8 counts). Therefore, it was not considered as a treatment-related change.

Other functional observational battery parameters and food consumption were not affected by the test substance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

Dose-related increase in mean activated partial thromboplastin time (APTT) was observed in males, together with statistically significantly higher figure in the high dose group. This change is considered treatment-related, although it disappeared in the recovery group.

Although some dose-related changes in haematological parameters (neutrophil count in males and monocyte count in females) were observed, there were no statistically significant differences when compared with the control groups.

Clinical Chemistry

No statistically significant or dose-related changes were found in all clinical chemistry parameters tested.

Effects in Organs

There were no treatment-related findings at the scheduled necropsies and microscopic examination.

The changes in absolute liver weights and weights relative to body or brain weight were statistically significant, but these changes were either not dose-related or within the historical control data, and without corresponding microscopic findings. Therefore they are considered to be not treatment-related findings.

Remarks – Results
There were no treatment-related effects, except a statistically significant increase in APTT in the 1000 mg/kg/day male group.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day, the highest dose tested. The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day for females and 250 mg/kg/day for males based on the isolated treatment-related increase in APTT in males at 1000 mg/kg/day.

TEST FACILITY Wil (2005)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE 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	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9-mix
Concentration Range in Main Test	a) With metabolic activation: 15-5000 µg/plate b) Without metabolic activation: 15-5000 µg/plate
Vehicle	Tetrahydrofuran
Remarks - Method	No significant protocol deviation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	≥5000	Negative
Test 2	NA	>5000	≥5000	Negative
Present				
Test 1	>5000	>5000	≥5000	Negative
Test 2	NA	>5000	≥5000	Negative

NA, not applicable.

Remarks - Results Precipitation was observed at 5000µg/plate in all test conditions, but neither of these affected the scoring of revertant colonies.

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any dose level either with or without metablic activation.

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Safepharm (2006a)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Human
Cell Type/Cell Line	Whole venous blood lymphocytes
Metabolic Activation System	Rat liver post-mitochdrial fraction and NADP plus isocitric acid
Vehicle	50% pluronic 127 in ethanol (w/w)
Remarks - Method	The highest concentration tested (1850 µg/mL) was above the solubility limit of the test substance after dosing into culture medium. No significant protocol deviation.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	12.5*, 17.9, 25.6*, 36.6, 52.3*, 74.7, 107*, 152, 218, 311, 444, 635, 907, 1300, 1850	3 h	22 h
Test 2	0.313, 1, 3.13*, 10*, 20*, 33.3*, 66.6, 100	22 h	22 h
Present			
Test 1	12.5*, 17.9, 25.6*, 36.6, 52.3*, 74.7, 107*, 152, 218, 311, 444, 635, 907, 1300, 1850	3 h	22 h
Test 2	0.313, 1, 3.13*, 10*, 33.3*, 100*	3 h	22 h

*Cultures selected for chromosomal aberration analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	NA	>1850	≥12.5	Negative
Test 2	NA	>100	≥20	Negative
Present				
Test 1	NA	>1850	≥12.5	Negative
Test 2	NA	>100	≥33.3	Negative

NA, not applicable.

Remarks - Results	No significant increase in cells with chromosomal aberrations, polyploidy, or endoreduplication was observed in the cultures analysed.
CONCLUSION	The notified polymer was not clastogenic to human whole venous blood lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Covance (2006)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mice/Crl:CD-1 (ICR)BR
Route of Administration	Intraperitoneal
Vehicle	Arachis oil
Remarks - Method	The main test was performed using only male mice as no marked difference in toxicity of the test material between the sexes was observed in a range-finding test. No significant protocol deviation.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	7 males	0	24
II (vehicle control)	7 males	0	48
III (single dose)	7 males	2000	24
IV (single dose)	7 males	2000	48
V (positive control, CP)	5 males	50	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	No death or clinical signs was seen in any of the dose group.
Genotoxic Effects	There were no statistically significant increases in the frequency of micronucleated polychromatic erythrocytes (PCEs) in any of the test substance dose group when compared to the control groups.
CONCLUSION	The notified polymer was not clastogenic under the conditions of this in vivo.
TEST FACILITY	Safepharm (2005)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

ENVIRONMENTAL FATE

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated Sewage Sludge micro-organisms from the Severn Trent Water plc sewage treatment plant at Loughbrough Leicestershire UK.
Exposure Period	28 Days
Auxiliary Solvent	None (Addition to solid supports)
Analytical Monitoring	Total Organic Carbon (TOC) Analyser
Remarks - Method	Triplicate samples of the test substance containing 10 mg Carbon/L were subjected to the inoculum. Due to low solubility of the test substance it was placed on solid supports (microscope slides and glass filter papers). A blank and reference substance (sodium benzoate) were run in duplicate. A further single toxicity control containing the reference substance and test substance was also run. The CO_2 produced was captured in two absorbers arranged in series. Samples are taken and analysed from the first absorber on a regular basis. The CO_2 was analysed in the second absorber on days 0 and 29. The inorganic carbon (IC) for the test substance is corrected for the IC in the blank and compared with the total organic carbon in the test material. Temperature: 21°C Photoperiod: Darkness

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0	1	30
3	0	3	70
8	1	8	75
10	2	10	77
14	1	14	76
28	18	28	85
29*	13	29*	86

* Corrected for CO_2 carried over to the second absorber.

Remarks - Results	The test substance appeared as a light brown dispersion with the test material clearly visibly adhered to the filter paper. The toxicity control showed 43% degradation by day 14 which was over the 25% required to show that the test substance was not inhibitory to the inoculum. The pH of the test preparations on day 28 were between 7.4 and 7.7. The inorganic to total carbon at the initiation of the test was between 0 and 2%.
CONCLUSION	The notified polymer is not considered readily biodegradable.
TEST FACILITY	SafePharm (2006b)

C.1.2. Bioaccumulation

The notified polymer has a high log Kow value. It is therefore unlikely to enter the aquatic compartment and bioaccumulate. Further, the notified polymer has a high molecular weight and is therefore not likely to cross biological membranes.

ECOTOXICOLOGICAL INVESTIGATIONS

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – semi static.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hour
Auxiliary Solvent	None
Water Hardness	136 mg $CaCO_3$/L
Analytical Monitoring	Visual; Total Organic Carbon (TOC)
Remarks – Method	A range finding study was performed by subjecting 3 fish to 100 mg/L and 1000 mg/L water accommodated fractions (WAF) of test substance. The WAFs were prepared by adding the loading rate of test material to test water. This was stirred for 24 hours and the WAF was extracted by mid-depth siphoning. Microscopic inspection showed no micro-dispersion or undissolved material in the WAF. A control was also run. On the basis of the results from the range finding test a definitive limit test was conducted by subjecting triplicate samples of 10 fish to a 1000 mg/L WAF (prepared as described above). Similarly no micro-dispersion or undissolved material in the WAF. Duplicate blanks were also run. The WAFs were changed daily. Temperature: 13.1-15.5°C. pH 7.4-7.6 mg O_2/L fresh media: 8.9-9.4 mg O_2 old media: 6.0-6.9 Photoperiod: 16 hours day; 8 hours dark; 20 minutes transition. Fish: 5±1 cm.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		20	0	0	0	0	0
1000		30	0	0	0	0	0

LC50	> 1000 mg/L WAF at 96 hours.
NOEC (or LOEC)	1000 mg/L WAF at 96 hours.
Remarks – Results	No sub-lethal effects were observed. The TOC measured in the test substance analysis, corrected for the TOC in the blanks at the initiation of the tests and at 24 hours was 0.03-0.25 mg C/L and 0-0.03, respectively.
CONCLUSION	The test substance is considered to be non-toxic to fish up to the limit of its water solubility.
TEST FACILITY	SafePharm (2006c)

C.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None

Water Hardness	248 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation
Remarks - Method	A range finding study was performed by subjecting 4 replicates of 10 daphnia to 1000 mg/L WAF of test substance. The WAFs were prepared by adding the loading rate of test material to test water. This was stirred for 24 hours and the WAF was extracted by mid-depth siphoning. Microscopic inspection showed no micro-dispersion or undissolved material in the WAF. A control was also run. On the basis of the results from the range finding test a definitive limit test was conducted by subjecting quadruplicate samples of 10 daphnia to a 1000 mg/L WAF (prepared as described above). Similarly no micro-dispersion or undissolved material in the WAF. Duplicate blanks and reference substance (potassium dichromate 0.32, 0.56, 1.0, 1.8 and 3.2 mg/L) were run. Temperature: 20.5-20.8°C. pH 8.0 mg O_2/L 8.7-8.8 Photoperiod: 16 hours day; 8 hours dark; 20 minutes transition.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 hours*	*48 hours*
Control		20	0	0
1000		40	0	0

LC50	> 1000 mg/L WAF at 48 hours
NOEC	1000 mg/L WAF at 48 hours
Remarks - Results	No sub-lethal effects were observed. The TOC measured in the test substance analysis, corrected for the TOC in the blanks at the initiation of the tests and at 48 hours was 0.619-0.659 mg C/L and less than the blank, respectively. The LC50 for the reference substance was 1.1 mg/L (95% CL 0.97-1.2).

CONCLUSION — The test substance is considered to be non-toxic to daphnia up to the limit of its water solubility.

TEST FACILITY — SafePharm (2006d)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE — Notified Polymer

METHOD — OECD TG 201 Alga, Growth Inhibition Test
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*)
Exposure Period	96 hours
Concentration Range	Nominal: 0-1000 mg/L WAF
Auxiliary Solvent	None
Water Hardness	Not specified.
Analytical Monitoring	Particle Counter
Remarks - Method	A range finding study was performed by subjecting duplicates of ~ 1×10^4 cells/mL algal cells to 100 and 1000 mg/L WAFs of test substance. The WAFs were prepared by adding the loading rate of test material to test water. This was stirred for 24 hours and the WAF was extracted by mid-depth siphoning. Microscopic inspection showed no micro-dispersion or undissolved material in the WAF. Duplicate controls were also run. On the basis of the results from the range finding test a definitive limit test

was conducted by subjecting six replicate samples of ~ 1×10^4 cells to a 1000 mg/L WAF (prepared as described above). Similarly no micro-dispersion or undissolved material in the WAF. Triplicate blanks were run.
Temperature: 24±1°C.
Photoperiod: Continuous; ~ 7000 Lux.

RESULTS

Biomass *EbC50* *mg/L at 72 hours*	*Growth* *ErC50* *mg/L at 72 hours*
> 1000 WAF	> 1000 WAF

Remarks - Results: The WAFs were observed to be clear colourless solutions at the beginning of the test and bright green dispersions at the end. No abnormalities were observed in any tests or controls. The TOC measured in the test substance analysis, corrected for the TOC in the blanks at the initiation of the tests and at 96 hours was less than the blank. This indicates that the level of test material in the WAF was below the level of quantification. The pH at the initiation of the test was 7.3-7.4, whilst it was 8.0-8.2 at its conclusion. This was considered acceptable. The maximum inhibition was 14% whilst the minimum was 2% promotion of growth.

CONCLUSION: The test substance is non-inhibitory to algal growth up to the limits of its solubility.

TEST FACILITY: SafePharm (2006e)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified Polymer

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Activated sewage sludge organisms from the aeration stage of Severn Trent Water plc STP at Loughbrough, Leicestershire UK.

Exposure Period: 3 hours

Concentration Range: Nominal: 1000 mg/L
Actual: Not determined.

Remarks – Method: A range finding study was performed by subjecting duplicates of the inoculum to a dispersion on filter paper of 100 and 1000 mg/L of test substance, containing synthetic sewage. Duplicate blanks and reference substance (3,5-dichlorophenol) were also run. On the basis of the results from the range finding test a definitive limit test was conducted by subjecting triplicate samples of the inoculum to 1000 mg/L dispersion on filter paper of the test substance and synthetic sewage. Duplicate blanks were run. Also a 3,5-dichlorophenol concentrations were run at 3.2, 10 and 32 mg/L.
Temperature: 21°C.
pH: 8.0-8.4

RESULTS

IC50: > 1000 mg/L WAF

NOEC: 1000 mg/L

Remarks – Results: The test solutions appeared as a dark brown dispersion with filter paper with test material adhered thereto. The IC50 of the reference substance

	was 8.4 mg/L, which was within the acceptable range of 5-30 mg/L.
CONCLUSION	The test substance is non-inhibitory to the respiration of activated sludge micro-organisms up to the limits of its solubility.
TEST FACILITY	SafePharm (2006f)

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