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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in XC 1367

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FULL PUBLIC REPORT

Polymer in XC 1367

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chevron Oronite Australia (ABN: 16 101 548 716)
Level 8, 520 Collins St
Melbourne, Victoria, 3000

NOTIFICATION CATEGORY
Standard: 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
Manufacture or import volumes
Identity of manufacturing sites

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

Repeated dose toxicity (analogue data)
Melting/boiling point
Water solubility
Hydrolysis as a function of pH
Partition coefficient
Adsorption/desorption
Soil adsorption
Dissociation constant
Autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Canadian EPA (2004)
Korean NSN (2004)
United States EPA (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
XC 1367 (<10% notified polymer)
SP 8860 (<10% notified polymer)
CP 8860 (<10% notified polymer)

METHODS OF DETECTION AND DETERMINATION

METHODS	Infrared (FTIR), Nuclear Magnetic Resonance (NMR) spectroscopy.
REMARKS	Reference spectra were provided

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

ADDITIVES/ADJUVANTS

Chemical Name	Mineral oil
Weight %	20-50%
Hazardous Properties	Not hazardous.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia as part of a lubricant additive package.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<25	<25	<25	<25	<25

USE
The notified substance is used as a dispersant for lubricating oil additives.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The additive containing <10% notified polymer will be imported in isotankers or 208L drums. After reformulation, the finished lubricant containing <1% notified polymer is transported by road or rail in bulk containers, drums, 20 L or 1 L containers.

5.2. Operation description

At blending sites the additive package (containing <10% notified chemical) will be transferred from drums, rail cars and tank trucks into storage tanks. The transfer process from the tank truck occurs by the use of 10 cm hosing.

Transfer from storage tanks to blend tanks will be automated, using computer controlled valves. The additive package is blended with other components to form the finished lubricant, which contains the notified chemical at <1%. The blending process occurs in a closed system and is computer controlled. The blended lubricant is transferred automatically to a storage tank. The finished lubricants are then packaged for shipment in drums, 1-4L containers, or bulk tank trucks.

The drumming facility uses automated weight scales to fill the drums, with a worker watching to ensure the drum filling mechanism properly enters the drum before the drum is filled. The bungs and labels are manually applied by the operators. Bulk tank truck or rail car filling is performed by a transfer hose. The small container packaging machine is fully automated and will fill 1-4L containers.

The finished lubricants will then be transported for use commercially (80-90%) or to service stations and consumer users (10-20%). The lubricants will likely be transported in the following manner: 50% in bulk containers, 30% in drums and 20% in 1-4L containers. These lubricants will be used for automotive and industrial gears and bearings.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Analysing additive package on arrival	1	10 mins	30 d/yr
Unloading tanks trucks and drums	1-2	30 mins	30 d/yr
Sampling finished oil	1-2	10 mins	220 d/yr
Loading finished oil into tank trucks	1-2	30 mins	220 d/yr
Commercial end users	<10000	8 hours	220 d/yr

Exposure Details

Warehousing and transport:

These workers would only be exposed to the notified chemical in the case of accidental rupture of the containers.

Formulation:

At blending sites, the notified chemical will be transferred from drums, rail cars and tank trucks into storage tanks. During transfer from drums, and connection and disconnection of lines, incidental skin contact from splashes, drips and spills is possible. The transfer process from the tank truck occurs by use of a 10 cm diameter hose. Connection of the hose takes 10 minutes. An air back flush system is used to prevent spillage during transfer.

Transfer from storage tanks to blend tanks will be automated, using computer controlled valves. The blending process occurs in a closed system and is computer controlled, and thus there should be no exposure at this stage. The blended lubricant is then transferred automatically to a storage tank, and then packaged for transport. The blending facilities are well ventilated, with control systems for accidental spills and wastewater treatment.

Workers may be exposed to the finished lubricant (containing the notified chemical at <1%) during the drum filling operations. However, exposure will be minimised by the use of PPE such as gloves, eye protection, protective clothing and hard hats.

The drumming facility uses automated weight scales to fill the drums, and worker exposure may occur as the operator watches (from about 1-2 meters away) to ensure the drum filling mechanism properly enters the drum before the drum is filled. Exposure may also occur when the bungs and labels are put on by the operators. The 1-4L container packaging machine is a fully-automated process. Again, worker exposure may occur as the operator watches (from about 1-2 meters away) to ensure the filling mechanism properly enters the container before it is filled.

If any transfer from storage tanks to bulk containers is necessary, it is performed as described above for the reverse process. Dermal exposure to drips and spills of blended lubricant is possible during the connection and disconnection of transfer hoses during the filling of bulk containers.

Laboratory staff will take samples of the notified chemical in the additive package as well as the blended oil products for testing. During sampling and analysis of the additive package there may be skin contact. However, minimal exposure will occur during the laboratory testing since it will occupy only a few minutes per batch.

End Users:

A proportion of the drums (30% of the total notified chemical) and some of the 1-4 L containers (20% of the total notified chemical) will be sold to commercial automotive service outlets (i.e. auto repair shops). A pneumatic pump will be inserted into the drum and used to transfer the lubricant. In many cases, stationary engines will be routinely lubricated using dedicated lubricating oil reservoirs and piping to add fluids directly without human intervention. For non-stationary automotive applications, workers will check lubricant levels manually and top-off as needed using fluids added via small plastic containers. Most of the commercial end users will recycle their used oil obtained from oil drains occurring during routine maintenance and repair work.

The bulk product (50% of the total notified chemical) will be sold to high volume commercial end users, such as truck and taxi fleets, where it will be used to lubricate gears and bearings. In the industrial and commercial environment, machinery is maintained by professional mechanics, who are likely to wear appropriate PPE and have access to engineering controls. For non-stationary automotive applications, workers will check lubricant levels manually and top-off as needed using fluids added via small plastic containers. It is likely that all of these end users will recycle their used oil.

10-20% of the notified chemical in lubricants will be sold to service stations and consumer users. Exposure to these products is described in the Public Exposure section below.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical is not manufactured in Australia. During blending, release to the environment may occur in the unlikely event of an accident during transport or an accidental leak. An air back flush system is used to prevent spillage during transfer from rail, cars or tank trucks into storage tanks at the blending facilities. The formulation processes occur in a closed system and are highly automated therefore losses are not expected. The isotanks, drums and blending equipment will be rinsed with clean lubricating oil, which will be used in the future blends or incinerated. In the unlikely event of an accident, the spillage will be contained within concrete bunds and either reclaimed or sent to on-site wastewater treatment facilities where residual hydrocarbon based products will be separated from the aqueous stream by the Australian Petroleum Industry (API) process, with a claimed removal of greater than 95%. The aqueous waste undergoes further treatment involving pond aeration and biological treatment before being released to the sewage system. The remaining oily waste will be incinerated. As a result of these processes, the accidental release from transport of the additive package and finished oils is unlikely to be significant.

Empty drums are steam cleaned with the resultant aqueous waste sent to on-site wastewater facilities. It is estimated that 3 kg of the notified chemical will be sent to the wastewater treatment per year, based on the maximum import of notified chemical.

RELEASE OF CHEMICAL FROM USE

Some minor and diffuse exposure will result from spills during addition of oil to vehicles. However, the greatest potential for exposure is through disposal of waste oil containing the additive.

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 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 for 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 of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways.

Consequently, assuming that oil removed by professional mechanics is disposed of appropriately (ie burning as workshop heating oil or sent for recycling), negligible release of the notified chemical should result from these professional activities. Assuming a worst case scenario of 14% of the used oil removed by the DIY enthusiasts, this oil will have the following fates: oil to be collected for recycling (up to 0.7 tonnes), buried or disposed of in landfill (up to 0.875 tonnes), disposed into stormwater drains (up to 175 kg) and used in treating fence posts, to kill weeds or disposed of in other ways (up to 1.75 tonnes), respectively.

Since gear oil and hydraulic fluid changes are likely to be carried out by specialists, and will be disposed of more appropriately, an amount less than 1% of the total import volume of the notified substance could be expected to enter the aquatic environment via disposal into the storm water system. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified material in high concentrations is very unlikely except as a result of transport accidents.

5.5. Disposal

Drums are sent to drum recyclers where they are steam cleaned and the water sent to wastewater treatment. It is assumed 0.1% of the chemical remains after use. Small containers sold to consumers are likely to be sent to landfill.

5.6. Public exposure

It is expected that during transport and storage, and replenishment of lubricant oil at service garages, exposure of the general public to the notified chemical will be low, except in the event of an accidental spill.

Up to 20% of the notified chemical will be reformulated and packaged in small containers for sale to service stations and the public. Public exposure to the notified chemical may occur during do-it-yourself replenishment of lubricant, through spills, splashes and contact with runs or drips on the outside of the container after filling. Exposure is also possible while handling automotive components that have been in contact with the lubricant. Exposure is likely to be by the dermal route, with the possibility of ocular and inadvertent oral exposure. It is unlikely that PPE will be worn.

6. PHYSICAL AND CHEMICAL PROPERTIES

Values for most physical and chemical properties were not provided. EPIWIN modelling was used in some cases to estimate values, based on an analogous chemical with a truncated alkane sidechain, which is more amenable to EPIWIN analysis. The two compounds modelled were a salt analogue of the notified chemical and its free diacid form.

Appearance at 20ºC and 101.3 kPa	Brown liquid
Boiling Point	Not determined
Remarks	Estimated as 559°C using EPIWIN estimation on an analogous chemical.
Density	915.1 kg/m^3 at 15.6°C
Remarks	Test report not provided.
Vapour Pressure	Not determined
Remarks	Estimated as <1.7x10^{-7} kPa based on highly-refined mineral oil.
Water Solubility	Not determined
Remarks	Estimated as 1.05 x 10^{-6} g/L using EPIWIN estimation on the salt analogue of the notified chemical.
Hydrolysis as a Function of pH	Not determined

Remarks The notified chemical does not contain functional groups that are susceptible to hydrolysis.

Partition Coefficient (n-octanol/water) Not determined

Remarks Estimated as 6.54 using EPIWIN estimation of the free diacid form of the analogue chemical.

Adsorption/Desorption Not determined

Remarks Estimated as 4.45 using EPIWIN estimation of the neutral acid form of the analogue chemical.

Dissociation Constant Not Determined

Remarks The notified chemical contains carboxylic acid functionalities that would be expected to display typical acidity.

Particle Size Not applicable as notified polymer is a liquid.

Flash Point 246°C

Remarks Test report not provided.

Flammability Limits Not determined.

Autoignition Temperature Not determined.

Explosive Properties Not expected to be explosive.

Reactivity

Remarks May react with strong acids or strong oxidising agents, such as chlorates, nitrates, peroxides etc.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >5000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	not performed
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation –non-adjuvant test.	limited evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days. Analogues of acidic portion of notified polymer.	NOAEL >700 mg/kg bw/day in drinking water
Rat, repeat dose oral toxicity – 28 days. Analogue of alkyl portion of notified polymer.	NOAEL >1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Erythrocyte Micronucleus Test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE: 51% notified polymer in mineral oil.

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/54/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.

- Species/Strain: Rat/Crl:(WI) BR
- Vehicle: Test substance was dosed undiluted
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	5000 mg/kg	0

- LD50: >5000 mg/kg bw
- Remarks - Results: No clinical signs or macroscopic findings were observed. Body weight gain over the study period was considered to be as expected for normal untreated animals.

CONCLUSION: The test substance is of low toxicity via the oral route.

TEST FACILITY: NOTOX B.V. (2002a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE: 51% notified polymer in mineral oil.

METHOD: OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).

- Species/Strain: Rat/Crl:(WI) BR
- Vehicle: Test substance was dosed undiluted.
- Type of dressing: Semi-occlusive.
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Scabs were observed in the treated skin area of one female at the end of the observation period.
Signs of Toxicity - Systemic	Red staining of the nose was noted in one male on day 1. No other signs of systemic toxicity were noted in any of the other animals.
Effects in Organs	No abnormalities.
Remarks - Results	None.

CONCLUSION The test substance is of low toxicity via the dermal route.

TEST FACILITY NOTOX B.V. (2002b)

7.3. Acute toxicity – inhalation

Not required as the substance is a liquid with a low vapour pressure.

7.4. Irritation – skin

TEST SUBSTANCE 51% notified polymer in mineral oil.

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	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	1.7	1.7	1.3	2	7 days	0
Oedema	1.3	0.3	0.7	2	72 hours	0

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

Remarks - Results	In all animals the erythema and oedema were also noted outside the application area. Scaliness was observed in one animal after 7 days only.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY NOTOX B.V. (2002c)

7.5. Irritation – eye

TEST SUBSTANCE 51% notified polymer in mineral oil.

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	0.1 mL of undiluted test substance was instilled into one eye of each rabbit.

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	0	0	0	1	1 hour	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0	0	1	1 hour	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results: Remnants of the test substance were present on the outside of the eyelids of all animals on day 1 and/or day 2.

CONCLUSION: The test substance is slightly irritating to the eye.

TEST FACILITY: NOTOX B.V. (2002d)

7.6. Skin sensitisation

TEST SUBSTANCE: 51% notified polymer in mineral oil.

METHOD: OECD TG 406 Skin Sensitisation – modified Buehler test.
Species/Strain: Guinea pig/Hartley
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 5% produced minimal irritation in the range finding study
MAIN STUDY
Number of Animals: Test Group: 20 Control Group: 10
INDUCTION PHASE: Induction Concentration:
topical: 100%
Signs of Irritation: Slight irritation in a number of animals, occurring more often as induction continued.
CHALLENGE PHASE
1st challenge: topical: 5%
Remarks - Method: No significant protocol deviations.
Data on historical controls was provided using α-hexylcinnamaldehyde at 2.5% and 1% (challenge).

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	5%	8/20	5/20
Historical controls	5%	None.	None.

Remarks - Results: All the animals exhibiting skin reactions showed a slight patchy erythema, assigned a score of +.

CONCLUSION: There was limited evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY: SLI (2003)

7.7.1 Repeat dose toxicity – Summary of Analogue Data

Data was not provided for the notified polymer.

For the acidic portion of the notified polymer, a summary of repeat dose studies was provided. No test reports were provided.

Acceptable analogue	*Endpoint*	*Conclusion**	*Effects Summary*
AA1	2-year repeat dose toxicity	NOAEL 700mg/kg bw/day	No treatment-related mortality at the high dose (3.5g/kg bw/day). Weight gains were lower for groups receiving ≥ 2.1g/kg bw/day. No significant gross pathology that was test-related was noted.
	Developmental toxicity	Not teratogenic	
	Reproductive toxicity	No effect on reproductive organs in repeated exposure scenarios	
AA2	90-day repeat dose toxicity	NOAEL 700-1400mg/kg bw/day	No treatment-related mortality at high dose (1.4g/kg bw/day). Reduced weight gain at high dose. No histopathological findings or organ weight changes.
	Developmental toxicity	Not teratogenic	
	Reproductive toxicity	No effect on reproductive organs in repeated exposure scenarios	
AA3	90-day repeat dose toxicity	NOAEL 875mg/kg bw/day	Suppression of body weight gain was observed > 2.1g/kg bw/day. Rats that died during the experiment were severely emaciated. No toxic lesions were found in any organs of these rats, however atrophy of the organs was observed.
	2-year repeat dose carcinogenicity	NOAEL 700 mg/kg bw/day	Dose-dependant inhibitory effect on growth observed. No statistically significant differences in overall tumour incidences
AA4	90-day repeat dose toxicity	NOAEL 700-1400 mg/kg bw/day	10% mortality at 1g/kg bw/day. Reduced body weight in surviving animals at this level. No histopathology findings at any level.
	Reproductive toxicity	No effect on reproductive organs in repeated exposure scenarios	

*Analogues were supplied to rats in drinking water. Where average daily intakes were not calculated, the NOAEL was estimated using the following values: Average rat body weight: 425 g; Average rat daily water intake: 30 ml/day.

A study report was provided for an analogue of the alkyl portion of the notified polymer, and is summarised below.

7.7.2 Repeat dose toxicity – 28 day Oral Gavage (Analogue)

TEST SUBSTANCE	Chemical analogous to the alkyl portion of the notified polymer.
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Crl:CD^{R}BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Peanut oil
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	6/sex	0	None.
II (low dose)	6/sex	200	None.
III (mid dose)	6/sex	500	None.
IV (high dose)	6/sex	1000	None.
V (control recovery)	6/sex	0	None.
VI (high dose recovery)	6/sex	1000	None.

Mortality and Time to Death

No mortality was observed during the study.

Clinical Observations

No systemic signs of toxicity were observed in the test or recovery groups. No changes were seen in body weight gain, absolute food consumption, or food efficiency. Relative food consumption was increased in high dose females (day 7) and high dose recovery males (day 35). This was not considered to be of toxicological significance as there were no changes in related parameters or statistically significant differences at other time periods.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were statistically significant increases in total protein (12%) and albumin (9%) and a 53% decrease in triglycerides observed in high-dose versus control males. These changes were probably chance occurrences since they were not observed in females or other dose groups and cannot be correlated with other effects.

Any other observed changes were within clinically normal limits, and either did not exhibit dose-related trends, or were observed only in recovery animals, and were not considered to be of toxicological significance.

Effects in Organs

A statistically significant increase of 6% was seen in the right testicular weight of treated versus control males in the recovery group. This finding was not considered toxicologically significant, as there was no change in total testicular weight for this group and non-recovery high dose males exhibited normal testicular weights.

All other findings were not unusual for animals of this species, strain and age.

Remarks – Results

None.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as >1000 mg/kg bw/day in this study.

TEST FACILITY Chevron (1989)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	51% notified polymer in mineral oil.
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*: WP2*uvr*A
Metabolic Activation System	10% rat liver S9
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 deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None	None	500, 1500 µg/plate	None
Present				
Test 1	None	None	500, 1500 µg/plate	None

Remarks - Results	Negative controls were similar to historical values. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (2002a)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	51% notified polymer in mineral oil.
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Rat/Crl:CD-1(ICR)BR
Route of Administration	Intraperitoneal injection
Vehicle	Arachis oil
Remarks - Method	In a preliminary range-finding test, there was no marked difference in toxicity to males or females. Therefore, males only were used for the main study.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	6/male	0	24
I (vehicle control)	6/male	0	48
II (low dose)	6/male	500	24
III (mid dose)	6/male	1000	24
IV (high dose)	6/male	2000	24
IV (high dose)	6/male	2000	48
V (positive control, CP)	6/male	50	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	None.
Genotoxic Effects	No statistically significant increases in the frequency of micronucleated PCEs in any of the test groups when compared to the control groups.
Remarks - Results	CP was used as the positive control and showed distinct increases in cells with structural chromosomal aberrations. A statistically significant decrease in the PCE/NCE ratio was observed in the 48-hour 2000 mg/kg dose group compare to control and this indicated adequate exposure of the target tissue, bone marrow.
CONCLUSION	The notified polymer was not clastogenic under the conditions of this in vivo mammalian erythrocyte micronucleus test.
TEST FACILITY	SPL (2002b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Centrifuged, washed and resuspended activated sludge from a sewage treatment works that treats predominantly domestic sewage.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Chemical Oxygen Demand (COD)
Remarks – Method	Test substance was an insoluble, sticky, viscous liquid and was sorbed onto a glass fibre filter paper prior to addition to the test vessel.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	6.5	7	52
14	7	14	67
28	3.5	28	73

Remarks - Results	The reference substance degradation exceeded 60% thus indicating that the study was valid. The toxicity control attained 37% after 14 days and 45% after 28 days indicating that the test substance was non-inhibitory to sewage microorganisms. The temperature and pH measured during the test were within acceptable limits.
CONCLUSION	The test substance is not readily biodegradable according to the OECD criteria requiring > 60% degradation within 10 days of commencement.
TEST FACILITY	SPL 2002c

8.1.2. Bioaccumulation

Based on the high calculated logKow of 6.54, the notified chemical has the potential to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test –Semi static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish –Semi-static.
Species	Rainbow Trout (*Oncorhynchus mykiss)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	149 mg $CaCO_3$/L
Analytical Monitoring	TOC

Remarks – Method	The test material was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. The mixtures (see below) were stirred at room temperature for 48 h and allowed to settle for 4 h. Following the settling period the WAF, separated from floating or settled test material, was removed with a siphon from the middle depth of the solution. WAFs were observed to be clear and colourless. Microscopic investigation showed no micro dispersion or undissolved material was present in the WAFs. Based on the results of the range-finding test, the definitive test was conducted at a nominal concentration of 1000 mg/L WAF.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	10	0	0	0	0	0
1000	-	30	0	0	0	0	0

LL50	>1000 mg/L WAF at 96 hours.
NOEC	1000 mg/L WAF at 96 hours.
Remarks – Results	All organisms of the control and the treatment groups survived the 96 h toxicity test. No sublethal effects were observed. Total organic carbon (TOC) analyses were performed at 0 and 24 h, no significant difference was observed between control and the test media. The temperature and pH measured during the test were within acceptable limits.

CONCLUSION	The test substance is considered to be non-toxic to fish up to the limit of its water solubility.
TEST FACILITY	SPL 2002d

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	254 mg $CaCO_3$/L
Analytical Monitoring	TOC
Remarks - Method	The WAFs were prepared according to the procedures in the fish test (see 8.2.1). Based on the results of the range-finding test, the definitive test was conducted at a nominal concentration of 1000 mg/L WAF.

RESULTS

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

EL50	>1000 mg/L WAF at 48 hours
NOEC	1000 mg/L WAF at 48 hours
Remarks - Results	All organisms of the control and the treatment groups survived the 96 h

toxicity test. No sublethal effects were observed. Total organic carbon (TOC) analyses were performed at 0 and 24 h, no significant difference was observed between control and the test media and all measurements were below the limit of quantitation (not supplied). The pH, temperature, conductivity and dissolved oxygen concentration measurements were within acceptable limits.

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

TEST FACILITY — SPL 2002e

8.2.3. Algal growth inhibition test

TEST SUBSTANCE — Notified Chemical

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: 1000 mg/L
Auxiliary Solvent	None
Water Hardness	Not Supplied
Analytical Monitoring	TOC
Remarks - Method	The WAF was prepared in a similar manner as the fish test (see 8.2.1). Based on the results of the range-finding test, the definitive test was conducted at a nominal concentration of 1000 mg/L WAF. Each test vessel was inoculated with an initial cell density of 10^4 cells per mL for treatments and control.

RESULTS

Biomass		*Growth*
E_bL50 *mg/L at 72 h*	*E_bL50* *mg/L at 96 h*	*E_rL50* *mg/L at 96 h*
>1000	>1000	>1000

Remarks - Results — The effect of the test substance on the growth of *Pseudokirchneriella subcapitata* has been investigated and gave EL50 values of greater than 1000 mg/L loading rate WAF. Correspondingly, the No Observed Effect Loading rate was 1000 mg/L Loading rate WAF. Total organic carbon (TOC) analyses were performed at 0 and 24 h, no significant difference was observed between control and the test media.

CONCLUSION — The test substance is not toxic to algae up to the limit of its water solubility.

TEST FACILITY — SPL 2002f

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE — Notified chemical

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

Inoculum	Activated sludge

Exposure Period	3 hours
Concentration Range	
Nominal	100 and 1000 mg/L
Remarks – Method	Range finding and definitive tests were performed. Based on the results of the range-finding study a "limit test" was conducted for the definitive study at a test concentration of 1000 mg/L (in triplicate) to confirm that at this concentration no effect on respiration of the activated sewage sludge was observed.

RESULTS

EC50	Test substance	>1000 mg/L	(30 minutes)
	Test substance	>1000 mg/L	(3 hours)
	Reference	13 mg/L	(3 hours)

NOEC	(3 hours) =1000 mg/L
Remarks – Results	The EC50 value for tests at 30 minutes and 3 hours are both greater than 1000 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 1000 mg/L. The validation criteria for the control respiration rates and reference material EC50 have been satisfied. It was considered unnecessary and unrealistic to test loading rates in excess of 1000 mg/L.

CONCLUSION	The effect of the test material on the respiration of activated sewage sludge micro-organisms gave a 3-Hour EC50 of greater than 1000 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 1000 mg/L. The test substance is practically non-toxic to sewage micro-organisms.
TEST FACILITY	SPL 2002g

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported and reformulated into lubricant oils at blending facilities. The used oil and the sludge collected from the on-site wastewater treatment facilities may be incinerated. The main environmental exposure is expected to result from inappropriate disposal of waste lubricant product, assuming that about 14% of oil changes in Australia are performed by DIY enthusiasts.

This disposal is however, widespread across Australia. Most of the improperly released notified chemical due to DIY activities is likely to become associated with soils or sediments, as will the notified chemical released to landfill as container residues. The notified chemical released into the aquatic environment would be expected to become associated with the sediments due to its estimated low water solubility. While some components of the notified chemical are not readily degradable, these can be expected to slowly degrade due to the biotic and abiotic processes.

The amount released to stormwater drains (less than 1% of the import volume) can enter the aquatic compartment and could be expected to associate with suspended organic material (due to the calculated high log Pow), settle out into the sediments and eventually biodegrade.

It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified chemical released into stormwater drains, which have the potential to directly enter the aquatic environment. However, a worst case estimated PEC might be calculated if it is assumed that all of the 1% of the notified chemical that is expected to be released into the stormwater (i.e. 1 tonne) drains into a single metropolitan area with a geographical footprint of 500 square kilometres and an average annual rainfall of 50 cm. With a maximum annual release into this localised stormwater system of 175 kg and the annual volume of water drained from this region estimated to be approximately 250 x 10^6 m^3, the resultant worst-case PEC is approximately 0.7 µg/L. It should be stressed that this result represents a worst case scenario, and that in reality releases of the chemical would be very much more diffuse than indicated here, and also at significantly reduced levels.

9.1.2. Environment – effects assessment

Based on the ecotoxicity data for fish and daphnia provided, the notified chemical is not toxic up to the limit of water solubility.

9.1.3. Environment – risk characterisation

The notified chemical is not toxic to the aquatic organisms tested up to the limit of its water solubility (estimated as about 1µg/L). Therefore, the worst-case PEC (0.7 µg/L) is expected to be below possible toxic levels and the resulting risk quotient (Q = PEC/PNEC) would be below 1. Further, the low water solubility of the notified polymer and its limited release to the aquatic environment (mainly via stormwater drainage) can expect to reduce the possibility of sufficient amounts to remain in solution to cause acute toxicity. The notified polymer's ability to become associated with the sediments will further reduce the risk to the aquatic life.

Overall, the environmental risk from the proposed blending and use of the notified chemical is expected to be low. However, the potential exists for physical fouling of aquatic organisms by undissolved material in the advent of a sizeable release to waterways. For this reason the notified chemical should be prevented from entering waterways.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Warehouse and transportation workers would only be exposed to the notified chemical in the case of accidental rupture of the containers.

During formulation of the lubricant additive into the final lubricant product, the main exposure will be from drips and spills during transfer into storage tanks through hoses and lines, and

during filling of the finished lubricant into drums. During the rest of the operation there is unlikely to be exposure, as the process is automated and enclosed. Laboratory workers may also be exposed during quality testing.

About 80-90% of the lubricant products (containing <1% notified chemical) will be sold to commercial users. These users will likely be professional mechanics and engineers, and are likely to wear gloves and overalls to limit dermal exposure. Exposure to the notified chemical is expected to be low, based on these controls, and the low concentration of the notified chemical in the products.

9.2.2. Public health – exposure assessment

Approximately 10-20% of the lubricant will be sold to service stations and consumer users; therefore public exposure will be widespread. Dermal exposure, and possible ocular, and inadvertent oral exposure to the notified chemical may occur when the blended oil products are added and drained from automobiles and when handling automotive components that have come into contact with the oil, as DIY end users are not likely to wear PPE while using the oil. It is expected that exposure to individuals will be intermittent, and the concentration (<1%) of the notified chemical within the oil will limit the total exposure levels.

The public may also be exposed to the notified chemical from spills onto roads, parking areas and soil. However, exposure will be limited by the dispersive use and low concentration of the notified chemical in products.

9.2.3. Human health – effects assessment

The notified polymer is of low acute toxicity via the oral and dermal routes, and there is not expected to be exposure via inhalation. Application of the notified polymer caused slight irritation to eyes, and slight irritation to skin, persisting up to 7 days after application.

In the sensitisation test, there was limited evidence of skin sensitisation, indicating that there may be the potential for dermal sensitising effects.

The notified chemical was not mutagenic or genotoxic in either of the tests performed.

For the repeat dose toxicity tests, analogue data were used. The acidic portion of the notified polymer was found to be of low toxicity, with a NOAEL of 700 mg/kg bw/day in drinking water in a 2 year study in rats. An analogue of the alkyl portion of the notified chemical was found to have a NOAEL of >1000 mg/kg bw/day.

Based on the available data, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002).

9.2.4. Occupational health and safety – risk characterisation

The lubricant additive package that is imported into Australia (<10% notified chemical) will be reformulated into lubricant products (containing <1% notified chemical) at a number of sites. Exposure to workers during formulation is not expected, due to the mainly automated transportation and formulation process. There may be some exposure via splashes and spills, however the low hazard of the notified chemical translates to low risk.

Commercial users of the lubricant product containing the notified chemical are likely to have minimal exposure to the notified chemical, due to the low concentration, and the use of personal protective equipment, such as gloves, overalls and work boots. Thus the risk of adverse affects for OH&S are low.

9.2.5. Public health – risk characterisation

Up to 20% of the imported notified chemical will be sold to service stations and the general public in lubricant oils. Many consumer users of the lubricants containing the notified chemical will not take precautions to minimise exposure. Thus, they will have intermittent dermal exposure, and possibly accidental ocular and oral exposure, to the notified chemical. However, the risk to public health will be low, due to the low concentration (<1% in the lubricant) and non-hazardous nature of the notified chemical.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified chemical 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.

On environmental grounds the notified substance would have the classification of Chronic 4.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a lubricant additive.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

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

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced or as diluted for use:
  - Avoid contact with eyes and skin
  - Wear chemical resistant apron, jacket and rubber boots.
  - Wear chemical resistant gloves
  - Wear safety goggles

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation and end use:
  - Implementation of general health surveillance and monitoring programs as required including any potential for skin sensitisation.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *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.

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

Environment

Disposal

- The notified chemical should be disposed of to landfill or be incinerated.

Emergency procedures

- Spills/release of the notified chemical should be handled by soaking up with inert absorbent material and follow state or local regulation for the disposal of the waste.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if

- Additional skin sensitisation information/studies on the notified chemical and adverse effects of the notified chemical have become available.

or

(2) Under Section 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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