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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

PIB Sulfonate

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Oronite Australia Pty Ltd (ABN 16 101 548 716) of Level 8, 520 Collins Street, Melbourne, Victoria

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 identification
Import volume
Identity of processing sites
Details of use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Use of analogue data for several toxicological endpoints
Vapour pressure
Hydrolysis as a function of pH
Absorption/Desorption
Flammability limits and autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
USA 2001, P-00-901, Consent Order issued.
Canada 2003
Korea 2003

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
XC 6156, SP6156

OTHER NAME(S)
PIB sulfonate, Polyalkenylsulfonic acid, calcium salts

SPECTRAL DATA

ANALYTICAL METHOD Electro-spray Ionization Mass Spectrometry, FTIR, NMR.

3. COMPOSITION

DEGREE OF PURITY
30 - 35%

ADDITIVES/ADJUVANTS

Chemical Name	Petroleum distillates		
CAS No.	various	*Weight %*	40% approximately

4. 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 will be imported as 0.1% - 20% of additive packages that are added to lubricant oils.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30 tonnes	10-30 tonnes	10-30 tonnes	10-30 tonnes	10-30 tonnes

USE **Non-Confidential**
Ingredient in gear oil lubricants, tractor hydraulic fluids, combustion engine lubricants

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

IDENTITY OF MANUFACTURER/RECIPIENTS
Lubricant oil blenders in Australia.

TRANSPORTATION AND PACKAGING
Oil additive packages containing the notified polymer will be imported by ship in drums, isotanks or in bulk. Bulk material will be transported to the blending plants in rail cars or road tankers. Drums or isotanks will be transported to the blending plants in the original containers. The additive packages are typically not regulated under the ADG Code.
After incorporation into the lubricant oil at the blending sites, these oils will be stored on-site before being packaged for sale to end-users, or transported in bulk to large commercial users. Packaging can be 200 L drums, 20 L pails or 4L and 1 L containers. The finished lubricants will have widespread use, and will be transported to numerous commercial, rural or industrial sites, as well as being supplied to the public through retail distribution chains.

5.2. Operation Description

Imported additive packages in bulk or drums and containing the notified polymer will be transported from the port of entry to the blending sites of lubricant oil manufacturers. Transfer of bulk material from the ship to rail or road tankers will be required. At the blending site both bulk and drummed additive packages may be transferred to storage tanks before being incorporated into lubricant oil, to give a final concentration in the oil of < 0.1% to 5%, depending on the use of the lubricant. Blending occurs at 60^0C in a closed highly automated system. Lubricant oils may be packaged at the blending site or transported in bulk to other sites. End-use lubrication may occur from dedicated reservoirs or from smaller containers, depending on the type, size and site of the machinery being lubricated. Consumer use would mostly involve combustion engine lubricant, with a maximum concentration of 3% of the notified polymer in the lubricant.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	10-20	1-2 hours	50 days/year
Blending	2-3 per site	0.5-1 hour	200 days/year

Laboratory staff	1-2 per site	0.25 hour	200 days/year
End Users	>100	10 min	220 days/year

Exposure Details
Transport and Storage:
Transport and storage workers should not be exposed to the notified polymer except in the case of an accidental spill.

Blending:
The notified polymer is transferred to the blending vessel using a drum pump and hosing. The transfer is automated but incidental skin contact could occur during connection and disconnection, from splashes and drips. The blending process occurs in a closed system and is computer controlled, thereby excluding the potential for occupational exposure. Transfer of the lubricant containing the notified polymer (maximum 5%) and the filling of drums is automatic, and worker intervention is not required. However, workers are required to insert bungs and label the drums and incidental skin contact with contaminated drum surfaces may occur.

Bulk road tanker filling is performed by transfer hose. Dermal exposure to drips and spills is possible during the connection and disconnection of transfer hoses.

The blending facilities are well ventilated. Workers will wear personal protective equipment such as gloves, eye protection, protective clothing and hard hats.

Laboratory Staff & Maintenance Workers:
Laboratory staff will take samples of the additive package containing the notified polymer for analysis. There is the potential for dermal exposure.

Empty drums are sent to drum recyclers, where they are steam cleaned. There is the potential for incidental skin contact during this process.

End Users:
The finished lubricants containing a maximum concentration of 5% of the notified polymer will be used mostly by high volume industrial and commercial lubricant customers who will use them to lubricate machinery. In many cases, any stationary machinery involved will be routinely lubricated using dedicated lubricating oil reservoirs and piping to add fluids directly without human intervention. For non-stationary applications, workers will check lubricant levels manually and top-off as needed using fluids added via small plastic containers typically. There is the potential for incidental dermal exposure during this process. Workers will wear overalls when using products containing the notified polymer.
Misting or aerosol formation is unlikely during use of the lubricants.

The notified polymer will be included in tractor hydraulic fluids at a maximum concentration of 5%, therefore farmers could potentially be exposed through use of this product. As above dermal exposure is the most likely route.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer is not manufactured in Australia. Release to the environment may occur in the unlikely event of an accident during transport or an accidental leak. A special 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 formulating processes occur in a closed system and are highly automated therefore losses are not expected. The isotanks, bulk containers 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 sand filtration

before being released to the sewage system. The remaining oily waste will be incinerated.

Empty drums are steam cleaned with the resultant aqueous waste sent to on-site wastewater facilities.

RELEASE OF CHEMICAL FROM USE
Some minor, 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 (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases 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 (i.e. burning as workshop heating oil or sent for recycling), negligible release of the notified polymer should result from these professional activities. Assuming a worst case scenario of 14% of the used oil removed by the DIY enthusiasts it is possible to have 20, 25, 5 and 50% of this oil to be collected for recycling (up to 1000 kg), buried or disposed of in landfill (up to 1.2 tonnes), and disposed into stormwater drains (up to 210 kg) and used in treating fence posts, to kill weeds or disposed of in other ways (up to 2.1 tonnes), respectively.

Since gear oil and hydraulic fluid changes are likely to be carried out by specialists, and 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 polymer 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 water is 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. It is estimated 10-20% of the finished lubricants are sold to consumers.

5.6. Public exposure

Approximately 10-20% of the finished lubricating oils will be sold to the consumer market. Typical products would be diesel or passenger car engine oils. These consumers would typically be automotive do-it-yourselfers or anyone who changes their own oil. These users may be dermally exposed to the notified polymer, which is present at a maximum concentration of 3% in the finished oil, if they come into contact with runs or drips on the outside of the container after filling.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Amber liquid

Boiling Point 338ºC at 101.3 kPa (related to adjuvant base oil)

Remarks Test method not supplied

Density	< 1000 kg/m^3 (no temperature specified)
Remarks	No test results supplied.
Vapour Pressure	< 10^{-4} kPa
Remarks	Notifier has estimated vapour pressure, noting that it is lower than lube oil.
Water Solubility	<0.001 g/L at 25ºC
METHOD	The water solubility of the notified polymer was estimated based on the 0.001 g/L value for alkaryl sulfonate analogues cited from literature (American Chemical Council 2001). Little TOC (1-2 mg C/L) was observed in WAFs prepared for aquatic toxicity testing.
Hydrolysis as a Function of pH	There are no hydrolysable groups.
Partition Coefficient (n-octanol/water)	Log Pow > 6
METHOD	The partition coefficient of the notified polymer was estimated based on the value for alkaryl sulfonate analogues cited from literature (American Chemical Council 2001). The notified polymer is expected not to interact with water.
Adsorption/Desorption	Quoted as "high", but no supporting data has been supplied. Would expect the polymer to associate with soils/sediments based on low solubility and high Log Pow.
Dissociation Constant	No data supplied. However, the notified polymer is a very strong acid and will remain dissociated throughout the environment at a pH range pf 4-9.
Flash Point	180 ºC
METHOD	ASTM Method D93 (Pensky-Martin Closed Cup)
Remarks	Study not provided
Flammability Limits	Data not provided
Autoignition Temperature	Data not provided
Explosive Properties	Will not detonate as a result of heat, shock or friction.
Remarks	Based on advice from notifier.
Reactivity	May react with strong oxidising agents, such as chlorates, nitrates and peroxides. Hazardous polymerisation will not occur.
Remarks	Based on advice from notifier.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicity data were submitted for the notified polymer. However, data were submitted for the mixture XC-6139, which is 30-35% notified polymer, 40% refined mineral oil, 20% unreacted polymer base and 5-10% sultones. Data were also provided for an analogue AOS, which is a 60:40 mixture of alkenyl sulfonate and hydroxyalkane sulfonate. Data for both the mixture and the analogue were accepted as providing some indication of the toxicological profile of the notified polymer.

Endpoint	*Chemical tested*	*Assessment Conclusion*
Rat, acute oral	XC 6139	low toxicity, LD50 > 5000 mg/kg
Rat, acute dermal	XC 6139	low toxicity, LD50 > 2000 mg/kg
Rat, acute inhalation	-	Not performed
Rabbit, skin irritation	XC 6139	slightly irritating
Rabbit, eye irritation	XC 6139	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test.	XC 6139	limited evidence of sensitisation.
Rat, oral repeat dose toxicity – 90 days.	AOS	NOAEL 200 mg/kg/day
Genotoxicity - bacterial reverse mutation	XC 6139	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	XC 6139	non genotoxic
Genotoxicity – in vivo mouse micronucleus	XC 6139	non genotoxic
Pharmacokinetic/Toxicokinetic studies	AOS	Rapidly metabolised and excreted. Limited dermal absorption in intact skin.
Rat, Developmental and reproductive effects	AOS	NOAEL 600 mg/kg/day
Mouse, Developmental and reproductive effects	AOS	No NOAEL/LOAEL could be assigned
Rabbit, Developmental and reproductive effects	AOS	No NOAEL/LOAEL could be assigned
Rat, Carcinogenicity – 2 years	AOS	No treatment-related tumour formation NOAEL 195 mg/kg/day

7.1. Acute toxicity – oral

TEST SUBSTANCE	XC 6139
METHOD	OECD TG 420 Acute Oral Toxicity, Fixed Dose Method, 1992. EC Directive 96/54/EC B.1 Acute Toxicity – Oral, Fixed Dose Method, 1992.
Species/Strain	Rat/Wistar
Vehicle	None
Remarks - Method	5000 mg/kg dose was based on US EPA requirements.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Sighting study	1 female	5000	0
I	5/sex	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	There were no deaths during the study period. Lethargy or piloerection were noted in 2 males only, on day 1.
Effects in Organs	Body weight gain over the study period was similar to that expected of untreated animals. No abnormalities were found at macroscopic post-mortem examination of the animals.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Notox (2001a)

7.2. Acute toxicity - dermal

TEST SUBSTANCE	XC 6139
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	None
Type of dressing	Occlusive. Dressing consisted of a surgical gauze patch, successively covered with aluminium foil and Coban flexible bandage. For females only, a piece of Micropore tape was additionally used for fixation of the bandages.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	None noted.
Signs of Toxicity - Systemic	Lethargy and/or snout chromodacryorrhoea (shedding of bloody tears) were noted in several animals during days 1-5. Slight ptosis (drooping) of various types (not specified) was noted in 1 male up to day 3. No changes in body weight gain were attributed to the treatment.
Effects in Organs	No abnormalities were found at macroscopic post-mortem examination of the animals.
Remarks - Results	
CONCLUSION	The notified polymer is of low toxicity via the dermal route.
TEST FACILITY	Notox (2001b)

7.3. Acute toxicity - inhalation

Acute inhalation testing was not submitted because the notified polymer is not volatile and is expected to have a very low vapour pressure. It will be used as part of oils, where oil mist toxicology is well established.

7.4. Irritation – skin

TEST SUBSTANCE	XC 6139
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	6 (1 sentinel + 5 tested later) male.
Vehicle	None
Observation Period	72 h
Type of Dressing	Semi-occlusive.
Remarks - Method	Varies from recommended method in using an additional 5 animals after sentinel showed an irritant response, rather than an additional 2 animals.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.3	1	24 h	0
Oedema	0	0	1 h	0

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

Remarks - Results

CONCLUSION The notified polymer is slightly irritating to skin.

TEST FACILITY Notox (2001c)

7.5. Irritation - eye

TEST SUBSTANCE XC 6139

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 6 (1 sentinel + 5 tested later)
Observation Period 72 h
Remarks - Method Varies from recommended method in using an additional 5 animals after sentinel showed an irritant response, rather than an additional 2 animals. After the 24 h observations, the eyes were examined with fluorescein stain, in order to determine epithelial damage to the cornea.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.3	1	24 h	0
Conjunctiva: chemosis	0	1	1 h	0
Conjunctiva: discharge	0	1	1 h	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results Examination with fluorescein stain 24 h after treatment revealed no corneal epithelial damage.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY Notox (2001d)

7.6. Skin sensitisation

TEST SUBSTANCE XC 6139

METHOD OECD TG 406 Skin Sensitisation - Buehler.
EC Directive 96/54/EC B.6 Skin Sensitisation - <insert test type>.
Species/Strain Guinea pig/ Charles River Crl:(HA)BR
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: not performed
topical: variable with very faint erythema evident in 5/8

animals at 24 h and/or 48 h at concentrations ranging from 5% to 100%. There was no irritation evident in 3/8 animals.

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 10 at each challenge

INDUCTION PHASE

Induction Concentration:
intradermal: not performed
topical: 100%

Signs of Irritation: Moderate erythema noted, causing second and third applications to be applied slightly posterior.

CHALLENGE PHASE

1st challenge: topical: 25% in mineral oil

2nd challenge: topical: 2.5% in mineral oil
topical: 25% in mineral oil

Remarks - Method

The procedure used varied from OECD and EC guidelines, in that control animals were not treated with the vehicle (mineral oil) during the induction phase.
New naïve control animals were used in the second challenge.
An additional concentration (2.5%) was tested in the second challenge.
The test protocol suggested that a purified sample of XC 6139 and a sample of XC 6139 impurities might be tested, as well as XC 6139. It appears from the study description that these additional materials were not tested.

A positive control study was conducted within 6 months of this testing, using 1%, 2.5% and 5% w/v alpha-hexylcinnamaldehyde (HCA) in acetone. In the test groups there were 0/10, 1/10 and 3/10 reactions greater than very faint erythema after 24 h, for 1%, 2.5% and 5% respectively, and 2/10, 2/10 and 3/10 reactions after 48 h. Most reactions were faint erythema, with one result of moderate erythema. In all control groups, there were 0/5 reactions greater than very faint erythema.

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	25%	11/20 (8 vf, 3f) [15%]	18/20 (9 vf, 9 f) [45%]	12/20 (9 vf, 3f) [15%]	17/20 (12 vf, 5f) [25%]
	2.5%	-	-	6 (6vf) [0%]	7 (6vf, 1f) [5%]
Control Group	25%	7/10 (6f, 1mod) [70%]	9/10 (2vf, 5f, 1mod) [60%]	4/10 (4vf) [0%]	5/10 (5vf) [0%]
	2.5%	-	-	0/10 [0%]	6/10 (4vf, 2f) [20%]

Key:
vf = very faint erythema
f = faint erythemal
mod = moderate erythema
[%] = percentage of animals with reactions, excluding those with very faint erythema.

Remarks - Results

Clinical signs of all animals were normal.
The first challenge showed a higher than expected level of reaction in

control animals, that did not occur with the new group of animals used in the second challenge. In judging the results, reactions of very faint erythema were excluded. In all test groups there was a trend to higher levels of reaction at 48 h, compared with 24 h, indicative of a sensitisation rather than irritant response. This trend was not evident in the control groups for 25%, but was seen in the 2.5% control group. It was noted that the level of reactions noted was comparable to those in a positive control test of HCA. However, the XC 6139 results may have been influenced by a higher level of irritancy.

CONCLUSION The notified polymer may have skin sensitising ability but due to the level of irritation observed in the controls, the results from this study are inconclusive.

TEST FACILITY Covance (2001)

7.7. Repeat dose toxicity

No repeat dose toxicity studies were provided for the notified polymer. However, summaries of three repeat dose toxicity studies in rodents for the analogue AOS were included.

In a 90-day feed study, groups of rats (number not specified) received AOS (89.7% active) at doses of 40, 200, or 1000 mg/kg/day (Study 1). A slight increase in the liver:body weight ratio was observed in animals of the high dose group. No other changes in haematologic or biochemical parameters, feed consumption, gross or microscopic lesions were noted.

In a 91-day feed study (Study 2), groups of rats (number not specified) received C_{14-16} AOS (34% active) at doses of 50, 150, or 500 mg/kg/day. No treatment-related toxic or histopathologic changes were observed. Anomalies were noted in haematologic parameters. No further details were given. However, it was reported that similar changes were noted in rats which received C16-18 AOS (34% active) at doses of 50,150 or 500 mg/kg/day also for 91 days (Study 3). In that study red blood cell counts, but not haemocrit or haemoglobin values, were significantly higher for females of the high dose group. Increased haemoglobin and haemocrit values were noted in females of the 150 mg/kg group, and significantly higher haemocrit values noted in males of the 50 mg/kg AOS group.

Remarks No individual animal data was available. From the limited information provided, there did not appear to be a dose-response relationship for changes in hematologic parameters noted in study 3. Therefore these are not considered to be treatment related. The increase in the relative liver weight in animals dosed at 1000 mg/kg/day (in Study 1) might suggest a hepatic effect at this dose.

CONCLUSION Based the liver effects at 1000 mg/kg/day in Study 1, the No Observed (Adverse) Effect Level (NO(A)EL) is established as 200 mg/kg bw/day in this study.

TEST FACILITY Little (1993) in International Journal of Toxicology (1998)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE XC 6139

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 uvrA.
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
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 PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				negative
Test 1	> 5000 µg/plate	> 5000 µg/plate	≥ 1500 µg/plate	negative
Test 2		> 5000 µg/plate	≥ 1500 µg/plate	negative
Present				negative
Test 1	> 5000 µg/plate	> 5000 µg/plate	≥ 1500 µg/plate	negative
Test 2		> 5000 µg/plate	≥ 1500 µg/plate	negative

Remarks - Results

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

TEST FACILITY SafePharm (2001a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 92/69/EC B10 Mutagenicity – *In Vitro* Mammalian Chromosome Aberration Test

Cell Type	Chinese Hamster Lung (CHL)
Metabolic Activation System	S9 from phenobarbitone/β-naphthoflavone induced rat liver.
Vehicle	Ethanol
Remarks - Method	

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 312.5, 625, 1250*, 1875*, 2500*, 3750	6 h	24 h
Test 2	0*, 78.13, 156.25*, 234.38*, 312.5*, 625*, 937.5	24 h	24 h
	0*, 39.06, 78.13*, 156.25*, 234.38*, 312.5*, 468.75	48 h	48 h
Present			
Test 1	0*, 312,5, 625, 1250, 1875*, 2500*, 3750,	6 h	24 h
Test 2	0*, 1250, 1875*, 2500*, 3750*, 4375, 5000*	6 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	2500			
Test 1		3750	312.5	None observed

Test 2 – 24h		625	625	None observed
Test 2 – 48h		234.4	312.5	None observed
Present	2500			
Test 1		Not achieved	312.5	None observed
Test 2		Not achieved	312.5	None observed

Remarks - Results: The test substance did not induce any statistically significant increase in the frequency of cells with aberrations in any of the exposure groups. Similarly, no increase in the number of polyploid cells occurred at any dose.

CONCLUSION: The test substance was not clastogenic to Chinese Hamster Lung cells *in vitro* under the conditions of the test.

TEST FACILITY: SafePharm (2002)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE: XC 6139

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Male albino Crl:CD-1(ICR)BR – Charles River
Route of Administration: Intraperitoneal

Vehicle: Arachis oil
Remarks - Method: A range-finding toxicity study was conducted in male and female animals.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I and II	7m, 7m	0	24, 48
III	7m	500	24
IV	7m	1000	24
V and VI	7m, 7m	2000	24, 48
VII - CP	5m	50	24

CP=cyclophosphamide. M=mitomycin C.

RESULTS

Doses Producing Toxicity: In the range-finding study, no deaths occurred (2m,2f) at the only dose, 2000 mg/kg. Therefore, males only were used in the main study.
Genotoxic Effects: No statistically significant increase in the frequency of micronucleated polychromatic erythrocytes (PCE) occurred at any dose with the test substance.
Remarks - Results: A statistically significant decrease in the ratio of PCEs to normochromatic erythrocytes (NCEs) was observed in the high dose 48h exposure group, with a lesser decrease in the ratio at 24h, thus confirming that absorption had occurred.

CONCLUSION: The test substance was not genotoxic to mice *in vivo* under the conditions of this micronucleus test.

TEST FACILITY: SafePharm (2001b)

ADDITIONAL INVESTIGATIONS

7.10. Developmental toxicity

TEST SUBSTANCE C_{14-18} AOS

METHOD

Species/Strain	Rat, Mouse, Rabbit
Route of Administration	Oral – gavage
Exposure Information	Exposure period: Rat: Days 6-15 of gestation Mouse: Days 6-15 of gestation Rabbit: Days 6-15 of gestation
Vehicle	Not specified
Remarks - Method	No test report was provided. Details of study were included in a report on AOS (International Journal of Toxicology, 1998).

RESULTS

Rat

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	Not specified	Not specified	0
II (low dose 1)	20	0.2	0
III (low dose 2)	20	2	0
IV (mid dose)	20	300	0
V (high dose)	20	600	0

Mouse

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	Not specified	Not specified	0
II (low dose 1)	20	0.2	0
III (low dose 2)	20	2	0
IV (mid dose)	20	300	0
V (high dose)	20	600	6

Rabbit

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	Not specified	Not specified	0
II (low dose 1)	13	0.2	0
III (low dose 2)	13	2	0
IV (mid dose)	13	300	1
V (high dose)	13	600	13

Mortality and Time to Death

No mortalities occurred in any of the rat dose groups. Six mice treated at the high dose died. All rabbits treated at the high dose died, one dam of the mid dose group also died. No information was provided regarding time to death.

Effects on Dams

No sign of maternal toxicity were observed in any of the treated rats. Five mice from the high dose group lost their litters. Diarrhoea, and body weight loss were observed in the rabbits that died. Both mice and rabbits of the low dose groups (1 and 2) had an initial reduction in body weight gain.

Effects on Foetus

Litter parameters (litter size, embryonic deaths, litter weight, mean pup weight) were unaffected at in the low dose groups (1 and 2) in mice and rabbits and in all treated rats. When total litter loss data were excluded, litter size and embryonic loss values for mice and rabbits at the two highest dose groups were comparable to control values. At all doses of AOS, litter and mean pup weights of mice were lower than those of concurrent controls, however, the values were within the range for historical controls.

The incidence of minor skeletal anomalies in pups was high in rabbits of the 300 mg/kg group (23% vs. 7%for controls), and the proportion of pups having an extra rib was significantly larger (87% vs 59% for controls. There were no pups to examine from the high dose group. In mice, cleft palates were observed in four pups of the 600 mg/kg group and in two of the 300 mg/kg group. A significantly high incidence of skeletal anomalies was seen in pups of the high dose group, however, the 1% incidence of abnormalities in controls was unusually low.

Remarks - Results
Foetal abnormalities were observed at treatment doses producing maternal abnormalities.

CONCLUSION
The maternal and developmental NOAEL in rat was established to be 600mg/kg bw/day in this study. There was evidence of skeletal effects at high dose and mid dose where maternotoxicity was observed. However, in absence of individual animal data, it is difficult to assign an NOAEL or LOAEL for mice and rabbits

TEST FACILITY Palmer et al (1975) in International Journal of Toxicology (1998)

7.11. Chronic toxicity/carcinogenicity

TEST SUBSTANCE Alpha-olefin sulfonate (AOS)

METHOD Similar to OECD TG
Species/Strain Sprague-Dawley – CFY strain
Route of Administration Oral – diet.

Exposure Information Total exposure: - 2 years
Dose regimen: ad libitum
.
Vehicle Powdered Laboratory Diet
Physical Form liquid in powder.
Remarks - Method Animals were housed initially at 5 per cage. Conditions controlled to provide 12 hours daylight and 12 hours darkness per 24h.

RESULTS

Group	*Number and Sex of Animals*	*Dose*		*Mortality*
		ppm w/w Nominal	*mg/kg/day Actual*	
I (control)	50m, 50f	0	0	22m, 25f
II	50m, 50f	1000	39, 57	23m, 19f
III	50m, 50f	2500	96, 132	27m, 27f
IV	50m, 50f	5000	195, 259	20m, 20f

Mortality and Time to Death
Time to death not stated. Cause of death included renal and respiratory infection, tumours of the subcutaneous tissues and pituitary gland, distributed evenly among the groups – effects commonly observed in this strain.

Clinical Observations
Reduced body weight gain after week 14, particularly for higher doses. Males of all groups showed loss of weight during last 2 months, greater in treated males than controls.
Minor decrease in food consumption in 500 ppm females during first year – not apparent during second year.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment-related findings

Pathology - macroscopic
Effects in all groups, similar to effects commonly observed in old rats.

Organs weights
No treatment-related changes.

Pathology - microscopic
No treatment-related histopathological changes.

Distribution of tumours
Pancreatic islet cell tumours – in treated groups only, highest incidence (4 rats) at 1000 ppm.
Adrenal tumours – in all groups, highest incidence in males at 2500 ppm.
Thyroid tumours - in all groups, highest incidence in females at 2500 ppm.
Pituitary tumours – in all groups.
Mammary gland tumours – in all female groups. Frequency of multiple tumour formation and tumour induction time similar for all groups.

Remarks – Results
The published report only of the study was available. No evidence of carcinogenicity due to treatment with the test substance was observed in the study.

CONCLUSION
Based on information in the report, namely decreased body weight gain, the no-observable-effect level (NOEL) is 2500 ppm (96 mg/kg/day). Based the absence of adverse effects, the no-observable-adverse-effect level (NOAEL) is 5000 ppm (195 mg/kg/day).

TEST FACILITY Hunter and Benson, in Toxicol 5: 359-370 (1976)

7.12. Pharmacokinetic/toxicokinetic

No pharmacokinetic studies were provided for the notified polymer. However, summaries of three metabolism studies conducted for the analogue AOS were included in a report (International Journal of Toxicology, 1998). A different route of administration was used in each of these studies.

Oral
In a metabolism study, ^{14}C-AOS was administered as a single oral dose of 100mg (50µCi)/kg to three male Wistar rats. The radioactive AOS was a mixture of approximately 55% sodium 3-hydroxy alkane sulfonate and 45% sodium alkenyl (2) sulfonate. The mixture was rapidly absorbed from the gastrointestinal tract (80% absorption) with peak activity in the blood 3 hours after dosing. Within 12 hours, radioactivity in the bile accounted for 4.3% of the dose. At 24 hours post dosing, approximately 0.08% of the administered AOS was detected in the cecal content; the concentrations in other tissues were less than 0.02% dose/g. at that time, 72% of the dose had been excreted in the urine and 22% in the faeces. No intact ^{14}C-AOS was detected in the urine.

Parenteral
An intravenous metabolism study using the radioactive AOS described above was conducted. A single dose of 10 mg (5µCi)/kg was administered to three male Wistar rats. Within 1 hour, half of the administered dose was excreted. By 6 hours post dosing, 90% of the administered dose had been eliminated. The concentrations of intact AOS in the liver and kidneys were comparable with blood concentrations. No intact AOS was detected in the urine.

Dermal
^{14}C-AOS was applied to the dorsal skin of groups of three male Wistar rats. The AOS was of the same composition as that described above. The treatment groups were as follows: (1) intact skin dried naturally after application; (2) intact skin wiped off 0.5 hour after application; (3)

intact skin wiped off 1.5 hour after application; (4) intact skin with a plastic cup containing the test substance (for continuous exposure); and (5) damaged skin dried naturally. In the groups where the applied AOS was wiped off after a specified time (groups 2+3), 60-70% of the applied radioactivity was recovered. Animals were killed at 24 hours. When 0.5ml of a 0.2% ^{14}C-AOS solution was applied to animals of group 1, 0.33% was recovered in the urine, 0.08% in the bile, and 0.21% in the main organs 24 hours after application. It was estimated that 0.6% of the applied dose had been absorbed. Comparing results of Groups 1, 2 and 3, it was determined that the dermal absorption was almost complete by 1.5 hours post application. The excretion in the urine and bile approached the highest rate around 3 hours after application; excretion then decreased, but was still detectable at 70-90 hours post application. When the 0.2% dose was applied for continuous contact (group 4), a small amount continued to be absorbed. In contrast, in damaged skin (group 5), 36.26% of the applied dose was recovered in the urine, 1.83% in the bile, and 12.28% in the major organs 30 hours after application. Thus, 50% of the applied dose had been absorbed.

TEST FACILITY Inoue et al (1982) in International Journal of Toxicology (1998)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: All testing was conducted with the closely related analogue XC 6139.

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test

Inoculum	Activated sewage sludge micro-organisms (Seven Trent Water Plc sewage treatment plant, Derbyshire UK)
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	Determination of CO_2 produced (DOC)
Remarks - Method	The degradation of the test material was assessed (at 10 mg C/L) by the determination of carbon dioxide produced. Control solutions with inoculum and the standard material, sodium benzoate, together with a toxicity control were used for validation purposes.

RESULTS

Day	*Sodium Benzoate Control* *% degradation*	*Test substance* *% degradation*	*Test Material plus Sodium Benzoate Toxicity Control* *% degradation*
1	15	0	9
3	46	0	23
8	51	4	47
14	69	9	48
22	90	10	73
29	96	9	83

Remarks - Results: The toxic control and sodium benzoate control satisfied validation criteria of the test by showing more than 60% biodegradability after 14 days.

CONCLUSION: Not readily biodegradable.

TEST FACILITY: SafePharm Laboratories (2001c)

8.1.2. Bioaccumulation

Remarks: No bioaccumulation test data or comments were provided in the notification dossier. A low water solubility and high partition co-efficient of $>10^6$ for analogues suggest that the notified polymer will have an affinity for lipids, and potential to bioaccumulate in exposed organisms. However, limited aquatic exposure will reduce this potential.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: All testing was conducted with the closely related analogue XC 6139.

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	3-96 h

Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Due to the low aqueous solubility and complex nature of the test material for the purposes of the definitive study the test material was prepared as a Water Accommodated Fraction (WAF). Total organic carbon (TOC) analyses were performed at 0 and 24 h, with no significant change compared to control, though levels were low (1-2 mg C/L). Physico-chemical parameters monitored throughout the study. Temperature 14±1°C, pH 7.5-7.7. Light:dark 16:8 h. No auxiliary aeration was provided to the test containers.
Remarks – Method	Range finding and definitive tests were performed. An amount of test material (21 g) was added via syringe to the surface of 21 L of dechlorinated tap water to give a 1000 mg/L loading rate. After stirring for 24 h and standing for 4 h, the WAF was extracted by mid-depth siphoning. Micro-inspection of WAFs showed no micro-dispersions or undissolved test material, therefore a glass wool plug was not used to filter the WAFs.

RESULTS

Nominal Loading Rate (mg/L)	*Number of Fish*	*Mortality*					
		3h	*6h*	*24h*	*48h*	*72h*	*96h*
Control (1)	10	0	0	0	0	0	0
Control (2)	10	0	0	0	0	0	0
1000 (1)	10	0	0	0	0	0	0
1000 (2)	10	0	0	0	0	0	0
1000 (3)	10	0	0	0	0	0	0

(n) = number of replicates

LL50 (Lethal Loading Rate)	>1000 mg/L at 96 hours
Remarks – Results	

CONCLUSION	The acute toxicity of the test material to the freshwater fish rainbow trout gave a 96-hour LL50 value of greater than 1000 mg/L loading rate WAF. Correspondingly, the No Observed Effect Loading rate was 1000 mg/L Loading rate WAF. The test substance is non toxic to fish up to the limit of its water solubility.
TEST FACILITY	SafePharm Laboratories (2001d)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	All testing was conducted with the closely related analogue XC 6139.
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static
Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Due to the low aqueous solubility and complex nature of the test material for the purposes of the definitive study the test material was prepared as a Water Accommodated Fraction (WAF). Total organic carbon (TOC) analyses were performed at 0 and 24 h, with no significant change compared to control. TOC levels were low (1-2 mg C/L). Physico-chemical parameters monitored throughout the study. Temperature 21±1°C, pH 7.8±0.2. Light:dark 16:8 h. No auxiliary aeration was provided to the test containers.
Remarks - Method	Range finding and definitive tests were performed.

Amounts of test material (20, 200 and 2000 mg) were added via syringe to the surface of 2 litres of reconstituted water to give the 10, 100 and 1000 mg/L loading rates respectively. After stirring for 24 h and standing for 4 h, the WAF was extracted by mid-depth siphoning. Micro-inspection of the WAFs showed no micro-dispersions or undissolved test material, therefore a glass wool plug was not used to filter the WAFs. The control group was maintained under identical conditions but not exposed to the test material.
Based on the results of the range-finding study a "Limit test" was conducted for the definitive study at a single loading rate of 1000 mg/L to confirm that no immobilisation or adverse reactions to exposure were observed.

RESULTS

There was no immobilisation in 40 daphnids exposed to a 1000 mg/L loading rate WAF for a period of 48 hours.

Inspection of the immobilisation data gave the following results:

Time (h)	*EL50 (mg/L)*	*95% confidence limit*
48	>1000	-

Remarks - Results: The No Observed Effect Loading rate after 24 and 48 hours exposure was 1000 mg/L Loading rate WAF. The No Observed Effect Loading rate is based upon zero immobilisation at this loading rate.
It was considered unnecessary and unrealistic to test loading rates in excess of 1000 mg/L.

CONCLUSION: The acute toxicity of the test material to the freshwater invertebrate *Daphnia magna* gave a 48-Hour EL50 value of greater than 1000 mg/L loading rate WAF. Correspondingly, the No Observed Effect Loading rate was 1000 mg/L Loading rate WAF. The test substance is non toxic to *Daphnia magna* up to the limit of its water solubility.

TEST FACILITY: SafePharm Laboratories (2001e)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE: All testing was conducted with the closely related analogue XC 6139.

METHOD: OECD TG 201 Alga, Growth Inhibition Test.
Species: *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*)
Exposure Period: 96 hours
Concentration Range
Nominal: 0, 100, 1000 mg/L
Auxiliary Solvent: None
Water Hardness: Not determined
Analytical Monitoring: Temperature 21°C. pH 7.1 (at 0 h) to 9.4 (at 96 hours)
Remarks - Method: Range finding and definitive tests were performed.
Amounts of test material (250 and 2500 mg) were each separately added on to the surface of 2.5 litres of culture medium to give the 100 and 1000 mg/L loading rates respectively. After stirring for 24 h and standing for 4 h, the WAF was extracted by mid-depth siphoning. Micro-inspection of WAFs showed no micro-dispersions or undissolved test material, therefore a glass wool plug was not used to filter the WAFs.
At the start of the range-finding study a sample of each test and control culture was removed and the cell density determined using a Coulter Multisizer II Particle Counter. The flasks were then plugged with polyurethane foam bungs and incubated (Gallenkamp INR – 401-010W)

at 24±1°C under continuous illumination (intensity 7000 lux) and constantly shaken at approximately 100 rpm for 96 hours. After 96 hours the cell density of each flask was determined using a Coulter Multisizer II Particle Counter. The control group was maintained under identical conditions but not exposed to the test material.
Based on the results of the range-finding study a "Limit test" was conducted for the definitive study at a single loading rate of 1000 mg/L to confirm that at the maximum test concentration given in the OECD/EEC Test Guidelines no effect on algal growth was observed.

RESULTS

EbL50 (72 h)	>1000 mg/L loading rate WAF
EbL50 (96 h)	>1000 mg/L loading rate WAF
ErL50 (0-96 h)	>1000 mg/L loading rate WAF

Where EbLx is the loading rate that reduced biomass by x% and ErLx is the loading rate that reduced specific growth rate by x%.

Remarks - Results

The No Observed Effect Loading rate (NOEL) was 1000 mg/L loading rate WAF. It has been noted that the pH has increased from initially 7.1 to 9.4 after 96 hours. This increase was considered to be due to the amount of carbon dioxide required by the large number of algal cells in the log phase of growth exceeding the transfer rate of CO_2 from the gaseous phase to the aqueous phase. In this situation CO_2 required for the photosynthesis and growth would be derived from bicarbonate in solution which results in an increase in pH of the culture. This increase in pH was considered to have had no adverse effect on the results of the study given that the increase in cell concentration in the control cultures exceeded the validation criterion given in the Test Guidelines.

CONCLUSION

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 and the test substance is not toxic to algae up to the limit of its water solubility.

TEST FACILITY

SafePharm Laboratories (2001f)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

All testing was conducted with the closely related analogue XC 6139.

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum

Activated sewage sludge and synthetic sewage, Severn Trent Water Plc sewage treatment plant, Derbyshire, UK.

Exposure Period

3 hours

Concentration Range

Nominal

100 and 1000 mg/L

Remarks – Method

Range finding and definitive tests were performed.
Amounts of test material (50 and 500 mg) were separately dispersed in approximately 250 mL of water. Synthetic sewage (16 mL), activated sludge (200 mL) and water were added to a final volume of 500 mL to give the required concentrations of 100 and 1000 mg/L. Test temperature 21°C, pH 7.5 and performed under normal lighting conditions. The control group was maintained under identical conditions but not exposed to the test material. A reference material 3,5-dichlorophenol was included in the range-finding test at concentrations 3.2 and 32 mg/L. 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	(30 minutes)	Test substance	>1000 mg/L
	(3 hours)	Test substance	>1000 mg/L
	(3 hours)	Reference	6.7 mg /L
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

SafePharm Laboratories (2001g)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The used oil and the sludge collected from the on-site wastewater treatment facilities may be incinerated. This will generate water vapour and oxides of carbon. The main environmental exposure is expected to result from inappropriate disposal of waste lubricant product, assuming a worst case scenario of about 14% of oil changes in Australia are performed by DIY enthusiast.

This improper disposal is however, widespread across Australia. Most of the improperly released notified polymer due to DIY activities is likely to become associated with soils or sediments, as will the notified polymer released to landfill as container residues. The notified polymer released into the aquatic environment would be expected to become associated with the sediments. While some components of the notified polymer 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 become associated with suspended organic material (due to the high Pow), settle out into the sediments and eventually be biodegraded.

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, a worst case estimated PEC might be calculated if it is assumed that all of the 1% of the notified substance (i.e. 300 kg) expected to be released into the stormwater drains in a single metropolitan area with a geographical footprint of 500 square kilometres, an average annual rainfall of 50 cm. With a maximum annual release into this localised stormwater system of 300 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 1.2 µg/L. It should be stressed that this result is very much 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

Of the data provided the notified polymer has a low ecotoxicity. Therefore, using the lowest datum of 1000 mg/L, a predicted no effect concentration (PNEC for aquatic ecosystems) of >10 mg/L has been derived by dividing the EC50 value by an uncertainty (safety) factor of 100 because toxicity data is available for three trophic levels. A PNEC of >10 mg/L will be used.

9.1.3. Environment – risk characterisation

Reading across from the data on similar chemicals, some of the components of the notified polymer are shown to be not toxic to fish, daphnia or algae up to the limit of their solubility. Therefore, the worst-case PEC is significantly below possible toxic levels and the resulting risk quotient (Q = PEC/PNEC) is significantly 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, high volatility and biodegradation will further reduce the risk to the aquatic life.

Given the potential for a small fraction of the formulated oil to enter the sewerage system, another worst-case scenario that may be considered is that 10% the notified substance is released to sewer and not removed during sewage treatment processes. Assuming a national population of 20 million and that each person contributes an average 200 L/day to overall sewage flows, the daily release on a nationwide basis to receiving waters is estimated to be 8.2 kg/day and the predicted concentration in sewage effluent on a nationwide basis is estimated as 2.05 µg/L (Environment Australia 2003). Based on the respective dilution factors of 1 and 10 for inland and ocean discharges of effluents, the PECs of the notified polymer in freshwater and marine water may approximate 2.05 and 0.205 µg/L, respectively. The resulting risk quotients

for the aquatic environment are < 2.05 x 10^{-4} and < 2.05 x 10^{-5} for freshwater and marine water, respectively. These values are significantly less than 1 and can be expected to be much lower due to treatment and attenuation within the sewerage system.

Overall, the environmental risk from the proposed reformulation and use of the notified polymer 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 polymer should be prevented from entering waterways.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and Storage

Workers should not be exposed to the notified polymer except in the case of an accidental spill.

Blending

Incidental dermal exposure to the notified polymer could occur during the connection and disconnection of the transfer pipes and sealing and labelling of drums. In the former case the notified polymer is present at a concentration up to 20% and in the latter the concentration is a maximum of 5%. Exposure is expected to be negligible during the rest of the blending process due to the use of engineering controls.

Laboratory Staff & Maintenance Workers

Minimal exposure will occur during the laboratory testing since it will only take a few minutes per batch.

Incidental skin contact is also identified for workers involved in steam cleaning of drums. However, personal protective equipment will be worn, thus minimising any dermal exposure.

End Use

Incidental dermal exposure with lubricants containing the notified polymer (maximum 5%) could occur during manual addition. The risk of inhalation exposure is deemed to be negligible due to the estimated low vapour pressure of the notified polymer and unlikely production of mists or aerosols.

9.2.2. Public health – exposure assessment

Incidental dermal exposure would result from the use of the lubricant products. The notified polymer is present at a concentration of 3%. Exposure is expected to be low due to the low concentration, limited contact time and expected low frequency of use.

9.2.3. Human health - effects assessment

Toxicokinetics, metabolism and distribution.

Summaries of three metabolism studies were provided for the analogue AOS. Oral, parenteral and dermal routes of administration were investigated.

Oral: the test substance was rapidly absorbed from the gastrointestinal tract and metabolised. The dose was excreted in both the urine and the faeces (72% and 22% respectively). No intact test substance was detected in the urine.

Parenteral: The test substance was determined to be rapidly absorbed and metabolised with the products excreted in urine. Again, no intact test substance was detected in the urine.

Dermal: Absorption by intact skin was determined to be low (0.6%), approximately 60 -70% of the dose absorbed was recovered in the urine and bile. Excretion in the urine and bile reached its highest rate around 3 hours however the dose was still detectable 70-90 hours post application. Absorption by damaged skin was high (50%). Again 60-70% of the dose absorbed was recovered in the urine and bile.

Based on an assumption that the notified polymer behaves similarly to the test substance, an accumulation of the notified polymer or its metabolites is not expected, owing to their rapid metabolism and excretion.

Acute toxicity.
The mixture containing the notified polymer at a concentration of 30-35% was of low oral and dermal toxicity in acute rat studies

Irritation and Sensitisation.
The mixture containing the notified polymer at a concentration of 30-35% was considered to be a slight skin and eye irritant. A skin sensitisation study was performed on guinea pigs using a mixture containing thee notified polymer. The notified polymer may have skin sensitising ability but due to the level of irritation observed in the controls, the results from this study are inconclusive.

In a report on the safety of AOS (International Journal of Toxicology (1998)), the sensitising potential of sultone impurities was assessed. It concluded that gamma sultones were potent sensitisers at very small concentrations The notified polymer contains sultone impurities, and as such there is a risk of a sensitisation reaction from exposure.

Repeated Dose Toxicity.
Summaries of three 90-day repeat dose toxicity studies in rodents for the analogue AOS were provided. There was some evidence of haematological effects in two out of three studies but these did not appear to be dose related. An increase in relative liver weight was observed at the high dose in one study. Without individual animal data it is not possible to state whether this is definitely treatment related but it might suggest a hepatic effect at this dose. Therefore based on this effect, the NOAEL was established to be 200 mg/kg bw/day in this study.

Mutagenicity.
The mixture containing the notified polymer at a concentration of 30-35% was negative in an Ames test. This same mixture was not clastogenic in a chromosomal aberration study in Chinese Hamster Lung cells and non genotoxic to mice *in vivo* in an erythocyte micronucleus test.

Carcinogenicity.
A published report of a 2-year carcinogenicity study was provided for the analogue AOS. No evidence of carcinogenicity due to treatment with the test substance was observed in the study. The no observable effect level (NOEL) was established to be 2500ppm (96 mg/kg/day) based on reduced body weight gain. The no observable adverse effect level (NOAEL) was established to be 5000ppm (195 mg/kg/day), the top dose.

Toxicity for reproduction.
A summary of a teratogenicity study for the analogue AOS was provided. Rats, mice and rabbits were included in the study. No signs of maternal toxicity or foetal abnormality were observed in any of the rat dose groups. Mortality was observed in all rabbits and 6/20 mice treated at 600 mg/kg/day and 1/13 rabbits treated at 300 mg/kg/day. Foetal abnormalities were observed at treatment doses producing maternal toxicity.

Hazard classification for health effects.
Based on the assumption that analogue data is acceptable and indicative of toxicity of the notified polymer, the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer is a slight skin and eye irritant. There is a risk of sensitisation following repeat exposure to low levels.

Blending
Exposure and hence the risk of irritation and sensitisation is most likely during the initial transfer of the additive package containing the notified polymer. Exposure is expected to be incidental only and further limited by the use of PPE. Exposure during the rest of the blending process is expected to be negligible and therefore the risk of adverse effects is negligible.

End Use

Exposure to the notified polymer could occur during the manual addition of the lubricants containing the notified polymer. Individuals showing signs of sensitisation should be moved to alternative work environments. Farmers that show signs of sensitisation should consider the use of an alternative product.

9.2.5. Public health – risk characterisation

Incidental exposure to the notified polymer can occur during use of lubricants. The risk to public health is deemed to be low due to the low concentration of the notified polymer and the expected low frequency of use.

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

10.1. Hazard classification

Based on the assumption that analogue data is acceptable and indicative of toxicity of the notified polymer, the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

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 No Significant Concern to public health based on its reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of an additive product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). 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 an additive product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS.

Health Surveillance

- As impurities present with the notified polymer may cause sensitisation, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced and in the lubricant end products:
  - Avoid skin contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves;

  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 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.

Public Health

- The following measures should be taken by end users to minimise public exposure to the notified polymer:
  - Avoid skin contact

Environment

Disposal

- The notified polymer will be a component of waste oil. It should be disposed of by recycling as waste oil or incinerated in accordance with approved State or Territory waste management regulations. Emptied containers (1-4 L) should be sent to landfill for disposal. Emptied drums should be sent to drum recyclers for steam cleaning prior to re-use, with wastewater treated and oil component concentrated prior to recycling as waste oil by licensed waste contractors.

Emergency procedures

Spills/release of the notified polymer should be handled by stoping the source of the spill where possible. Then containing the release to prevent further contamination of soil, surface water or ground water. Clean up spill as soon as possible by applying non-combustible adsorbent materials in disposable containers and dispose of in a manner consistent with government regulations.

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 Sub Section 64(1) of the Act; if

– The notified polymer is imported as a raw material.

or

(2) Under Sub 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.

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