File No: STD/1164

07 September 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

X81-337-11

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Carter Holt Harvey Australia Pty Ltd (ABN 77 000 601 892)
Como Office Tower
644 Chapel Street
South Yarra VIC 3141

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

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

Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Purity
Composition
Identity of Chemical Analogue Accepted for Toxicological Assessment

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

Dissociation constant
Flammability
Acute dermal toxicity
Acute inhalation toxicity
Skin irritation
Eye irritation
Skin sensitisation
Mammalian genotoxicity
Toxicity to fish
Chronic toxicity to Daphnia
Toxicity to algae
Ready biodegradation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Notified in 2005 to the USA, EU, China, Korea and the Philippines.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
X81-337-11

SPECTRAL DATA

METHOD	UV/Visible spectroscopy Infrared (IR) spectroscopy ^{1}H Nuclear Magnetic Resonance (NMR) spectroscopy
Remarks	Reference spectra were provided.
TEST FACILITY	Arizona Chemical BV

METHODS OF DETECTION AND DETERMINATION

METHOD	Gas chromatography.
Remarks	Reference chromatogram was provided.
TEST FACILITY	Arizona Chemical BV

3. COMPOSITION

DEGREE OF PURITY
>80%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Rosin		
CAS No.	8052-10-6	*Weight %*	2.0
Hazardous Properties	May cause skin sensitisation at concentrations ≥ 1.0%.		

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia within formulated lubricants at concentrations up to 1%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100	100	100	100	100

USE
Imported lubricant formulations will be used by vehicle manufacturers for "factory fill" applications, by service garages for lubricant replacement, and by the general public in DIY applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Not yet known.

IDENTITY OF MANUFACTURER/RECIPIENTS
Not yet known.

TRANSPORTATION AND PACKAGING
Formulated lubricants will be imported in 1-200 L sealed drums or containers.

5.2. Operation description

Factory fill – vehicle manufacturers

Formulated oil will be transferred from 200 L import drums to new engines by mechanical means. The drum will be mounted on a moveable trolley with a dip-pipe and pump arrangement that will facilitate

transfer of a pre-determined amount of oil into the engine oil filler point. Filling will take approximately one minute; frequency of filling operations is estimated at 5 minute intervals. When the drum is empty, it will be removed from the trolley and replaced by a full one. The old drum is then turned on its side and allowed to drain into the new one.

Service garage
Formulated oil will be supplied in 200 L drums. Drums will be placed on a purpose-designed cradle and a tap placed in one of the bung-holes provided. When required, the operator will draw off sufficient oil via the tap into a small vessel that will then be used to pour the oil into the oil filler point.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport & storage	10-20	1-2	50
Professional end users	>1000	1-8	200

Exposure Details
Factory fill – vehicle manufacturers
The filling operator will hold a handle attached to the delivery tube from the 200 L import drum to the engine oil filler point. During this operation and during transfer of empty drum residue to the new drum, dermal and ocular exposure are possible in the case of accidental spills or splashes. Operators will wear goggles, gloves and an apron.

Service garage
Dermal exposure is possible during drawing off of oil into a smaller vessel and pouring from the vessel into the oil filler point. Workers are expected to wear overalls, however it is not likely that goggles or gloves will be routinely worn.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical is not manufactured in Australia but will be imported in formulated lubricant products. Accidental spills, leaks and catastrophic mechanical failure during a transport accident are the most likely reasons for environmental release. Engineering controls (eg. drum specifications) and emergency clean-up procedures (ie. spill response instructions on the Material Safety Data Sheet and label) will limit the impact on the environment of such incidents.

RELEASE OF CHEMICAL FROM USE
Some minor and diffuse exposure will result from spills during addition of oil to vehicles. This is expected to account for less than 1% (1000 kg of the notified chemical at the maximum import rate). 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), approximately 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, it is possible to have 20, 25, 5 and 50% of this oil to be collected for recycling (up to 2.8 tonnes), buried or disposed of in landfill (up to 3.5 tonnes), and disposed into stormwater drains (up to 700 kg) and used in treating fence posts, to kill weeds or disposed of in other ways (up to 1.75 tonnes), respectively.

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 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.

5.6. Public exposure

The public will be exposed to the notified chemical at concentrations up to 1% in lubricating oil products. Consumers may use disposable gloves to keep their hands clean, however it is not likely that any other personal protective equipment will be routinely used. However, due to the low concentration of the notified chemical in end use products and the relatively low frequency of use for most consumers, public exposure is expected to be low and intermittent.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Pale brown semi-solid.

Melting Point 28-55ºC

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Differential scanning calorimetry method. The range reported is a softening range.
TEST FACILITY	SafePharm (2004a)

Boiling Point >400ºC at 99.4-99.8 kPa

METHOD	EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Differential scanning calorimetry method.
TEST FACILITY	SafePharm (2005a)

Density 973 kg/m^3 at 20ºC

METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Gas comparison pycnometer method.
TEST FACILITY	SafePharm (2004a)

Vapour Pressure 7.9×10^{-6} kPa at 25ºC

METHOD	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Vapour pressure balance method. The test substance is classified as slightly volatile (Mensink *et al.* 1995).
TEST FACILITY	SafePharm (2005a)

Water Solubility $<9.68 \times 10^{-5}$ g/L at 20ºC

METHOD	Visual estimation method.
Remarks	The standard EU method was not appropriate, so a visual estimation was performed. Samples were ultrasonicated for 30 min prior to visual inspection where excess test material remained at the above concentration. The pH of the test

solutions was measured to be approximately pH 4.3. Calculated estimates for components of the notified chemical using an atom-fragment contribution method gave results ranging from of 5.117 x 10^{-18} – 0.04798 mg/L.

TEST FACILITY SafePharm (2004a)

Hydrolysis as a Function of pH Hydrolytically stable.

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

Component	*pH*	*T (°C)*	*$t_{½}$*
A	4	25	> 1 year
	7	25	> 1 year
	9	50	69.0% hydrolysis after 5 days
B	4	25	> 1 year
	7	25	> 1 year
	9	25	> 1 year
C	4	25	> 1 year
	7	25	> 1 year
	9	25	> 1 year

Remarks Samples were analysed by gas chromatography which was able to distinguish the three components. Less than 10% hydrolysis was observed at pH 4, 7 and 9 after 5 days at 50°C for all but Component A at pH 9. This is likely to result from the low water solubility.

TEST FACILITY SafePharm (2004a)

Partition Coefficient (n-octanol/water) log P_{ow} > 6.20

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC Method.

TEST FACILITY SafePharm (2004a)

Adsorption/Desorption log K_{oc} > 5.63

METHOD EC Directive 92/69/EEC C.19 Adsorption Coefficient.

Remarks HPLC Screening Method.

TEST FACILITY SafePharm (2004a)

Dissociation Constant Not determined.

Remarks The notified chemical does not contain functional groups capable of undergoing association or dissociation.

Particle Size Not applicable to a semi-solid.

Flash Point 214ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.

Remarks Closed cup equilibrium method.

TEST FACILITY SafePharm (2005a)

Flammability Limits Not determined.

METHOD Based on the flash point result the notified chemical is not classified as flammable according to ADG criteria.

Based on the known properties of the notified chemical and its chemical structure,

negative results are predicted for flammability in contact with water or with an oxidising substance. Negative results are also predicted for pyrophoric properties.

Based on the high auto-ignition temperature, the notified chemical is not liable to spontaneous combustion.

Autoignition Temperature 360ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks None.
TEST FACILITY SafePharm (2005a)

Explosive Properties Predicted to be non-explosive.

Remarks The chemical does not have oxidising properties based on known chemical and physical properties and its chemical structure.

There is no known incompatibility with other substances.

There are no known conditions contributing to instability.

The notified chemical is considered to be stable. However, the chemical will burn if involved in a fire, evolving noxious fumes (e.g. carbon oxides).

Reactivity

Remarks The chemical does not have oxidising properties based on known chemical and physical properties and its chemical structure.

There is no known incompatibility with other substances.

There are no known conditions contributing to instability.

The notified chemical is considered to be stable. However, the chemical will burn if involved in a fire, evolving noxious fumes (e.g. carbon oxides).

7. TOXICOLOGICAL INVESTIGATIONS

Acute oral toxicity and bacterial mutagenicity were tested for the notified chemical. All other toxicity end points were assessed using data from studies using a close chemical analogue that was previously notified as STD/1136 by the current notifier.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 >2500 mg/kg bw low toxicity
Rat, acute dermal	low toxicity
Rat, acute inhalation LC50	not performed
Rabbit, skin and eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days.	NOEL 50 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley (CD)
Vehicle Arachis oil BP
Remarks - Method None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 female	2000	0/3
2	3 female	2000	0/3

LD50 >2500 mg/kg bw
Signs of Toxicity One animal failed to gain bodyweight during the second week of the study.

No other adverse signs were observed.
Effects in Organs None observed.
Remarks - Results None.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY SafePharm (2004b)

7.2. Acute toxicity – dermal

TEST SUBSTANCE A chemical analogue of the notified chemical.

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain Rat/Crl: CD (SD) IGS BR
Vehicle None.
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	There were no signs of local toxicity.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity. One female showed a bodyweight decrease in the first week of the study but expected body weight gain during the second week. All other animals showed expected bodyweight gains throughout the study.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	None.

CONCLUSION The analogue chemical is of low toxicity via the dermal route.

TEST FACILITY SafePharm (2004d)

7.3. Acute toxicity – inhalation

The test was not conducted. The notified chemical is a non-volatile semi-solid hence is not expected to be an inhalation hazard when imported as a component of liquid formulations.

7.4. Irritation – skin

TEST SUBSTANCE A chemical analogue of the notified chemical.

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	72 hours
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	0.3	0.7	0.7	2	48 hours	0
Oedema	0.3	0.3	0.3	2	24 hours	0

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

Remarks - Results Area of test site: dorsal/flank region. Well-defined erythema and slight oedema was observed in all test animals at the 1-hour observation period, which resolved over 24 to 48 hours.

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY SafePharm (2002a)

7.5. Irritation – eye

TEST SUBSTANCE A chemical analogue of the notified chemical.

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 No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0.3	0.3	2	24 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0.3	0	2	24 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks – Results Minimal to moderate conjunctival irritation was noted in all animals one hour after treatment with minimal conjunctival irritation in 2 animals at the 24-hour observation period. No signs of irritation were observed in one animal at 24 hours. No signs of irritation were observed in any animal at the 48-hour observation period.

CONCLUSION The analogue chemical is slightly irritating to the eye.

TEST FACILITY SafePharm (2002b)

7.6. Skin sensitisation

TEST SUBSTANCE A chemical analogue of the notified chemical.

METHOD Magnusson and Kligman maximisation method
OECD TG 406 Skin Sensitisation
EC Directive 96/54/EC B.6 Skin Sensitisation
Species/Strain Guinea pig/Dunkin Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
Intradermal: Not determined. At 1% (v/v) in arachis oil BP, moderate and confluent erythema was seen at injection sites, persisting for >72 hours.
Topical: Not determined. At 25% (v/v) in arachis oil BP, discrete or patchy erythema was seen up to 24 hours.
MAIN STUDY
Number of Animals Test Group: 10 Control Group: 5
INDUCTION PHASE Induction Concentration:
intradermal: 1% (v/v) in arachis oil BP
topical: undiluted

Signs of Irritation	Intradermal injection: Moderate and confluent erythema was seen at 24 hours and 48 hours in all treated animals. Discrete and patchy erythema was seen at 24 hours and 48 hours in all control animal receiving 100% arachis oil BP Topical: Staining was noted at the topical induction site of all test group animals, lasting for 2 hours, but did not affect the evaluation of skin responses. Moderate and confluent erythema, with slight oedema, was seen in every test group animal at 2 hours. Bleeding was noted in three test group animals at the 2-hour observation. Discrete or patchy to moderate and confluent erythema, without oedema, was seen in every test group animal after 24 hours. Small superficial scattered scabs were noted in one test group animal. No reactions were seen for any animals receiving the control dose.
CHALLENGE PHASE	
1st challenge	intradermal: not conducted topical: 75% (v/v) in arachis oil BP – right flank 50% (v/v) in arachis oil BP – right flank
Remarks - Method	Erythema and oedema were assessed 2 hours after topical induction, in addition to the usual assessment after 24 hours. Both 75% and 50% concentrations of the notified chemical were used in the topical challenge phase to ensure that the maximum non-irritant concentration was used in the study. Test sites were not pre-treated with sodium lauryl sulfate before topical induction.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after 1st challenge*	
		24 h	*48 h*
Test Group	75% (right flank)	1	0
	50% (left flank	0	0
Control Group	0	0	0

Remarks - Results	The slight erythema observed in one animal receiving a challenge dose of 75% at the 24 hour observation period, but not the 48 hours observation period, was most likely residual erythema caused by irritation.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.
TEST FACILITY	SafePharm (2002c)

7.7. Repeat dose toxicity

TEST SUBSTANCE	A chemical analogue of the notified chemical.
METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Crl:CD (SD) IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Arachis oil BP
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	0
II (low dose)	10/sex	5	0
III (mid dose)	10/sex	50	0
IV (high dose)	10/sex	1000	0

Mortality and Time to Death

All animals survived until the end of the study.

Clinical Observations

Increased salivation was detected up to one hour after dosing for animals of either sex treated with 1000 mg/kg bw/day from day 14 onwards. This is commonly observed following oral gavage administration of a slightly irritant or unpalatable test material. Males treated with 50 or 1000 mg/kg bw/day showed a statistically significant increase in sensory reactivity parameters. These were attributed to abdominal discomfort associated with the gavage procedure.

Males treated with 5 and 50 mg/kg bw/day showed a statistically significant ($p<0.05$) increase in bodyweight gain during week 2 compared to controls (15% and 19% respectively) with all other weekly bodyweight gains not significantly different from controls. In the absence of a dose-related response, or findings in other weeks, this is considered not to be of toxicological significance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Blood chemistry analysis revealed that males treated with 1000 mg/kg bw/day showed statistically significant increases ($p<0.05$) in cholesterol (17%) and creatinine (8%) levels. In the absence of a dose-related response this is considered not to be of toxicological significance.

Males treated with 1000 mg/kg bw/day showed a statistically significant decrease in erythrocyte count ($p<0.05$, 4%). In the absence of any other haematological changes, and given the marginal nature of the decrease, this is considered not to be of toxicological significance.

Effects in Organs

The following effects were observed in the 1000 mg/kg bw/day group:

- increased absolute spleen weight ($p<0.05$, 20%) in males.
- increased relative kidney weight ($p<0.01$, 9%) in females
- increased absolute ($p<0.01$, 22%) and relative adrenal weight ($p<0.01$, 20%) in females.

The toxicological significance of these findings is uncertain as there were no supporting histopathology findings.

In the liver, the following effects were observed:

- increased absolute liver weights in males ($p<0.001$, 36%) and females ($p<0.001$, 24%), and
- increased relative liver weights in males ($p<0.001$, 28%) and females ($p<0.001$, 22%).

A marginal effect on hepatocyte size was observed in females treated with 1000 mg/kg bw/day ($p<0.05$) with a few animals from this group exhibiting centrilobular hepatocyte enlargement.

Remarks – Results

The most marked changes occurred in the liver of animals in the 1000 mg/kg bw/day group. The elevated relative and absolute liver weights in male and female rats are suggestive of an adaptive response in the liver to the notified chemical in the high dose treatment group. Animals in the 1000 mg/kg bw/day also showed increases in spleen, kidney and adrenal weight. None of these changes were observed in the 50 mg/kg bw/day group.

CONCLUSION

The No Observed Effect Level (NOEL) of the analogue chemical in male and female rats was established as 50 mg/kg bw/day in this study on the basis of both relative and absolute weight changes in the liver at 1000 mg/kg bw/day.

TEST FACILITY SafePharm (2004e)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
USA, EPA (TSCA) OPPTS harmonised guidelines
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	β-naphthoflavone- and phenobarbitone-induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Acetone.
Remarks - Method	None.

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 observed up to 5000.	None observed.	5000	None observed.
Test 2		None observed.	5000	None observed.
Present		None observed.	5000	None observed.
Test 1	None observed up to 5000.	None observed.	5000	None observed.
Test 2				

Remarks - Results Positive control chemicals induced marked increases in the frequency of revertant colonies. Concurrent negative controls were within historical ranges.

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

TEST FACILITY SafePharm (2004c)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE A chemical analogue of the notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Lymphocytes cultured from the blood of a suitable volunteer
Metabolic Activation System	S9
Vehicle	Acetone
Remarks - Method	2500 µg/ml was used as the maximum dose due to precipitation at 5000 µg/ml.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 39, 78.1, 156.25, 312.5*, 468.75*, 625*	24 hours	24 hours
Test 2	0*, 78.1, 156.25, 312.5, 625*, 1250*, 2500*	4 hours	24 hours
Present			
Test 1	0*, 78.1, 156.25, 312.5, 625*, 1250*, 2500*	24 hours	24 hours
Test 2	0*, 78.1, 156.25, 312.5, 625*, 1250*, 2500*	4 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not performed	Up to 39% mitotic inhibition	>2500 µg/plate	negative
Test 2	Not performed	Up to 14% mitotic inhibition	>2500 µg/plate	negative
Present				
Test 1	Not performed	Negligible mitotic inhibition	>2500 µg/plate	negative
Test 2	Not performed	Up to 22% mitotic inhibition	>2500 µg/plate	negative

Remarks - Results

The notified chemical did not induce a statistically significant increase in the frequency of cells with chromosomal aberrations in either the absence or the presence of a liver enzyme metabolic system in either of two separate experiments.

Treatment with positive control substances induced distinct increases in cells with structural chromosomal aberrations.

CONCLUSION

The analogue chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

SafePharm (2004f)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Mixed culture of activated sewage sludge micro-organisms (Severn Trent Water plc sewage treatment works); tripled rinsed; suspended solids 3.0 g/L prior to use.
Exposure Period	28 d
Auxiliary Solvent	None
Analytical Monitoring	CO_2 in produced gas and dissolved organic carbon in solution
Remarks - Method	Test material (38.4 g) was dispersed directly in the culture medium (200 mL) and subjected to ultrasonication (30 mins) prior to dispersal in inoculated culture medium made up to 3 L and added to 5 L glass bottles. Bottles were sealed and CO_2-free air bubbled into the stirred solutions (40 mL/min) and maintained in the dark. Initial test material concentration was 12.8 mg/L (10 mg C/L). The CO_2 produced was captured and analysed approximately daily. Test temperature 21°C. Each test vessel was inoculated to give a final concentration of 30 mg suspended solids/L. Test solutions pH range: 7.4-7.5.

RESULTS

Test substance (12.8 mg/L)		*Sodium benzoate (17.1 mg/L; 10 mg C/L)*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0	1	22
2	0	2	47
6	9	6	60
14	42	14	82
20	47	20	93
28	49	28	95

Remarks - Results	All test validation criteria were met. The reference substance (sodium benzoate) degraded by 95% after 28 d confirming the suitability of the inoculum and test conditions. In the toxicity control, the test material attained 68% degradation by day 28 confirming that the test substance was not toxic to the sewage micro-organisms used in the study.
CONCLUSION	The test material did not achieve 60% degradation after 28 days; hence, it was not readily biodegradable under the test conditions.
TEST FACILITY	SafePharm (2003)

8.1.2. Bioaccumulation

Not determined. The notified chemical has an affinity for lipids and may potentially be capable of passing biological membranes; however, the limited potential for release to water indicates a low potential for accumulation in aquatic organisms.

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	136 mg $CaCO_3$/L
Analytical Monitoring	GPC
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 1 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 and a glass wool plug was not used when siphoning. Based on the results of the range-finding test, the definitive test was conducted at a nominal concentration of 1000 mg/L WAF. Ten fish were allocated to each test vessel of treatment groups and controls. The pH readings (7.6-8.2) temperature (13.0-14.4°C) and dissolved oxygen concentrations (6.7-10.0 mg/L) were within acceptable levels during the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	20	0	0	0	0	0
1000	0.106-0.701*	30	0	0	0	0	0

*Measured concentrations of the individual components of the test material in fresh solutions were in the range 0.106-0.701 mg/L for each of the components.

LL50	>1000 mg/L WAFat 96 hours.
NOEC	1000 mg/L WAF at 96 hours.
Remarks – Results	The test material consists of a number of components, given that toxicity cannot be attributed to a single component or a mixture of components but to the test material as a whole the results are based on the nominal loading rates. After each 24 h dosing period there was a general decline tp 0.0557-0.398 mg/L of the components. All organisms of the control and the treatment groups survived the 96 h toxicity test. No sublethal effects were observed.

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

TEST FACILITY SafePharm (2004g)

8.2.2. Acute 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	142 mg $CaCO_3$/L
Analytical Monitoring	GPC

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 1 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 micro dispersion or undissolved material were present in the WAFs and a glass wool plug was used when siphoning. Based on the results of the range-finding test, the definitive test was conducted at a nominal concentration of 1000 mg/L WAF. Ten daphnids were allocated to each test vessel of treatment groups and control. Four replicate test vessels were prepared with duplicate controls. The pH readings (7.4-8.2) temperature (20.8-20.9°C) and dissolved oxygen concentrations (5.9-8.6 mg/L) were within acceptable levels during the test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
1000	2.12-2.38*	40	0	0

*Measured concentrations of the individual components of the test material in the fresh solutions were in the range 2.12-2.38 mg/L for each of the components.

EL50	>1000 mg/L WAF at 48 hours
NOEC	1000 mg/L WAF at 48 hours
Remarks - Results	The test material consists of a number of components, given that toxicity cannot be attributed to a single component or a mixture of components but to the test material as a whole the results are based on the nominal loading rates. After each 24 h dosing period there was a general decline tp 1.50-1.57 mg/L of the components. No immobilisation of daphnia was observed throughout the duration of the 48 h toxicity test. No sublethal effects were observed.

CONCLUSION	The test substance is considered to be non-toxic to Daphnia up to the limit of its water solubility.
TEST FACILITY	SafePharm (2004h)

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	14.94 mg/L $CaCO_3$
Analytical Monitoring	GPC
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 24 h and allowed to settle for 1 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 micro dispersion were present in the WAFs and a glass wool plug was used when siphoning.

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

Analysis of the test samples t 0 hours showed measured concentrations of between 0.451 and 0.571 mg/L for the individual components of the test material. The test material consists of a number of components, given that toxicity cannot be attributed to a single component or a mixture of components but to the test material as a whole the results are based on the nominal loading rates. After 96 hours there was a decline in the measured concentrations of all three components to below the limit of quantification (LOQ) of the analytical method 0.248 mg/L.

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.

CONCLUSION

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

TEST FACILITY

SafePharm (2004i)

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 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 substance (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	Test substance	>1000 mg/L	(30 minutes)
	Test substance	>1000 mg/L	(3 hours)
	Reference	10 mg/L	(3 hours)
NOEC	(3 hours) =1000 mg/L		
Remarks – Results	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 notified chemical 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 (2004j)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported in formulated lubricant oils. 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 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.

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 can be calculated if it is assumed that all of the notified chemical that is expected to be released into the stormwater drains is 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 700 kg and the annual volume of water drained from this region estimated to be approximately 250×10^6 m^3, the resultant PEC is approximately 2.8 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 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, Daphnia, algae and sewage micro-organisms provided, the notified chemical is not toxic up to the limit of water solubility (estimated as < 97 μg/L).

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. Therefore, the worst-case PEC (2.8 μg/L) is expected to be below possible toxic levels and the resulting risk quotient (RQ = PEC/PNEC) would be below 1. Further, the PEC is based on a worst case and the low water solubility of the notified chemical together with its limited release to the aquatic environment (mainly via stormwater drainage) can expect to minimise the amount remaining in solution to cause acute toxicity. The ability of the notified chemical to become associated with 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 acceptable. 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

Factory fill – vehicle manufacturers

The filling operator will hold a handle attached to the delivery tube from the 200 L import drum to the engine oil filler point. During this operation, and transfer of empty drum residue to the new drum, dermal exposure is possible, and ocular exposure is also possible in the case of accidental spills or splashes. Operators will wear goggles, gloves and an apron and therefore exposure should be minimised.

Service garage

Dermal exposure is possible during drawing off of oil into a smaller vessel from the 200 L drum and pouring from the vessel into the oil filler point. Workers are expected to wear overalls, however it is not likely that goggles or gloves will be routinely worn so exposure can be significant.

9.2.2. Public health – exposure assessment

The public will be exposed to the notified chemical at concentrations up to 1% in lubricating oil products. Consumers may use disposable gloves to keep their hands clean, however, it is not likely that any other personal protective equipment will be routinely used. Due to the low concentration of the notified chemical in end use products, and the relatively low frequency of use for most consumers, public exposure is expected to be low and intermittent.

9.2.3. Human health – effects assessment

The notified chemical was tested for acute oral toxicity in rats and mutagenicity in bacteria but data on the other endpoints were accepted for a close analogue previously notified by the same notifier. The notified chemical was of low acute oral toxicity in rats (LD50 > 2500 mg/kg bw) and low acute dermal toxicity in rats (LD50 > 2000 mg/kg bw). It was a slight skin irritant and a slight eye irritant in rabbits. It was not a skin sensitiser in guinea pigs and was not genotoxic in bacteria or human lymphocytes in vitro. The NOEL for oral repeat dose toxicity in rats was 50 mg/kg bw/day in a 28-day oral repeat dose study with effects seen at 1000 mg/kg bw/day based on limited to changes in organ weights without histopathological correlates.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical was determined to be of low intrinsic hazard based on a full toxicological data package for a standard notification. The majority of the data were for a close analogue but are applicable to the notified chemical. In addition the imported lubricants contain the notified chemical at a low concentration of up to 1%. On these bases the risk to workers adding lubricants during factory fill of new cars or standard garage services is low. In addition work practices during factory fill should preclude high exposure to lubricants. However, mechanics performing oil changes do not routinely wear gloves and exposure can be prolonged. Nevertheless, the risk to workers even in this worst case should be low. Although the notified chemical is predicted to be sensitising on the basis of Rosin content, the content in the imported lubricants should be 0.02% and therefore the lubricants are unlikely to be skin sensitisers.

9.2.5. Public health – risk characterisation

The public may be exposed during engine oil changes although for individuals these changes will be intermittent and of short duration. Given the low hazard of the notified chemical and its low concentration in lubricants, the risk of adverse health effects to the public should be negligible. As noted above, although the notified chemical is predicted to be sensitising on the basis of Rosin content, the content in the imported lubricants should be 0.02% and therefore the lubricants are unlikely to be skin sensitisers.

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

10.1. Hazard classification

Based on the available data the notified chemical 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

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 described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical 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 chemical 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 implement the following safe work practices to minimise occupational exposure during handling of the notified chemical [as introduced]:
  - *Avoid contact with eyes and skin*
- 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.

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

– the concentration of the notified chemical in imported products exceeds 1% (w/w)

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.

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