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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

HiTEC 055

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Afton Chemical Asia Pacific LLC (ABN: 99 109 644 288)
Level 9, Berry Street
North Sydney NSW 2059

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
CAS number
Molecular formula
Structural formula
Molecular weight
Spectral data
Purity
Impurities
Import volume
Use details

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/716

NOTIFICATION IN OTHER COUNTRIES
US PMN (2004)
Canada Schedule I (2005)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
X-15249

MARKETING NAME(S)
HiTEC 055

METHODS OF DETECTION AND DETERMINATION

METHOD	IR spectroscopy, HPLC-MS
Remarks	Reference spectra were provided

3. COMPOSITION

DEGREE OF PURITY

> 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. Approximately 80% of the notified chemical will be imported as a component of products in bulk in drums, or marine isotanks containers at up to 1.2% for reformulation in to end-use products. Approximately 20% of the notified chemical will be imported as a component of end-use products at up to 0.10%.

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

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

USE
The notified chemical will be used as an additive in end-use lubricant products such as gear lubricant or vehicle transmission oil at concentration of 0.05-0.10%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney, Melbourne, Brisbane and Perth

IDENTITY OF MANUFACTURER/RECIPIENTS
Major lubricating oil manufacturers.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in marine isotanks or 205 L steel drums as a component of a lubricant additive package. Immediately following import, the isotanks or drums will be transported by road or rail to lubricating oil manufacturers. The lubricant additive will be reformulated to finished gear lubricant or vehicle transmission oil, which will be packaged into 1 L bottles, 4 L bottles, or 205 L or 250 L drums.

5.2. Operation description

The notified chemical will not be manufactured in Australia. The notified chemical will be imported in ready to use end-products (0.05-0.10%, notified chemical) or as a component of lubricant additive packages (0.6-1.2%, notified chemical) for reformulation.

Storage
Lubricant additive packages (containing 0.6-1.2% notified chemical) imported in marine isotanks are transferred to storage tanks at customers blending facilities. Hose lines are connected manually to the isotanks and the additive package is pumped (using an air back flush system to prevent spilling automatically) into storage tanks. Lubricant additive packages imported in drums are stored at customers' warehouses until required for reformulation.

Blending
Lubricant additive packages containing the notified chemical are transferred from local storage tanks to the blending vessel occurs by automated means using hard piping and computer-controlled valves. Lubricant additive packages containing the notified chemical from imported drums are transferred to a

blending tank by manual decanting or automated drum pumping. The charging of the blending tank with the additive takes approximately 10 minutes. The blending process is automated, occurs in a closed system at 40ºC to 70ºC and takes up to one hour. Quality control sampling may occur immediately after blending.

Packaging
Once the blending is finished, the blended oil products (containing 0.05-0.10% w/w notified chemical) is automatically filled into 1 L bottles, 4 L bottles or 205 L or 250 L drums. The filling of the 1 L and 4 L bottles is highly automated and drums are typically filled using automated weight scales.

End-Use
The majority of the blended oil products (80-90%) containing the notified chemical will be sold into the industrial market for use by OEMs and 10-20% will be sold to automotive mechanics. The blended oil products will be added to and drained from systems during these operations. Do-it –yourself enthusiasts may drain the blended oil products from the systems.

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
Reformulation (blending, packaging and cleaning)	2-3/site	0.5 – 1 hour	200 days/year
Quality control (laboratory staff)	1-2/site	0.20-0.25 hours	200 days/year
Maintenance	2-3/site	1-3 hours	10 days/year
End-users (OEM's & Service Professional)	> 100	1-8 hours	200 days/year

Exposure Details
Transport and Storage
During transport of the lubricant additive package containing 0.60-1.20% (w/w) notified chemical and reformulated lubricant additive products containing 0.05-0.10% (w/w) of the notified chemical workers may come into dermal and ocular contact with the notified chemical through accidental leaks and spillages of the drums and containers and during the connection/disconnection of transfer lines. Typically, these workers are likely to wear overalls, safety boots, and gloves when handling drums and/or containers.

Blending
During the reformulation process, dermal and ocular exposure to the notified chemical at up to 1.2% is possible due to incidental splashes and spillages arising during certain blending processes. For example, when pumping the imported product from drums into blending tanks when connecting/disconnecting transfer lines workers may be potentially exposed to the notified chemical at a concentration up to 1.20%.

The blending process occurs in an automated closed system, thereby excluding the potential for occupational exposure.

The blending facilities are well ventilated, with control systems for accidental spills and wastewater treatment. Typically, workers involved in the blending activities receive training in the handling of additive packages, and wear personal protective equipment such as gloves, eye protection, protective clothing as required.

Packaging
Once blended the formulated products are packaged in 1L bottles, 4 L bottles, or 205 or 250 L drums. The filling of the 1 L and 4 L bottles is highly automated. The drumming facilities typically uses automated weight scales to fill the drums and workers observe the filling from 1-2 metres away to ensure drum filling apparatus properly enters the drum before filling. Once filling is completed workers are required to insert bungs and label the containers as required. Dermal contact with contaminated drum surfaces may occur.

Cleaning and Maintenance
The blending tank and the transfer lines are cleaned by rinsing with clean lubricating oil. Maintenance workers handling the equipment used for blending and filling may come into dermal contact with residues containing the notified chemical.

Quality control
Laboratory staff will take samples of the blended oil products for testing. During sampling and analysis of the blended product there may be dermal contact.

End Users
Occupational exposure to the products containing the notified chemical will also occur at motor manufacturing and repair facilities throughout Australia. End users may be exposed to the finished products containing 0.05-0.1% (w/w) of the chemical. Exposure may occur during the transfer the blended oil products from the storage containers into the vehicle being serviced and during cleaning of equipment.

Typically Original Equipment Manufacturer (OEM) workers and automotive mechanics have been trained in the proper handling of lubricants products and typically wear personal protective equipment (PPE) including gloves, eye protection and protective clothing as required.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. It will be imported as part of either a lubricant additive package containing 0.60 to 1.20 wt % of the notified chemical or as part of a finished lubricating oil containing 0.05 to 0.10 wt % of the notified chemical. It is estimated that approximately 80% of the total import of notified chemical will be imported as part of a lubricant additive package (a maximum of 1600 kg/year) with the remaining 20% imported as part of a finished lubricating oil (a maximum of 400 kg/year). Local operations will include transport, storage, blending and filling/packaging.

Additive packages and finished lubricants will be imported into Australia in isotanks and drums. Using ISO 9001 and ISO 14001 procedures, spills and leaks during transport, storage and blending are expected to be <0.001% (<20 g/year of the notified chemical) before waste treatment. Any spills or leaks are sent to the facility's on-site chemical/storm waste water system that includes a water and oil separator which removes approximately 90% of the oil and notified chemical from the waste water. The waste oil containing the notified chemical is then sent for incineration or to a used oil recycler who re-refines the waste oil into fresh lubricant oil base stock using hydrocracking technology. The bottoms product containing the notified chemical from the re-refining process becomes asphalt. The waste water from the separator process is sent to a pond where it is further treated by induced air-flotation and biological treatment with the waste sludge incinerated off-site. After biological treatment, the waste water is often further filtered through a biodisk and sand before being released. This additional process removes a further 8% of the spilled notified chemical (a total of 98% reduction from the original spill). In total, <0.4 g/year notified chemical will be released to the environment from spills during unloading.

Unlike the blending tanks, the isotanks and drums are generally cleaned after use with oil, which is sent for used oil recycling. About 0.1 wt % of the oil would remain in the drum or isotank after emptying. Therefore, a maximum of 2 kg/year of the notified chemical would be sent to recycling, resulting in 40 g/year to be released due to cleaning (based on 98% removal efficiency).

The blending operations will take place at specially constructed sites owned and operated by major lubricant manufacturers. It is anticipated that there will be minimal release of the notified chemical during transfer from the storage containers to the blending tanks, as a special air back flush system prevents any spillage. Blending occurs in fully enclosed automated systems. Blending tanks will be cleaned with lube oil, which will typically be recycled during subsequent blending, or incinerated. Any spills incurred in the blending operations will be contained within concrete bunds and either reclaimed or sent to on-site waste-water treatment facilities where residual hydrocarbon based products will be separated from the aqueous stream by the Australian Institute of Petroleum (API) process.

The notified chemical will be blended into finished lubricant at a maximum of 0.10% by weight. The filling processes are computer automated, so minimal spills due to loading are expected. Losses from spills and leaks in the filling/packaging process are expected to be <200 g of the finished lubricant, or 0.2 g of the notified chemical per year.

RELEASE OF CHEMICAL FROM USE

The finished lubricants will be sold in 1 and 4 L plastic containers and 205 or 250 L drums to industrial and professional service customers. At the end of its useful life, having performed its function as a friction modifier, the notified chemical will substantially be no longer present in the spent fluid.

Very little of the finished lubricant is expected to be available to general public consumers. The filling of new automobiles and related equipment will be by Original Equipment Manufacturers (OEMs) and the filling of on-road automobiles at service centre will be performed by professionals. There may be some accidental losses when finished lubricant is added to the transmission or gear box. In these cases, any spills of the finished lubricant by OEMs and service professionals are expected to be disposed of responsibly either to oil recyclers or by incineration.

The only potential for release of the chemical by the public is by do-it-yourself (DIY) enthusiasts who may drain the spent fluid from the transmission or gear box of their vehicle. In general, draining spent lubricant from transmissions and gear boxes is not a routine practice for public users. However, the notified chemical is not expected to be present in the spent fluid as it must degrade over time in order to perform its intended function. Therefore, the estimated release is negligible and any spills are expected to be disposed of responsibly either to oil recyclers or by incineration.

In the closed systems of the transmissions and gear boxes, there is no expected release of the chemical to the environment under normal conditions of use, except for oil leaks. Estimates for the release of the notified chemical due to on-road leaks is a maximum of 2 g/year. Any releases due to leaks would be diffuse.

A survey by the AIP (1995) indicates that around 86% of oil changes take place in specialized automotive service centers, where old oil drained from crankcases could be expected to be disposed of responsibly either to oil recycling or by incineration. Assuming this is the case, negligible release of the notified chemical should result from these professional activities. The remaining 14% are removed by 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. Meinhardt (2002) estimated that DIY activities account for 7-10% of the unaccounted used oil. The finished fluids containing the notified chemical will be for Automatic Transmissions and Gear Axles, for which draining of the spent fluids are even more likely than for the crankcase (engine) oils, to be carried out in specialized service centers by specialists with less irresponsible disposal practices.

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. However, at the end of its useful life, most of the notified chemical will no longer be present in the spent fluid.

In a worst case scenario, assuming that only 75% of the notified chemical is degraded during use and assuming that 14% of all used oil containing the notified chemical will be removed by DIY enthusiasts, the notified chemical (based on the maximum import volume of 2 tonnes) under DIY activities could be collected for recycling (~ 14 kg), buried or disposed of in landfill (~ 17.6 kg), disposed of in stormwater drains (~ 3.6 kg) and used in treating fence posts, to kill weeds or disposed of in other ways (~ 36 kg).

Therefore, at most, ~3.6 kg of the total import volume of the notified chemical could be expected to enter the aquatic environment via disposal into the stormwater system. Releases resulting from use or disposal of used oil would be expected to be very diffuse.

5.5. Disposal

For finished lubricant blenders, residual material left in the blend tank or transfer lines are flushed with clean lubricating oil and the washing is then typically used as diluent oil for subsequent blends rather than be incinerated.

In the case of accidental spillage at blending facilities, the material is sent to the facility's on-site chemical/storm waste water system that includes a water and oil separator which removes approximately 90% of the oil and notified chemical from the waste water. The waste oil containing the notified chemical is then sent for incineration or to a used oil recycler who re-refines the waste oil into fresh lubricant oil base stock. The bottoms product containing the notified chemical from the re-refining process becomes asphalt.

The waste water from the blending facility's separator process is sent to a pond where it is further treated by induced air-flotation and biological treatment with the waste sludge incinerated off-site. After biological treatment, the waste water is often further filtered through a biodisk and sand before being released.

Any spills of the finished lubricant is expected to be disposed of responsibly either to oil recyclers or by incineration.

5.6. Public exposure

Dermal and ocular exposure to up to a maximum of 0.1% notified chemical may occur by do-it-yourself enthusiasts who may drain the spent fluid from the transmission or gear box of their vehicle. The notified chemical is not expected to be present in the spent fluid, as it must degrade over time in order to perform its intended function.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White waxy solid

Melting Point/Freezing Point 37 to 64 ± 0.5°C

METHOD OECD TG 102 Melting Point/Melting Range.
Remarks Determined by differential scanning calorimetry.
Statement of GLP.
TEST FACILITY Safepharm (2006a)

Boiling Point >400°C at 102.05kPa

METHOD OECD TG 103 Boiling Point.
Remarks Determined by differential scanning calorimetry.
No significant oxidative or thermal decomposition occurred up to 400°C.
Statement of GLP.
TEST FACILITY Safepharm (2006a)

Density 1010 kg/m^3 at 22.0 ± 0.5 °C

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Determined using the gas comparison pycnometer method.
Statement of GLP.
TEST FACILITY Safepharm (2006a)

Vapour Pressure < 6.6 x 10^{-7} Pa at 25 °C

METHOD OECD TG 104 Vapour Pressure.
Remarks The calculation of vapour pressure was performed using the Handbook of Chemical Property Estimation Methods. The predicted value was determined using

MPBPWIN Version 1.41 based on three components of the test material.
Statement of GLP.

TEST FACILITY Safepharm (2006b)

Water Solubility $< 9 \times 10^{-4}$ g/L at 20 °C

METHOD OECD TG 105 Water Solubility.

Remarks No definitive experimental determination of the water solubility of the test material was possible due to the surface active properties of the test material. Using a flask method, the mixtures were shaken at 30°C for 72 h and then equilibrated at 20ºC for a period of 24 h. The water solubility was determined visually, from the excess and undissolved test material, to be less than 9×10^{-4} g/L of solution at 20.0 ± 0.5ºC.

By monitoring the major component in the test material by HPLC-MS and computer estimations performed by a fragment constant methodology, the solubility was determined to be less than or equal to 2.2×10^{-4} g/L of solution at 20.0ºC. However, due to the readiness of the test material to form emulsions in water, the stability of these emulsions to centrifugation and the unsuitability of filtration techniques for low concentration solutions of hydrophobic substances, it was concluded that the analytical result may continue to overestimate the true water solubility of the test material.

TEST FACILITY Safepharm (2006a)

Hydrolysis as a Function of pH

Remarks No assessment of the hydrolytic stability was possible by Method 111 of the OECD Guidelines for Testing of Chemicals, 13 April 2004, due to negligible solubility of the test material in water.

The method guideline limits the maximum test solution concentration to that of half the water solubility of the test material. Although in this case no definitive water solubility value could be determined due to the surface active properties of the test material, a computer estimation of the water solubility of each individual component was generated. This value was 1.66×10^{-3} mg/L of solution for the main component of the test material. Therefore the test material was concluded to be essentially insoluble in water and the maximum permitted test concentration was <1 µg/L.

TEST FACILITY Safepharm (2006a)

Partition Coefficient (n-octanol/water) log Pow at 20ºC = 7.65 – 7.76

METHOD KOWWIN, version 1.67, © 2000 US Environmental Protection Agency

Remarks No experimental determination of the partition coefficient was possible due to the surface active properties of the test material. Using predictive fragment constant methodology software, KOWWIN, version 1.67, © 2000 US EPA, the partition coefficient of the test material was estimated to be $\log_{10} P_{ow}$ of 7.65 - 7.76.

TEST FACILITY Safepharm (2006a)

Adsorption/Desorption – screening test log K_{oc} = 4.83 – 5.06 based upon three components

METHOD QSAR calculated based upon EC Commission Directive 93/67/EEC

Remarks No determination of the adsorption coefficient was possible due to the surface active properties of the notified chemical. Furthermore, two of the three components present in the test material account for 95% of the acidic functional groups. The HPLC estimation method is not valid for either surface active substances or organic acids. Therefore, an estimate of the adsorption coefficient was obtained by calculation using Quantitative Structure Activity Relationships (QSAR), the details of which are provided in the technical guidance documents in

support of EC Commission Directive 93/67/EEC on risk assessment for new substances (European Commission 1996).

TEST FACILITY Safepharm (2006a)

Dissociation Constant pKa = 2.31 ± 0.50 units

METHOD Value predicted using software by Advanced Chemistry Development Inc., ACD/pKa, version 8.03

Remarks No determination of the dissociation constant was possible due to negligible solubility of the test material in water. The dissociation constant was estimated using specialized predictive software, Advanced Chemistry Development Inc., ACD/pKa, version 8.03. The predicted value of the dissociation constant for the donation of a proton by the major component, accounting typically for 91.1% composition of the test material, was 2.31 ± 0.50 units.

TEST FACILITY Safepharm (2006a)

Particle Size Not determined.

Remarks Test not applicable – substance is a waxy solid with a low melting point.

Flash Point 129 ± 2 ºC

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

Remarks Determined using the closed cup equilibrium method.
Statement of GLP.

TEST FACILITY Safepharm (2005)

Flammability Not determined.

Remarks The notified chemical is a low melting point solid. Based on the flash point the notified chemical is likely to be combustible.

Autoignition Temperature 354 ± 5ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks Statement of GLP.

TEST FACILITY Safepharm Laboratories Ltd. (2006b)

Explosive Properties Not Explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

Remarks Expert Statement.
A negative result is predicted on structural grounds.
The substance is not expected to have explosive properties, since there are no chemical groups that would infer explosive properties and the oxygen balance of the chemical is < -200

TEST FACILITY Safepharm Laboratories Ltd. (2006b)

Oxidising Properties Non-oxidising

METHOD EC Directive 92/69/EEC A.21 Oxidizing Properties (Liquids).

Remarks Expert Statement.
A negative result is predicted on structural grounds

TEST FACILITY Safepharm Laboratories Ltd. (2006b)

Reactivity

Remarks The notified chemical is considered to be non-oxidizing and is not explosive. No incompatible chemicals have been identified with the notified chemical. Typical decomposition products are oxides of carbon and phosphates, no other toxic gases/vapours have been identified. The notified is expected to be degrade over

time under the conditions of use.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 >2000 mg/kg bw, low toxicity
Rat, acute dermal	LD50 >2000 mg/kg bw, low toxicity
Rabbit, skin irritation	irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 30/mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure – Limit test
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Corn oil
- Remarks - Method: Statement of GLP. No significant protocol deviations.

RESULTS

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

- LD50: >2000 mg/kg bw
- Signs of Toxicity: Clinical abnormalities observed during the study included transient incidences of congested breathing, few faeces, soft stools, mucoid stools, faeces small in size, rough coat and faecal strain. Slight bodyweight loss was noted in one female during the study from days 7-14.
- Effects in Organs: No abnormal findings were observed at necropsy.

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

TEST FACILITY CRL (2004)

7.2. Acute toxicity – dermal

TEST SUBSTANCE 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/Sprague-Dawley
- Vehicle: Arachis oil BP (used to moisten the test substance)
- Type of dressing: Semi-occlusive.
- Remarks - Method: Statement of GLP. No significant protocol deviations.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Very slight erythema was noted at all treatment sites which persisted for less than 3 days for males and less than 5 days for females.
Signs of Toxicity - Systemic	There were no deaths or test substance related clinical signs or remarkable body weight changes during the study period.
Effects in Organs	No macroscopic findings were observed at necropsy.

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

TEST FACILITY Safepharm (2006c)

7.3. Acute toxicity – inhalation

REMARKS Test not performed

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance moistened with deionised water.
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Statement of GLP. Deviations from protocol: • 3-minute and 1-hour dosing periods were used in addition to the protocol 4-hour dosing period. • Animals were examined for signs of irritation immediately after patch removal (3-minute and 1-hour exposure) or 1 hour after patch removal (4-hour exposure) and at approximately 24, 48 and 72 hours and up to 7 days after patch application.

RESULTS

3-Minute exposure period

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	1	0.3	1	< 7 days	0
Oedema	0	0	0	0	N/A	0

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

1-hour exposure period

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	1.7	1.3	2	< 7 days	0
Oedema	0	0.3	0	1	< 48 hours	0

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

4-hour exposure period

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	2	2	2	< 7 days	0
Oedema	0	0.3	0.3	1	< 48 hours	0

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

CONCLUSION	The notified chemical is irritating to the skin.
TEST FACILITY	CRL (2004b)

7.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks - Method	Statement of GLP. No significant protocol deviations. Corneal surface examined using fluoroscein sodium dye.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.7	1.7	1.7	2	< 7 days	0
Conjunctiva: chemosis	1.7	1.7	1.7	2	< 7 days	0
Conjunctiva: discharge	1.3	1	0.3	2	< 72 hours	0
Corneal opacity	0.7	1	0.7	1	< 7 days	0
Iridial inflammation	1	0.3	0	1	< 7 days	0

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

Remarks - Results	Additional ocular findings included slight dulling of the normal luster of the cornea (2/3 test eyes) and sloughing of the corneal epithelium (1/3 eyes). These effects were not observed after the 1-hour observation.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	CRL (2004c)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – modified Buehler
Species/Strain	Guinea pig/Hartley-derived
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 0.1 % w/v in propylene glycol (practically non-irritating)
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 2.5% w/v in propylene glycol
Signs of Irritation	Slight to moderate erythema and very slight to slight oedema was observed in all animals following each induction. Desquamation was observed in some animals following the first and second induction and all animals following the third induction.
CHALLENGE PHASE	
1st challenge	topical: 0.1% w/v in propylene glycol

2nd challenge	Not required
Remarks - Method	Statement of GLP. No significant protocol deviations. The study also consisted of a hexylcinnamaldehyde positive control test and challenge group.

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	0.1 %	0/20	1/20	-	-
Control Group	0.1%	0/10	0/10	-	-

* scores of $\geq$ 1

Remarks - Results	24 hours following challenge, dermal reactions in the test animals were limited to slight patchy erythema in four animals with the remaining animals showing no dermal reactions. 48 hours following challenge, slight erythema was observed in one animal with other dermal reactions limited to slight patchy erythema in four animals with the remaining animals showing no dermal reactions. Similar reactions were observed at the challenge dose in the preliminary study. The positive control confirmed the sensitivity of the test.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	CRL (2003)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Arachis oil BP
Remarks - Method	Statement of GLP. Protocol deviations included: No post-exposure observation period.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	30	0/10
III (mid dose)	5/sex	300	0/10
IV (high dose)	5/sex	1000	0/10

Mortality and Time to Death

All animals survived until scheduled necropsy.

Clinical Observations

Increased salivation was observed immediately after dosing for all animals treated with 1000 and 300 mg/kg bw/day. Isolated incidences were also noted in one male treated with 30 mg/kg bw/day and two control animals. Noisy respiration and/or sneezing was also noted in animals treated with 1000 mg/k bw/day and to a lesser extent 300 mg/kg bw/day. Wet fur and/or staining around the snout mouth and eyes was noted in animals of either sex treated with 1000 mg/kg bw/day. One male and two females treated with 1000 mg/kg bw/day showed hunched posture, tiptoe gait, decreased respiration, diuresis and/or were piloerect on isolated occasions during the treatment period.

Sensory Observations

No treatment related clinical signs were noted in males or females in treatment week four.

Grip Strength

No treatment related differences in the mean fore- and hindlimb grip strength were noted when compared with controls after four weeks of treatment.

Locomotor Activity

No treatment related differences in the mean locomotor activity were noted when compared with controls after four weeks of treatment.

Functional Observations

No treatment related clinical signs were noted in males or females in treatment week four.

Food Consumption

A reduction in food consumption was noted only in males treated with 1000 mg/kg bw/day throughout the treatment period although not statistically significant. Weekly food efficiency was reduced during the final week of treatment for animals of either sex treated with 1000 mg/kg bw/day.

Body Weight

A reduction in bodyweight gain was noted only in males treated with 1000 mg/kg bw/day.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

The mean activity of aspartate aminotransferase was increased in males treated with 300 mg/kg/day (14%, not significantly), significantly increased in males treated with 1000 mg/kg/day (70%, $p<0.01$) and significantly increased in females treated with 300 (19%, $p<0.05$) and 1000 (76%, $p<0.01$) mg/kg/day. The mean activity of alanine aminotransferase was significantly increased ($p<0.01$) in males and females treated with 300 (80% for males, 62% for females) or 1000 (330% for males, 373% for females) mg/kg/day, when compared with controls after four weeks of treatment. The mean activity of alkaline phosphatase was increased in males and females treated with 30 (23%, 31%, respectively) and 300 (27%, 30%, respectively) and 1000 (106%, $p<0.01$ for males and 73%, $p<0.05$ for females) mg/kg/day.

The mean activity of albumin was significantly increased ($p<0.05$) in males and females treated with 300 (4%, 12%, respectively) and 1000 (8% and 10%, respectively) mg/kg/day. The albumin/globulin ration was significantly increased ($p<0.01$) in males and females treated with 300 (32%, 20% respectively) and 1000 (73%, 29%, respectively) mg/kg/day.

The mean activity of cholesterol was decreased in males treated with 300 (4%, not significant) and 1000 (23%, $p<0.05$) mg/kg/day.

The mean concentration of glucose was significantly increased in females treated with 1000 (29%, $p<0.01$) mg/kg/day.

A decrease in total protein concentration in males treated with 30 (6%, $p<0.05$), 300 (7%, $p<0.01$) and 1000 (13%, $p<0.01$) mg/kg/day was observed.

The mean activity of creatinine was increased (9%, $p<0.05$) in males treated with 1000 mg/kg/day when compared with controls after four weeks of treatment. The mean activity of urea was significantly increased (42%, $p<0.01$) in males treated with 1000 mg/kg/day.

The mean activity of bilirubin was decreased in males treated with 300 (48%, not significant) or 1000 (73%, p<0.01) mg/kg/day. The mean concentration of plasma chloride was decreased significantly in females treated with 1000 (3%, p<0.05) mg/kg/day.

Haematology
The mean corpuscular haemoglobin and mean corpuscular volume was significantly decreased (p<0.05) in females of the high dose groups (4%, 4%, respectively). The mean corpuscular haemoglobin concentration was significantly decreased in males treated with 300 (3%, p<0.01) and 1000 (4%, p<0.01). In the absence of any significant differences from control values for haemoglobin or haematocrit values these differences are considered to be incidental and not toxicologically relevant. The platelet count was increased in males treated with 1000 (36%, p<0.01) mg/kg/day and in females treated with 30, 300 and 1000 (18%, p<0.05, 23%, p<0.05, 30%, p<0.01, respectively), however, values were within the range of historical controls and no effect was observed on clotting time.

Effects in Organs
Organ weights
A significant increase in the absolute and relative (liver to body weight) liver weight were observed in males treated at 30 (6%, p<0.05), 300 (16%, p<0.01) and 1000 (72%, p<0.05) mg/kg/day and females treated at 300 (17%, p<0.01) and 1000 (64%, p<0.01) mg/kg/day. This finding was considered to be test-item related because it could be correlated with the microscopic changes. A decrease in both absolute and relative (heart to body weight) heart weight (figures shown are for relative heart weight changes) were observed in males treated with 1000 (9%, p<0.05) mg/kg/day. There were no microscopic findings that accompanied this change and therefore this finding was not considered toxicologically relevant.

Macroscopic/Microscopic Findings
At necropsy, at the end of the treatment periods enlarged livers in males (4/5) and females (2/5) treated with 1000 mg/kg/day were observed. Sloughing of the non-glandular region of the stomach was also observed for one male and one female (both animals had shown weight loss and hunched posture prior to termination) but was only confirmed microscopically for the male. Other necropsy findings at the high dose level included pale kidneys for two males, small seminal vesicles for two males and reddened lungs for one female. Two males treated with 300 mg/kg/day showed enlarged livers and one male showed small seminal vesicles. Thickening of the glandular and non-glandular regio of the stomach was observed for one male treated at 30 mg/kg/day however this finding was considered to be incidental and not treatment related.

At histopathological examination performed at the end of the treatment centrilobular enlargement was seen in 4/5 males and females treated at 300 mg/kg/day and all animals treated at 1000 mg/kg/day. A higher incidence of groups of basophilic tubules was seen in all female rats treated at 1000 mg/kg/day and 4/5 males treated at 300 and 1000 mg/kg/day. However, this was also observed in 3/5 male control rats. Hypertrophy of follicle lining cells of the thyroid gland was observed in 3/5 males treated at 300 and 1000 mg/kg/day and 4/4 females treated at 300 and 1000 mg/kg/day. Vacuolation of histocytes of the mesenteric lymph node was observed in all males treated at 1000 mg/kg/day.

Remarks – Results
The increased liver weights at 300 mg/kg/day and 1000 mg/kg/day together with associated biochemical (increase liver enzymes and decreased cholesterol) and histopathological changes, were considered to be potentially adverse. Although one male treated at 30 mg/kg/day showed an enlarged liver, this was not supported by corresponding histopathological changes and therefore this was not considered treatment related.

Follicular cell hypertrophy observed in the thyroid may be as a result of increased thyroxine production as a secondary effect of the liver enzyme changes.

The higher incidence of basophilic tubules may be associated with increased levels of urea and creatinine, although these blood changes were only observed in males treated at 1000 mg/kg/day.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 30 mg/kg bw/day in this study, based on the potentially adverse treatment related effects in the liver and biochemical changes observed at 300 mg/kg/day in this study.

TEST FACILITY SafePharm (2006d)

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.
Plate incorporation procedure

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100,
E. coli: WP2uvrA$^-$

Metabolic Activation System S9 fraction from phenobarbitone/β-naphthoflavone induced rat livers.

Concentration Range in Main Test
Test 1
a) With and without metabolic activation: up to 5000 µg/plate

Test 2
a) With metabolic activation: up to 5000 µg/plate
b) Without metabolic activation: up to 5000 µg/plate (TA98, WP2uvrA$^-$), up to 1500 (TA100, TA1535, TA1537)

Vehicle Tetrahydrofuran

Remarks - Method Preliminary toxicity test conducted on strains TA100 and WP2uvrA$^-$.

Statement of GLP. No significant protocol deviations. Positive controls used:

N-Ethyl-N-nitro-N-nitrosoguanidine: TA100, TA1535, WP2uvrA$^-$
9-Aminoacridine: TA1537
4-Nitroquinoline-1-oxide: TA98

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	≥ 150 (TA100)			
Test 1		≥ 150 (TA1537), ≥ 500 (TA1535, TA100), ≥ 5000 (TA98)	≥ 1500	negative
Test 2		≥ 150 (TA100, TA1535, TA1537)	≥ 1500	negative
Present	≥ 500 (TA100)			
Test 1		≥ 150 (TA1535, TA1537), ≥ 1500 (TA100) ≥ 5000 (TA98)	≥ 1500	negative
Test 2		≥ 150 (TA1535, TA1537), ≥ 500 (TA100)	≥ 1500	negative

Remarks - Results The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of activation. Negative controls were within the historical control range. Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY SafePharm (2006e)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Cell Type Human Lymphocytes
Metabolic Activation System S9 fraction from phenobarbitone/β-naphthoflavone induced rat livers.
Vehicle Dimethyl sulphoxide
Remarks - Method Statement of GLP. No significant protocol deviations. Doses selected on the basis of toxicity observed in the preliminary toxicity test.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	31.02*, 62.03*, 124.06*, 248.13, 372.19, 496.25	4	24
Test 2	7.76, 15.51*, 31.02*, 62.03*, 93.05, 124.06	24	24
Present			
Test 1	15.51, 31.02*, 62.03*, 124.06*, 186.1, 248.13	4	24
Test 2	15.51*, 31.02*, 62.03*, 124.06*, 186.10, 248.13	4	24

*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	124.06	≥ 248.13	> 496.25	negative
Test 2	124.06	≥ 93.05	> 248.13	negative
Present				
Test 1	248.13	≥ 186.1	> 496.25	negative
Test 2	248.13	≥ 186.1	> 248.13	negative

* based on ≥ 50% reduction in mitotic index

Remarks - Results The test substance did not induce any statistically significant increases in the frequency of cells with chromosome aberrations or in the number of polyploid cells either in the presence or absence of activation. Negative controls were within the historical control range. Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY Safepharm (2006f)

7.10. Genotoxicity – in vivo

Not performed.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD
- Inoculum: Activated sludge
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring: DOC
- Remarks – Method: The test consisted of the test substance (10 mg C/L), reference (sodium benzoate; 10 mg C/L) and control (inoculated culture) in duplicate and a toxicity control consisting of the test material and reference (20 mg C/L). The test was performed in the dark at 21°C. Samples taken on days 0, 1, 2, 3, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 27, 28 and 29 were analysed for CO_2. The pH of the test preparation was determined on day 28.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% degradation*	*Day*	*% degradation*
0	0	0	0
2	8	2	37
6	23	6	46
10	29	10	60
16	35	16	61
20	36	20	65
28	43	28	78

Remarks - Results: The test material attained 43% degradation after 28 days and thus is not considered to be readily biodegradable. The toxicity control attained 65% degradation after 28 days confirming that the test material was not toxic to the sewage micro-organisms. Sodium benzoate attained 62 and 78% degradation after 14 and 28 days, respectively, confirming the suitability of the inoculum.

It is noted that ultrasonication was used to aid the dispersion of the test material. It was observed that the contents of all test solutions were light brown slightly cloudy dispersions with no undissolved material visible.

CONCLUSION: The notified chemical is not considered to be readily biodegradable.

TEST FACILITY: Safepharm Laboratories Ltd (2006g)

8.1.2. Bioaccumulation

There is a potential for the notified chemical to bioaccumulate based on the estimated Pow of 7.65 - 7.76. However, the water solubility is very low and if bioaccumulation occurs it will do so at a very slow rate. Further, release to the aquatic compartment will be very low.

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	ca. 100 mg $CaCO_3$/L
Analytical Monitoring	HPLC-ELSD.
Remarks – Method	Based on the preliminary range finding test, fish in two groups of 10 were exposed to a nominal limit concentration of 0.20 mg/L for a 96 h exposure under semi-static conditions. The test solution was prepared by dissolving the test material (100 mg) in DMF (50 mL) as the solvent stock solution. An aliquot (2 mL) of the stock solution was then dispersed in dechlorinated tap water (20 L) to give the nominal test concentration of 0.2 mg/L. The number of mortalities and sub-lethal effects of exposure in each test and control vessel were determined 3 and 6 h after the start of exposure and then daily until termination at 96 h. Temperatures, pHs and dissolved oxygen were measured throughout the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0.20	<LOQ	20	0	0	0	0	0

LOQ = Limit of Quantitation (down to 5.1 mg/L)

LC50	>0.2 mg/L at 96 hours.
NOEC	0.2 mg/L at 96 hours.
Remarks – Results	During acclimatisation, temperature values (13.2 to 15.4ºC) were outside of the range given in the protocol of 14.0 ± 1ºC. However, these deviations were considered not to have affected the outcome or validity of the test given that no significant mortality occurred during the acclimatisation period. Neither mortality nor sub-lethal effects were observed at the nominal test concentration of 0.2 mg/L. The water quality parameters were within acceptable limits throughout the test. Analysis of the solvent stock solution showed measured concentrations were 99-109% of nominal concentrations throughout the exposure period. Precipitation of the test material was observed visually at concentrations in excess of 0.20 mg/L indicating this to be the maximum limit of water solubility under the test conditions. The test solutions were observed to be clear colourless solution throughout the duration of the test. Results were based on nominal test concentrations only.
CONCLUSION	The notified chemical is considered to be non-toxic to rainbow trout (*Oncorhynchus mykiss*) up to its limit of water solubility.
TEST FACILITY	Safepharm Laboratories Ltd. (2006h)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test - 48 hour, Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - 48 hour, Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	DMF
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC

Remarks – Method	Based on the preliminary range finding test, 20 daphnids (4 replicates of 5 animals) were exposed to a nominal test concentration of 0.20 mg/L (prepared as for the fish test above) for 48 h under static conditions. Immobilisation and any adverse reactions were recorded after 24 and 48 h. Potassium dichromate was used as the reference control. Temperatures, pHs and dissolved oxygen were measured throughout the test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0.20	<LOQ	20	0	0

LC50	>0.20 mg/L at 48 hours
NOEC	0.20 mg/L at 48 hours
Remarks – Results	No immobilisation was observed at the test concentration of 0.20 mg/L. The water quality parameters were within acceptable limits throughout the test. The test solutions were observed to be clear colourless solutions throughout the duration of the test. Analysis of the solvent stock solution showed a measured concentration of 100% of nominal concentration indicating the test system was prepared correctly. Results were based on nominal test concentrations only. The 48 h EC50 for the reference material was 0.97 mg/L (CL: 0.85-1.1 mg/L), within the acceptable range.

CONCLUSION	The notified chemical is considered to be non-toxic to *Daphnia magna* up to the limit of its water solubility.
TEST FACILITY	Safepharm Laboratories Ltd. (2006i)

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	*Scenedesmus subspicatus* (Green Algae)
Exposure Period	72 hours
Nominal Concentration	0.20 mg/L
Auxiliary Solvent	DMF
Water Hardness	Not reported.
Remarks - Method	Following a preliminary range finding test, algae were exposed to a nominal test concentration of 0.20 mg/L (six replicate flasks, prepared as above) for 72 h under constant illumination and shaking at a temperature of 24°C. Samples of the algal population was removed at 0, 24, 48 and 72 h and cell concentrations determined for each control and treatment group. pHs of the solutions were measured at initiation of the test and after 72 h exposure.

RESULTS

EbC50 (mg/L) at 72 h	*NOEC (mg/L)*	*ErC50 (mg/L) at 72 h*	*NOEC (mg/L)*
> 0.20	0.20	> 0.20	0.20

Remarks – Results	The results indicate that neither the growth nor the biomass of algae was affected at the nominal concentration of 0.2 mg/L over the 72 h exposure period. There were no statistically significant differences between the

solvent control and the treatment group. Therefore, the NOEC was determined to be 0.20 mg/L.

At the start of the test, control, solvent control and test cultures were observed to be clear colourless solutions. At the end of the test, these were observed to be pale green dispersions. Analysis of the solvent stock solution showed a measured concentration of 105% of nominal concentration indicating the validity of the test concentrations. Results were based on nominal test concentrations only. Temperature was maintained throughout the test but pH of the control cultures were observed to increase form pH 7.5 at 0 h to pH 8.5 at 72 h.

CONCLUSION The notified chemical is considered to be non-toxic to alga (*Scenedesmus subspicatus)* up to the limit of its water solubility.

TEST FACILITY Safepharm Laboratories Ltd. (2006j)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported and reformulated into lubricant oils at the blending facilities. 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 and phosphorous. 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 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 and calculated high Pow. While some components of the notified chemical are not readily degradable, these can be expected to slowly degrade due to the biotic and abiotic processes.

The maximum amount released to stormwater drains (estimated as 3.6 kg) can enter the aquatic compartment and could be expected to become associated with suspended organic material (due to the calculated high Pow), settle out into the sediments and eventually be biodegraded.

It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified chemical 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 notified chemical that is expected to be released into the stormwater drains is released 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 3.6 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 0.014 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

Based on the ecotoxicity data for fish, daphnia and algae provided, the notified chemical is practically non-toxic up to the limit of its water solubility of 0.2 mg/L. A PNEC of >2 µg/L is calculated using a safety factor of 100 and the acute 48 h EC50 >0.2 mg/L for *Daphnia magna* as toxicity data are available for three trophic levels.

9.1.3. Environment – risk characterisation

The worst case risk quotient PEC/PNEC for the aquatic environment as a single site discharge is (0.014/>2) <0.007 and (0.0014/>2) <0.0007 for fresh water and marine water, respectively. This is significantly less than 1, indicating no immediate concern to the aquatic compartment. Further, the notified chemical is expected to become associated with the sediments, and biodegradation will further reduce the risk to the aquatic life.

Draining spent lubricant from transmissions and gear boxes is generally not a routine practice for DIY enthusiasts. Rather it is more likely to be performed by service professionals with less irresponsible disposal practices. Further, the notified chemical is not expected to be present in the spent fluid as most of it will degrade over time in order to perform its intended function. Consequently, the release of the notified chemical from DIY enthusiasts who drain spent fluids is likely to be lower than that estimated.

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

notified chemical should be prevented from entering waterways

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Reformulation

Although exposure to the notified chemical can occur during formulation of the blended oil products and associated activities, this is expected to be low due to the mainly automated practices and the low concentration of the notified chemical (<1.2%). The estimated dermal exposure is 0.5 mg/day, based on EASE model (EASE) using reasonable worst case defaults for the exposure scenario 'coupling and decoupling of a transfer line' (European Commission, 2003a) and assuming the notified polymer is present at concentration of 1.2%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 0.007 mg/kg bw/day. Exposure would be limited by the use of PPE. Following formulation, quality control, packaging and cleaning and maintenance workers exposure is expected to be minimal due to the nature of the work done and the low concentration of the notified chemical (<0.1%).

Inhalation exposure to the notified chemical is not expected due to the predicted low vapour pressure and processes are unlikely to generate aerosols.

End-Use

There is potential for dermal exposure to the notified chemical during transfer of the blended oil products from storage containers into the vehicle being serviced. The estimated dermal exposure is 0.4 mg/day, based on EASE model (EASE) using reasonable worst case defaults for the exposure scenario 'manual addition of liquids' (European Commission, 2003a) and assuming the notified polymer is present at concentration of 0.1%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 0.006 mg/kg bw/day. Exposure would be limited by the use of PPE. Exposure may also occur when draining spent fluid from transmission or gear box, however, the notified chemical is not expected to be present in the spent fluid and as such exposure would be expected to be minimal.

Inhalation exposure to the notified chemical is not expected due to the predicted low vapour pressure and processes are unlikely to generate aerosols.

9.2.2. Public health – exposure assessment

DIY enthusiasts who drain the spent fluid from the transmission or gear box of their vehicle have the potential to be exposed to the notified chemical, most likely by dermal exposure to the hands and forearms. However, exposure is expected to be infrequent and minimal due to the low concentration of the notified chemical in the blended oil (<0.1%) and the degradation of the notified chemical under the conditions of use.

Using the EASE model (assuming wide dispersive use with incidental contact and direct handling), estimated dermal exposure to the notified chemical is 0.001-0.01 mg/cm^2/day assuming the notified chemical is present at 0.1% in the oil. For a 60kg member of the public with 1960 cm^2 exposed surface area (hands and forearms) and assuming 100% absorption, worst case systemic exposure is estimated to be 0.03-0.3 mg/kg bw/day. This is expected to be an overestimate of exposure as the notified chemical is expected to degrade under the conditions of use and draining spent lubricant from transmissions and gear boxes is generally not a routine practice for DIY enthusiasts.

9.2.3. Human health – effects assessment

Acute toxicity.

Based on the studies provided, the notified chemical is of low acute toxicity via the oral and dermal routes.

Irritation and Sensitisation.

Based on the studies provided the notified chemical is considered to be irritating to the skin, slightly irritating to the eyes but is not likely to induce skin sensitisation. Skin irritation effects were observed even with a short exposure time (3 minutes).

Repeated Dose Toxicity.
In a 28-day oral repeat dose study in rats, a No Observed Adverse Effect Level (NOAEL) was established as 30 mg/kg bw/day, based on the potentially adverse treatment related effects in the liver and biochemical changes observed at and above 300 mg/kg/day in this study. In addition to these effects on the liver, treatment related effects on bodyweight and the stomach and potential treatment related effects on the kidney were observed at 1000 mg/kg/day.

Mutagenicity.
The notified chemical showed no evidence of mutagenicity or clastogenicity *in vitro.*

Hazard classification for health effects.
Based on the available data, the notified chemical is 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 is irritating to skin and slightly irritating to eyes. Slight irritant effects were observed even after a short exposure period (3 minutes). However, although exposure to the notified chemical can occur during reformulation and end-use activities the risk of irritation effects is reduced due to the low concentration of the notified chemical (<1.2%). The risk of irritation would also be reduced by the use of PPE.

Based on modelled data, similar maximum levels of exposure are expected in reformulation and end-use workers (0.007 mg/kg bw/day). Based on a NOAEL of 30 mg/kg bw/day derived from a 28-day rat oral study, the margin of exposure (MOE) is calculated as 4285. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for workers.

9.2.5. Public health – risk characterisation

Although the notified chemical is irritating to skin and slightly irritating to eyes, the public will only be exposed to the notified chemical at a concentration of < 0.1% and hence the risk of irritation effects is considered to be low. Based on modelled data, worst-case exposure was estimated to be 0.03-0.3 mg/kg/day. Based on a NOAEL of 30 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 100-1000. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk to public health from these other proposed uses is considered to be low.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R38 Irritating to skin

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.

	Hazard category	***Hazard statement***
Skin corrosion/irritation	3	Causes mild skin irritation

Chronic hazards to the aquatic environment*	4	May cause long lasting effects to aquatic life

* considered appropriate for the notified chemical on the basis that the notified chemical is not readily biodegradable and no acute toxicity is recorded at levels up to the water solubility.

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 when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical 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 (were) 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R38 Irritating to skin

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc ≥20%: (Xi) R38 Irritating to skin

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and in blended oil products:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used as a precauion by workers to minimise occupational exposure to the notified chemical as

introduced and in blended oil products:
- Eye protection
- Impervious 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 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.

Disposal

- The notified chemical should be disposed of by landfill or incineration.

Emergency procedures

- For small spills, add absorbent (soil may be used in the absence of other suitable materials) and use a non-sparking or explosion-proof means to transfer material to a sealable, appropriate container for disposal. For large spills, dike spilled material or otherwise contain material to ensure run-off does not reach a waterway. Placed spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent run-off to surface waterways.

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(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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