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August 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Z-70

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

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

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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FULL PUBLIC REPORT

Z-70

This assessment report is for an extension of original assessment certificate for Z-70. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Holder of the original assessment certificate (No.2461, STD/1223)
Lubrizol International, Inc. (ABN 52 073 495 603)
28 River St.
SILVERWATER NSW 2128

Applicant for an extension of the original assessment certificate:
Mobil Oil Australia Pty Ltd (ABN 88 004 052 984)
29 Francis St.
YARRAVILLE VIC 3013

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 IDENTITY
- MEANS OF IDENTIFICATION
- PURITY
- IDENTIFICATION OF HAZARDOUS AND NON-HAZARDOUS IMPURITIES
- USE
- IMPORTATION VOLUME
- SITES OF MANUFACTURE

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

- Dissociation constant
- Particle size
- Flammability limits
- Acute inhalation toxicity
- Induction of germ cell damage
- Bioaccumulation

NOTIFICATION IN OTHER COUNTRIES
US, Canada, EU, Japan

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Z-70
OS 218407B

MARKETING NAME(S)
OS 218407A (finished product containing 0.1-2.5% Z-70)

S010-1150-05-139 (additive concentrate containing 1-8% Z-70)

Extension Applicant:
MARKETING NAME(S)
Chemical 1 in Mobil 1 Synthetic ATF
Chemical 1 in Mobil Multi-Vehicle ATF

METHODS OF DETECTION AND DETERMINATION

METHOD	Infrared spectroscopy
REMARK	The Infrared spectrum data was provided.
TEST FACILITY	Lubrizol Corporation (2005)

3. COMPOSITION

DEGREE OF PURITY
High

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. It will be initially imported as an ingredient (at concentration of 0.1 to 2.5%) in a finished fluid. However, it is possible in the future that the notified chemical will be imported as an additive concentrate (at concentration of 1 to 8%) for further formulation.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes					
Lubrizol Int.	1-3	1-3	1-3	1-3	1-3
Mobil Oil Aust.	3-10	3-10	3-10	3-10	3-10

USE
The notified chemical is a lubricant additive for use in automotive transmission fluids at concentration 0.1 to 2.5%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Western Australia, Queensland, Victoria.

IDENTITY OF MANUFACTURER/RECIPIENTS
Lubrizol International, Inc.
28 River St.
Silverwater NSW 2128

Extension Applicant:
Mobil Oil Australia Pty Ltd
29 Francis St.
YARRAVILLE VIC 3013

TRANSPORTATION AND PACKAGING
Both finished product and additive concentrate, packaged in 20 L drums, will be transported via road from wharf to customer sites for either end use or further formulation.

Extension Applicant:

Finished oil products containing the notified chemical (<2.5%) will be imported in 208 L drums and transported by road or rail for repackaging and distribution to storage facilities or directly to customers.

5.2. Operation description

Formulation/blending:

If blending occurs in the future, the additive concentrate containing 1 to 8% Z-70 is transferred from storage to a blending area via forklifts and decanted from drums into blending tanks via either an automated pumping process or hand pumps. The blending process is fully automated and under local exhaust ventilation. The end products will be packaged automatically into containers ranging from drums for bulk shipment to large customers, such as OEMs, to pint size plastic containers for aftermarket, garages or do-it-yourself (DIY) sales. Similar materials and products are blended in the same equipment, therefore, any residual material left in the blend tank or transfer lines remains for the next batch. Sampling is conducted during the blending process. The equipment is cleaned using mineral oil which will be recycled.

End use – bulk use

Most (>75%) of the automotive transmission fluids containing 0.1 to 2.5% Z-70 is likely to be used by automobile manufacturers for factory fill operations. The end product will be pumped from drums directly to the transmission through dedicated lines which is an automated process.

End use – non-bulk use

The remainder (<25%) automotive transmission fluids containing 0.1 to 2.5% Z-70 will be for garages and do-it-yourself (DIY) use. The end product will be repackaged into smaller containers before non-bulk uses. The repackaging process is automated and the end product is pumped directly from the bulk container to the smaller bottles (plastic 1 L).

The majority of the non-bulk end uses, e.g. by garage workers and the general public via DIY application, is expected to be manual replacement of transmission fluid or 'topping off' the fluid level as needed. However, these actions are not typical since most transmission fluids are fill for life.

Extension Applicant:

Finished oil products containing the notified chemical (<2.5%) will be repackaged into product containers ranging in size 1-20 L.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hrs/day)*	*Exposure Frequency (days/year)*
Transport and storage	2-3	1-3	4-6
Blending	1-2	1-3	10-20
Packaging	2-3	2-5	10-20
Equipment cleaning	2-3	2-4	10-20
Repackaging	1-2	1-3	10-20
End use	1-3	2-4	Difficult to estimate

Exposure Details

Transport and storage

Exposure to the notified chemical (at a concentration of <10%) is unlikely to occur, except in the event of an accidental spillage and breach of packaging.

Formulation

During formulation of the notified chemical into finished products, worker exposure to the additive concentrate (maximum concentration of 8%) is limited during transfer and mixing due to the enclosed and automated process. During sampling and final product packaging, workers may be exposed to the notified chemical (concentration up to 2.5%) by skin, inhalation or ocular contact with residues dripping off the fill pipe and during equipment cleaning. However, exposure should be minimised by use of mechanical ventilation systems, automated processes and personal protective equipment (PPE).

End uses
Dermal, ocular and inhalation exposure may occur during repackaging and end use of finished product containing the notified chemical, especially at sites where manual handling occurs. However, due to the low concentration of the notified chemical in the finished product, workers' exposure is expected to be low. Use of effective ventilation, automated process and PPE will further reduce the possible exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Initially the notified chemical will not be manufactured or reformulated in Australia; although it is possible that the chemical will be imported as a concentrate and reformulated in Australia in the future.

If reformulation from a concentrate occurs in the future, it is expected that this process will be highly automated with minimal release of the chemical. The residue in packing containers would be rinsed with oil for charging to the next batch. Similarly rinses from cleaning of equipment would be charged to the next batch.

RELEASE OF CHEMICAL FROM USE
The trend for automatic transmissions is for sealed units which are filled for the life of the transmission. It is expected the majority of the notified chemical will be used in this type of application with some of the product requiring re-packaging for top up applications by non-bulk users including garages and DIY enthusiasts.

Approximately 0.5% (<65 kg per annum) of the notified chemical is expected to remain in import containers as residue after repacking or filling of transmissions with the product.

Assuming that 25% (<3250 kg per annum) is used in top up applications and that 1% remains in these containers then a further maximum of 30 kg per annum will remain as residue in the repackaged product.

It is expected that only a small amount (<5%; <650 kg) of the lubricants would be released to the environment either form incorrect disposal from DIY enthusiasts and leaks from transmissions. This is likely to occur throughout Australia in a disperse manner.

Although some transmissions require the fluid to be replaced during servicing, many are now sealed units which are filled for the life of the transmission. These are expected to be serviced only by professional mechanics and often do not require replacement of the automatic transmission fluid (ATF) for the life of the transmission. The lubricants are expected to be collected either at the end of the useful life of the transmissions; or if required during servicing, and properly disposed of.

5.5. Disposal

Residues in import drums are expected to be cleaned out by licensed drum recyclers and properly disposed of (most likely by incineration).

Residue from the repackaged product is likely to be disposed of as domestic waste and deposited to authorised landfill.

Used lubricants may be recycled, re-refined, burnt as low grade burner fuel or disposed of by incineration.

Transmissions which may not be fully drained of the product comprising the notified chemical are likely to be disposed of to landfill or undergo metal recycling at the end of their useful lives.

5.6. Public exposure

Public exposure to the finished product containing 0.1 to 2.5% Z-70 via skin, optical, inhalation and potentially ingestion is likely due to the manual application of the DIY products and the unlikely use of PPE. However, the public exposure is expected to be limited due to its infrequent use by the public, assuming that most consumers do not change their own transmission fluid and this is an activity that would occur infrequently during the lifetime of the automobile oil.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Clear amber liquid

Pour Point -4.2ºC

METHOD OECD TG 102 Melting Point/Melting Range.
TEST FACILITY SafePharm Laboratories (2006a)

Boiling Point >359.9ºC at 100.7 kPa

METHOD OECD TG 103 Boiling Point.

Remarks Determined by differential scanning calorimetry.
Slight gradual volatilisation which became more significant from approximately 327.9ºC was observed. No value for an exact boiling point could be determined.
A calculated boiling point gave a result of 644.9 ºC.
TEST FACILITY Safepharm (2006a)

Density 888 kg/m^3 at 20 ± 0.5ºC

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Determined by pycnometer
TEST FACILITY Safepharm (2006a)

Vapour Pressure 2.3 x 10^{-11} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined with a vapour pressure balance.
TEST FACILITY Safepharm (2006b)

Water Solubility < 1.60 × 10^{-3} g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
Remarks A preliminary test was conducted by the Flask Method by adding an aliquot (0.0016 g) of test material to 1000 mL of distilled water. The sample was shaken for 24 hours and equilibrated for 24 hours at 20 ± 0.5C and visually observed. The test substance showed low water solubility. Computer modelling (WSKOWWIN v 1.41) estimated the water solubility to be 1.21 × 10^{-8} g/L at 25°C. The low water solubility is expected as the notified chemical has few hydrophilic groups.
TEST FACILITY Safepharm (2006a)

Hydrolysis as a Function of pH Not Tested

Remarks The notified chemical contains functional groups capable of undergoing hydrolysis. However, due to low water solubility hydrolysis is unlikely. Hydrolysis as a function of pH is only applicable for chemicals with water solubility greater than 10^{-6} g/L. The notified chemical is likely to have lower water solubility than this, based on the modelled data.

Partition Coefficient (n-octanol/water) log Pow = > 6.01 (Temperature not specified)

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks HPLC Method. More than 97.5% of the notified chemical had a log Pow value of >6.01 and more than 60.6% had a log Pow value of > 9.40. The test substance was eluted from the column after all of the reference materials. Computer modelling (KOWWIN v 1.67) estimated the Pow to be 9.75.
TEST FACILITY Safepharm (2006a)

Adsorption/Desorption – screening test $\log K_{oc} > 5.63$ (Temperature not specified)

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).
Remarks More than 96% of the notified chemical had a log Pow value of >5.63 The test substance was eluted from the column after all of the reference materials. Computer modelling (KOWWIN v 1.67) estimated the Pow to be 9.75.
TEST FACILITY Safepharm (2006a)

Dissociation Constant Not Tested

Remarks The notified chemical does not contain any functional groups likely to ionise in the environmental pH range (4-9).

Particle Size Not applicable (liquid substance)

Flash Point 226 ± 2ºC at 102.5 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Determined by a closed cup equilibrium method
TEST FACILITY Safepharm (2006b)

Flammability Limits Not performed

Remarks The notified chemical has a low vapour pressure and high flash point.

Autoignition Temperature 368 ± 5ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY Safepharm (2006b)

Explosive Properties Not performed

Remarks The notified chemical is not expected to have explosive properties and no explosive properties have been demonstrated in handling.

Reactivity Not performed

Remarks The notified chemical is not an oxidiser and is expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*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	moderately irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – local lymph node assay (LLNA)	evidence of sensitisation
Rat, repeat dose <route of exposure> toxicity – 28 days.	NOEL = 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chinese Hamster Lung (CHL) cells	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain Rat/ Sprague Dawley CD
Vehicle Notified chemical was administered neat
Remarks - Method Statement of GLP was provided.
No significant deviation from the protocol.

RESULTS

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

LD50 > 2000 mg/kg bw
Signs of Toxicity No signs of systemic toxicity
Effects in Organs No abnormalities were noted following terminal necropsy on day fourteen.
Remarks - Results All animals survived the study and showed expected gain in body weight during the 14-day observation period.

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

TEST FACILITY Safepharm (2006c)

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).
Species/Strain Rat/ Sprague Dawley CD
Vehicle Notified chemical was administered neat
Type of dressing Semi-occlusive.
Remarks - Method Statement of GLP was provided.
No significant deviation from the protocol.

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	Slight erythema was observed at all treatment sites one and two days after application and returned to normal by day 3. Crust formation was observed at the treatment sites of 3 male and 3 female animals, three to five days post application and returned to normal by day 6.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed during the study.
Effects in Organs	No abnormalities were noted following terminal necropsy on day fourteen.
Remarks - Results	All animals survived the study and showed expected gain in body weight during the 14-day observation period

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

TEST FACILITY Safepharm (2006d)

7.4. Irritation – skin

TEST SUBSTANCE 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 Males
Vehicle	Notified chemical was used undiluted
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant deviation from the protocol.

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	2	2	2	2	7 days	0
Oedema	1	1	1	1	3 days	0

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

Remarks - Results	Light brown discolouration was observed in all animals on day three. By day seven, crust formation was observed in all animals. All reactions were reversible by day fourteen.

CONCLUSION The notified chemical is moderately irritating to the skin.

TEST FACILITY Safepharm (2006e)

7.5. Irritation – eye

TEST SUBSTANCE 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 Males
Observation Period	72 hours

Remarks - Method No significant deviation from the protocol.

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	0.33	0.33	2	24 h	0
Conjunctiva: chemosis	0	0.33	0.33	1	24 h	0
Conjunctiva: discharge	0	0.33	0.33	1	24 h	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 No effects to the cornea or iris were observed in the study.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Safepharm (2006f)

TEST FACILITY

7.12T. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation - Local lymph node assay
EC Directive 2004/73/EC B.42 Skin Sensitisation - Local lymph node assay.
Species/Strain Mouse CBA/CaBkl (Females)
Vehicle Acetone/olive oil 4:1
Remarks - Method No significant deviation from the protocol.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*		*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	1774.15	(± 790.35)	n/a
25	4151.76	(± 763.16)	2.34
50	7359.84	(± 2080.41)	4.15
100	7812.47	(± 1416.61)	4.40
Positive Control (α-Hexylcinnamaldehyde)			
5	Not documented		2.76
10	Not documented		3.34
25	Not documented		8.91

Remarks - Results No deaths or signs of systemic toxicity were observed in the preliminary or main studies.

Moderate redness to the head and neck was noted on day 5 of the preliminary study in which undiluted test substance was applied in the same manner as in the main test.

An Effective Concentration inducing a SI of 3 (EC_3) was then calculated to be 34.12%, Kimber et. al, (2001).

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY Safepharm (2006g)

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	Sprague-Dawley Crl:CD (SD) IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Arachis oil BP
Remarks - Method	Two recovery groups were included, control and high dose groups each containing 5 male and 5 female animals. Recovery treatment-free period was 14 days after which all animals were subject to gross necropsy examination and histopathological evaluation similar to the non-recovery treatment groups. Dose finding studies was performed with 18 animals (9/sex) using control and two test doses, 500 and 1000 mg/kg day for 14 consecutive days.

RESULTS

Dose finding test
No unscheduled deaths occurred. Clinical observations, bodyweight and results of necropsy at the end of the study were all normal.

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	25	0
III (mid dose)	5/sex	250	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	1
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death
One control male was killed on humane grounds due to severity of clinical observation on day 26 most probably attributed to a physical injury. Since this was a control animal the clinical signs are clearly not treatment related. No other unscheduled deaths were observed during the study.

Clinical Observations

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Statistically significant increase of neutrophils was found in group IV females, and slight statistical increase of APTT (Activated Partial Thromboplastin Time) was observed in groups 3 and 4 females. These changes are considered not to be related to the treatment with the notified chemical, as they did not reflect clear dose dependent relationship.

Statistically significant decrease of blood triglycerides was observed in females of groups II,III and IV compared to the control. However this decrease was not considered biologically significant as all values are within the normal expected for females and the difference maybe attributed to the high triglyceride value for the control group, which was higher than the normally expected level for females.

Effects in Organs
No treatment related macro or microscopic changes were observed.

Remarks – Results
No clinically observable signs of toxicity were detected.

Behavioural assessment also did not reveal any treatment related changes in the parameters measured (17 parameters). Functional performance and sensory reactivity test were also normal in all groups.

There were no significant differences in food and water consumption and body weights between groups.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study, based on absence of treatment related changes in clinical and laboratory observations and tests.

TEST FACILITY Safepharm (2006h)

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.

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

Metabolic Activation System 10% Phenobarbitone/β-naphthoflavone induced rat liver microsome preparations (S9 mix)

Concentration Range in Main Test a) With metabolic activation: 50, 150, 500, 1500 and 5000 µg/plate
b) Without metabolic activation: 50, 150, 500, 1500 and 5000 µg/plate

Vehicle Acetone

Remarks - Method A preliminary cytotoxicity was performed using a range of 10 concentrations of the notified chemical from 0.15 to 5000 µg/plate and vehicle control using *S. typhimurium*: TA100 and *E. coli*: WP2uvrA$^-$ strains.

Appropriate known mutagens were tested in parallel to the notified chemical with and without metabolic system to validate the sensitivity of the assay.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation µg/plate*	*Genotoxic Effect*
Absent				
Test 1	Not observed	Not observed	500	Not observed
Test 2	Not observed	Not observed	500	Not observed
Present				
Test 1	Not observed	Not observed	500	Not observed
Test 2	Not observed	Not observed	500	Not observed

Remarks - Results No cytotoxicity was observed in the preliminary toxicity test at any of the tested concentrations.

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

TEST FACILITY Safepharm Laboratories (2005)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE 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: Chinese Hamster Lung (CHL) cells

Metabolic Activation System: Phenobarbitone/β-naphthoflavone induced rat liver microsome preparations (S9 mix) at 2% and 5%.

Vehicle: Acetone

Remarks - Method: A preliminary toxicity test was performed in the dose range between 19.53 to 5000 µg/ml. Growth inhibition and mitotic index were examined to evaluate toxicity after 24h continuous treatment without metabolic activation and after 6h treatment in the presence and absence of metabolic activation followed with 18h of incubation.

Known mutagens were tested in parallel to the notified chemical.

CHL cells have an average generation of approximately 17 hours when growing under normal experimental conditions.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (h)*	*Harvest Time(h)*
Absent			
Test 1	0*; 19.53 ; 39.06; 78.13*; 156.25*; 234.38; 321.25	6	24
Test 2	0*; 9.77;19.53* ; 39.06*; 78.13*; 156.25; 234.38	24	24
Present at %			
Test 1 @ 5%	0*; 156.25; 312.5*; 625*; 1250*; 2500*; 5000	6	24
Test 2 @ 2%	0*; 156.25*; 312.5*; 625*; 1250; 2500; 5000	6	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	≥ 156.25 (6h exposure) * ≥ 78.13 (24h exposure)*	≥156.25	≥ 78.13	no
Test 2	-	≥ 78.13	≥ 78.13	no
Present				
Test 1	Dose related growth reduction up to 312.5**	≥ 625	≥ 78.13	no
Test 2	-	Not dose related	≥ 78.13	no

* Based on inhibition of Cell Growth Index; ** Based on inhibition of Mitotic index

Remarks - Results: Slight increase in chromatide gaps was observed at the highest concentration scored 2500 µg/mL.

The positive controls showed significant increases in mutagenic colonies, confirming the effectiveness of the test conditions.

CONCLUSION The notified chemical was not clastogenic to Chinese Hamster Lung (CHL) cells treated in vitro under the conditions of the test.

TEST FACILITY	Safepharm (2006i)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified Chemical

METHOD
- Inoculum: Activated Sewage Sludge
- Exposure Period: 29 Days
- Auxiliary Solvent: Adsorbed onto surface of silica gel
- Analytical Monitoring: TOC analyser
- Remarks - Method: Due to the test substance's poor water solubility, 39.0 mg was adsorbed onto 100 mg of granular silica gel. A further 100 mL of culture medium was added and dispersed with high shear mixing. The final concentration of test substance in inoculum was 13 mg/L (≡ 10 mg carbon/L). Duplicate analyses of test substance were run. Duplicate controls consisting of inoculated culture medium and 100 mg/L of silica gel; and a reference test, consisting of sodium benzoate (10 mg carbon/L) as reference material, and inoculum were also run. A single toxicity test was also conducted by adding test material, reference material 100 mg silica gel and inoculum. CO_2 was captured by absorption (0.05 M NaOH) in two consecutive absorbers. The amount of CO_2 produced was measured in the first absorber on each test day and measured in the second absorber only at the start and end of the test.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	8	1	33
6	12	6	78
10	28	10	77
14	49	14	87
22	61	22	98
28	67	28	93
29	67	29	92

- Remarks - Results: Degradation of the test material and sodium benzoate in the toxicity control was 61% and 63% at days 28 and 29 respectively. This showed that the test material was not inhibitory towards the inoculum. The reference substance showed satisfactory degradation at 10 and 28 days. The inorganic carbon (IC) to total carbon (TC) in the test material suspension was less than 5%, which satisfied the validation criterion. All of the tests were light brown cloudy dispersions, but no undissolved test materials were observed. The pH of all tests was between 7.6-7.7. Day 29 results were corrected for the CO_2 present in the second absorber.

CONCLUSION: The test substance showed rapid biodegradation but did not satisfy the criterion of >60% degradation after 10 days to be classified as readily biodegradable.

TEST FACILITY: Safepharm (2006j)

8.1.2. Bioaccumulation

- Remarks: Not Tested. Although the test substance was not considered readily biodegradable, it showed rapid biodegradation, with 67 % biodegradation

after 28 days. The notified chemical is therefore unlikely to bioaccumulate. Release to the aquatic environment will also be very low.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified Chemical

METHOD: In accordance with OECD TG 203 Fish, Acute Toxicity Test and 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	~ 150 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation; Gas Chromatography (GC)
Remarks – Method	A range finding test was performed by preparing two water available fractions (WAFs) of test substance of nominal concentrations of 100 and 1000 mg/L by stirring the mixture of test substance and purified water for 23 hours and allowing the mixture to settle for 1 hour before siphoning the WAF. Three fish were subjected to the WAFs for 96 hours. The main test was conducted by subjecting ten fish to WAFs (concentrations detailed below) of the test substance (prepared in the same manner as described previously). As microscopic examination of the WAFs with the highest loading rates showed micro-dispersions all of the test substances were filtered. The test solutions were replaced every 24 hours. The actual concentrations were determined by GC and Total Organic Carbon (TOC) on fresh an old samples at 0, 24 (old), 72 (fresh) and 96 (old) hours. pH 7.6-8.1 Temperature 14.0-15.2°C Dissolved Oxygen 9.0 – 10.3 mg O_2/L Light: 16 hours light and 8 hours dark with 20 minute transition.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Not Detected	10	0	0	0	0	0
100	0.193-0.300	10	0	0	0	0	0
180	0.320-0.799	10	0	0	0	0	0
320	0.411-0.675	10	0	0	1	1	1
560	0.770-1.62	10	0	0	0	2	2
1000	0.809-2.24	10	0	0	2	10	10

LC50	610 mg/L WAF at 96 hours
NOEC (or LOEC)	180 mg/L WAF at 96 hours.
Remarks – Results	No mortalities were observed in the range finding test. The WAFs after filtering were observed to be clear and colourless and microscopic examination showed no oily globules. Fish in the 320, 560 and 1000 mg/L test substances were observed to have increased pigmentation, a loss of equilibrium and/or swimming at the bottom. Fish in these test substances that were observed to be moribund were killed for ethical reasons and recorded as mortalities. Analysis of the test substance was also performed by TOC. The results showed concentrations of 0.11- 3.97 mg/L after correction of TOC in the control and showed and increase in concentration corresponding to the nominal concentrations. The result

was calculated by probit analysis. No calculation was performed on the actual values.

CONCLUSION The loading of WAF of test substance is practically non toxic to fish, but the actual concentrations indicate that the test substance is toxic to fish.

TEST FACILITY Safepharm (2006k)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified Chemical

METHOD In accordance with OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test and EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Approximately 250 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation; GC
Remarks - Method	A range finding test was performed by preparing three WAFs of test substance of nominal concentrations of 10, 100 and 1000 mg/L by stirring the mixture of test substance and purified water for 23 hours and allowing the mixture to settle for 1 hour before siphoning the WAF. Ten daphnids were subjected to the WAFs for 96 hours. The main test was conducted by subjecting duplicate test sample of ten daphnia to WAFs (concentrations detailed below) of the test substance (prepared in the same manner as described previously). As microscopic examination of the WAFs with the highest loading rates showed micro-dispersions all of the test substances were filtered. A reference substance (0.32, 0.56, 1.0, 1.8 and 3.2 mg/L of potassium dichromate) was also run. The actual concentrations were determined by GC and Total Organic Carbon (TOC) on fresh an old samples at the beginning (0 hours) and end of the test (48 hours). pH 8.0 Temperature 20.4-20.8°C Dissolved Oxygen 8.3-8.4 mg O_2/L Light: 16 hours light and 8 hours dark with 20 minute transition.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 hours*	*48 hours*
Control	Not Detected	20	0	0
100	0.0980-0.243	20	0	0
180	0.0970-0.265	20	0	10
320	0.202-0.516	20	0	20
560	0.435-0.624	20	0	20
1000	0.273-0.799	20	10	20

LC50	0.21 mg/L (95% Confidence Limits) at 48 hours based on mean measured concentrations (180 mg/L WAF)
NOEC (or LOEC)	0.171 mg/L at 48 hours (100 mg/L WAF)
Remarks - Results	All of the daphnia died in the 1000 mg/L test substance of the range finding test. The WAFs after filtering were observed to be clear and colourless and microscopic examination showed no oily globules. The EC50 of the reference substance was 0.97 mg/L. Analysis of the test substance was also performed by TOC. The results showed

concentrations of 0-2.63 mg/L after correction of TOC in the control and showed and increase in concentration corresponding to the nominal concentrations. The result was calculated by trimmed Spearman-Karber method.

CONCLUSION The test substance is highly toxic to daphnia.

TEST FACILITY Safepharm (2006l)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified Chemical

METHOD In accordance with OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	Green Algae *(Scenedesmus subspicatus)*
Exposure Period	72 hours
Concentration Range	Nominal: 10-160 mg/L Actual: 0.0158-0.112 mg/L
Auxiliary Solvent	None
Water Hardness	Not Specified
Analytical Monitoring	Particle counter; GC
Remarks - Method	A range finding test was performed by preparing three WAFs of test substance of nominal concentrations of 10, 100 and 1000 mg/L by stirring the mixture of test substance and purified water for 23 hours and allowing the mixture to settle for 1 hour before siphoning the WAF. Algae were exposed to the WAFs for 72 hours. The main test was conducted by subjecting triplicate test samples of algae of cell density of approximately 10^4 cells per mL to the WAFs (concentrations detailed below) of the test substance (prepared in the same manner as described previously). The actual concentrations were determined by GC and Total Organic Carbon (TOC) on fresh an old samples at the beginning (0 hours) and end of the test (48 hours). pH: 7.8-8.0 Temperature: 24±1°C Light: Continuous at an intensity of approximately 7000 Lux.

RESULTS

Inhibition of Growth Rate & Biomass

Nominal Loading Rate mg/L	Measured Loading Rate mg/L *	% Inhibition Biomass	% Inhibition Growth
Control	ND	-	-
10	0.0158	1	0
20	0.0635	10	3
40	0.0333	23	5
80	0.053	18	2
160	0.112	68	19

* Average of samples taken at 0 and 72 hours.
ND = Not Determined

Biomass		*Growth*	
EbC50 Nominal mg/L at 72 h	*EbC50 Actual mg/L at 72 h*	*ErC50 Nominal mg/L at 72 h*	*ErC50 Actual mg/L at 72 h*
130	0.094	> 160	>0.11

Remarks - Results	The algae in the 1000 mg/L of test substance showed 102% and 138% inhibition of biomass and growth rate respectively in the range finding test. The WAFs were observed to be clear and colourless and microscopic examination showed no particles or micro-dispersions. After 72 hours the cultures appeared as green dispersions. No abnormalities were observed in the cultures. Analysis of the test substance was also performed by TOC. These tests were unable to differentiate the amount TOC in the control and the test substances. The reported EbC50 and ErC50 to a reference substance (potassium dichromate) are 0.66 mg/L and 0.27 mg/L respectively. No details were given to the testing of the reference substance.
CONCLUSION	The loading of WAF of test substance is practically non toxic to alga, but the actual concentrations indicate that the test substance is toxic to alga.
TEST FACILITY	Safepharm (2006m)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified Chemical
METHOD	In accordance with OECD TG 209 Activated Sludge, Respiration Inhibition Test, EC Directive 88/302/EEC C.11 Biodegradation and US EPA Draft Ecological Effects Test Guidelines OPPTS 850.6800.: Activated Sludge Respiration Inhibition Test
Inoculum	Activated Sewage Sludge
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L Actual: Not Determined
Remarks – Method	Activated sludge organisms from the Severn Trent Water Plc sewage treatment plant at Loughborough, Leicestershire, UK, which treats predominantly domestic sewage sludge were used. A range finding test was conducted using duplicate samples of a control and single samples 100 mg/L and 1000 mg/L of test substance. A reference substance (3,5-dichlorophenol) was also run at 3.2 mg/L and 32 mg/L. Synthetic sewage was added to the test substances and the O_2 consumption rates were measured and compared with the control. The main test was conducted by subjecting triplicate samples of 1000 mg/L of test substance to the inoculum and synthetic sewage sludge and measuring the O_2 consumption rate. A comparison was then made to the control which was run in duplicate. A reference substance (3,5-dichlorophenol) was also at concentrations of 3.2, 10, and 32 mg/L. pH 7.8-8.3 Total Hardness 100 mg $CaCO_3$/L
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The range finding test showed that 1000 mg/L of test substance had 0% inhibition of respiration of activated sewage sludge. The test substances were observed as dark brown homogenous dispersions of test material. The average % inhibition of the main test at 3 hours was -2%. The reference substance had an IC50 of 11 mg/L, which was within the accepted value of 5-30 mg/L. Some of the initial and final dissolved oxygen concentrations were below the test guidelines (6.5 mg/L and 2.5 mg/L respectively). This was not considered to have an adverse effect as the oxygen consumption rate was determined over the linear portion of the oxygen consumption trace.
CONCLUSION	The test substance is not considered inhibitory to sewage sludge up to the concentration tested.
TEST FACILITY	Safepharm (2006n)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will share the same fate as the automatic transmission fluids (ATF) in which it is blended. Most (> 75%) of the ATF is likely to be sold to automobile manufactures for factory fill operations with the remainder (<25%) repackaged in small containers for garages and do-it-yourself (DIY) use. It is expected that 0.5% residue will remain in the "empty packaging" for import containers and it is estimated that 1% will remain in small packaging. Small packaging is likely to be sent to landfill, whilst larger operations are likely to send empty containers to licensed drum recyclers. It is expected that at most 30 kg of the notified chemical will be disposed of to landfill from small packaging.

Although some transmissions require the fluid to be replaced during servicing, the trend for automatic transmissions is for sealed units which are filled for the life of the transmission. These are expected to be serviced only by professional mechanics and often do not require replacement of the ATF for the life of the transmission. The lubricants are expected to be collected either at the end of the useful life of the transmissions or if required during servicing, and properly disposed of. Used lubricants may be recycled, re-refined, burnt as low grade burner fuel or disposed of by incineration. Automatic transmissions containing residual amounts of the notified chemical are expected to be disposed of to landfill or enter metal recycling.

It is expected that only a small amount (<5%; <650 kg) of the ATF would be released to the environment either from incorrect disposal from DIY enthusiasts and leaks from transmissions. This is likely to occur throughout Australia in a disperse manner. The notified chemical is likely to degrade relatively rapidly.

The notified chemical is expected to be decomposed during re-refining to simpler organic molecules and completely combusted to oxides of carbon and nitrogen; and water vapour if burnt.

9.1.2. Environment – effects assessment

Organism	Duration hours	End Point	Toxicity mg/L
Fish	96	LC50	610 WAF
Daphnia	48	LC50	0.19-0.23
Algae	72	EbC50	0.094
Algae	72	ErC50	>0.11
Micro-organisms	3	IC50	>1000

The predicted no effect concentration (PNEC) of the notified chemical may be calculated by dividing the lowest endpoint by a safety factor of 100 (as ecotoxicity data exist for three trophic levels). A value of 0.94 µg/L is derived.

9.1.3. Environment – risk characterisation

Although a predicted environmental concentration (PEC) and hence risk quotient (RQ) cannot be calculated, the RQ is expected to be low as the exposure of the notified chemical to the aquatic environment is expected to be minimal. Furthermore due to the notified chemical's low water solubility it is unlikely that the entire amount of chemical entering the aquatic environment will be available to aquatic species. The notified chemical also undergoes relatively rapid biodegradation. This will further mitigate the risk to aquatic organisms. The notified chemical therefore is unlikely to pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During formulation of the notified chemical into finished products, worker exposure to the additive concentrate (maximum concentration of 8%) is limited during transfer and mixing due to the enclosed and automated process. During sampling and final product packaging, workers

may be exposed to the notified chemical (concentration up to 2.5%) by skin, inhalation or ocular contact with residues dripping off the fill pipe and during equipment cleaning. However, exposure should be minimised by use of mechanical ventilation systems, automated processes and personal protective equipment (PPE).

Dermal, ocular and inhalation exposure may occur during repackaging and end use of finished product containing the notified chemical, especially at the sites manual handling occurs. However, workers' exposure is expected to be low due to use of effective ventilation, automated process and PPE.

Extension Applicant:
The proposed use and increase in introduction volume under the extension is not expected to significantly alter occupational exposure..

9.2.2. Public health – exposure assessment

Public exposure to the finished product containing 0.1 to 2.5% Z-70 via skin, optical, inhalation and potentially ingestion is likely due to the manual application of the DIY products and the unlikely use of PPE. However, the public exposure is expected to be limited due to its infrequent use by the public.

Extension Applicant:
The proposed use and increase in introduction volume under the extension is not expected to significantly alter public exposure.

9.2.3. Human health – effects assessment

Systemic toxicity
No toxic kinetic data are available for the notified chemical. It has low acute oral and dermal toxicity with LD50>2000 mg/kg bw.
Subchronic, 28-day administration of up to 1000 mg/kg bw/day of the notified chemical did not result in any significant observed effects in the treated rats (NOEL = 1000 mg/kg bw/day).

Topical toxicity
The notified chemical was found to be moderately irritating to the skin (light brown discolouration and crust formation) and slightly irritating to the eyes of rabbits. There was also evidence of sensitisation as determined by the increase of DNA synthesis in the Mouse auricular lymph nodes.

Mutagenicity
The notified chemical did not induce mutations in bacterial test and failed to induce significant chromosomal aberrations in mammalian cells in vitro. These results suggest that the notified chemical is not likely to be mutagenic to humans.

Other toxicities

TOPKAT (v 6.01) estimates were produced by Health Canada (report submitted). The NTP Carcinogenicity Call for the female mouse predicted the notified substance to be non-carcinogenic (Probability= 0.000).

The notified substance does not contain any structural features commonly associated with adverse human health effects.

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). The following risk and safety phrases apply to the chemical:
R38 Irritating to the skin (cut-off for classification ≥ 20%)
R43 May cause sensitisation by skin contact (cut-off for classification ≥ 1%)

9.2.4. Occupational health and safety – risk characterisation

Considering the intended use of the notified chemical the main routes of exposure for all types of workers are dermal, ocular and inhalation.

Workers handling the notified chemical during formulation of finished products may be exposed to maximum concentration of 8% in the additive concentrate. Considering the hazardous nature of the notified chemical there is a risk of skin sensitisation for these workers. However the risk is not considered to be high as handling of the concentrate will be limited to transfer into an enclosed and automated mixing process. The risk of skin sensitisation will be further reduced by employment of safe work practices and the appropriate use of personal protective equipment (PPE) including appropriate aprons and gloves. The MSDS for the additive concentrate should carry a warning with regard to the skin sensitising potential.

There is also a risk for skin irritation for workers involved in formulation of products containing the notified chemical. However, the risk is low as the concentration of the notified chemical is <20% and appropriate PPE, such as skin protection, will be used.

Workers involved in sampling and final product packaging are also at risk of skin sensitisation considering the possible dermal exposure to maximum of 2.5% of notified chemical. However, exposure is expected to be minimal due to the use of automated processes and personal protective equipment.

End use of the formulated products, namely, addition or changing of gear oils may result in frequent exposure to a range of products containing 0.1-2.5% of notified chemical. Risk of skin sensitisation is considered to be low when using products containing less than 1% of notified chemical. However, use of products containing ≥ 1% of notified chemical will be associated with increased risk of skin sensitisation. In these cases, use of PPE would minimise the risk. In addition products containing the notified chemical at concentration ≥ 1% should carry an appropriate label (see recommendations) and be accompanied by an appropriate MSDS.

The risk for transport or storage workers is considered to be low given that exposure may only occur in the event of accidental spillage.

The notified chemical has low acute and subchronic toxicity and is not mutagenic to mammalian cells in vivo. Therefore the risk of significant systemic adverse effects from exposure to the notified chemical is low.

Overall, the main risk for workers handling products containing the notified chemical is related to skin sensitisation and irritation. The skin sensitisation risk applies mainly to products containing ≥ 1% of the notified chemical and can be reduced by appropriate operational safety procedures and using of PPE.

9.2.5. Public health – risk characterisation

Products containing 0.1 to 2.5% will be available to the public for DIY manual application. During this process dermal, ocular and inhalation exposure is likely especially considering that members of the public are likely not to use PPE. Considering the skin sensitising potential of the notified chemical and the likely dermal exposure, the risk for skin sensitisation cannot be excluded especially for highly sensitive individuals. However, the risk is expected to be reduced significantly due to its infrequent use by the public.

Risk of skin irritation is low due to the expected low concentration of the notified chemical in the finished products available to the public. The MSDS available to the public should carry relevant warning statement regarding skin sensitisation and irritation.

10. RISK ASSESSMENT RELATING TO EXTENSION APPLICATION

Extension Applicant:

Use and fate of the notified polymer will not change under the proposed extension. The circumstances in the extension application are not expected to significantly change the environmental and health impacts. Therefore there are no changes required in the risk assessment.

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

11.1. 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:

Xi – Irritant
R38 Irritating to the skin
R43 May cause sensitisation by skin contact

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***
Aquatic Toxicity	1	Very toxic to aquatic life
Skin irritation	3	Warning: May cause mild skin irritant*
Skin sensitisation	1	Warning: May cause an allergic skin reaction

* Applies to some authorities

11.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

11.3. Human health risk assessment

11.3.1. Occupational health and safety

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

11.3.2. Public health

There is No Significant Concern to public health when used following the recommended safety instructions on the labels of the products available to the public.

12. MATERIAL SAFETY DATA SHEET

12.1. 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.

12.2. 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.

13. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following [health, environmental and physico-chemical] hazard classification for the notified chemical:

- R38 Irritating to the skin
- R43 May cause sensitisation by skin contact

- S24/25 Avoid contact with skin and eyes
- S37 Wear suitable gloves

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc ≥ 1% R43 May cause sensitisation by skin contact
  - Conc ≥ 20% R38 Irritating to skin

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

- Products containing ≥1% notified chemical and available to the public must carry the following safety directions on the label:
  - May cause sensitisation

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical during formulation for in finished products:
  - Couplings should be employed for transfers between storage and blending tanks and blending tanks should be fully enclosed.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during formulation and use of finished products:
  - spillage should be avoided
  - spillage should be cleaned up using appropriate absorbents and placed into containers for disposal
  - contact with skin should be avoided

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during formulation and use of finished products:
  - nitrile or neoprene gloves
  - chemical impervious clothing
  - safety glasses or face shield

  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.

Public Health

- The following measures should be taken by notifier to minimise public exposure to the notified chemical:
  - Products available to the public should contain the following warning statement: Wear gloves when using, may cause allergic skin reaction.

13.1. 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 consumer products has changed, or is likely to change significantly.

(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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