File No STD/1084

April 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

WX-70

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chevron Oronite Australia of Level 8, 520 Collins Street MELBOURNE VIC 3000

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, structure, molecular formula, molecular weight, spectral data, purity, identity and percent non-hazardous impurities, import volumes, manufacture process, and manufacturing sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a function of pH, Flammability limits, Chromosome damage, Fish and Daphnia Acute Toxicity, Algal Growth Inhibition, and Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US: Pre-Manufacture Notification submitted in 2003.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Fatty acid, reaction product with alkylamino alcohol, propoxylated

MARKETING NAME(S)
WX-70

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	NMR & IR

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-100	30-100	30-100	>100	>100

USE
The notified chemical will be used as a fuel additive.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF RECIPIENT
Chevron Oronite Australia

TRANSPORTATION AND PACKAGING
The notified chemical will be transported to Australia by ship in bulk (marine isotanks) and in drums. Initially, sales will likely be in 200 L drums.

The notified chemical will be transported from the shipping dock directly to the customer site where it will be stored in the customers warehousing facility until required for blending. Similarly, the finished petrol will be stored at the customer's distribution centre prior to tank truck transport to service stations and large fleets.

The additive package containing WX-70 will be repackaged into 350, 500, and 600 mL bottles in Australia.

5.2. Operation Description
The operations which will take place in Australia are transport, storage, blending, repackaging and end use of the fuel additive package containing the notified chemical.

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
Analysing additive package on arrival	1/site	10 minutes	80 days/year
Unloading isotanks	1-2/site	½ hour	80 days/year
Sampling finished petrol	1-2/site	10 minutes	220 days/year
Loading petrol into tank trucks	1-2/site	½ hour	220 days/year
Distribution to service stations	10-20	½ hour	220 days/year

Exposure Details

Transport and storage
The additive package will be imported in isotanks (~17,000 kg/shipment) or in drums (~190 kg/drum). Transport and storage workers are not expected to be exposed to the notified chemical during transporting except in the case of an accidental spill.

After blending, tank trucks will distribute the petrol containing WX-70 to service stations and large

fleets. The petrol will be loaded by one worker wearing protective clothing, rubber gloves, safety glasses and a hardhat. The product is pumped into the tank truck from a storage tank through hard piping. Transportation workers will likely have access to engineering controls and wear protective clothing to eliminate exposure.

After repackaging, the aftermarket fuel tank treatment products will be distributed by trucks to mass merchandizing stores like auto part stores.

The main route of exposure for transport and storage workers will be dermal. These workers will wear overalls, safety boots and gloves when handling containers.

Blending site
For isotank shipments, the additive package containing a maximum of 2 wt% of the notified chemical will be unloaded by one worker wearing protective clothing, rubber gloves, safety glasses and a hardhat. The worker connects a 10 cm by 1.8-2.4 m long flexible hose to the bottom of the isotank using cam lock couplings. The top of the isotank is opened and the additive package is pumped from the tank to a storage tank through hard piping. The area around and under isotank is cement with an open drain that has a steel grate on top. After the isotank is unloaded, the hose is automatically pigged.

For drum shipments, the additive package will be unloaded by one worker wearing protective clothing, rubber gloves, safety glasses and a hardhat. The additive packages are pumped into a storage tank or directly into an in-line blender. The transfer process takes 10 minutes for a worker to place a pump and transfer the contents. During connection and disconnection of lines, incidental skin contact from splashes, drips, and spills is possible.

Blending of the fuel additive occurs automatically into petrol using computer controlled additive injection equipment. The final concentration of WX-70 in petrol will be 130 ppm.

Repackaging
Most of the additive package containing WX-70 will be repackaged into 350, 500, and 600 mL bottles. The packaging companies would not further dilute or add solvent, but package the bottles directly from product received from Chevron. WX-70 will be packaged into bottles using automatic packaging equipment. Concentrations of WX-70 in the bottles would be 0.9-2.0 wt% depending on the size of the fuel tank.

Laboratory Staff
Laboratory staff will take samples additive package as well as the blended petrol products for testing. During sampling and analysis, there may be skin contact. However, minimal exposure will occur during the laboratory testing since it will occupy only a few minutes per batch and the concentrations of WX-70 in the samples are low.

End uses
Loading the petrol containing WX-70 at the customer site is expected to be done using ISO 9001 procedures. The area around and under the car is cement with an open drain that has a steel grate on top. After the vehicle is unloaded, the hose is automatically pigged to the rail car or tank truck. The hose end is kept on an oily drain when not in use. The potentially exposed workers include workers who pump petrol into automotive fuel tanks, or into small engines such as chain saws, snowmobiles and outboard engines.

The packaged petrol treatment containing WX-70 would be marketed in mass merchandizing and auto part stores, and used at auto repair shops by skilled trade professionals. Workers who add the bottles to the fuel tanks are skilled trade professionals at auto repair shops. They would have skin or eye exposure from drips or runs left on the outside of the container after emptying into the fuel tank.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Environmental release of the notified chemical is unlikely during importation, storage and

transportation, and accidental spills, leaks and catastrophic mechanical failure during a transport accident is the most likely reason for environmental release. Established engineering controls (eg. container construction and specifications) and emergency clean-up procedures will limit the impact on the environment of such incidents.

Containers holding the notified chemical will be transported directly from the Port facility to various bulk fuel formulation facilities for storage prior to blending into bulk fuel. Blending is undertaken using automated procedures using computer-controlled additive injection equipment. The imported product for addition to bulk fuel will contain 15-50 % (wt) of the notified chemical.

The notifier has indicated that unloading of isotanks and drums may potentially result in the release of the notified chemical of 0.122 kg/y (refer below). Using ISO 9001 procedures, spills and leaks are estimated to be less than 50 grams (1-25 grams) per unloaded, or 6 kg/y before wastewater treatment. The end of the pump hose is kept in an oily drain when not in use. Any spills or leaks are sent to a stormwater collection and treatment system consisting of an on-site chemical wastewater system with an API water and oil separator to separate the oil from water. Approximately 90% of the notified chemical will be removed from the wastewater influent by the API. Waste oil containing the notified chemical is collected by oil contactors for refining and reuse. The bottoms product containing the notified chemical from the re-refining process is used in asphalt. The wastewater flows to a pond for further treatment by induced air flotation and biological treatment. Waste sludge from biological treatment is sent off-site for incineration. After biological treatment, the wastewater is passed through a biodisk filter, then sand filter, before the treated water is released to the environment. According to the notifier, this additional treatment would remove a high proportion of the notified chemical.

Emptied isotanks and drums are generally cleaned after use with oil, which is sent to an oil recycling facility. It is estimated that 0.1% of the notified chemical would remain in the drum or isotank after emptying. Cleaning of the bulk isotanks and drums may result in aqueous waste containing 200 kg/y of the notified chemical, with waste contained and treated as described above.

After blending, bulk fuel containing the notified chemical (130 ppm) will be stored prior to transportation by road tanker or rail car to service station customers and other bulk fuel suppliers/facilities where the fuel containing the notified chemical will be stored in bulk in underground, and potentially aboveground, storage tanks (UST/AST) or other containers (eg. drums).

The notifier indicates that distribution of fuel by tanker to fuel retail outlets occurs with limited environmental release of chemical.

In general, release from bulk storage tanks (eg. USTs) to the subsoil and groundwater environment surrounding these tanks may occur over time due to corrosion and leakage of tanks or rupture of pipes and fittings. USTs have been installed throughout Australia at terminals and refineries, fuel depots, service stations, and many private facilities and organisations have USTs for fuel storage. Not all USTs leak. However, many in Australia have and have required decommissioning and land remediation. The length of service of the tank is one of a number of factors increasing the risk of UST leakage. Other factors include the type of construction materials, presence of liners, fuel type, fittings/pipes and environmental conditions surrounding the UST. Major fuel suppliers generally have tank decommissioning and replacement programs and install leak detection equipment on their tanks to prevent leaks from occurring and to trigger pollution abatement procedures to minimise risks to the environment where leaks are detected.

Except in the cases of gross spillage of fuel containing the notified chemical, eg. leakage from USTs or aboveground spillages, very little release to the soil compartment is likely and apart from areas in the vicinity of such spills and leaks no accumulation of the notified chemical is likely in soils. While mobility in soil and groundwater is expected to be low due to the high affinity of the notified chemical for organic material, no data are available on solubility in fuel. The notified chemical is expected to degrade over time by biodegradation processes.

RELEASE OF CHEMICAL FROM USE

Fuels containing the notified chemical will have a widespread and diffuse use pattern in Australia.

The notified chemical will be used mainly (~80%) for repackaging in Australia directly into after-market products consisting of 350 mL, 500 mL and 600 mL bottles. Concentration of the notified chemical in after market products will range from 0.9-2.0 % (wt), depending on the size of the fuel tank the treatment is intended to be used in. After-market products would be distributed for sale at various retail outlets. Release of the notified chemical during formulation is unlikely due to the automated and sealed equipment and engineering controls used during the process and established spill response procedures. Accidental spills are the most likely factor contributing to environmental release.

Customers will purchase the after-market products for addition to fuel tanks, with minor drips/runs during container opening and emptying the most likely route for environmental release during use.

Customers of service station operators and other fuel facilities will add the fuel to motor vehicles and other fuel-powered motors (eg. lawn mowers, chain saws, pumps, snow mobiles, outboard engines), or add quantities to drums and other approved fuel containers for later use. Minor environmental release may potentially occur at fuel pump outlets during pumping due to drips and runs from pump hose outlets.

The notifier estimates 0.25 % of notified chemical may occur in after-market container residues after containers are emptied (i.e. 18 mg/bottle), which would be either sent to plastic container recycling facilities for processing and reuse or incinerated (~60-70%) or landfill (~40%).

The notifier indicates that the notified chemical is completely consumed during combustion in internal combustion engines. Combustion products would include oxides of carbon and nitrogen. A minor quantity may potentially pass through the engine and exhaust uncombusted under certain operating conditions.

5.5. Disposal

The majority of the notified chemical will be combusted to oxides of carbon and nitrogen when used in internal combustion engines. Spills during unloading will be collected for wastewater treatment. Emptied imported containers will be cleaned, with waste oil refined and reused. The bulk of release is expected due to disposal of emptied aftermarket containers to landfill, from where the notified chemical is unlikely to be mobile but is likely to biodegrade over time.

5.6. Public Exposure

The public that may be exposed to the notified chemical when pumping petrol into automotive or motorcycle fuel tanks, or into other engines used for home and gardens activity such as chain saws, snowmobiles and outboard engines. Consumers who add the bottles of additives to their own fuel tanks may also be exposed to the notified chemical.

The main routes include skin or eye exposure from drips or runs left on the outside of the petrol pump at service stations, or the outside of the additive containers after emptying into the fuel tank.

Activity	*No. of Humans Exposed*	*Duration of Exposure*	*Engineering Controls*	*% in Formulation*
Pumping petrol	> 10,000	10 min., 52 d/yr	Petrol pump vapour recovery systems	130 ppm
Fuel Tank Treatments	> 100,000	10 min., 52 d/yr	None	0.9 - 2

6. PHYSICAL AND CHEMICAL PROPERTIES Appearance

at 20^{o}C and 101.3 kPa Pale yellow liquid

Melting Point/Freezing Point <-21^{o}C

METHOD OECD TG 102 Melting Point/Melting Range.
TEST FACILITY SafePharm Laboratories (2003a).

Boiling Point 363°C at 102.74 kPa (decomposition occurs)

METHOD OECD TG 103 Boiling Point.
Remarks Gradual decomposition starts from approximately 157°C.
TEST FACILITY SafePharm Laboratories (2003a).

Density 984 kg/m^3 @ 20°C

METHOD OECD TG 109.
TEST FACILITY SafePharm Laboratories (2003a).

Vapour Pressure 2.6 x 10^{-7} kPa at 25°C

Remarks Method OECD 104. Determined using a vapour pressure balanced system with measurements at several temperatures and linear regression analysis.
TEST FACILITY SafePharm Laboratories (2003b).

Water Solubility < 5.00x10^{-4} g/L at 21.5±0.5 °C

METHOD OECD TG 105 Flask Method. An aliquot (1 mg) was diluted with 2000 mL of reverse osmosis water adjusted to pH 7 (HCl/NaOH), shaken for 1 h and observed still to have excess test material. Water solubilities were also calculated as 5.96x10^{-4} and 1.08x10^{-3} g/L for the two main components using fragment constant methodology.
TEST FACILITY SafePharm Laboratories (2003a).

Hydrolysis as a Function of pH Not determined despite the pressure of several potentially hydrolysable functionalities. Test not conducted according to OECD TG 111 for several reasons. Recovery trials attempting to extract the test material from the water were inconsistent and there was interference at low concentrations. A GPC method of analysis is not suitable for hydrolysis assessment since the method is predominantly qualitative and not quantitative. The method is not stability indicating, since degradation products may elute at the same time to that of the parent material if they are of similar molecular weight. Method 111 is not suitable for complex reaction mixture test materials. The test material is essentially insoluble in water and Method 111 is not suitable for test materials that are insoluble in aqueous media. The analysis methods used in the partition coefficient and adsorption co-efficient test are not suitable for quantitative analysis. Components of the test material either elute on or near the dead time of the HPLC column or retain indefinitely and require forcing off the column using 100% organic solvent. Reproducibility of this data quantitatively would be exceptionally difficult and almost impossible.

Partition Coefficient (n-octanol/water) Approximately 80% of the components of the test substance (WV-70) had a Log P_{ow} of <0.3 and approximately 17.1% had a Log P_{ow} of >3 based on retention times of reference standards.

METHOD OECD TG 117 (HPLC)
TEST FACILITY SafePharm Laboratories (2003a).

Adsorption/Desorption At pH 5.0, K_{oc} values for ~22% of the components of the

test material are <2.19x10^4. About 78% of the test material has a K_{oc} >4.27x10^5.

At pH 8.5, K_{oc} values for 5% of the components of the test substance are <8.57x10^4. About 95% of the test material has a K_{oc} >4.27x10^5.

METHOD Method OECD 121. HPLC screening method. Test material (1 g) was diluted in 100 mL methanol. The HPLC dead time was determined by measuring the retention time of formamide (purity 99.5%, 1.21x10^3 mg/L solution in methanol). Solutions of reference standards were also prepared in methanol. The sample, formamide and reference standard solutions were injected into the HPLC in duplicate.

TEST FACILITY SafePharm Laboratories (2003a).

Dissociation Constant Not determined. Testing was not performed due to the insolubility of the test material in water. For the test method to work, the material must be at least partially soluble in water. Additionally, the test material is a complex reaction mixture with various components and possible chemical structures and the test method is not suitable for mixtures. A simplified structure of one component of the reaction mixture was determined using ACD Chemsketch (Advanced Chemistry Development Inc Version 3.50, 9 April 1998). The dissociation constant of the only nitrogen atom was estimated to be 6.75±0.20.

Particle Size Not applicable for liquid.

Flash Point 183 ± 2°C

METHOD EU A9

TEST FACILITY SafePharm Laboratories (2003b).

Flammability Limits Not available

Autoignition Temperature 378 ± 5°C

METHOD EU A15

TEST FACILITY SafePharm Laboratories (2003b).

Explosive Properties There are no chemical groups that would imply explosive properties or oxidising properties.

METHOD EU A14 and Draft A21.

TEST FACILITY SafePharm Laboratories (2003b).

Reactivity The notified chemical is not expected to be highly reactive. It is expected to be stable under ambient conditions.

Fat (or n-octanol) Solubility Miscible in all proportions with standard fat at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances. Mixtures of test material and liquefied and mixed standard fat were added to three separate flasks which were stoppered, sealed and shaken at 37±0.5°C for 3 h and phases observed.

TEST FACILITY SafePharm Laboratories (2003a).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50 > 2500 mg/kg bw, low toxicity
Rat, acute dermal	LD50 >2000 mg/kg bw, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, sensitisation - mouse local lymph node assay	evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOAEL=1000 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non genotoxic
Genotoxicity – in vivo micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE WX-70

METHOD
- Species/Strain: Rat/Sprague-Dawley CD
- Vehicle: None.
- Remarks - Method: GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 female	2000	None
2	3 female	2000	None

- LD50: >2500 mg/kg bw
- Signs of Toxicity: Hunched posture was observed in 3 females 1-4 hours after dosing. No other signs of systemic toxicity were noted during the study.
- Effects in Organs: None.
- Remarks - Results: None.

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

TEST FACILITY SafePharm Laboratories (2002a).

7.2. Acute toxicity - dermal

TEST SUBSTANCE WX-70

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
- Species/Strain: Rat/
- Vehicle: None.
- Type of dressing: Semi-occlusive.
- Remarks - Method: GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None.

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Very slight to well-defined erythema and very slight oedema were noted at the treatment sites of all animals 1-4 days after dosing.
Signs of Toxicity - Systemic	One female showed a bodyweight loss during the second week of the study.
Effects in Organs	None.
Remarks - Results	None.

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

TEST FACILITY SafePharm laboratories (2003c).

7.3. Acute toxicity - inhalation

No study was provided.

7.4. Irritation – skin

TEST SUBSTANCE WX-70

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	1	0.7	2	72 hours	0
Oedema	0.7	0.7	0.7	1	48 hours	0

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

Remarks - Results In the above study, loss of skin elasticity was seen at one treated skin site at the 72-hour observation.

In addition, one male rabbit received 1-hour exposure of WX-70 and showed very slight erythema at 24 and 48 hours after treatment. The same animal also had a skin site received 3-minute exposure and no sign of erythema or oedema was noticed.

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY SafePharm Laboratories (2003d).

7.5. Irritation - eye

TEST SUBSTANCE WX-70

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks - Method	GLP & QA.

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	0.3	1.7	0.7	2	72 h	0
Conjunctiva: chemosis	0.3	0.7	0.3	2	48 h	0
Conjunctiva: discharge	0	1.3	0.3	2	72 h	0
Corneal opacity	0	0	0			0
Iridial inflammation	0	0	0			0

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

Remarks - Results: Pale yellow coloured staining was observed around all treated eyes during study.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: SafePharm Laboratories (2003e).

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

TEST SUBSTANCE: WX-70

METHOD — OECD TG 429 Skin Sensitisation: Local Lymph Node Assay.

Species/Strain	Mouse/CBA/Ca & CBA/CaOlaHsa
Vehicle	Dimethyl formamide (DMF)
Remarks - Method	GLP & QA.

RESULTS

Concentration	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
25%	2314.34	5.23
50%	4827.17	10.91
100%	9091.12	20.54
Vehicle Control		
	442.57	N/A

Remarks - Results: There were no deaths during the study. No signs of systemic toxicity were observed in the test or vehicle control animals. The bodyweight changes between test and vehicle control groups were comparable.

The Stimulation Index showed that the notified chemical is a sensitiser.

Historic data of positive controls (α-hexylcinnamaldehyde) were included in the report.

CONCLUSION: There was evidence of induction of a lymphocyte proliferative response

indicative of skin sensitisation to the notified chemical.

TEST FACILITY — SafePharm Laboratories (2003f).

7.7. Repeat dose toxicity

TEST SUBSTANCE — WX-70

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/diet/drinking water.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period:
Vehicle	Water
Remarks - Method	GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	None.
II (low dose)	5/sex	15	None.
III (mid dose)	5/sex	150	None.
IV (high dose)	5/sex	1000	None.

Mortality and Time to Death
None.

Clinical Observations
In the high-dose animals, increased salivation was observed up to 10 minutes after dosing from day 5 onwards. Two incidents of noisy respiration were noted for a male on day 5 and day 11, and one case of res/brown staining around the mouth was seen in a female after dosing on day 20. A statistically significant increase in overall percentage mobile activity was detected in high-dose males. The increase was minimal and, in isolation, was considered to have arisen fortuitously.

No such clinical observations were observed for animals of either sex treated with low or mid-doses.

No treatment-related effects were detected in the test or control animals throughout the treatment period in functional observations, behavioural assessments, sensory reactivity assessments, bodyweight, food and water consumptions.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no treatment-related changes in the test or control animals in haematological or blood chemical investigations.

Pathology
There were no treatment-related changes in the test or control animals in organ weights, necropsy or histopathology investigations.

Remarks – Results
Since the clinical signs observed in the high-dose groups were isolated and in the absence of recurrent observations throughout the study, these signs were considered to be unrelated to the treatment.

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

TEST FACILITY	SafePharm Laboratories (2003g).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	WX-70
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 uvrA.
Metabolic Activation System	Rat S9-mix preparation.
Concentration Range in Main Test	a) With metabolic activation: 0-5000 µg/plate. b) Without metabolic activation: 0-5000 µg/plate.
Vehicle	acetone
Remarks - Method	GLP & QA.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	500		5000	
Test 1		≥150	5000	Not observed
Present	1500		5000	
Test 1		≥1500	5000	Not observed

Remarks - Results	The positive controls had expected effects in the study.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories (2002b).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	WX-70
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	Rat S9-mix preparation
Vehicle	DMSO
Remarks - Method	GLP & QA.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 39.06, 78.13, 156.25, 312.5, 625, 1250, 2500 & 5000	3 h	19 h
Test 1 (repeat)	0, 50, 100, 150, 175, 200*, 250*, 300* & 350	3 h	20 h
Test 2	0, 50, 100, 125, 150, 175, 200, 250 & 300	20 h	20 h
Test 2 (repeat)	0, 5, 10, 20, 40, 60*, 80*, 100*, & 120	20 h	20 h
Present			
Test 1	0, 39.06, 78.13, 156.25, 312.5, 625, 1250, 2500 & 5000	3 h	19 h

Test 1 (repeat)	0, 100, 200, 300, 400, 450*, 500*, 550*, & 600	3 h	20 h
Test 2	0, 350*, 400, 450*, 500*, 550, 575, 600 & 625	3 h	20 h

*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		≥312.5	>5000	
Test 1 (repeat)		≥350		Not observed.
Test 2		≥125		
Test 2 (repeat)		≥120		Not observed.
Present				
Test 1		≥625	>5000	
Test 1 (repeat)				Not observed.
Test 2		≥550		Not observed.

Remarks - Results: The positive controls had expected effects in the study. The concentrations used for metaphase analysis were relatively low due to marked cytotoxicity, with and without metabolic activation.

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

TEST FACILITY: Huntingdon Life Sciences (2003)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE: WX-70

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

Species/Strain: Mouse/Cr1:CD-1(ICR)BR
Route of Administration: Oral – gavage
Vehicle: Arachis oil BP
Remarks - Method: GLP & QA.

	Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
1	Vehicle control	7	0	48
2	Vehicle control	7	0	24
3	Positive control	7	50 (CP)	24
4	WX-70	7	1500	48
5	WX-70	7	1500	24
6	WX-70	7	750	24
7	WX-70	7	375	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity: One animal of group 4 had hunched posture, lethargy, decreased respiratory rate, laboured respiration, dehydration, ptosis and tiptoe gait.

Genotoxic Effects: The positive controls had expected effects in the study.

No statistically significant decreases in the PCE/NCE ratio were observed in the 24 or 48-hour test groups when compared to their control groups.

	However, a marked decrease in the PCE/NCE ratio was observed in the group 4.
Remarks - Results	The notified chemical was found not to produce a significant increase in the frequency of micronuclei in polychromatic erythrocytes of mice under the condition of the test.
CONCLUSION	The notified chemical was not clastogenic in this in vivo micronucleus test under the conditions of the test.
TEST FACILITY	SafePharm Laboratories (2003h).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

Test Substance	WX-70
Method	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Filtered (glass wool) secondary treated sewage effluent (1 mL filtrate/L test medium), Thorndale Trickling Filter Treatment Works, UK (mostly receiving domestic sewage).
Exposure Period	28 d
Auxiliary Solvent	None
Analytical Monitoring	pH range: 6.6-7.5. Temp: 22±2 °C.
Remarks - Method	Eighteen (18) bottles were filled with mineral salts medium and inoculated with sewage effluent (1 mL/L) and test substance was added to give a nominal concentration of 3 mg/L. Oxygen levels and oxygen consumption (mg O_2/L) were measured in test and control groups and compared to calculated theoretical oxygen demand (ThOD; mgO_2/mg).

Results

WX-70 Test Substance 3 mg/L (nominal)		*Sodium benzoate 5 mg/L*	
Day	*Mean % degradation*	*Day*	*Mean % degradation*
5	16	5	65
7	20	7	68
11	23	11	77
14	27	14	78
18	32	18	75
21	31	21	79
25	34	25	81
28	35	28	85

Remarks - Results	Sodium benzoate was degraded within acceptable test parameters.
Conclusion	The notified chemical is not readily biodegradable under the conditions tested.
Test Facility	Huntington Life Sciences Ltd (2002).

8.1.2. Bioaccumulation

Test Substance	Not determined. The affinity for octanol indicates that some of the

constituents in the notified chemical may have the potential to bioaccumulate but aquatic exposure is expected to be very low.

8.1.3. Combustion and Air Emissions

The notifier submitted a Standard FTP-75 Vehicle Emission Test Plan and results for the notified chemical for emissions of total hydrocarbons (THC), CO, NOx, CO_2 or non-methane hydrocarbons (NMHC) and fuel economy (Haagen, 2003). Three vehicles were tested (2002 2.2 L Chevrolet Cavalier, 2002 2.3 L Honda Accord and 2002 4.0 L Ford Explorer). Vehicles tested had previously driven 20000-50000 km to ensure internal carbon deposition. Emissions were measured after a cold start, and after 10 minutes, a hot start but few other details are available.

In addition (from anonymous overhead presentation), vehicle exhaust emissions were determined for a 1998 Toyota Camry (1803 cc) using Japanese Method 10.15 Mode Emission Test. As no variability in measured values was reported, it is not possible to determine whether the results were statistically significant; however, results were the same or not particularly dissimilar to controls for THC, CO, NOx, CO_2 and FC.

Using Japanese 11 Mode Emission Test undertaken by the National Institute of Environmental Research, Korea), emissions from a 2000 Toyota Comfort (1803 cc) and a Sonata were determined. No variability is results were reported; however, emissions of CO, HC and NOx were similar or lower than the control.

Overall, use of the notified chemical had no statistically significant effect on average exhaust emissions of THC, CO, NOx, CO_2 or NMHC for the vehicles tested. Some individual vehicles had increased tailpipe emissions of certain compounds (eg. THC, CO, NOx, NMHC). Fuel economy was not significantly altered when the notified chemical was used.

The notifier also provided a report on particulate emissions from a DISI engine (Mitsubishi Charisma GDI), tested at speeds of 40, 60, 80 and 100 km/h, that indicated there was a reduction in the emission of ultra fine particles (dp < 100 nm) and no effect on the emission of larger particles after using the notified chemical when compared to the control.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

Test Substance	WX-70
Method	OECD (1992) TG 203 Fish, Acute Toxicity Test – Semi-static and OECD (2000) Guidance Document on Testing of Difficult Substances and Mixtures.
Species	Rainbow trout (*Oncorhynchus mykiss*). Mean length 4.7 cm. Mean weight 1.46 g.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Test parameters measured at 0, 24, 48, 72, and 96 hours. pH range: 7.6-7.9. Dissolved oxygen range: 8.4-8.9 mg O_2/L. Temp. range: 14.2-14.8°C (acceptable). Photoperiod: 16 h light: 8 h dark, with dawn/dusk transition. Test water pre-tested for impurities. Test concentrations in the test media were determined analytically by HPLC-MS with recoveries within acceptable limits.
Remarks – Method	Laboratory tests were preformed in compliance with UK Good Laboratory Practice standards. Preliminary (range-finding) and definitive tests were performed. After a 24 h period in the former, the test material formed floating oil globules at concentrations above 0.60 mg/L (i.e. the

dispersibility limit of the test substance) and this concentration was used as the test concentration. Test Solution: An amount (100 mg) of test material was dissolved in dechlorinated tap water and the volume adjusted to 1 L to give a 100 mg/L stock dispersion. An aliquot (132 mL) of mixed stock solution was dispersed in water and the volume adjusted to 22 L to allow a test volume of > 20 L and test concentration of 0.6 mg/L. This was clear and colourless and only dissolved test material was shown to be present by centrifugation. Analysis showed this to be stable and therefore the nominal concentration was used.

Results

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	Not reported	20 (2 replicates of 10)	0	0	0	0	0
0.6	Not reported	20 (2 replicates of 10)	0	0	0	0	0

LC50	>0.6 mg/L at 96 hours.
NOEC	0.6 mg/L at 96 hours.
Remarks – Results	No sublethal effects were observed after 96 h exposure.
Conclusion	The notified chemical was not toxic to the fish species tested under the conditions of the test up to the limit of dispersibility of the test material (i.e. 0.6 mg/L).
Test Facility	SafePharm Laboratories Ltd (2004c).

8.2.2. Acute toxicity to aquatic invertebrates

Test Substance	WX-70
Method	OECD TG 202 Daphnia sp. Acute Immobilisation Test – Semi-static referenced as Method C.2 of EC Directive 92/69/EEC and OECD (2000) Guidance Document on Testing of Difficult Substances and Mixtures.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Test parameters measured at 0, 24 and 48 hours. pH range: 7.8-8.0. Dissolved oxygen range: 8.5-8.9 mg O_2/L. Temp. range: 20.8-20.9 °C (acceptable). Photoperiod: 16 h light: 8 h dark, with dawn/dusk transition. Test water pre-tested for impurities. Test concentrations in the test media were determined analytically by HPLC-MS with recoveries within acceptable limits.
Remarks - Method	Laboratory tests were preformed in compliance with UK Good Laboratory Practice standards. Preliminary (range-finding) and definitive tests were performed. After a 24 h period in the former, the test material formed floating oil globules at concentrations above 0.60 mg/L (i.e. the dispersibility limit of the test substance) and this concentration was used as the test concentration. Test Solution: An amount (100 mg) of test material was dissolved in reconstituted water and the volume adjusted to 1 L to give a 100 mg/L stock dispersion. An aliquot (600 mL) of mixed stock solution was dispersed in water and the volume adjusted to 1 L to give a test concentration of 0.60 mg/L. This was clear and colourless and only dissolved test material was shown to be present by centrifugation. Analysis showed this to be stable and therefore the nominal concentration was used.

Results

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	Not reported	40 (4 replicates of 10)	0	0
0.60	Not reported	40 (4 replicates of 10)	0	0

LC50	>0.6 mg/L at 48 hours
NOEC	0.6 mg/L at 48 hours
Remarks - Results	No other effects were observed.
Conclusion	The notified chemical was not toxic to the invertebrate species tested under the conditions of the test up to the limit of dispersibility of the test material (i.e. 0.6 mg/L).
Test Facility	SafePharm Laboratories Limited (2004b).

8.2.3. Algal growth inhibition test

Test Substance	WX-70
Method	OECD TG 201 Alga, Growth Inhibition Test referenced as Method C.3 EC Directive 92/69/EEC and OECD (2000) Guidance Document on Testing of Difficult Substances and Mixtures.
Species	Green algae *(Scenedesmus subspicatus)*
Exposure Period	72 hours
Concentration Range	
Nominal	0 and 0.60 mg/L
Actual	Not reported
Auxiliary Solvent	None
Water Hardness	100 mg CaCO3/L
Analytical Monitoring	Test parameters measured at 0, 24, 48 and 72 hours. pH range: 7.5-7.9. Temp. range: 24±1°C (acceptable). Photoperiod: continuous 7000 lux. Test culture pre-tested for impurities. Test concentrations in the test media were determined analytically by HPLC-MS with recoveries within acceptable limits. At initiation, nominal density was 10^4 cells/mL.
Remarks - Method	Laboratory tests were preformed in compliance with UK Good Laboratory Practice standards. Preliminary (range-finding) and definitive tests were performed. After a 24 h period in the former, the test material formed floating oil globules at concentrations above 0.60 mg/L (i.e. the dispersibility limit of the test substance) and this concentration was used as the test concentration. Six replicates were tested each in 100 mL of solution. Test Solution: An amount (120 mg) of test material was dispersed in culture medium and the volume adjusted to 1 L to give a 120 mg/L stock dispersion from which a 1.2 mg/L stock dispersion was separately mixed with algal suspension (500 mL) to give the required test concentration of 0.60 mg/L. This was clear and colourless and only dissolved test material was shown to be present by centrifugation. Analysis showed this to be stable and therefore the nominal concentration was used.

Results

Biomass	*Growth*
0.6 mg/L at 72 h	*0.6 mg/L at 72 h*
0% inhibition	0% inhibition

Remarks - Results	E_rC50 and E_bC50 > 0.6 mg/L. NOEC = 0.6 mg/L. There were no

	abnormalities detected in any cell cultures.
Conclusion	The notified chemical did not inhibit growth or biomass of the algae species tested under the conditions of the test up to the limit of dispersibility of the test material (i.e. 0.6 mg/L).
Test Facility	SafePharm Laboratories Limited (2004a)

8.2.4. Inhibition of microbial activity

Test Substance	WX-70
Method	OECD TG 301 D Ready Biodegradability: Closed Bottle Test
Inoculum	Filtered (glass wool) secondary treated sewage effluent (1 mL filtrate/L test medium), Thorndale Trickling Filter Treatment Works, UK (mostly receiving domestic sewage).
Exposure Period	5 d
Concentration Range	
Nominal	3 mg/L
Remarks – Method	Four (4) bottles were filled with mineral salts medium and inoculated with sewage effluent (1 mL/L) and test substance (3 mg/L) and sodium benzoate (5 mg/L) were added and incubated at 22±2°C. The results were compared to ready biodegradability test results (refer Section 8.1.1). Oxygen levels and oxygen consumption (mg O_2/L) were measured in test and control groups and compared to calculated theoretical oxygen demand (ThOD; mgO_2/mg).
Results	
Remarks – Results	Sodium benzoate had been degraded by 65% of its ThOD after 5 days of incubation and between 68% and 85% between Days 7 and 28. In the presence of the test substance, sodium benzoate had been degraded by 64% after five days. The inoculum was viable and the difference in test results indicates that the test material did not have an inhibitory effect to the degradation of sodium benzoate by the microbes in the test media.
Conclusion	The notified chemical was not inhibitory to sewage effluent microbes under the test conditions.
Test Facility	Huntington Life Sciences Ltd (2002).

8.3. Biochemical oxygen demand (BOD)

Test Substance	Not determined. Theoretical oxygen demand (ThOD) of WX-70 was calculated from its empirical formulae to be 1.98 mgO2/mg (Huntington Life Sciences (2002)).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The importation, manufacture, handling, storage and transportation of the notified chemical for use in fuels are unlikely to involve large releases into the environment. Accidental releases are likely to be at managed facilities or of a diffuse nature since fuel is used throughout Australia. Therefore, it is likely that environmental exposure to the notified chemical as a result of atmospheric, soil, water or food contamination would be very low. Disposal of notified

chemical residues in emptied containers to landfill is not expected to result in migration from these repositories to other environmental compartments.

9.1.2. Environment – effects assessment

Aquatic toxicity data for 3 taxa (fish, invertebrate, algae) indicate no effects at the limit of dispersibility of the test substance (i.e. NOEC 0.6 mg/L), which was the highest test concentration used. The test substance did not inhibit sewage effluent microbes at a concentration of 3 mg/L. A predicted no effect concentration (PNEC) for the notified chemical for freshwater aquatic organisms of 0.06 mg/L has been derived by dividing the lowest NOEC value by an uncertainty factor of 10. In the absence of aquatic toxicity data for marine organisms, the derived PNEC for freshwater is adopted with caution.

9.1.3. Environment – risk characterisation

The notified chemical may potentially be released to the environment during transportation, handling and use of the notified chemical, and mainly due to accidental spills, leaks or drips/runs. Established engineering controls, waste management procedure and spill response procedures would minimise the impact to the environment. Imported product, blended fuel and aftermarket products contain concentrations of the notified chemical in excess of the PNEC (aquatic) and would pose a risk if spilled or leaked to the environment. However, release to the aquatic environment is considered unlikely under the proposed use pattern.

The very low vapour pressure of the notified chemical indicates that volatilisation to the atmosphere is unlikely to be a significant migration pathway for releases to the environment. In soils and groundwater, the notified chemical is likely to be immobile in due to adsorption to organic matter and soil particles. Biodegradation is likely to occur in the environment. Following a release to the aquatic environment, dissolution in water is unlikely due to the very low water solubility, and release of high concentrations would likely result in floating free product. Partitioning to suspended particulates and accumulation in sediments is likely based on the high adsorption co-efficient (Koc), and bioaccumulation may occur. A PEC estimate in not possible due to the very low likelihood of aquatic exposure.

Data from motor vehicle emission and fuel consumption tests using several vehicle types indicated that use of the notified chemical in fuel had no statistically significant effect on average exhaust emissions of THC, CO, NOx, CO_2 or NMHC for the vehicles tested. Fuel economy was not significantly altered when the notified chemical was used and ultra fine particle emissions were much less while emission of other particles (>100 nm) was unchanged.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Skin contact is possible during transfer operations (hose coupling/uncoupling) of the additive package and the blended products containing the notified chemical at waterfront, formulation sites, and customers' facilities.

At the repackaging/formulation sites, inhalation exposure is unlikely as the process is unlikely to generate aerosols and ventilation systems are in place. During the automatic blending, operators will have low exposure by skin contact since they are only required to take samples for quality control purposes. During packaging of the finished products into bottles and drums, skin contact may occur for operators involved in overseeing the filling process where manual intervention is required and during bunging and labelling of the drums. However, in all instances potential exposure is for brief periods only.

Workers may have repeated skin or eye contamination with the finished products containing the notified chemical during repairing and servicing of vehicles or other small engine equipment. However, as the concentration of the notified chemical in the products is low (<2% in the products and 130 ppm in the end-use preparation), the potential exposure for these end users is low.

9.2.2. Public health – exposure assessment

Individuals who maintain their automotive, recreational and/or garden equipment requiring fuel additive replenishment will have contact with the products containing the notified chemical. Infrequent dermal exposure (most likely to the hands and forearms), and accidental ocular, oral and inhalation exposure could occur in these individuals. The notified chemical comprises at less than 2% in blended products and 130 ppm in fuel tanks, thus the public exposure is considered to be low.

9.2.3. Human health - effects assessment

WX-70 is of low acute oral and dermal toxicity in rats. It was a slight skin and eye irritant in rabbits. In a mouse local lymph node assay, evidence of sensitisation was found in mice treated with WX-70.

In a 28-day repeat dose oral study in rats, the NOAEL is established as 1000 mg/kg/day, the highest dose used in the study. No significant treatment-related findings were observed.

WX-70 was found to be non-mutagenic in a bacteria reverse mutation test, and non-clastogenic in an in vitro human lymphocytes test and an in vivo mouse micronucleus test.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is predicted to be slightly irritating eyes and skin. It is unlikely to exhibit irritant effects at the low concentrations. The main concern of occupational health is the skin sensitisation effects. Any products containing equal and more than 1% notified chemical are classified as hazardous, and any workers who become sensitised with the notified chemical should avoid further handling of the chemical. Risk from repeated exposure is considered to be low since at 1000 mg/kg/day (the NOAEL), the amount of product equivalent will be large and workers would not be expected to be exposed repeatedly to large amounts.

Dermal contact will be the main route of exposure and the occupational exposure is considered to be low. Pumps are used for transferring processes and automatic equipment is used for repackaging and formulation. In addition, the engineering controls such as automation and enclosure are in place and workers will wear personal protective equipment. Therefore, the adverse health risk for workers handling the notified chemical is assessed to be low, however, precautions are necessary as the notified chemical is a skin sensitiser.

9.2.5. Public health – risk characterisation

The main concern of public health in handling products containing the notified chemical is skin sensitisation. Any products containing 1% or more notified chemical need to be marked as hazardous substances with proper warning statements. Consumers who become sensitised to the notified chemical should be advised to avoid any further handling of products containing the chemical.

Lubricant products containing the notified chemical in 1 and 4 L bottles are for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified chemical. However, the health risk for public will be low because of the low concentrations of notified chemical present in the products, and the intermittent use pattern.

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:

R43: May cause sensitisation by skin contact.

As a comparison only, the classification of the 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 sensitisation	1	May cause an allergic skin reaction

Due to the aquatic toxicity tests performed finding no toxicity at the highest concentrations tested, the classification of the notified chemical using the GHS was not possible (i.e. L(E)C50 >0.6 mg/L).

10.2. Environmental risk assessment

onsidered 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 Low Concern to public health based on its reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - Sensitisation (Xn): R43 (May cause sensitisation by skin contact)

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - concentration cut-off ≥ 1%: R43 (May cause sensitisation by skin contact)

- Products containing equal and more than 1% notified chemical and available to the public must carry the following safety directions on the label:
  - S24 (Avoid contact with skin)
  - S37 (Wear suitable gloves)

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - enclosure of mixing tanks during formulation
  - local exhaust ventilation during transfer of notified chemical from drum to mixing tank.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - during transfer to mixing tank, avoid splashing
  - for use of products containing the notified chemical, minimise spray use during cleaning operations
  - sensitised workers should be advised not to further handling the notified chemical

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - neoprene or nitrile rubber gloves
  - protective clothing
  - safety eye protection.

  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 to minimise public exposure to the notified chemical:
  - The risk and safety phrases should be displayed on the labels of products containing ≥1% notified chemical for public uses.

Environment

Disposal

- The notified chemical should be used for its intended purpose or recycled if possible. Waste product may be hazardous and may require specific waste disposal management in accordance with State/Territory waste disposal regulations.

Emergency procedures

- Spills/release of the notified chemical should be handled by controlling the source of the spill/leak, containing the spill/leak to prevent further contamination of environmental media (soils, surface waters, groundwater). Keep out of sewage and drainage systems and all bodies of water. Clean up spill as soon as possible. Use appropriate techniques such as non-combustible adsorbent material or pumping. Where feasible and appropriate, remove contaminated soil. Place contaminated materials in labelled, sealable containers for storage, handling, transportation and disposal.

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 subsection 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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