File No: NA/967

February 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Ester 6

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Hellay Laboratories Pty Ltd (ABN: 49050 136 528) of 9 Monterey Rd, Dandenong Victoria 3175 has submitted a standard notification statement in support of their application for an assessment certificate for Ester 6.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and purity have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: Ester 6

3. PHYSICAL AND CHEMICAL PROPERTIES

The physical and chemical properties tabulated and discussed below were determined at the Huntingdon Life Sciences Laboratories, England, using accepted EEC and OECD methods and guidelines. Unless referenced otherwise, the results are summarised from test reports provided in the notification dossier (Huntingdon 2000a).

Appearance at 20°C & 101.3 kPa:	Clear yellow to amber liquid
Boiling Point:	Decomposition at >295°C before boiling at 101.3 kPa
Freezing Point:	< -25ºC
Relative Density:	0.980 at 20°C
Vapour Pressure:	1.7 x10^{-7} Pa at 25°C
Water Solubility:	<0.02 mg/L at 25°C
Fat Solubility	Miscible in all proportions of fat
Partition Co-efficient (n-octanol/water):	log P_{ow}>7.7
Hydrolysis as a Function of pH:	Not determined, see notes

Fat Solubility:	Miscible in all proportions
Kinematic Viscosity:	127 mm^2/s at 20ºC
Dynamic Viscosity:	124 mPa.s at 20ºC
Adsorption/Desorption:	Log Koc >5
Dissociation Constant:	Not determined (see notes below)
Flash Point:	226°C (closed cup) (EEC method A.9)
Flammability Limits:	Not flammable (see notes below)
Autoignition Temperature:	398°C (EEC method A.15)
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable to shock and heat (EEC method A.14)

3.1 Comments on Physico-Chemical Properties

The freezing point is <-25°C (OECD TG 102). The substance was observed to thicken but did not solidify as the temperature decreased to -25°C. Upon heating, the notified chemical was observed to darken significantly above 295°C, indicating decomposition (OECD TG 103). There was no sign of boiling at temperatures up to 400ºC.

The vapour pressure of the notified chemical was determined using a vapour pressure balance method according to OECD TG 104. A series of three measurements were performed between temperatures of 79 and 148ºC. Mass differences, condensation rates, and sample temperatures were monitored during the test. The mean vapour pressure at 25ºC was extrapolated using measurements taken during runs 2 and 3 to plot the relationships between changing pressure and temperature. The results indicate the substance is not volatile.

A water solubility test was conducted in accordance with OECD TG 105. Approximately 10 to 20 mg of test substance was added to 110 mL purified water in vials, purged of nitrogen, sealed, and mixed at 30ºC for 1, 2, and 3 days. The samples were then filtered through pre-wetted glass microfibre filters. Extracts comprising 100 mL filtrate and two parts ethyl acetate were removed, and the extracts evaporated under nitrogen at 45ºC until dry. The residues were redissolved in acetone for analysis using gas chromatography. The chemical was found to be poorly soluble in water.

The new substance is a fat-soluble, tetra-ester. Fat solubility was conducted on the test material, using a standard fat simulant (HB 307, OECD TG 116) and it was found to be miscible in all proportions of fat.

The partition coefficient, log P_{ow}, of the notified chemical was estimated by dividing the individual solubilities of ESTER 6 in n-octanol (ie. 1000 g/L) by the solubility in water (ie.

0.02 mg/L). The normal OECD methods of determining this parameter were not used because the estimated log P_{ow} value falls outside the limits applicable to these methods (ie. OECD Methods 107 & 117 are applicable over log Pow values –2 to 4 and 0 to 6, respectively). The partition coefficient indicates a high affinity to lipids.

The adsorption coefficient, K_{oc}, of the notified polymer was estimated from the empirical relationships with the partition coefficient, P_{ow}, and the water solubility, S (Lyman *et al.* 1982). The estimated log K_{oc} value, based on the partition coefficient, is >5.6, whereas the estimated log K_{oc} based on the water solubility is >4.6. On the basis of these values, the log K_{oc} of ESTER 6 was estimated to be >5. These results indicate the notified chemical is immobile in soils.

The dissociation constant was not measured due to low water solubility (ie. <1mg/L) of the notified chemical. There are no groups able to dissociate.

The hydrolysis as a function of pH values was not measured due to low water solubility (ie. <1mg/L) of the notified chemical. The esters present have the potential to hydrolyse but not in the environmental pH range of 4 to 9 due to the low solubility.

The flammability test was not performed as it was found that the notified chemical did not evolve gas on exposure to water in other studies. Pyrophoric properties were not determined as the notified chemical did not ignite on prolonged exposure to air.

4. PURITY OF THE CHEMICAL

The degree of purity has been exempted from publication in the Full Public Report and the Summary Report.

Hazardous Impurities: None

Non-hazardous Impurities (> 1% by weight): None

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified chemical will be imported into Australia exclusively as a component of finished hydraulic oil formulations in 200 L steel drums. The concentration of the notified chemical in the finished hydraulic oils will be 95 %.

Import volumes for the notified chemical will be less than 10 tonnes per annum increasing to 100 tonnes in 5 years.

The finished hydraulic oils will be added directly to hydraulic systems in large mobile equipment. The hydraulic oils will be transferred from the 200 L steel drums directly to hydraulic systems using a standard drum pump.

6. OCCUPATIONAL EXPOSURE

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical except in the event of accidental spillage.

Worker exposure to the notified chemical may occur when filling hydraulic systems and during maintenance. Dermal contact is considered to be the main route of occupational exposure. Exposure to mists and vapours is not expected due to the low vapour pressure of the notified chemical. The notifier estimates that approximately 100 workers will be exposed to the notified chemical. As the time between draining for synthetic hydraulic oils is 6000-7000 hours, which can range over 1-2 years, and that the hydraulic oil volumes in this type of equipment can range from 76-760 L, the number of hours per day and days per year that workers could be exposed to the notified chemical is very low. Exposure will be controlled through the use of personal protective equipment including impermeable gloves and industrial clothing.

Disposal contractors may experience dermal exposure to the notified chemical during disposal. The notifier has indicated the notified chemical may be disposed of by landfarming and processing through sewage treatment facilities, burnt for fuel or burnt in a high temperature incinerator.

7. PUBLIC EXPOSURE

Members of the public may be exposed to the notified chemical in the event of an accident involving the breakage of the steel drums in which it is imported. Such an occurrence is unlikely. The relatively rapid biodegradability of the oil and the closely regulated disposal of used oil will mean that contact with the notified chemical in the environment is unlikely. The finished oil containing the notified chemical is applied directly to the hydraulic systems of large mobile equipment at environmentally sensitive sites. These sites are not likely to be attended by members of the public. The circumstances in which the notified chemical is transported, warehoused and used are such that the potential for public exposure to the notified chemical is minimal. If contact does occur it is most likely to be dermal and of an infrequent and transient nature.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Release to the environment of the notified chemical is not anticipated during transport or storage except in the event of a transport accident. In equipment maintenance workshops, minor releases of the notified chemical onto workshop floors could occur as a result of operational spills during filling and maintenance of the hydraulic systems when the lubricant is transferred from drums via a standard drum pump direct to the systems.

Recommended procedures in the event of accidental spills are addressed in the MSDS. Accidental spills should be adsorbed on fire retardant treated sawdust, diatomaceous earth or similar material and disposed of at approved facilities in accordance with current laws and

regulations.

Release of the hydraulic oil could occur during mining, forestry, agricultural or excavation operations through leakages from mobile industrial equipment. Leakages would be expected to occur in ditches, forested areas, agricultural soils, or any area where the hydraulic equipment is used. Release into waterways is not expected, but could conceivably occur if used oil is leaked onto the ground and then washed into waterways during erosion and runoff events.

It is estimated that up to 500 kg of the notified chemical could remain in the import containers after use. It is expected that the residues washed from the import drums during reconditioning will be incinerated. Residues left in containers not recycled will likely be disposed of through municipal or industrial disposal routes.

Hydraulic oils in industrial equipment require changing after a specified time to ensure the oils work effectively. The time between draining for synthetic hydraulic oils is in the range of 1-2 years depending on the number of hours of usage of equipment. The volume of oil in the hydraulic system can range from 76 to 760 L depending on the type and size of the equipment. As such release to the environment of the notified chemical could occur at end use through improper disposal of the used lubricant product when it is removed from hydraulic systems.

Recommendations for pathways of disposal of the used oil are given in the MSDS. Disposal of the used oil can be done by burning in an enclosed, controlled burner provided such burning is not limited by the controlling authorities. The notified chemical is also suitable for recycling through licensed dealers or disposal through licensed waste disposal sites. Landfarming and processing through sewage treatment facilities are also options for disposal provided the required approval is given.

8.2 Fate

Hydraulic oils in industrial equipment require changing after about 1 to 2 years to ensure the hydraulic systems operate effectively. All of the imported chemical contained in the hydraulic oil could potentially be presented for disposal when the oil is changed or removed from equipment. The amount of lubricant oil resurfacing as used oil will depend on the type of use, with some applications resulting in all of the used oil being generated as waste, and others resulting in all the oil being burned or lost through leakage (Macpherson, 1997). According to LaGanza (1997), leakages from mobile hydraulic equipment are highly probable, and hence, there may be very little used oil generated from this application. Macpherson (1997) also noted that hydraulic equipment used in the mining industry tended to generate less used oil than other uses because most of the oil is lost through leakages from damaged hoses.

The fate of used oils in Australia has been the subject of a number of surveys. An Australian Institute of Petroleum survey (AIP, 1998) indicated that at least 60% of all used oils generated are collected for recycling to be resold mainly as fuel oil. The fate of the 40% of used oil not collected for recycling includes its reuse as a fuel extender especially in the mining, agricultural, forestry and transport sectors, and its use as a dust suppressant and weed killer. In some states, there is also evidence of significant stockpiles of used oil held with

collectors or at industrial and mining sites awaiting collection.

While the AIP report indicated no evidence that bulk used oil was being dumped, they did admit to some uncertainty as to the fate of 40% of used oil generated, but not collected for recycling. Based on the preceding information, the fate of the notified base stock oil could include the following: (1) recycling and reuse through a licensed dealer or reuse at the site of use, (2) disposal by incineration, (3) disposal in landfill, and (4) illegal dumping, for example, into stormwater drains.

Any notified chemical recycled for fuel or disposed of by incineration would result in the evolution of water vapour and oxides of carbon. Any chemical entering sewage treatment facilities is expected to partly degrade in the sewer depending on the residence time. The base ester is not readily biodegradable, but is inherently biodegradable. In a ready biodegradability Modified Sturm Test (OECD 301B), performed against nominal test concentrations equivalent to 20 mg carbon/L, about 28% of the chemical was degraded after 6 days and 70% by the end of 29 days, without a biodegradation plateau being achieved (Huntingdon, 2000b). In the test sample containing a reference substance, sodium benzoate, and the test substance, 61% was degraded after 13 days, while in the test sample containing only the reference substance, 71% was degraded after 6 days and 87% after 28 days. These results indicate the test was viable and that Ester 6 did not have any inhibitory effects on the activity of the microbial inoculum. However, the test substance did not meet the test requirements of degrading by 60% within a 10 day window, which would define it as readily biodegradable. Any chemical not degraded in the sewer is expected to partition into sludge, which will be disposed of in landfill with solid wastes.

Any oil on the ground either in landfill, leaked from equipment, or following its use as a dust suppressant or weed killer would eventually be absorbed into the soil and become associated with organic components and mineral particles in the soil matrix. The chemical is not expected to leach from the soil compartment. The high log K_{oc} value and low water solubility indicate the chemical will have a strong tendency to sorb to soil organic matter and clay.

In the soil environment, the polymer is expected to slowly degrade through abiotic and biotic processes. For example, Ester 6 contains ester functional groups that are amenable to hydrolysis and which may enhance abiotic breakdown, although this will be slow in the environmental pH range of between 4 and 9 due to the low water solubility. Microbial degradation of the notified chemical would be expected to eventually breakdown the material. The rate of degradation would vary with the suitability of conditions, such as the kind and number of microorganisms, oxygen availability and suitable temperatures.

The notified chemical exhibits some potential to bioaccumulate. Much of the ability of a substance to cross biological membrane depends on its molecular weight, and the balance between its hydrophilicity and lipophilicity. Chemicals with molecular weights between 100 and 600, have an increased bioaccumulation potential, compared to substances of higher molecular weights. Maximum potential to accumulate occurs at a MW of about 350 (Connell, 1990). The notified chemical has a molecular weight of >600, outside the range of high bioaccumulation potential.

Chemicals with log P_{ow} values between 2 and 12 have the capacity to bioaccumulate, and show a maximum accumulation potential at values of about 6. In addition, chemicals with water solubilities of less than 18 mole/L, can potentially bioaccumulate. A maximum

capacity to bioaccumulate occurs at water solubilities of about 0.002 mole/L. The log P_{ow} of the notified chemical is >7.7 and the water solubility is <0.027 mol/L, both values within the range describing general characteristics for bioaccumulation (Connell, 1990). However, exposure to the aquatic compartment is likely to be minimal.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Ester 6

Test	*Species*	*Outcome*	Reference
acute oral toxicity	rat	LD_{50} > 2000 mg/kg bw	Huntington Life Sciences, 1999a
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg bw	Huntington Life Sciences, 1999b
skin irritation	rabbit	Slightly irritating	Huntington Life Sciences, 1999c
eye irritation	rabbit	Non irritating	Huntington Life Sciences, 1999d
skin sensitisation	guinea pig	Not sensitising	Huntington Life Sciences, 1999e

9.1.1 Oral Toxicity (Huntington Life Sciences, 1999a)

Species/strain:	Sprague-Dawley rat
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Oral intubation
Test method:	OECD TG 420
Mortality:	None
Clinical observations:	No signs of treatment related toxicity were noted.
Morphological findings:	No treatment related abnormalities were noted.
Comment:	1 female showed very slight weight loss between days 8-15 while another had a cyst on the right ovary. 1 male had a slightly dilated right kidney.
LD_{50}:	>2000 mg/kg bw

Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Huntington Life Sciences, 1999b)

Species/strain:	Sprague-Dawley rat
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2000 mg/kg bw under semi-occlusive dressing for 24 hours.
Test method:	OECD TG 402
Mortality:	None
Clinical observations:	No signs of treatment related toxicity were noted.
Morphological findings:	No treatment related abnormalities were noted.
Comment:	Yellow ano-genital stains were observed in 1 female and 1 male on days 1 and 2 respectively. At necropsy one female had slightly discoloured lungs and another moderate dilatation of the right kidney. No skin irritation was observed-all Draize scores were zero.
LD_{50}:	>2000 mg/kg bw
Result:	The notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

The notifier has applied for a variation of scheduled requirements for this endpoint.

9.1.4 Skin Irritation (Huntington Life Sciences, 1999c)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	1 male, 2 females
Observation period:	3 days
Method of administration:	0.5 mL of the test substance as a single 4 hour semi-occlusive application to intact skin
Test method:	OECD TG 404

Draize scores:

Time after treatment (days)	***Animal #***		
	1	***2***	***3***
Erythema			
1	1[a]	0	0
2	1	0	0
3	0	0	0
Oedema			
1	0	0	0
2	0	0	0
3	0	0	0

[a] see Attachment 1 for Draize scales

Comment: The relative humidity in the animal room was out of range for 4 of 5 intervals.

Result: The notified chemical was slightly irritating to the skin of rabbits.

9.1.5 Eye Irritation (Huntington Life Sciences, 1999d)

Species/strain: New Zealand White rabbits

Number/sex of animals: 1 male, 2 females

Observation period: 3 days

Method of administration: 0.1 mL of the test substance into the conjunctival sac of one eye of each animal.

Test method: OECD TG 405

Comment: The only irritation observed was a slight to moderate conjunctival redness and severe discharge in all 3 animals 1 hour post application. These effects had cleared by 24 hours post application. No eye irritation was observed-all Draize scores were zero.

Result: The notified chemical was not irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Huntington Life Sciences, 1999e)

Species/strain: guinea pig/Dunkin-Hartley.

Number of animals: 10 test, 5 control.

Induction procedure:

test group:

day 1 Pairs of intradermal injections (0.5 mL) to the scapular region as follows:

- 1:1 Freund's Complete Adjuvant (FCA) and distilled water;
- 5% test material in propylene glycol;
- 5% test material in 1:1 FCA and distilled water.

day 8 Undiluted test substance under occlusive dressing for 48 hours.

control group: As for test animals without the test material.

Challenge procedure:

day 22 50% or 100% test material in mineral oil under occlusive dressing for 24 hours.

Test method: OECD TG 406

Challenge outcome:

Challenge concentration	*Test animals*		*Control animals*	
	*24 hours**	*48 hours**	*24 hours*	*48 hours*
50%	0/10**	0/10	0/5	0/5
100%	0/10	0/10	0/5	0/5

* time after patch removal

** number of animals exhibiting positive response

Comment: All animals survived, gained weight and were free of clinical signs during the study. The susceptibility of the animals used in the study was demonstrated by a positive response to the known sensitiser hexylcinnamic aldehyde (HCA).

Result: The notified chemical was not sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Huntington Life Sciences, 2000)

Species/strain: rat/Sprague-Dawley.

Number/sex of animals: 5/sex/group, including additional control and top dose recovery groups.

Method of administration: Oral (gastric intubation). Vehicle: corn oil.

Dose/Study duration: 0, 15, 150 and 1000 mg/kg bw/day for 28 consecutive days.

Test method: OECD TG 407

Clinical observations:
No treatment related effects on mortality, body weight, food consumption, motor activity or functional observational battery evaluations were noted.

Clinical chemistry/Haematology
Mean test group haematology, clinical chemistry and urinalysis values were comparable to controls. The few test group values that were statistically different from controls were within normal ranges and did not show a dose response relationship.

Organ weights:
The absolute and relative mean adrenal weight of females treated with 150 mg/kg bw/day although decreased compared to controls, was within normal ranges. The decrease was not observed at 1000 mg/kg bw/day.

The relative mean liver weight of females treated with 1000 mg/kg bw/day although increased compared to the control female value, was within normal ranges. This increase was not observed in recovery animals at 1000 mg/kg bw/day.

Histopathology:
There were no macroscopic or microscopic treatment related effects.

Result:
The No Observed Adverse Effect Level (NOAEL) for Ester 6 was the top dose of 1000 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Huntington Life Sciences, 1999f)

Strains: *S. typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100; *Escherichia coli* strain WP2*uvrA.*

Metabolic activation: Induced rat liver microsomal fraction (S9).

Concentration range: 0, 5-5000 microgram/plate.

Test method: OECD TG 471

Comment: No evidence of mutagenic activity was detected in the presence or absence of the metabolic activator. No signs of toxicity were observed. The negative controls were within normal limits and the positive controls (2-nitrofluorene,

sodium azide, 2-(2-furyl)3-(5-nitro-2-furyl) acrylamide and 9-aminoacridine (-S9); 2-aminoanthracene and benzo(a)pyrene (+S9)) demonstrated the sensitivity of the test.

Result: The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in human lymphocytes in vitro (Huntington Life Sciences, 1999g)

Cells: Human lymphocytes.

Metabolic activation system: Induced rat liver microsomal fraction.

Dosing schedule:

• *Metabolic Activation*	• ***Experiment Number***	• *Test concentration (μg/mL)*	• *Controls*
-S9	1	Treatment time = 3 hours; expression time = 18 hours. Test concentration = 0*, 15.63, 31.25, 62.5, 125, 250, 500*, 1000*, and 2000* microgram/mL.	Positive: Mitomycin C Negative: Vehicle = DMSO
	2	Treatment time = 21 hours. Test concentration = 0*, 15.63, 31.25, 62.5, 125, 250*, 500*, 1000*, and 2000* microgram/mL.	
+S9	1 (S9 = 5%)	Treatment time = 3 hours; expression time = 18 hours. Test concentration = 0*, 15.63, 31.25, 62.5, 125, 250, 500*, 1000*, and 2000* microgram/mL.	Positive: CP Negative: Vehicle = DMSO
	2 (S9 = 5%)	Treatment time = 3 hours; expression time = 18 hours. Test concentration = 0*, 15.63, 31.25, 62.5, 125, 250, 500*, 1000*, and 2000* microgram/mL.	

CP - cyclophosphamide
DMSO – dimethylsulphoxide
* - cultures selected for metaphase analysis

Test method: OECD TG 473

Comment:	No statistically significant increase in the frequency of chromosomal aberrations was seen at any dose level. Positive controls demonstrated the sensitivity of the test and negative controls were within historical limits. Precipitation was observed at 500- 2000 microgram/mL. There was no treatment-related reduction in mitotic index at any dose.
Result:	The notified chemical was non clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats (each LD50 > 2000 mg/kg). It was slightly irritating to the skin of rabbits, was not an eye irritant in rabbits and was not a skin sensitiser in guinea pigs. No systemic toxicity was observed in a 28-day oral repeated dose study in rats (NOAEL = 1000 mg/kg/day) and neither mutagenicity in bacteria nor clastogenicity in human lymphocytes was observed.

The notified chemical is not determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided ecotoxicity test studies for fish, *Daphnia*, green algae, and microorganisms. The results of these tests are summarised in the table below. All tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practice, unless otherwise stated.

Test	***Species***	***Results***
Acute Toxicity (OECD TG 203)	Rainbow Trout *Oncorhynchus mykiss*	96 h LL_{50} > 1000 mg/L NOEL ≥ 1000 mg/L
Acute Immobilisation (OECD TG 202)	*Daphnia magna*	48 h LL_{50} > 1000 mg/L NOEL ≥1000 mg/L
Algal Growth Inhibition (OECD TG 201)	*Selenastrum capricornutum*	72 h EL_{50} > 1000 mg/L NOEL ≥ 1000 mg/L
Activated Sludge Respiration Inhibition (OECD TG 209)		3 h EC_{50} > 1000 mg/L NOEL ≥ 1000 mg/L

* NOEL - no observable effect loading rate

Fish

An acute toxicity to fish test (OECD TG 203) was performed under semi-static conditions to assess the toxicity of Ester 6 to Rainbow Trout (*Oncorhynchus mykiss*). A preliminary rangefinding test was conducted over a 96-hour period using nominal concentrations of 10, 100 and 1000 mg/L to determine appropriate test concentrations. No fish mortalities were

observed during the rangefinding test (Huntingdon, 2000c).

Following the rangefinding test, a definitive test was conducted against groups of 10 juvenile Rainbow Trout over a period of 96 hours using nominal loadings of 0 (control) and 1000 mg/L of the notified chemical. The test was carried out in filtered, de-chlorinated and softened tap water with total hardness of about 200 mg/L $CaCO_3$. During the test, the water temperature was held at 15 ±2°C, dissolved oxygen levels were in excess of 86-92% saturation, and pH remained between 7.7 and 8.2. No mortalities or treatment related effects were observed during the test.

The test medium was prepared by direct addition of the test substance to the test water. The mixture was stirred overnight and then allowed to stand for 3 hours before removing the water accommodated fraction via a sampling tube. Test concentrations were verified at 0, 24, 72, and 96 hours using GLC analysis. For most of the test, the aqueous mixture of Ester 6 formed a colourless dispersion, with measured concentration in the test water ranging between 0.16 and 0.274 mg/L. However, on the last occasion of preparation (at 72 hours) globules of the undissolved material were observed on the surface of the test medium, and the measured level of Ester 6 in the test water was 0.913 mg/L.

The water accommodated fraction of Ester 6 had no toxic effects at nominal loading rate of 1000 mg/L over the 96-hour test period. Consequently, the lethal loading rate (LL_{50}) could not be determined. It was concluded that the lethal level for the notified chemical must be >1000 mg/L, the no-observed effect loading rate must be ≥1000 mg/L, and the substance is not toxic to fish up to the limit of its water solubility.

Daphnia
To select appropriate test concentrations, two preliminary rangefinding tests were performed over 48 hours against 4 replicates of 5 juvenile daphnids using nominal loading rates of 0 (control), 1, 10, 100 and 1000 mg/L of test material. Within 24 hours of the first exposure period, some of the *Daphnia* were trapped at the surface of the test media. This was attributed to the aqueous mixture having been stirred at a rate that resulted in the production of a micro-emulsion in which the undissolved test substance remained suspended in the aqueous phase. A second rangefinding test was carried out using the same test concentrations, but with aqueous media that had been stirred at a slower rate (Huntingdon, 2000d).

Following the rangefinding test, a definitive static test was performed over a 48 hour period against 20 daphnids using nominal loading rates of 0 (control) and 1000 mg/L of the test substance. The test was carried out in filtered, de-chlorinated and softened tap water with total hardness of about 50 mg/L $CaCO_3$. During the test, the water temperature was held at 20 ±2°C, dissolved oxygen levels were in excess of 93-95% saturation, and pH remained between 7.6 and 7.8. No *daphnia* were immobilised during the definitive test.

The test medium was prepared by direct addition of the test substance to the test water. The mixture was stirred for approximately 20 hours at a rate sufficient to give a vortex depth of 10% height of the water column. The test medium was allowed to stand for 3 hours before removing the water-accommodated fraction via a sampling tube. Test concentrations were verified from pooled samples taken from each test vessel at 0 and 48 hours using GLC analysis. Mean measured concentration of Ester 6 in test water ranged between 5 to 7 µg/L, although these were below the limit of accurate quantification, deemed to be 10.6 µg/L. There was no mention of undissolved test material occurring in the test media during the definitive

test.

The 48-hour median effect loading rate (EL_{50}) was not identified. It was concluded that the lethal level for the notified chemical must be >1000 mg/L, the no-observed effect loading rate must be ≥1000 mg/L, and the substance is not toxic to *daphnia* up to the limit of its water solubility.

Algae
An Algal Growth Inhibition test was performed to assess the effects of the notified chemical on the growth of freshwater green algae. To ascertain appropriate test concentrations, a preliminary rangefinding test was performed against the algae over a period of 72 hours, using nominal test concentrations of 0 (control), 1.0, 10, 100 and 1000 mg/L of test material (Huntingdon, 2000e).

Following the rangefinding test, a definitive test was performed over a period of 72 hours against replicates (6 per concentration) of green algae using cell densities of 10^4 cells/mL and nominal concentrations of 0 (control) and 1000 mg/L, of the notified chemical. During the test, temperatures were maintained at between 23°C. Illumination intensities were maintained at 8863 lux. Increases in pH values over the test period did not exceed 0.3 pH units.

The aqueous mixture was prepared by adding the test substance directly to sterile culture medium, and stirring the mixture for approximately 23 hours at a rate sufficient to give a vortex depth of 10% the height of the column. The mixture was then allowed to stand for 3 hours and the water accommodated fraction removed via a sampling tube. Test concentrations were verified using GLC at the start of the test and after 72 hours. Concentrations of the notified chemical in the test media showed a decline in the test culture containing the algal cells, but not in the test media incubated without algal cells. However, the algal growth rate and the algal biomass were not inhibited by the presence of the test material, and no microscopic abnormalities in the algal cells were observed.

The 72-hour median effect loading rate (EL_{50}) was not identified. It was concluded that the median lethal level for the notified chemical must be >1000 mg/L, the no-observed effect loading rate must be ≥1000 mg/L, and the substance is not toxic to green algae up to the limit of its water solubility.

Microorganisms
An Activated Sludge Respiration Inhibition Test (OECD 209), was conducted over an incubation period of 3 hours against activated sludge from municipal sewage, using nominal concentrations of 0 (control), 10, 100 and 1000 mg/L of the notified chemical. A reference inhibitor substance, 3,5-dichlorophenol, was also employed as a positive control. The rate of oxygen consumption by microorganisms was not inhibited after 3 hours incubation at any of the test concentrations.

The oxygen consumption of the blank controls containing only sewage sludge and synthetic sewage was 91% of the rate at the start of the test, whereas the 3-hour EC_{50} of the reference substance was 7.6 mg/L, therefore the test was deemed valid.

Ester 6 had no inhibitory effect on the respiration rate of activated sludge at any of the concentrations employed in the test. Therefore the EC_{20}, EC_{50}, and EC_{80} of the test substance could not be calculated. It was concluded that these effects concentrations are not practically

achievable using Ester 6 even when added at concentrations well above the limit of its water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Usage patterns indicate that a large portion of the imported chemical contained in the hydraulic base stock could enter the environment as used oil following oil changes in hydraulic equipment or through leakages from mobile equipment during normal operations.

The notifier anticipates that most oil changes will be carried out by trained mechanics in closed equipment maintenance workshops, and hence used oil will be disposed of responsibly through the proper channels. AIP (1998) figures suggest that 60% of used oil in Australia is collected for recycling, while the remaining 40% is likely to follow a range of fates including recycling, reuse, and improper disposal. A worst case scenario figure for release through improper disposal is difficult to estimate, but could be up to 40% on the basis of the uncertain fate of this quantity of the used oils generated.

Oil leakage during operation of mobile machinery and equipment is highly probable. The volume of oil held in a piece of machinery depends on the type of machinery with some equipment containing large volumes (up to 760 L according to the notifier). As such, the quantity of leaked oil is likely to vary with the size and age of machinery. In well-maintained equipment, leaks would be expected to involve small quantities and slow rates of release. Release would also be distributed over a broad area given the anticipated nationwide use of the chemical. Leaked oils would enter the ground and reside in the soil compartment. Release into waterways is not anticipated, but could occur if used oil is leaked onto the ground and then is washed into waterways during erosion and runoff events.

Any notified chemical entering soil or water compartments would become adsorbed onto sediment or organic particles. The notified chemical is not readily biodegradable, but is inherently biodegradable. Hence, any chemical residing in the natural environment or in sewage treatment facilities is expected to eventually degrade through both biological and physico-chemical processes.

The notified chemical is not toxic to aquatic organisms up to the limit of its water solubility and is considered to have low potential for bioaccumulation due to low exposure. Hence safety margins toward these organisms are expected to be high.

Given that the oil is not toxic to aquatic organisms and is inherently biodegradable, the overall environmental hazard from the notified chemical is not expected to be significant. This is provided that the material is used as indicated, and that disposal of used oil takes place via the proper routes such as recycling and incineration.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

Based on the toxicological data provided, the notified chemical would not be acutely toxic via the oral or dermal routes. It is not likely to be a skin sensitiser or to be genotoxic. It is not

likely to be an eye irritant but could be a slight skin irritant. Upon repeated exposure, organ or systemic effects are not expected. The notified chemical would not be classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of the toxicological data provided.

Occupational Health and Safety
Hydraulic oil containing the notified chemical will be imported in 200 L steel containers, each containing 95% notified chemical. Exposure to hydraulic oils containing the notified chemical during transport is not expected to occur except in the event of accidental spillage.

Dermal exposure to the notified chemical may occur when filling hydraulic systems and during maintenance of equipment. Dermatitis may result after repeated exposure to the notified chemical, however, due to the expected low frequency of exposure, the risk is small. Also the use of personal protective equipment, such as impermeable gloves and industrial clothing, will reduce any risk of adverse health effects.

Disposal contractors may experience dermal exposure to the notified chemical during disposal. The risk to disposal contractors of adverse effects from oil contaminants is likely to be greater than that due to the notified chemical.

Conclusion
The toxicological profile, mode of use and use of personal protective equipment indicate that the potential for significant risks to human health through occupational exposure to the notified chemical is low.

Public Health
The very low likelihood of contact with the notified chemical and the toxicological profile of the notified chemical suggest that it will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical [as introduced]:
  - impermeable gloves
  - industrial clothing

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying*

Hazardous Substances, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of at an approved facility.

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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REFERENCES

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Huntington Life Sciences (1999d) Ester 6: primary eye irritation study in rabbits. Study no. 99-0539. East Millstone, New Jersey.

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NOHSC (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Canberra, Australian Government Publishing Service.

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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