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August 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Alkane 4

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Alkane 4

1. APPLICANT

Hellay Laboratories of 8/9 Monterey Road DANDENONG VIC 3075 has submitted a standard notification statement in support of their application for an assessment certificate for Alkane 4.

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of Alkane 4 to be exempt from publication in the Full Public Report. The data items were:

chemical name;
CAS number;
molecular and structural formulae;
molecular weight;
purity and impurities;
additives and adjuvants; and
spectral data.

Alkane 4 is not considered to be hazardous based on the nature of the chemical and the data provided.

Method of Detection and Determination: infrared spectroscopy, gas chromatography

Comments on Chemical Identity

A report with Infrared spectrometric data was submitted for the identification of the notified substance.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	slightly viscous clear liquid, no odour
Melting Point	< -20°C
Boiling Point:	165-317°C at 101.3 kPa
Specific Gravity:	0.818 at 20°C
Vapour Pressure:	2.5 x10 $^{-7}$ Pa at 25°C
Water Solubility:	<0.482 mg/L at 20°C
Partition Co-efficient (n-octanol/water):	log K_{ow} >3.87
Hydrolysis as a Function of pH:	not determined, see comments below
Adsorption/Desorption:	$\log_{10} K_{oc}$ >3.8, see comments below
Dissociation Constant:	not determined, see comments below
Flash Point:	>300°C (closed cup)
Autoignition Temperature:	362°C
Explosive Properties:	not explosive
Reactivity/Stability:	stable to light and heat

Comments on Physico-Chemical Properties

Tests were performed according to EC test guidelines (European Commission, 1992a) at facilities complying with UK Principles of Good Laboratory Practice. Full test reports were submitted.

Melting/boiling points, density, water solubility and partition coefficient (Hogg AS Bartlett AJ, 1995) and vapour pressure (Howarth R Tremain SP Bartlett AJ, 1995) were determined.

Preliminary water solubility testing determined the solubility to be approximately 0.3 g/L. Considering these preliminary results, aliquots of the test material (such that approximately 333 times this saturation concentration would be present), were weighed into three separate flasks. After addition of glass double distilled water to the flasks, they were shaken at approximately 30°C and after standing at 20°C for a period of not less than 24 hours, the contents of the flasks were centrifuged, filtered and the concentrations determined by gas

chromatography. The notifier claims that a limit value is quoted since the presence of the notified chemical in the samples is considered to be due to incomplete separation rather than true solution.

Hydrolysis testing was not conducted due to the low water solubility. The notifier claims that hydrolysis is not likely to occur in the environment, based on the known chemical properties of the substance and its chemical structure. *Environment Australia* notes that the chemical contains no functionalities that would be subject to hydrolysis, or dissociate, under the expected environmental conditions of use.

A preliminary assessment of the partition coefficient, calculated from the ratio of the solubilities of the chemical in pure n-octanol and water, determined the log P_{OW} > 6.5. The definitive test determined the log P_{OW} > 3.87 as the water solubility was less than the limit of detection. *Environment Australia* expects the partition coefficient to be >> 4.

The adsorption/desorption value was calculated/estimated from the log K_{OW} and characteristics of two structurally related compounds. Details of these calculations or the related compounds were not supplied. The K_{OC} of greater than 6 310 indicates that the chemical is likely to be immobile in soils (McCall J P Laskowski R L Dishburger H J, 1981). This is supported by the chemical's low water solubility.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported into Australia as a component in a finished oil in 200 L steel drums or 200 000 L iso-containers. The notified chemical will be used as a synthetic base fluid for use in lubricating oils for industrial (gear and hydraulic) and automotive applications. Approximately 15% of the imported volume is intended for automotive applications with the remainder for industrial applications. The concentration of the substance in the finished lubricants will range between 9 to 15% by weight.

The import volume in the first year will be 180 tonnes rising to 290 tonnes by the fifth year.

As the notified chemical is imported in finished lubricants, there are no manufacture or reformulation processes in Australia. However, some (approximately 15%) of the imported product will be repackaged into 1L to 4L containers. This volume will be sold to automotive supply stores, garages and dealers. The notifier is unsure of the quantity that will be sold to the general public for private use.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported as a component of a finished oil in 200 L steel drums or in 20 000 L iso-containers. Exposure to waterside and transport workers is unlikely except in the event of a spill.

Inhalation exposure to the notified chemical during repackaging, and in its end use applications is not expected as the notified chemical has a very low vapour pressure and is of a viscous nature thereby minimising the potential for vapour and aerosol formation. Therefore, the principal route of exposure is expected to be by skin contact.

Repackaging

No reformulation will occur in Australia. The finished oil will be repackaged for consumer use from the original import containers into 1L to 4L plastic containers. Repackaging will be principally carried out at one oil company site. Repackaging is expected to take 4 to 10 days per annum (40 000 kg of product containing Alkane 4 per 8 hour workshift). Less than 50 workers may be exposed during repackaging. For this activity workers may use a variety of pumps to transfer the finished oil and may include those operated by hand, air or electrical means. A pump would be inserted into the bung opening of the drum. Automated pumps will be used for repackaging the notified chemical from iso-containers and the majority of drums. Manual pumps will be used for repackaging if the number of drums (and/or surrounding conditions) limit the use of automated pumps. Manual pumping typically involves smaller volumes as the purpose is to provide samples to send to customers. The simplest type of pump is a hand operated one, with a closable return actuated by a spring, which will return drippage to the drum without the possibility of contamination. Pump equipment will be cleaned by either having air blown through the lines, or flushing them with water or a solvent (depending on the compatibility with other products).

The notifier indicates that under normal conditions of pump equipment use, no spillage or leakage during repackaging is anticipated. The notifier states that workers will be equipped with chemical impervious gloves and standard industrial work clothes and that standard local exhaust ventilation exists in repackaging facilities.

Dermal exposure to the notified chemical is expected during repackaging as some drips and spills may be expected on each transfer from opening of drums and when lines are connected or disconnected, in particular, when manually operated pumps are used.

End use

During use of the finished oil in the industrial setting, workers may be exposed dermally to drips and spills on the manual addition to and removal from closed systems. It is expected there will be a similar likelihood of exposure to used oil when it is pumped into and removed from tanks for disposal by incineration.

For automotive applications, workers such as garage mechanics may be exposed dermally while charging and draining the engine. The oil is transferred typically via a funnel into the engine. Oil drained from engines is typically poured into a spent oil container for collection by a contractor. The total volume to be used in automotive lubricants is 27 to 43 tonnes. Protective clothing for garage mechanics is likely to be limited to overalls, therefore, dermal exposure is the predominant route of exposure during oil-change.

Disposal
Disposal of waste oil is accomplished by a contractor at industrial and automotive service sites. The possibility of dermal exposure exists from drips and spills as the used oil is pumped into and removed from tanks. The oil is either then burned as fuel or disposed of by high temperature incineration. As with garage mechanics, protective clothing for contractors is limited to overalls and possibly gloves.

7. PUBLIC EXPOSURE

The notified chemical will be imported as a component of a finished oil in 200 L steel drums or in 20 000 L iso-containers, then transported by road to the repackaging site. There will be no manufacture of reformulation processes in Australia. There will be minimal public exposure from use as an industrial oil.

In the event of an accidental spillage during transport, the public may be exposed to the notified chemical. However, exposure will be minimal if the spills are contained and cleaned up by the recommended practices as outlined in the notifier's Material Safety Data Sheet.

It is expected that there will be widespread public exposure to the notified chemical as the automotive oil containing the notified chemical is sold through retail outlets. Public exposure will occur when changing the oil at home where dermal exposure to the automotive oil is the most likely exposure route. The notified chemical will be released into the environment when the used oil is disposed of (preferably by incineration) or recycled. Residues in the 1L and 4L containers used by the general public are estimated at less than 0.008 kg. The containers are made of recyclable plastic and consumers are encouraged to recycle them.

8. ENVIRONMENTAL EXPOSURE

Release

The finished lubricant product will be fully imported. Some repackaging, estimated at approximately 15% of the imported volume will be repackaged for commercial use, with the remainder for industrial use.

Repackaging will be principally carried out by one company at one site, with limited losses expected. Workers will use both automated and manual pumps to transfer the oil from the isocontainers and the majority of drums to the repackaging equipment. These are cleaned by having air blown through the lines, or flushing them with water or a solvent (depending upon the compatibility with other products). The resultant waste will be collected by a hazardous waste disposal company.

During use, the finished automotive lubricant oils containing the notified chemical are generally considered to be contained in the sumps of diesel and gasoline engines until the lubricant is changed. The notifier claims that the new synthetic oil product has a longer life than mineral based oils, thus its draining interval is longer. Use of the chemical product in

industrial settings as gear and hydraulic oil will involve manual addition to and removal from various systems. However, these oils are rarely changed and both are considered closed systems. Nevertheless, environmental exposure to drips and spills is still possible.

Release of the lubricants to the environment may occur due to leaks and during oil/lubricant changes. Some of the notified substance will be combusted during use. Collected used oil and lubricants will be either re-used, recycled, cleaned or burnt (for their fuel value).

The notifier has estimated the residue of notified chemical remaining in the 200 L drums to be < 0.2 kg and in the isocontainers < 25 kg. Empty drums and iso-containers will be collected by a reconditioner, with washings from the cleaning process passed to an approved on-site waste water treatment plant. Residues in the 1 and 4 L containers used by the general public are estimated at < 8 mg. The notifier claims that consumers are encouraged to recycle these containers. However, *Environment Australia* believes that most of these will be disposed of to landfill.

Fate

The notified substance will be used in lubricants and will share their fate. Therefore, most spent oil will be combusted (if used for fuel value) or recycled. A minor component will be released to the environment from spills and leaks, but this would be widely dispersed. If the notified substance was washed off road surfaces, it is expected to be adsorbed to the adjacent soil and sediments.

Collection of waste lubricants is more easily accomplished from industrial and commercial users than from the section of the community that changes its own, the Do It Yourself (D-I-Y) market (ANZECC, 1991). However, it is claimed that the D-I-Y market accounts for only 4.9% of total oil sales in Australia (14% of auto-engine oil's sales), though the availability of this oil for collection is not well understood (Snow R, 1997). This could potentially lead to a release of used oil to the environment. The 1995 survey undertaken by the Australian Institute of Petroleum (Anon., 1995) determined that 56% of used oil [1] generated will be collected. The balance (44%) will remain uncollected, either stored, or disposed of inappropriately, for example, through burial, landfill and stormwater drains, used as fence paint or dust suppressant or to kill grass.

The notified chemical has been determined to be not readily biodegradable in the CO_2 Evolution (Modified Sturm) Test (Handley JW Mead C, 1995). The chemical attained only 6% degradation after 28 days and therefore can not be considered biodegradable under the strict terms and conditions of the OECD Test Guideline 301B (Organisation for Economic Co-operation and Development, 1981). However, the Guideline states that because of the stringency of the test, a result less than 60% yield of CO_2 within 28 days does not necessarily mean that the test compound is not biodegradable under environmental conditions. The chemical was found to be non-inhibitory to the sewage sludge micro-organisms used in the study.

The potential for bioaccumulation was not determined. Due to the chemical's molecular weight (506) and partition coefficient (log K_{OW} > 3.87) bioaccumulation may be perceived as

[1] Used oil is defined as oil contaminated through use that has the potential for collection. It is approximately

an issue of concern (Connell, 1989). However, the very low water solubility (less than 9.53 x 10^{-4} mole.m^{-3}) should reduce the potential. Also, the notified substance is expected to undergo slow degradation in the environment. In any event, significant exposure to aquatic organisms should not occur as any environmental release should be low and diffuse throughout Australia. Therefore, significant bioaccumulation is unlikely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Alkane 4

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >5 000 mg/kg	(Driscoll R, 1995a)
acute dermal toxicity	rat	LD_{50} >2 000 mg/kg	(Driscoll R, 1995b)
acute inhalation toxicity	rat	LC_{50} >5.06 mg/L	(Blagden SM, 1995)
skin irritation	rabbit	non irritating	(Driscoll R, 1995c)
eye irritation	rabbit	non irritating	(Driscoll R, 1995d)
skin sensitisation	guinea pig	non sensitising	(Driscoll R, 1995e) (Morris TD, 1995)

9.1.1 Oral Toxicity (Driscoll R, 1995a)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage, dose level: 5 000 mg/kg; dose volume: 6.14 mL/kg; test material used as supplied
Clinical observations:	no signs of systemic toxicity were noted during the study
Mortality:	there were no deaths during the study

Morphological findings:	no abnormalities detected on Day 14
Test method:	limit test according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	>5 000 mg/kg
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Driscoll R, 1995b)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	semi-occluded patch; 24 hour exposure; dose level: 2 000 mg/kg; dose volume: 2.46 mL/kg; test material used as supplied
Clinical observations:	no signs of dermal irritation nor signs of systemic toxicity were noted during the study
Mortality:	there were no deaths during the study
Morphological findings:	no abnormalities were detected on Day 14
Test method:	limit test according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity (Blagden SM, 1995)

Species/strain:	rat/ Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	nose only exposure; mean achieved aerosol atmosphere of 5.06 mg/L (range 4.84 – 5.44 mg/L) for 4 hours; particle size distribution: mean mass

	median aerodynamic diameter: 1.2 µm; inspirable fraction % <4µm = 90.1; test material used as supplied
Clinical observations:	during exposure several animals showed wet fur and two females showed increased respiratory rate; on removal from the chamber, hunched posture and pilo-erection were common and there were incidents of increased respiratory rate, ptosis (dropping of the upper eyelid), isolated incidents of decreased respiratory rates and red/brown staining on the head; effects noted 1-hour post exposure were confined to hunched posture, piloerection and three animals showed increased respiratory rate; from Day 2 onwards all animals appeared normal
Mortality:	there were no deaths during the study
Morphological findings:	no abnormalities were detected on Day 14
Test method:	limit test according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
LC_{50}:	>5.06 mg/L
Result:	the notified chemical was of low acute inhalation toxicity in rats

9.1.4 Skin Irritation (Driscoll R, 1995c)

Species/strain:	rabbit /New Zealand White
Number/sex of animals:	2 male, 4 female
Observation period:	3 days
Method of administration:	0.5 ml of the test material as supplied was applied to clipped, intact skin of the dorsal flank and secured under cotton gauze for 4 hours; after 4 hours cotton wool soaked with industrial grade methylated spirits was used to remove residual test material
Test method:	according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Comment:	slight erythema was noted at two treated skin sites

	30 minutes after patch removal and persisted at one treated site at the 24 hour observation time; all treated skin sites appeared normal at the 48 & 72 hour observation times
Result:	the notified chemical was not irritating to rabbit skin

9.1.5 Eye Irritation (Driscoll R, 1995d)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5 male, 4 female
Observation period:	3 days; 1 h, 24 h, 48 h and 72 h after treatment
Method of administration:	0.1 mL of test material applied as supplied into conjunctival sac of right eye of each animal (3 male, 3 female); in three animals (2 male, 1 female) the eyes were irrigated with 100 mL lukewarm tap water for 1 minute, 30 seconds after instillation
Unirrigated eyes:	conjunctival redness was noted in four treated eyes one hour after treatment; no ocular effects were noted at the 24 hour observation time; no corneal or iridial effects were noted during the study
Irrigated eyes:	conjunctival redness was noted in one treated eye one hour after treatment; no corneal or iridial effects were reported during the study
Test method:	according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was not irritating to rabbit eye

9.1.6 Skin Sensitisation

9.1.6.1 Magnusson and Kligman Maximisation Study in Guinea Pig (Driscoll R, 1995e)

Species/strain:	guinea pig/ Dunkin-Hartley
Number of animals:	20 test, 10 control
Induction procedure:	Day 1: to a clipped area of the shoulder region,

each animal received 3 by 0.1 mL intradermal injections as follows:

- Freund's Complete Adjuvant (FCA): distilled water (1:1 ratio)
- 25% w/v of test material in dried arachis oil B.P
- 25% w/v of test material in 1:1 preparation of FCA plus distilled water;

Day 7: occluded application of 100% test material to same clipped skin area for 48 hours;

Challenge procedure: Day 21: occluded application of neat (100%) test material on the shorn right flank and similarly applied 75% w/v of test material in dried arachis oil B.P on the shorn left flank of each animal for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
75%	0**/20	0/20	0/10	0/10
100%	0/20	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method: according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

Result: the notified chemical was not sensitising to guinea pig skin under the conditions of this test system

9.1.6.2 Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Technique) (Morris TD, 1995)

Species/strain: guinea pig/ Hartley

Number of animals: 10/sex - test group;
5/sex - control group

Induction procedure: Days 1, 7 & 14: 0.3 mL of the neat (100%) test material was applied topically for a 6 hour exposure, via fastened, occluded chambers, to the same clipped area of the left shoulder

Primary challenge procedure: Day 28: application of the neat test material as per the induction procedure, but on a non previously exposed site

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
100%	0/20	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method: similar to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

Comment slight, patchy erythema was observed in 11 of 20 test animals at 24 hours and 8 of 20 animals at 48 hours; the incidence and severity of these responses were comparable to the control group

Result: the notified chemical was not sensitising to guinea pig skin under the conditions of this test system

9.2 Repeated Dose Toxicity – Limit Test (Coles LJ Brooks PN, 1995)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: main group: 5/sex test group; 5/sex control group
14 day-recovery group: 5/sex test group; 5/sex control group

Method of administration: (oral) gavage, at a dose volume of 1.23 mL/kg

Dose/Study duration: test material used as supplied at a dose level of 1000 mg/kg daily for 28 days

Clinical observations: no deaths were observed; no clinical signs of toxicity observed; no significant differences in mean food or water consumption or bodyweight gain

Clinical chemistry/ Haematology no changes in clinical chemistry parameters;

statistically significant increase in group mean neutrophil and eosinophil count was detected for treated females in comparison with controls; individual values were within the normal range in this testing laboratory, with the exception of one female which showed a general increase in leucocyte fractions; this was an

	isolated finding and not considered exposure related; no differences in haematology parameters of any of the male groups were observed.
Organ Weights:	statistically significant reduction in group mean relative liver weights for treated females; all values were within the normal range in this testing laboratory and, the reduction was not considered to be of toxicological significance because there were no morphological changes to support an effect in this organ.
Pathology:	macroscopic: no treatment related abnormalities were observed; microscopic: no treatment related lesions were observed
Test method:	according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	no signs of systemic toxicity were observed with the notified chemical when administered orally at 1 000 mg/kg/day to rats over a 28 day period

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium/ Escherichia coli* Reverse Mutation Assay (Thompson PW, 1995)

Strains:	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100; *Escherichia coli* WP2uvrA$^-$
Dose levels:	0, 15, 50, 150, 500, 1 500, 5 000 µg/plate
Test method:	according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was not considered to be mutagenic in the bacterial strains tested in the absence or presence of metabolic activation provided by rat liver S9 fraction

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Durward R, 1995)

Species/strain:	mouse/CD-1
Number and sex of animals:	5/sex/dose
Dose levels:	0, 1 250, 2 500, 5 000 mg/kg
Method of administration:	notifiede chemical via single intraperitoneal

	injection; positive control (cyclophosphamide) via i oral administration
Test method:	according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Comment:	there was a statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in the 24 hour, 5 000 mg/kg dose group; this response was within the historical controls of the testing facility and not seen as part of a dose response relationship
Result:	the notified chemical was not clastogenic in bone marrow cells of the mouse, *in vivo*

9.3.3 Chromosome Aberration Assay in Human Lymphocytes (Wright NP, 1995)

Cells:	human (male) lymphocytes
Dose levels:	0, 625, 1 250, 2 500, 5 000 µg/mL in 20 hours; 0, 1 250, 2 500, 5 000 µg/mL in 44 hours;
Test method:	according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was considered to be non-clastogenic to human lymphocytes tested in the absence or presence of metabolic activation provided by rat liver S9 fraction

9.4 Overall Assessment of Toxicological Data

The notified chemical is of low acute inhalation, dermal and oral toxicity in rats (oral LD_{50} >5 000 mg/kg, dermal LD_{50} >2 000 mg/kg and inhalation LC_{50} >5.06 mg/L).

The notified chemical is not irritating to rabbit eyes or skin and is not considered to be a skin sensitiser in guinea pigs.

In a 28-day repeat dose oral toxicity study (limit test) in the rat, no treatment related systemic toxicity was observed at the single dose level tested of 1 000 mg/kg/day.

The notified chemical was not found to be mutagenic in bacteria and did not induce an increase in micronuclei in the *in vivo* mouse micronucleus assay. The notified chemical did not induce clastogenic effects in the *in vitro* human lymphocyte cytogenetic assay.

Based on the data provided the notified chemical would not be classified as hazardous

according to the National Occupational Health and Safety Commission *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994a)

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out according to OECD/EC test methods (Organisation for Economic Co-operation and Development, 1995-1996, European Commission, 1992b) at facilities complying with UK Principles of Good Laboratory Practice.

Test	Species	Results (loading rate of WAF)	References
Acute Toxicity Semi-static WAF [a] 96 hour OECD TG 203	Rainbow trout (*Oncorhynchus mykiss*)	LLR_{50} [b] > 1 000 mg/L NOEC 1 000 mg/L	(Handley JW Sewell IG Bartlett AJ, 1995)
Acute Immobilisation Static WAF [a] 48 hour OECD TG 202	Water Flea (*Daphnia magna*)	ELR_{50} [c] > 1 000 mg/L NOEC 1 000 mg/L	(Handley JW Wetton PM Bartlett AJ, 1995)
Growth Inhibition Static 96 hour OECD TG 201	Algae (*Selenastrum capricornutum*)	E_bLR_{50} [d] > 1 000 mg/L $E_\mu LR_{50}$ [e] > 1 000 mg/L NOEC ≥ 1 000 mg/L	(Handley JW Mead C Bartlett AJ, 1995)

a) WAF: water accommodated fraction - see comments in text below;
b) LLR: lethal loading rate;
c) ELR: effective loading rate;
d) E_bLR_{50}: effective loading rate that reduced biomass by 50%; and
e) $E_\mu LR_{50}$: effective loading rate that reduced specific growth rate (24-48 hours).

Based on the results of range-finding studies, limit tests were conducted for the definitive studies. The toxicity of the notified chemical on fish, water fleas and algae was examined using a Water Accommodated Fraction (WAF) with a loading rate of 1 000 mg/L. The test media was stirred for 20 hours, with the mixture then allowed to stand for 4 hours prior to the removal of the aqueous phase or WAF.

Analysis of the WAF was carried out by Total Organic Carbon (TOC) analysis. The results showed the concentrations of the carbon in the test vessels to be around the limit of detection of the analytical method.

All exposures are expressed in terms of the original concentration of the chemical in water at the preparation of the WAF (the loading rate), irrespective of the actual concentration of the chemical in water. During all testing, the WAF was observed to be a clear, colourless solution.

Fish
A semi-static test regime was employed in this study involving a daily renewal of the test media to ensure that the concentrations of the notified chemical remained near nominal. There were no mortalities or behavioural observations in 20 fish exposed to 1 000 mg/L loading rate WAF for 96 hours.

Water Flea
Forty daphnids (4 replicates of 10 animals) were exposed to the WAF of the test material for 48 hours under static test conditions. There was no immobilisation of the daphnids or adverse reactions to exposure observed in any of the replicates.

Algae
These results are based on an initial rate loading rate of 2 000 mg/L which was diluted by the addition of the algal suspension to give an equivalent loading rate of 1 000 mg/L.
Six flasks, each containing 100 mL of the WAF, were prepared for the treatment group and three flasks for the control group. Samples were taken at 0, 24, 48, 72 and 96 hours. Neither the growth (μ) nor biomass (b) were affected by the presence of 1 000 mg/L loading rate WAF over the 96 hour exposure period. There were no significant differences ($P \geq 0.05$) between the control and test groups, with only 3% inhibition of growth observed at 72 hours and 1% inhibition observed at 96 hours.

Conclusion
The ecotoxicity data for the notified chemical indicates that it is non-toxic to fish, aquatic invertebrates and algae up to the limit of its solubility. The chemical was found to be non-inhibitory to sewage sludge micro-organisms in the ready biodegradation study (Handley JW Mead C, 1995) - see Environmental Fate above.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The end use of the notified substance is as a small (9 to 15%) component of imported lubricants. The main environmental exposure will be from inappropriate disposal of waste lubricant. A worst case scenario would be if all the uncollected oil was dumped into a sewer in some country centre. This would give a concentration of about 28.6 mg/L per day [2]. For a major city, the amount would only be about 0.28 mg/L per day, due to the much higher dilution factors expected.

However, the notifier has established that only 15% of the imported volume will be for automotive uses, with the remainder for industrial purposes. Collection of waste lubricants is more easily accomplished from industrial and commercial users than from the D-I-Y market. Therefore, should only 15% of the imported volume be inappropriately disposed according to the above scenarios, the concentration in the sewer of a country centre would be about 4.29 mg/L, while for a major city 42.9 μg/L.

[2] Given 44% of used oil is not collected, then of the 290 tonnes of notified substance imported at maximum import rates, 52.2 tonnes would not be collected (i.e. 18% x 15 tonnes). This would be 143.0 kg/d (i.e. 52.2 tonnes/365 d). The dilution at a rural town could reasonably be expected to be about 5 ML, while for a major city, say Melbourne, it would be 500 ML. This would give final concentrations of the notified substance

However, the D-I-Y market only accounts for 4.9% of total oil sales in Australia (Snow R, 1997). Further, it is believed that a large proportion of D-I-Y sales are used for top-up purposes, and do not generate used oil directly (Anon., 1995). It is also expected that the substance will be moderately adsorbed to the sludge during the waste water treatment process due to the notified substance's relatively low water solubility. Therefore, the actual concentration in the effluent will be significantly less. As the use is Australia wide, that is, not concentrated in one town or city, and with good industrial and public practice, concentrations of the notified substance exposed to the environment are expected to be further reduced.

Ecotoxicity tests indicate that the WAF of the notified substance is expected to be non-toxic to aquatic organisms.

Environmental exposure due to leaks and spills during oil/lubricant changes should not be significant. These will be widely dispersed, with the chemical expected to adsorb to sediments and slowly degrade.

Disposal of containers with waste oil (oil residues and used oil containing the notified substance) should not result in any significant environmental exposure. Waste oil may be recycled or incinerated. Incineration of the oil for fuel value or due to container reconditioning will destroy the chemical. Used/waste oil collected by industrial and commercial users, that is, not re-used, is expected to be disposed of to approved industrial facilities. D-I-Y consumer oil, if disposed of to domestic landfills, should remain in the containers. If leaks occur, the notified chemical should be contained within the landfill site, due to its immobility. Also, the chemical is expected to be present at low concentrations in and widely dispersed throughout landfills in Australia.

Overall, the environmental hazard from the proposed use of the notified chemical is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is of low acute oral, dermal and inhalation toxicity, is not irritating to skin or eyes and is not sensitising to animal skin. The notified chemical did not cause systemic toxicity in a repeat dose toxicity test and was not mutagenic in *in vivo* and *in vitro* test systems. Based on the results of toxicity tests, Alkane 4 would not be classified as hazardous according to the National Occupational Health and Safety Commission *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994a).

The notified chemical will be imported as a component (between 9 to 15%) of finished lubricant oils in 200L steel drums or in 20 000L iso-containers. No reformulating will occur, but the finished oil will be repackaged into 1L to 4L containers.

Dermal exposure to drips and spills, although expected to be low, is the predominant route of exposure for workers involved in repackaging the imported oil containing the notified chemical, in its end use applications and during its disposal. Inhalation exposure is expected to be minimal because the notified chemical and the finished oil are viscous, therefore, have

reduced potential to generate aerosols. In addition, the notified chemical has very low vapour pressure, so vapour accumulation in the workplace air is not likely. Standard local exhaust systems exist in repackaging facilities, which serve to further reduce inhalation exposure. During repackaging activities the notifier recommends that workers wear chemical impervious gloves and industrial clothing, to minimise dermal exposure. Given the low hazard associated with the notified chemical, intermittent low level exposure to the notified chemical and low concentration of the notified chemical in the oil, the occupational health risk posed to workers performing these tasks is considered to be low.

Under normal working conditions, waterside, transport and storage workers are unlikely to be exposed to the notified chemical and the occupational health risk posed to these workers is considered negligible.

Various skin lesions can occur from dermal contact with petroleum based oils (Rietschel RL et al, 1995, Kraus RS, 1998, Olishifiski JB, 1988). The notifier indicates that workers involved in repackaging of the finished oil are required to wear chemical impervious gloves and standard industrial work clothes. However, to minimise the occurrence of occupational dermatoses, protective gloves and overalls (see Section 12) are recommended for all workers who may experience dermal exposure to the finished oil containing the notified chemical. Workers should be instructed to follow good hygiene practices to control dermal exposure to oils and to remove any oil that has come into contact with the skin as soon as practicable with soap and water. Workers should be advised of the potential for occupational dermatoses following repeated skin exposure to petroleum based products and to report any skin changes to the occupational health and safety officer at their workplace. Further guidance on preventing the occurrence of occupational skin diseases can be found in the NOHSC guide Occupational Diseases of the Skin (NOHSC, 1990). The notifier's MSDS outlines first aid measures in the event of eye contact.

There is negligible potential for public exposure to the notified chemical arising from its use in industrial oils. There may be widespread public contact with the notified chemical when incorporated into 1L to 4L plastic containers for standard mineral oil based automotive oils, but it has low toxicity and the pattern of exposure would be intermittent. It is therefore considered that the notified chemical will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimize occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);

- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);

- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/ Standards New Zealand, 1998);

- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the oil containing the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practiced to minimize the potential for skin contact to oils and removal of any oil that has come into contact with the skin as soon as practicable with soap and water;
- Workers should be advised to report any skin changes to the occupational health and safety officer at their workplace; and
- A copy of the MSDS should be easily accessible to employees.

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, 1994b).

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. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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