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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Alkane 8

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Alkane 8

1. APPLICANT

Hellay Laboratories Pty Ltd of 8/9 Monterey Rd DANDENONG VIC 3075 has submitted a standard notification statement in support of its application for an assessment certificate for Alkane 8.

2. IDENTITY OF THE CHEMICAL

For the notified chemical, Alkane 8, the following items of information are exempted from publication in the Full Public Report and the Summary Report.

chemical name,
CAS number,
molecular and structural formulae,
molecular weight,
spectral data, and
details of the chemical composition

Other Names:	Alkane 8
Trade Names:	MCP 1596, SHF 56
Method of Detection and Determination:	UV, IR, NMR and gas chromatography

Alkane 8 is not considered to be a hazardous substance under health effects criteria, based on the nature of the chemical and data provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	colorless viscous liquid
Melting Point:	< -20°C (92/69/EEC Method A1)
Boiling Point:	>185°C at 101.3 kPa (differential scanning colorimetry method, 92/69/EEC Method A2)

Specific Gravity:	0.818 at 20°C (pycnometer method, 67/548/EEC Method A3)
Vapour Pressure:	3.2×10^{-11} kPa at 25°C (vapour pressure balance, 92/69/EEC Method A4)
Water Solubility:	$< 9.17 \times 10^{-5}$ g/L at 20°C (flask method, 67/548/EEC Method A6)
Partition Co-efficient (n-octanol/water):	log P_{ow} >4.96 (flask method, 67/548/EEC Method A8)
Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	Log K_{oc} > 4.53 (HPLC Screening Method)
Dissociation Constant:	not determined (see comments below)
Flash Point:	225±2°C (closed cup)
Flammability Limits:	not determined (see comments below)
Autoignition Temperature:	344±5°C
Explosive Properties:	not explosive
Reactivity/Stability:	stable to light and heat
Fat Solubility:	miscible at 37°C (OECD TG 106)

Comments on Physico-Chemical Properties

Tests were performed according to EEC and OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice. Full test reports were provided (Hogg, 1997, Tremain, 1997a,b).

The notified chemical decomposes from 185°C prior to boiling.

The concentration of notified chemical in the sample solutions was determined by gas chromatography (GC). The concentration (water solubility) was determined to be less than 9.17×10^{-5} g/L, the limit of detection.

Hydrolysis and dissociation testing were not conducted due to the low water solubility. The notifier claims that the notified chemical will not hydrolyse or dissociate because it is a branched chain alkane and does not contain functional groups that could change the hydrolysis potential or dissociable groups. It is noted that the substance contains no functionalities that would be subject to hydrolysis or dissociation under the expected

environmental conditions of use.

From the report provided by the notifier, the procedure to determine the adsorption coefficient was that outlined in the draft "HPLC-screening method for the determination of the adsorption-coefficient on soil comparison of different stationary phases" by Kördel, Stutte and Kotthoff (Hogg, 1997). The soil adsorption coefficient of greater than 3.39×10^4 indicates that the notified chemical will be immobile in soil (McCall, Laskowski & Dishburger, 1981).

The notified chemical was determined to be miscible in all proportions with standard fat at 37.0°C. Observations indicated the notified chemical had formed one phase after shaking.

The notifier claimed that flammability and pyrophoric tests were not conducted since negative results are expected in view of experience in use and handling. An explosive test was not conducted since a negative result would be expected in view of the chemical structure.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

5. USE, VOLUME AND FORMULATION

The notified chemical is used as a base fluid in synthetic automotive and hydraulic lubricants. The notifier estimates approximately 25% will be used in industrial applications and 75% in automotive applications. The concentration of the notified chemical will be 60-90% for automotive engine oils and 30-50% for hydraulic fluids. Hydraulic fluids have many uses, including fluids for car automatic transmissions, brakes and power steering. They are also used in machines such as farm and construction equipment. Hydraulic fluids are also used in many types of industrial machinery.

The notified chemical will not be manufactured in Australia. It will be imported as a component of a finished product in 200 L steel drums or in 20 000 L iso-containers. Import volumes for the notified chemical are as follows:

Year	1	2	3	4	5
Import Volume (tonnes)	100	154	300	300	—

Some of the imported product containing notified chemical will be repackaged into 1 L and 4 L containers for sales direct to the public. This will be undertaken by one oil company at one site. Repackaging may utilize pumps operated by hand, air or electrical means. However, automated pumps will be used for repackaging the notified chemical from iso-containers and the majority of drums.

6. OCCUPATIONAL EXPOSURE

Dermal contamination is considered to be the main route of occupational exposure. As the

notifier will import product containing the notified chemical, the exposure will be restricted to the product only. The notified chemical is not volatile, however, inhalational exposure may occur if oil mists are generated.

Transport and storage
Exposure to transport workers is possible in the rare event of an accident. In the event of a transport accident, the spill is to be contained and precautions taken to prevent contamination of soil and surface water entering drains.

Repackaging into 1 L and 4 L containers (for public use)
The number of the workers exposed to the notified chemical during repackaging is not provided. Repackaging will occur mainly at one commercial site. Occupational exposure may occur during transfer, clean-up of used containers, disposal of used containers and indirectly via contamination on the outside of containers.

On the arrival of the iso-containers or drums, the product containing the notified chemical will be repackaged into 1 L and 4 L small containers. Pumps are used to transfer the products into repackaging equipment. A pump will be inserted into the bung opening of the drum. The pump may be manual or automatic. Manual pumping typically involved smaller volumes as the purpose is to provide samples to send to customers. The simplest type of manual pump is hand operated with a closable return actuated by a spring, which will return drippage to the drum without the possibility of contamination. Automated pumps will be used for repackaging the notified chemical from iso-containers and the majority of drums. Automatic pumps can be operated by electricity or compressed air. Air driven pumps may generate oil mist. This may cause some degree of occupational exposure.

Dermal exposure may occur during the cleaning and maintenance of pump equipment. Pump equipment will be cleaned by either having air blown through the lines, or flushing them with water or an organic solvent (depending on the compatibility with other products). Exposure to drips and spills may occur may occur when workers connect and disconnect transfer lines, particularly when manual pumps are used. When the containers are put into cardboard boxes, packaging workers may experience dermal exposure if hydraulic fluid contaminates the outside of the containers.

Used drums and iso-containers will be cleaned and collected by a reconditioner. Washings from the cleaning process will be passed to an on-site waste water treatment plant and the drums and iso-containers will be put back into circulation. Cleaning workers may become contaminated with the notified chemical.

Material Safety Data Sheet (MSDS) for Alkane 8 states that the notified chemical should be used in well ventilated area and industrial eye protection practices should be employed. Workers employed in handling oils are normally equipped with chemical impervious gloves and standard industrial work clothes.

End use
End users of the products containing the notified chemical include automotive mechanics, and industrial plant operators, including maintenance workers. Thousands of workers could be exposed to the notified chemical.

For automotive applications, workers such as garage mechanics may receive frequent skin exposure while charging and draining the engine. Automotive oil contains a high percentage (60-90%) of the notified chemical. The oil is transferred typically via a funnel into the engine. Oil drained from engines is usually poured into a spent oil container for collection by a contractor. Protective clothing worn by garage mechanics is likely to be limited to overalls, therefore, dermal exposure would be the predominant route of exposure.

Workers involved in the maintenance and repair of machines and equipment may also be contaminated with the notified chemical. Hydraulic fluids contain less of the notified chemical (at 30-50%) than in automotive engine oils. The notifier did not provide any information on the use pattern or frequency of use for these workers.

Workers handling the hydraulic fluid may be exposed dermally to drips and spills when adding and removing the oil from enclosed change systems. Workers may also become contaminated with spent oil when removing it for disposal.

Disposal
Waste oil contractors remove spent oil from industrial and automotive service sites. They may experience dermal exposure 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. Protective clothing for contractors is likely to be limited to overalls and possibly gloves.

7. PUBLIC EXPOSURE

Automotive oils will be supplied to automotive supply stores, automotive garages and automotive dealers. Release to the environment of the oils may occur due to engine leaks and during engine oil changes. Residues in the 1L and 4L containers used by the general public are estimated at < 8 g. The containers are made of recyclable plastic and consumers are encouraged to recycle them.

It is expected that there will be widespread public exposure to the notified chemical as the automotive oil containing the notified chemical is sold directly to the public. Public exposure will occur when changing the oil at home where dermal exposure to the automotive oil is the most likely exposure route. There will be minimal public exposure from use as industrial oil.

8. ENVIRONMENTAL EXPOSURE

Release

The finished lubricant product will be fully imported. Some repackaging into 1 L and 4 L containers for commercial use will be required. The pumps and repackaging equipment will be 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. In industrial situations the chemical product will be used as a hydraulic fluid. This will involve the manual addition to and removal of hydraulic fluid from various systems. However, these fluids are rarely changed and hydraulic systems are considered closed with limited potential for environmental exposure.

Release of the lubricants to the environment may occur due to leaks and spills, and during oil/lubricant changes. Some of the notified chemical will be combusted during use. Collected used oil and lubricants will be either reused, 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 iso-containers < 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. The drums and iso-containers will be put back into circulation. Residues in the 1 L and 4 L containers used by the general public are estimated at < 8 g. The notifier claims that consumers are encouraged to recycle these containers. However, it is expected that most of these will be disposed of to landfill.

Fate

The notified chemical 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 chemical 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 engine oil (the do-it-yourself (D-I-Y) market (ANZECC, 1991)). It is claimed that the D-I-Y market accounts for 4.9% of total oil sales in Australia (14% of auto-engine oil sales), though the availability of this oil for collection is not well understood (Snow, 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] will be collected. The balance (44%) will remain uncollected, either stored, or disposed of inappropriately, e.g. 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 (Armitage, 1998). The chemical attained 51.9% degradation (of theoretical) after 28 days and therefore cannot be considered biodegradable under the strict terms and conditions of the OECD Guideline TG 301B. However, the

[1] Used oil is defined as oil contaminated through use that has the potential for collection. It is approximately 41% of total Australian lubricant sales, with the balance consumed (combusted) during use.
[2] The guideline requires 60% degradation within 28 days. This level must be reached within 10 days after 10% degradation.

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 (OECD, 1981). The chemical was found to be non-inhibitory to the sewage sludge micro-organisms used in the study.

The primary biodegradability of the notified chemical was assessed using the Coordinating European Council's CEC L-33-A-93 test method (Low, 1997). This method evaluates the primary biodegradability of lubricants in water. Test flasks containing mineral salts, the notified chemical (49 mg/L) and a sewage inoculum were incubated. Poisoned flasks containing the same and mercuric chloride (to inhibit microbial activity) were run in parallel. After 21 days, primary biodegradability, expressed as the percentage difference in residual oil content between the poisoned flasks and the respective test flasks, was determined to be 85%.

The potential for bioaccumulation was not determined. Due to the chemical's molecular weight (458 g/mol), partition coefficient (log K_{OW} > 4.96) and fat solubility, bioaccumulation may be perceived as an issue of concern (Connell, 1989). However, the very low water solubility (less than $2.02x10^{-4}$ mole/m^3) should reduce this potential. Also, the notified chemical is expected to undergo significant 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, bioaccumulation is unlikely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Alkane 8

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >2000 mg/kg	Hempstock, 1997a
acute dermal toxicity	rat	LD_{50} >2000 mg/kg	Hempstock, 1997b
skin irritation	rabbit	slight irritant	Hempstock, 1997c
eye irritation	rabbit	slight irritant	Hempstock, 1997d
skin sensitisation	guinea pig	not sensitising	Hempstock, 1997e

9.1.1 Oral Toxicity (Hempstock, 1997a)

Species/strain: Sprague-Dawley rat

Number/sex of animals: 5 males, 5 females

Observation period: 14 days

Method of administration: gavage

Clinical observations:	no signs of treatment related toxicity were noted
Mortality:	nil
Morphological findings:	no treatment related abnormalities were noted.
Test method:	limit test, based on OECD TG 401 (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 mg/kg
Result:	Alkane 8 had very low acute oral toxicity in rat

9.1.2 Dermal Toxicity (Hempstock, 1997b)

Species/strain:	Sprague-Dawley rat
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	semi-occluded patch; 24 hour exposure
Clinical observations:	no signs of dermal irritation and no treatment related signs of systemic toxicity were noted
Mortality:	nil
Morphological findings:	no treatment related abnormalities were noted
Test method:	limit test, in accordance with OECD TG 402 (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 mg/kg
Result:	Alkane 8 had very low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

No study was available.

9.1.4 Skin Irritation (Hempstock, 1997c)

Species/strain:	New Zealand White rabbits

Number/sex of animals: 3 male

Observation period: 7 days

Method of administration: a single 4-hour, semi-occluded application of neat material (0.5 mL) to intact skin

Draize scores (Draize, 1959):

Time after treatment (days)	***Animal #***		
	1	***2***	***3***
Erythema			
1	1[a]	1	2
2	0	0	1
3	0	0	1
7	0	0	0
Oedema			
1	0	1	1
2	0	0	0
3	0	0	0
7	0	0	0

[a] see Attachment 1 for Draize scales

Test method: in accordance with OECD TG 404 (Organisation for Economic Co-operation and Development, 1995-1996)

Result: slight erythema was noted at all treated skin sites at one hour after patch removal.

Alkane 8 is a slight irritant to rabbit skin.

9.1.5 Eye Irritation (Hempstock, 1997d)

Species/strain: New Zealand White rabbits

Number/sex of animals: 3 male

Observation period: 3 days

Method of administration: 0.1 mL into conjunctival sac of one eye.

Test method:	in accordance with OECD TG 405 (Organisation for Economic Co-operation and Development, 1995-1996)
Draize score:	Draize scores for cornea, iris and conjunctiva (redness, chemosis and discharge) were zero for all the animals during the study except one rabbit had Draize score of 1 for redness 24 hours after application
Result:	Moderate conjunctival irritation was noted in two treated eyes with minimal conjunctival irritation in the remaining eye one hour after treatment. Minimal conjunctival redness was noted in one treated eye at 24 hr observation. Two treated eyes appeared normal at 24 hr observation. One treated eye appeared normal at 48 hr observation. Alkane 8 is a slight irritant to rabbit eye.

9.1.6 Skin Sensitisation (Hempstock, 1997e**)**

Species/strain:	female Dunkin-Hartley guinea pigs
Number of animals:	20 test, 10 control
Induction procedure:	Day 0: three intradermal injections (0.1 mL each) made with Freund's Complete Adjuvant plus distilled water (1:1 ratio), 25% (w/v) of test material in arachis oil B.P., and 25% (w/v) of test material in 1:1 preparation of Freund's Complete Adjuvant plus distilled water. Day 7: neat test material applied with occlusive dressing for 48 hours.
Challenge procedure:	Day 21: use 50% (w/v) and 25% (w/v) of Alkane 8 in arachis oil BP for a dermal application of 24 hours.

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	0**/19***	0/19	0/10	0/10
50%	0/19	0/19	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response
- *** one animal in test group found dead on Day 15

Test method:	Magnusson and Kligman maximisation study, in accordance with OECD TG 406 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	Alkane 8 was not a skin sensitizer in guinea pigs

9.2 Repeated Dose Toxicity (Thomas, 1997)

Species/strain:	Sprague-Dawley rats
Number/sex of animals:	5/sex/group (including control group)
Method of administration:	oral administration (gavage)
Dose/Study duration:	150, 400 and 1 000 mg/kg/day in arachis oil BP for 28 consecutive days
Clinical observations:	One control female showed a small, dorsal scab on Day 8 whilst two 150 mg/kg/day females and one female from the 1000 mg/kg/day treatment group showed fur loss and/or red/brown staining. All animals showed normally expected body weight gain development throughout treatment. There was no adverse effect on dietary intake.
Clinical chemistry/Haematology	There were no treatment related changes detected in the blood chemical and haematological parameters measured. Analysis of the data did not reveal any statistically significant intergroup differences.
Gross pathology:	Two females treated with 1 000 mg/kg/day showed pallor of the liver at necropsy. The study authors attributed this to minor variability in the volume of blood removed during exsanguination at terminal kill. One of those animals had a thickened stomach glandular region with a small haemorrhagic area. One 400 mg/kg/day male showed an enlarged, malformed and thickened bladder, hydronephrosis of kidneys and a malformed and small prostate gland at necropsy.

Histopathology:	No treatment related effects were observed.
Organ weights:	There were no treatment related changes detected in the organ weights measured.
Test method:	similar to OECD TG 407 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	Alkane 8 had a no observed effect level (NOEL) of 1 000 mg/kg/day in the repeat dose oral study.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Thompson, 1997)

Strains:	*Salmonella typhimurium* TA1535, TA1537, TA1538, TA98, TA100
Concentration range:	0, 50, 150, 500, 1 500 and 5 000 μg/plate with or without metabolic activation (vehicle: tetrahydrofuran)
Test method:	in accordance with OECD 471 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	non-mutagenic in bacteria in the presence or absence of rat liver metabolising system

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Durward, 1997a)

Species/strain:	CD-1 mouse
Number and sex of animals:	5 males and 5 females per group
Doses:	0, 500, 1 000 and 2 000 mg/kg for 24 hours treatment group, and 0 and 2 000 mg/kg for 48 hours treatment group (arachis oil for control group)
Method of administration:	a single intraperitoneal dose
Test method:	in accordance with OECD TG 474 (Organisation for Economic Co-operation and Development, 1995-1996)

Result:	no statistically significant increase in frequency of micronucleated polychromatic erythrocytes (PCE), or decreases in the ratio of PCE to normochromatic erythrocytes (NCE) were observed in the 24 or 48 hour dosing groups; Alkane 8 was not genotoxic under the test conditions.

9.3.3 Chromosome Aberration Test in Human Lymphocytes *in vitro* (Durward, 1997b)

Species/strain:	human lymphocytes
Doses:	experiment 1: 0, 39.06, 78.13, 156.25, 312.5, 625, 1 250, 2 500 and 5 000 µg/mL with or without metabolic activation experiment 2: 0, 156.25, 312.5, 625, 1 250, 2 500 and 5 000 µg/mL with or without metabolic activation for 20 hours treatment group, and 0, 1 250, 2 500 and 5 000 µg/mL with or without metabolic activation for 44 hours treatment group (vehicle: ethanol)
Test method:	according to OECD TG 473 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	Alkane 8 did not induce a significant increase in the frequency of cells with chromosome aberrations or polyploid cells with and without metabolic activation, Alkane 8 was non-clastogenic to human lymphocytes *in vitro*

9.4 Overall Assessment of Toxicological Data

Alkane 8 was of low acute oral and dermal toxicity (LD_{50} > 2 000 mg/kg for each route) in rats. The limit tests resulted in no deaths of the test species. The notified chemical was found to be slightly irritating to rabbit eyes and skin. Dermal exposure did not result in skin sensitization in guinea pigs.

No acute inhalation study was available. Instead comparative data on inhalation toxicity and molecular weight and size was provided. Studies on related olefins suggest that branched alkanes of low molecular weight may be acutely toxic by inhalation. However, as the molecular weight increases via an increase in olefin molecular size, the inhalation toxicity decreases. The notifier stated that data on 1-dodecene, dimer, hydrogenated (CAS No. 151006-61-0), molecular weight 338, indicates the substance is harmful upon inhalation although this data was not provided. Comparative data on 1-dodecene, trimers, hydrogenated (CAS No. 151006-62-1), molecular weight 506, give an LC_{50} of 1 500 mg/L. A blend of

hydrogenated C12 dimers and trimers, with an approximate molecular weight of 358 had an inhalation LC_{50} of < 3.09 mg/L. A blend of hydrogenated C12 trimers and polymers had an inhalation LC_{50} of > 5.15 mg/L. Alkane 8 has an average molecular weight of 458 and is a hydrogenated mixture of dimers and trimers. Based on existing data, the acute inhalation toxicity of the notified chemical is expected to be low and warrant at most a harmful classification under the hazardous substances health effects criteria (NOHSC, 1994a).

Rats exposed orally to repeated doses of up to and including 1 000 mg/kg/day showed no clinical signs of toxicity nor statistically significant changes in blood chemical parameters, histological abnormalities, morphological or microscopic changes. The NOEL for the 28 day oral repeat dose study is 1 000 mg/kg/day.

Alkane 8 did not induce gene mutation in *Salmonella typhimurium*. There was no increased frequency of chromosomal aberrations in human lymphocytes *in vitro*. In a mouse micronucleus study, the test material was non-genotoxic.

The notified chemical cannot be determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) in relation to the toxicological data provided.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods at facilities complying with OECD Principles of Good Laboratory Practice.

Test	Species	Results (Loading rate/WAF [a])	References
Acute Toxicity Static [b], 96 hour OECD TG 203	Rainbow trout (*Oncorhynchus mykiss*)	LL_{50} [c] > 5 000 mg/L NOEC = 5 000 mg/L	Collins, 1998a
Acute Immobilisation Static [d], 48 hour OECD TG 202 (Pt I)	Water Flea (*Daphnia magna*)	EL_{50} [e] > 5 000 mg/L NOEC = 5 000 mg/L	Collins, 1998b
Chronic Immobilisation Static Renewal [d], 21 day OECD TG 202 (Pt II)	Water Flea (*Daphnia magna*)	EL_{50} [e] > 5 000 mg/L NOEC = 5 000 mg/L	Putt, 1998
Growth Inhibition Static [d], 72 hour OECD TG 201	Green Alga (*Pseudokirchneriella subcapitata*)	E_rL_{50} [f] > 5 000 $mg.L^{-1}$ E_bL_{50} [f] > 5 000 $mg.L^{-1}$ NOEC = 1 000 $mg.L^{-1}$	Hoberg, 1998

a. WAF: Water accommodated fraction.
b. Oil-water dispersions of 100, 500, 1 000, 2 000 and 5 000 mg/L.
c. LL_{50} is the loading rate of the test substance in dilution water that causes mortality of 50%.
d. WAFs of 100, 500, 1 000, 2 000 and 5 000 mg/L.

e. EL50 is defined as the effective loading rate of the test substance in dilution water that causes immobilisation of 50%.
f. E_rL_{50} and E_bL_{50} are defined as the effective loading rate of the test substance that reduced growth rate and biomass, respectively, by 50% as compared with the control.

Fish

Preliminary Test
Rainbow trout were exposed under static conditions to oil-water dispersions with loading rates of 1.0, 10, 100 and 1 000 mg/L. Throughout the 96 hour exposure period, all test loading rates were observed to contain a light surface film which increased with increasing loading rate. No mortalities or sublethal effects were observed.

Definitive Test
Oil-water dispersions of the notified chemical were prepared using a continuous mixing system with each exposure aquarium containing a glass mixing chamber. The appropriate amount of test substance was added directly into this chamber, with a mechanical mixer used to stir the substance within the mixing chamber throughout the exposure period. During the mixing process, the water soluble portion of the substance was dispersed through the screened narrow openings of the mixing chamber into the exposure section of the test vessel.

Throughout the exposure, all test solutions were observed to be clear and colourless with visible signs of undissolved test substance (i.e. surface film) which increased with increasing test loading rate. The 96-hour measured concentrations of notified chemical in the WAF at loading rates of 100, 500, 1 000, 2 000 and 5 000 mg/L were < 0.021, 0.77, 0.44, 1.3, 0.83 and 2.7 mg/L, respectively.

During the study no loading rate caused ≥ 50% mortality. Therefore, the LL_{50} was empirically estimated to be greater than 5 000 mg/L, the highest loading rate tested. Following test termination, no mortalities or sublethal effects were observed

Daphnids

Acute

Preliminary Test
Daphnids were exposed under static conditions to water accommodated fractions (WAFs) of notified chemical with loading rates of 1.0, 10, 100 and 1 000 mg/L. All test solutions were observed to be clear and colourless throughout the 48 hours. No immobilisation or adverse effects were observed among the daphnids.

Definitive Test
Each WAF was prepared individually by volumetrically adding the appropriate amount of notified chemical to produce loading rates of 100, 500, 1 000, 2 000 and 5 000 mg/L. These dilutions were then stirred for 24 hours then allowed to stand for 1 hour. At the end of the settling period, all solutions were observed to be clear and colourless with visible signs of undissolved test substance increasing with increasing loading rate. After the settling period, the WAF of each loading was drawn off directly into each replicate exposure vessel.

The results of the analysis of exposure solutions for the notified chemical concentrations during the exposure period were all below the limit of detection, i.e. < 0.0208 mg/L. Throughout the exposure period, all treatment solutions were observed to be clear and colourless.

During the study, no loading rate caused ≥ 50% immobilisation. Therefore, the EL_{50} was empirically estimated to be greater than 5 000 mg/L, the highest loading rate tested. At test termination, no immobilisation or adverse effects were observed among the daphnids.

Chronic

Preliminary Test
In a 15 day range finding study, daphnids were exposed to loading rates of 100 and 1 000 mg/L under static renewal conditions. After 15 days of exposure, mean survival of 100% was observed among daphnids at both levels. Sixty-seven and 64 offspring per female were released by daphnids exposed to 100 and 1 000 mg/L loading rates, respectively. This compares to 52 offspring per female during the same period by the control organisms.

Definitive Test
Considering the preliminary test results, loading rates were individual WAFs of 100, 500, 1 000, 2 000 and 5 000 mg/L. These were prepared as per the test solutions for the acute Water flea definitive test, as described above. Test solutions were replaced every second day. Except for the 2 000 and 5 000 mg/L loading rates on test day 0 and 10, all the measured concentrations were below the limit of detection, i.e. < 0.0208 mg/L. The highest concentration measured analytically in any loading rate tested was 0.038 mg/L.

Survival of adult daphnids was determined daily, with measurements of offspring production taken daily from day 7. During each observation interval, the offspring were removed, counted and discarded. Observations of abnormal behaviour were made each interval.

At test termination, survival among daphnids exposed to the loading rates tested (100 to 5 000 mg/L) ranged from 90 to 100%. Statistical analysis determined no significant difference between survival at these loading rates and the survival observed among the control daphnids. Considering daphnid survival, the EL_{50} for the notified chemical was empirically estimated to be greater than 5 000 mg/L, the highest loading rate tested.

Further, the number of offspring per female among daphnids exposed to all loading rates averaged between 150 and 164. This was not significantly different from the number of offspring produced by the control organisms, i.e. 147 offspring per female. Throughout the exposure period, no young were observed to be immobilised in any of the loading rates tested.

The results indicate that a loading rate up to 5 000 mg/L had no adverse effect on survival or reproduction of daphnids. The LOEC is greater than 5 000 mg/L.

Algae

Preliminary Test
The algae were exposed under static conditions to WAFs with loading rates of 1.0, 10, 100 and 1 000 mg/L. Following 72 hours exposure, average cell densities in the loading rates were 260, 256, 245, $216x10^4$ cells/mL, respectively. The control culture contained an average of $260x10^4$ cells/mL.

Definitive Test
The WAFs were prepared as per the test solutions for the acute Water flea definitive test described above. The algae were exposed to loading rates of 100, 500, 1 000, 2 000 and 5 000 mg/L. The 0 and 72 hour measured concentrations were 0.029, 0.048, 0.56, 0.14 and 1.6, and 0.031, 0.038, 0.18, 0.11 and 1.9 mg/L, respectively. Although substantially below the loading rates, the measured concentrations of the notified chemical were consistent at each time interval. Based on this consistency, the author believes that the results represent the water solubility limit of the notified chemical at the stated loading rate.

Since less than a 50% reduction in growth rate and biomass was observed at the highest concentration tested, the E_rL_{50} and E_bL_{50} values were empirically estimated to be greater than 5 000 mg/L. The NOEC for both growth and biomass was determined to be 1 000 mg/L, as significant reductions in growth rate and cell biomass were noted at the higher test concentrations, i.e. 1.3% and 2.0% reduction in growth rate and 5.1% and 7.7% reduction in biomass at 2 000 and 5 000 mg/L, respectively.

Upon test termination, subcultures from the 5 000 mg/L solution (the highest loading rate tested) were incubated for six days under conditions consistent with those maintained during the definitive exposure. The exposure concentration was 100 mg/L, the lowest loading rate tested. After six days, cell density increased from $0.92x10^4$ cells/mL to $156x10^4$ cell/mL, indicating that the notified chemical has algistatic rather than algicidal effects on the growth of algae at the highest loading rate tested. However, it is believed that this is inconsequential should exposure be continuous.

Conclusion

The ecotoxicity data for the notified chemical indicates that it is non-toxic to fish, aquatic invertebrates (acute and chronic exposures) 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 (Armitage, 1998).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The end use of the notified chemical is as a major component of imported automotive and industrial (hydraulic) lubricants. The concentration of the notified chemical will be 60-90% for automotive oils and 30-50% for hydraulic fluids.

The main environmental exposure will be from inappropriate disposal of waste lubricant. A (very much) worst case scenario would be if all the uncollected oil at maximum import volumes was dumped into a sewer in a country centre. This would give a concentration of

about 29.7 mg/L per day [3]. For a major city, the amount would be about 0.30 mg/L per day, due to the much higher dilution factors expected.

However, the notifier has established that 75% of the imported volume will be for automotive uses. The collection of waste lubricants is known to be more easily accomplished from industrial and commercial users than from within the D-I-Y market. The D-I-Y market accounts for 4.9% of total oil sales in Australia (Snow, 1997) and a large proportion of D-I-Y sales are used for top-up purposes and do not generate used oil (Anon, 1995). Therefore, should 4.9% of the imported volume designated for automotive use be inappropriately disposed of via the D-I-Y end users, the concentration in the sewer of a country centre would be about 1.1 mg/L, while for a major city would be 0.01 mg/L.

It is also expected that the notified chemical will be strongly adsorbed to the sludge during the waste water treatment process due to the very low water solubility. Therefore, the actual concentration in the effluent will be significantly less. As availability and use will be Australia wide, and not concentrated in one town or city, and anticipating responsible industrial and public disposal practice, concentrations of the notified chemical in the environment are expected to be further reduced.

Ecotoxicity tests indicate that the WAF of the notified chemical is expected to be non-toxic to aquatic organisms. Predicted environmental concentrations (as calculated in the above) exceed the water solubility of the notified chemical.

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

Disposal of containers containing waste oil (oil residues and used oil containing the notified chemical) should not result in any significant environmental exposure. Waste oil may be recycled or incinerated. Incineration of the oil for fuel value or during container reconditioning will destroy the substance. 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 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. 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

[3] Given 44% of used oil is not collected, then of the 300 tonnes of notified chemical imported at maximum import rates, 54.12 tonnes would not be collected, i.e. 44% x 41% x 300 t. This would be 148.3 kg/d (i.e. 54.12 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 chemical of 29.7 $mg.L^{-1}$ per day and 0.30 $mg.L^{-1}$ per day, respectively.

Based on the submitted toxicological data, the notified chemical cannot be determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). The acute and repeat dose toxicity of the chemical is low. However, it was found to be slightly irritating to both eyes and skin. No data on dermal absorption for the notified chemical were available.

The notified chemical will be imported as a component of a finished product within the range of 30-90% in 200 L steel drums or in 20 000 L iso-containers. No reformulation will occur, but some of the finished oil will be repackaged into 1 L and 4 L containers for public use.

Dermal exposure to drips and spills may occur for workers involved in repackaging the imported product containing the notified chemical, and during end use, clean-up and disposal. Inhalation exposure is expected to be minimal because the notified chemical and the finished oil are viscous, therefore, have limited potential to generate aerosols. In addition, the notified chemical has very low vapour pressure, so vapour accumulation in the workplace air is not likely. Repackaging will take place in well-ventilated areas, thereby serving to further reduce inhalation exposure.

Transport and storage
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.

Repackaging
Workers may experience some exposure during repackaging predominantly when connecting and disconnecting lines to drums or iso-containers and the dispensing equipment. During repackaging activities it is recommended that workers wear gloves and industrial clothing, to minimise dermal exposure. Given the low systemic toxicity of the notified chemical and the fact that workers may experience intermittent low level exposure, the occupational health risk posed to workers performing these tasks is considered to be low.

End use
Use of the oil in the industrial settings as gear or hydraulic oil involves manual addition to and possibly from various systems. Exposure to drips and spills is possible. The notifier has not indicated the frequency or duration of the tasks in industrial (non automotive) situations, so this report recommends that hand protection in particular be used by workers during these tasks.

For automotive workers, exposure will be frequent as changing oil is a normal task done a number of times a day. They may wear overalls, but may not routinely wear gloves.

Disposal
Workers involved in disposal of used oil may experience exposure to the notified chemical. These workers should control exposure by wearing gloves and overalls when handling used containers.

The notified chemical is a slight skin and eye irritant. The chances of experiencing topical effects may not be high, but various skin lesions can occur from dermal contact with petroleum based oils (Rietschel RL et al, 1995, Kraus RS, 1998, Olishifiski JB, 1988). The

MSDS indicates that workers involved in repackaging of the finished oil are required to wear eye protections and follow good personal hygiene practices. However, to minimise the occurrence of occupational dermatoses, protective gloves and overalls 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.

Public Health
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 1 L and 4 L plastic containers for standard mineral oil based automotive oils, but it has low toxic hazard and the pattern of exposure would be intermittent. Based on the low toxic hazard and use pattern of the notified chemical, it is considered that the notified chemical will not pose a significant risk to public health.

13. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was prepared in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994c).

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.

14. RECOMMENDATIONS

To minimise occupational exposure to Alkane 8 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 or mittens should conform to AS 2161 (Standards Australia/Standards New Zealand, 1998);

- Spillage of 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 practised to minimise the potential for ingestion;
- 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.

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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Attachment 1

The Draize Scale 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 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