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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Alkane 7

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NICNAS

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Alkane 7

1. APPLICANT

Hellay Australia Pty Ltd of 8/9 Monterey Rd DANDENONG VIC 3075 (ABN 49 050 136 528) has submitted a standard notification statement in support of their application for an assessment certificate for Alkane 7.

2. IDENTITY OF THE CHEMICAL

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

Other Names:	Alkane 7
Marketing Name:	MCP 1595

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physicochemical properties relate to the notified chemical.

Appearance at 20°C & 101.3 kPa:	A clear colourless liquid.
Boiling Point:	Decomposed from 184°C; estimated to be 262°C.
Freezing Point:	< -20°C
Specific Gravity:	0.81228 at 20°C
Vapour Pressure:	5.9×10^{-10} kPa at 25°C
Water Solubility:	$< 6.98 \times 10^{-6}$ g/L at 20°C
Partition Co-efficient (n-octanol/water):	Log Pow > 5.07
Hydrolysis as a Function of pH:	Not determined
Adsorption/Desorption:	Log Koc > 4.53
Fat Solubility:	Miscible in all portions with standard fat at 37°C.
Dissociation Constant:	Not determined
Flash Point:	205°C (closed cup)
Flammability Limits:	Not determined
Autoignition Temperature:	326°C

Explosive Properties:	Not determined
Reactivity/Stability:	Not determined

3.1 Comments on Physico-Chemical Properties

All tests were performed by Safepharm Laboratories Ltd (1997a).

The boiling point was not determinable as the test material decomposes above 184°C with no sign of boiling, indicating decomposition. The value is estimated at 262°C from the vapour pressure data.

The vapour pressure provided was determined using a vapour pressure balance and Method A4 of Commission Directive 92/69/EEC. Linear regression analysis was used to calculate vapour pressure at 25 °C. The low value determined indicates that the notified chemical is classified as being very slightly volatile.

The water solubility was determined using the flask method detailed in Method A6 of Commission Directive 92/69/EEC. The notified chemical is classified as being very slightly soluble which is consistent with its hydrocarbon structure.

The fat solubility of the notified chemical was determined using OECD TG 116.

The partition coefficient has was determined using the shake-flask method detailed in Method A8 of Commission Directive 92/69/EEC and the estimate provided for the adsorption coefficient, Koc was obtained by the HPLC method detailed in the OECD draft guideline (1988). The low water solubility is consistent with the high log Pow, indicating a very high affinity for the organic component of soils and sediments. This is confirmed by the high log Koc. As such, the notified chemical is classified as being very hydrophobic and immobile in soil.

The dissociation constant was not determined as the substance has no chemical mode of dissociation.

The hydrolysis of the material was not examined due to its lack of water solubility (<0.1mg/L) and the non-availability of a sufficiently sensitive specific method of analysis.

The test material was subjected to thermal and mechanical sensitivity tests. A friction test was not conducted on the liquid.

Flammability tests were not performed as it was found out the new substance did not evolve gas on exposure to water during the performance of other tests.

Pyrophoric properties of the material were not determined as it was found out the substance did not ignite on prolonged exposure to air.

Explosive properties of the material were not determined as a negative result can be predicted from the oxygen balance calculation, and the absence of potential explosive groups on the compound.

Reactivity can be predicted negative from the chemical structure. Fat solubility was also conducted on the test material, it was found to be miscible in all proportions with standard fat at 37°C.

4. PURITY OF THE CHEMICAL

Degree of Purity:	High
Hazardous Impurities:	None

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a synthetic base stock for engine oils.

The notified chemical will not be manufactured in Australia. It will be imported as a component (20-60%) in a finished product in 200 L steel drums and repackaged into 1 L plastic bottles.

Import volumes for the notified chemical will be <200 tonnes per annum in the first 5 years.

6. OCCUPATIONAL EXPOSURE

Inhalation exposure to the notified chemical during repackaging, and in its end use applications is not expected as it has a 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. As the notifier will import product containing the notified chemical, the exposure will be restricted to the product only.

Transport and storage

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

Repackaging

The repackaging process will consist of transferring the material from 200 L container to an enclosed storage tank, then into 1 L plastic bottles for consumer uses. Less than 100 workers may be exposed during repackaging. Workers typically use a variety of pumps to transfer the finished oil. These 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 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).

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.

Workers are expected to wear chemical impervious gloves and standard industrial work clothes. Local exhaust ventilation is in place in repackaging facilities.

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. 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

Materials from equipment washing during repackaging will be reused or sent to a waste handler for disposal. Landfarming and processing through sewage treatment facilities may be available disposal options but necessary approvals must first be obtained from appropriate regulatory authorities. Specific characteristics of the waste at the time of disposal may affect the availability of the above options. Used oil contractors may burn the used oil for fuel. If however, due to contamination from large amounts of water, low flash petroleum products or other contaminants, it can not be used as fuel, it can be burnt in a high temperature incinerator. It is estimated that <1 kg of the substance will remain in the container after use. In the case of workers involved in disposal of used oil,

the risk of adverse health effects from oil contaminants is likely to be greater than that due to the notified chemical.

7. PUBLIC EXPOSURE

Public contact with the notified chemical following a transport or facility spillage is unlikely. Accidental spillage during home vehicle maintenance is also unlikely. Overall the opportunity for contact with the notified chemical lies in infrequent or unlikely occurrences. Any contact will most likely be dermal, infrequent and transient. The potential for public exposure is therefore minimal.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

At the customer repackaging facility, losses during the highly automated repackaging process are not expected. The equipment used will be cleaned with oil and these washings will be used in the formulation of the next batch or another oil blend. In these situations release would only be through accidental spills, which would be recycled or collected for incineration. Any Alkane 7, expected to be less than 1 kg, remaining in the import containers will be washed with mineral oil prior to disposal.

Some minor, diffuse, exposure will result from spills during addition of oil to vehicles. However, the greatest potential for exposure is through disposal of wastes containing the notified chemical. A survey by the Australian Institute of Petroleum (AIP 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (ie. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases could be expected to be disposed of responsibly - either to oil recycling or incineration. The remaining 14% are removed by “do it yourself” (DIY) enthusiasts, and in these cases some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. However, in a more recent survey tracing the fate of used lubricating oil in Australia (Snow 1997), it was found that only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways.

Consequently, assuming that oil removed by professional mechanics is disposed of appropriately (ie. burning as workshop heating oil or sent for recycling), negligible release of the notified chemical should result from these professional activities. The DIY proportion of oil changes could potentially lead to release of up to 7 tonnes per annum of the notified chemical from the improper disposal of used oil. Most of this is likely to become associated with soils or sediments, as will approximately 15 tonnes of the notified chemical released to landfill as container residues.

Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified chemical in high concentrations is very unlikely except as a result of transport accidents.

Approximately 5% of the waste oil produced by DIY enthusiasts may be disposed to waterways via the stormwater system. This equates to less than 1 tonne of the total import volume of the notified substance that could be expected to enter the aquatic environment. It would be expected to then become associated with the sediments.

8.2 Fate

A biodegradation study was conducted using the notified chemical according to OECD TG 301B – Ready Biodegradability; CO2 Evolution Test (Convance Laboratories 1997a).

Activated sludge, obtained from Burley Menston Sewage Treatment Plant in Yorkshire, was mixed with the test substance or standard material (sodium benzoate) at a final concentration of 10 mg/L. The biodegration of sodium benzoate was 79% after 28 days, indicating the test conditions were valid. After 28 days at 21°C, the biodegradation of the test substance was determined to be 54%, which indicates the notified chemical is not

readily biodegradable in aerobic environments. According to Guideline 301B, the substance cannot be considered to be readily biodegradable as it failed to satisfy the 10 day window criterion whereby 60% degradation must be attained within 10 days of the degradation exceeding 10%. However, despite the low apparent rate for biodegradation, it is expected that if placed into landfill the material would be slowly degraded through the slow biological and abiotic processes operative in these facilities. These processes could be expected to produce carbon dioxide, methane and water.

The high Koc and Pow values for the notified polymer indicate that it will be immobile in landfill and adsorb onto and become associated with the organic component of soils and sediments. Similarly, in the event of accidental release into the water compartment, it is likely to become associated with suspended organic material, and eventually be incorporated into sediments.

While the notified chemical meets several of the general characteristics of organic chemicals which exhibit bioaccumulation (Connell 1990), it has a low water solubility value (1.1 × 10-8 mol m-3) which is indicative of low bioavailability and hence the material is unlikely to bioaccumulate.

Incineration of waste oil containing the notified chemical would destroy the substance with evolution of water vapour and oxides of carbon. Sludges from waste treatment plants or oil recycling facilities could also be incinerated.

Material containing the notified chemical placed into landfill as a result of irresponsible disposal practices, or from other sources, such as oil treated fence posts, etc. would be adsorbed into and become associated with soil and slowly degrade as described above.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Alkane 7

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD50>2 000 mg/kg	Hempstock, 1997a
acute dermal toxicity	rat	LD50>2 000 mg/kg	Hempstock, 1997b
skin irritation	rabbit	Non skin irritant	Hempstock, 1997c
eye irritation	rabbit	Slight eye irritant	Hempstock, 1997d
skin sensitisation	guinea pig	Non skin sensitiser	Hempstock, 1997e

9.1.1 Oral Toxicity (Hempstock, 1997a)

Species/strain:	Sprague-Dawley CD strain rat
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Oral intubation; undiluted test material; dose 2 000 mg/kg.
Test method:	OECD TG 401
Mortality:	None

Clinical observations:	No signs of treatment related signs of systemic toxicity were noted.
Morphological findings:	No treatment related abnormalities were noted.
Comment:	None
LD_{50}*:*	>2 000 mg/kg
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Hempstock, 1997b)

Species/strain:	Sprague-Dawley CD strain rat
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Semi-occluded dermal application; 24 hour exposure; dose 2 000 mg/kg.
Test method:	OECD TG 402
Mortality:	None
Clinical observations:	No signs of dermal irritation and no treatment related signs of systemic toxicity were noted.
Morphological findings:	No treatment related abnormalities were noted.
Draize scores:	Draize scores for erythema and oedema were zero for all animals during the study.
Comment:	None
LD_{50}*:*	> 2 000 mg/kg
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

No inhalation study report was provided.

9.1.4 Skin Irritation (Hempstock, 1997c)

Species/strain:	New Zealand White rabbit
Number/sex of animals:	3 males
Observation period:	72 hours
Method of administration:	Semi-occluded application; 4 hour exposure; dose 0.5 mL of test material as supplied.
Test method:	OECD TG 404

Draize scores[a]*:*

Time after treatment (hour)	*Animal #* *1*	*2*	*3*
Erythema			
1	1	0	0
24	0	0	0
48	0	0	0
72	0	0	0
Oedema			
	Draize scores for oedema were zero for all animals during the study.		

[a] see Attachment 1 for Draize scales

Comment: Slight erythema was noted at one treated skin site at the 1 hour observation.

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

9.1.5 Eye Irritation (Hempstock, 1997d)

Species/strain: New Zealand White rabbits

Number/sex of animals: 3 males

Observation period: 3 days

Method of administration: 0.1 mL into conjunctival sac of one eye. The other eye served as a control.

Test method: OECD TG 405

Draize scores:

	Time after instillation (hour)			
Animal	***1***	***24***	***48***	***72***
Cornea				
	Draize scores for cornea (opacity and area) were zero for all animals during the study.			
Iris				
	Draize scores for iris were zero for all animals during the study.			

Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	1	0	1	0	0	1	0	0	0	0	0
2	1	1	1	1	0	0	0	0	0	0	0	0
3	1	0	0	1	0	0	1	0	0	0	0	0

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Comment:	Individual mean scores: Conjunctival redness - 0.66:0.33:0.66; Chemosis - 0:0:0; Discharge – 0:0:0. All three animals exhibited minimal conjunctival irritation. No iridial or corneal effects were noted.
Result:	The notified chemical was slightly irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Hempstock, 1997e)

Species/strain:	Dunkin-Hartley Guinea pigs
Number of animals:	20 test, 10 control
Induction procedure:	
test group: day 0	Three pair intradermal injections (0.1 ml each) were made: • Freund's complete adjuvant (FCA) and distilled water (1: l); • 25% notified chemical in arachis oil BP; and • 25% notified chemical in a 1 :1 preparation of FCA and distilled water.
day 7	Neat notified chemical was applied with occlusive dressing for 48 hours.
control group: day 0	FCA and distilled water (1 :1); arachis oil BP; 50% arachis oil BP in FCA and distilled water (1: 1).
day 7	Same as the test group except in the absence of the notified chemical.
Challenge procedure:	
day 21	Occluded application of 75% notified chemical in arachis oil BP and 100% notified chemical; 24 hour exposure
Test method:	OECD TG 406

Challenge outcome:

	Test animals		**Control animals**	
Challenge concentration	**24 hours***	**48 hours***	**24 hours**	**48 hours**
75%	**0/19	0/19	0/10	0/10
100%	8/19	0/19	4/10	0/10

* time after patch removal

** number of animals exhibiting positive response i.e. Draize score ≥1.

Comment:	One animal in test group died on day 18.

After intradermal induction, well defined to moderate/severe erythema (grade 2 and 3) was observed in test animals, and slight erythema (grade 1), in control animals. After topical induction, slight erythema (grade 1-2) was noted in test animals. No skin reactions were observed in control animals. Draize scores for erythema in test and control animals after intradermal and topical inductions were listed below:

	Test group	***Control group***
Intradermal induction		
24 hours	Score 2: 37 sites	Score 0: 6 sites
	Score 3: 3 sites	Score 1: 14 sites
48 hours	Score 1: 8 sites	Score 0: 6 sites
	Score 2: 27 sites	Score 1: 14 sites
	Score 3: 5 sites	
Topical induction		
1 hour	Score 1: 19 animals	Score 0: 10 animals
	Score 2: 1 animals	
24 hours	Score 0: 12 animals	Score 0: 10 animals
	Score 1: 8 animals	

Since irritation effects were observed in both test and control groups after inductions, and the positive ratio between test and control animals after challenged was similar, the notified chemical is therefore not considered to be a skin sensitiser.

Result: The notified chemical was non-sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Jones et al., 1997)

Species/strain: Sprague-Dawley Crl:CD BR strain rats

Number/sex of animals: 20 male, 20 female (5/sex per dose group)

Method of administration: Gastric intubation, oral administration

Dose/Study duration: 0, 150, 400 and 1000 mg/kg/day for 28 consecutive days (vehicle: arachis oil BP)

Test method: Commission Directive 92/69/EEC (Method B7)

Clinical observations:
No deaths occurred during the study.

No adverse effects of treatment were indicated from the physical observations. There were no effects on body weight changes, food and water consumption.

Clinical chemistry/Haematology
There were no treatment-related changes in the haematological parameters measured. A slight statistically significant reduction in neutrophil count was noted in females at 400 or 150 mg/kg/day.

There were no treatment related changes in clinical chemical measurements.

Necropsy:
There were neither treatment related changes in organ weights, nor macroscopic abnormalities.

Histopathology:
There were no treatment related changes on microscopic examinations.

Comment:
The slight reduction in neutrophil count in females at 400 or 150 mg/kg/day did not show a dose related trend, therefore was regarded as fortuitous.

Result:
The No Observed Effect Level (NOEL) was determined to be 1 000 m/kg/day.

9.3 Genotoxicity

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

Strains:	*Salmonella typhimurium* TA98, TA100, TA1535, TA1537, TA 1538
Metabolic activation:	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.
Concentration range:	Each dose concentration was tested in triplicate, in the presence and absence of S9-mix. Two experiments were performed. 0, 50, 150, 500, 1 500, and 5 000 μg/plate with or without rat liver S9 (vehicle: tetrahydrofunan). Positive controls: (without S9 mix) N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG) for TA100 and TA1535, 9-aminoacridine (9AA) for TA1537, 4-nitro-o-phenylenediamine (4NOPD) for TA1538, 4-nitroquinoline-1-oxide (4NQO) for TA98. (with S9 mix) 2-aminoanthracene (2AA) for all strains.
Test method:	OECD TG 471
Comment:	The notified chemical was non-toxic to the strains used under the conditions of the test. An oily precipitate was observed ≥500 μg/plate, which did not interfere with the scoring of revertant colonies. Under the conditions of the study, the test material caused no substantial increases in revertant colony numbers over control counts at any concentration in either the presence or absence of the rat liver microsomal enzymes. All positive controls responded appropriately.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in Human Lymphocytes in vitro (Durward, 1997)

Cells:	Human peripheral lymphocytes
Metabolic activation system:	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.
Dosing schedule:	Each dose concentration was tested in duplicate, in the presence and absence of S9-mix. Two experiments were performed (vehicle: acetone).

Metabolic Activation	Experiment Number	Test concentration (μg/mL)	Controls
-S9	1	Harvest time = 20 hours 0, 39, 78.1, 156.25, 312.5, 625, 1 250*, 2 500*, 5 000* μg/mL	Positive: EMS Negative: vehicle
	2	Harvest time = 20 hours 0, 156.25, 312.5, 625, 1 250*, 2 500*, 5 000* μg/mL Harvest time = 44 hours 0, 1 250, 2 500, 5 000* μg/mL	
+S9	1	Harvest time = 20 hours 0, 39, 78.1, 156.25, 312.5, 625, 1 250*, 2 500*, 5 000* μg/mL	Positive: CP Negative: vehicle
	2	Harvest time = 20 hours 0, 156.25, 312.5, 625, 1 250*, 2 500*, 5 000* μg/mL Harvest time = 44 hours 0, 1 250, 2 500, 5 000* μg/mL	

EMS - ethyl methanesulphonate
CP - cyclophosphamide
* - cultures selected for metaphase analysis

Test method:	OECD TG 473
Comment:	Alkane 7 did not induce a significant increase in the frequency of cells with chromosome aberrations or polyploid cells in the presence or absence of a liver enzyme metabolising system. All positive controls responded appropriately.
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 dermal toxicity in rats. It was a slight eye irritant, but not a skin irritant in rabbits. The notified chemical was not considered to be a skin sensitiser in guinea pigs.

In a 28-day repeat dose oral toxicity study in rats, no treatment related systemic toxicity was observed, and the NOEL was determined to be 1 000 mg/kg/day.

The notified chemical was not found to be mutagenic in bacteria and did not induce clastogenic effects in an *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, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Full test reports on the ecotoxicity studies for Alkane 7 were provided by the notifier.

Test	Species	Results
96 h Acute Toxicity **OECD TG 203**	Rainbow Trout Oncorhynchus mykiss	LC_{50} > 3500 mg/L NOEC ≥ 3500 mg/L
48 h Immobilisation OECD TG 202	Water Flea Daphnia magna	EC_{50} > 0.097 mg/L WAF NOEC ≥ 0.097 mg/L WAF
72 h Growth Inhibition OECD TG 201	Algae *Pseudokirchneriella subcapitata*	EL_{50} > 5000 mg/L WAF NOEC ≥ 5000 mg/L WAF

* NOEC - no observable effect concentration

The tests on fish (Safepharm Laboratories Ltd 1997b) were performed using a static methodology. Observations were performed at 3, 6, 24, 48, 72 and 96 hours. The test was performed using ten specimen fish per loading rate at a temperature of 14 ºC. The tests were conducted using test substance at the nominal concentrations of 100, 500, 1000, 2500 and 5000 mg/L. These solutions were prepared by dispersing the test material (4, 20, 40, 100 and 200 g) separately in dechlorinated water (40 L) to give the required nominal concentrations. During the test the solutions were agitated by shielded propeller stirrers and the notifier indicates that they were cloudy, turbid dispersions with an oily slick at the water surface. Analysis of the test solutions after 96 h showed measured concentrations to range from 52.3–5764 mg/L. After 96 h, the results of the definitive study showed that no mortalities or sublethal effects were observed in any of the test vessels. The 96-hour LC_{50} for the notified chemical to *Oncorhynchus mykiss* is expected to be greater than 3500 mg/L based on mean measured concentrations.

The ecotoxicity tests on daphnia and algae were performed on the Water Accomodated Fraction (WAF) of the notified chemical. The WAF was prepared by adding an amount of Alkane 7 to water to give the required loading rate and the resulting solution was then stirred for 23 hours. The mixture was then allowed to stand for 1 hour prior to the removal of the aqueous phase.

The immobilisation tests with *Daphnia* (Safepharm Laboratories Ltd 1997c) were also performed under static conditions with observations performed at 24 and 48 hours. The test was performed in duplicate using 10 daphnids per flask at a temperature of 21 ºC. The tests were conducted using a water accommodation fraction (WAF) of the test substance made up at nominal concentrations of 100, 500, 1000, 2500 and 5000 mg/L. During the tests the all WAF's were observed to be clear, colourless solutions. Analysis of the WAF after 48 h showed measured concentrations to range from 0.0308–0.0266 mg/L. After 48 h, no immobilised daphnids were observed in any of the test vessels. The 48-hour EC_{50} for the notified chemical to *Daphnia magna* is expected to be greater than 0.097 mg/L based on mean measured concentrations.

Algae were exposed to the test substance at concentrations of 1000, 2500 and 5000 mg/L for 72 h at 24˚C under constant illumination and shaking (Safepharm Laboratories Ltd 1997d). Analysis of the WAF after 72 h showed the measured concentrations were below the limit of quantification. Three replicate test flasks were prepared for the test substance and three controls. No abnormalities were detected in any of the replicate test samples. Neither biomass or growth rate of *Pseudokirchneriella subcapitata* was adversely affected by the test substance, giving a 72 h EL_{50} of greater than 5000 mg/L and NOEC of greater than or equal to 5000 mg/L.

The ecotoxicity data indicates the notified chemical is not toxic to aquatic organisms up to the limit of its water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is considered to be small provided that the material is used as indicated, and that disposal of used oil takes place via the routes indicated above. As a component of automotive lubricants, the notified material has the potential to be released to the environment during lubricant change, but losses during lubricant formulation and transfer to engine crankcases would be small. It is expected that around 86% of the notifier chemical would be destroyed through incineration and/or oil recycling activities.

About 14% of the material will be used by automobile enthusiasts, and it is expected that much of this, up to 50% (ie. 7% of the total import volume), will be released through disposal into landfill, stormwater drains, and other routes. If deposited into landfill the material will be immobilised through adsorption onto soil particles. The material is not readily biodegradable, but in a landfill is expected to be slowly degraded through micro-biological and abiotic processes. Incineration would produce water vapour and oxides of carbon.

Approximately 5% of the waste oil produced by DIY enthusiasts may be disposed to waterways via the stormwater system. This equates to less than 1 tonne of the notified chemical that could be expected to enter the aquatic environment. The notified chemical is not toxic to aquatic organisms up to the limit of its water solubility. Due to its high Pow and high hydrocarbon content the notified chemical would be expected to become associated with suspended organic material which would settle out into the sediments and eventually biodegrade to carbon dioxide, methane and water.

Given the above considerations, the overall environmental risk is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is of very low acute oral and low dermal toxicity. It is not irritating or sensitising to animal skin, is a slight eye irritant. The notified chemical did not cause systemic toxicity in a repeat dose toxicity test and was not mutagenic in *in vitro* test systems. Based on the results of toxicity tests, Alkane 7 would not be classified as hazardous according to the National Occupational Health and Safety Commission *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Occupational health and safety

The notified chemical will be imported as a component (between 20 to 60%) of finished lubricant oils in 200 L steel drums. No reformulating will occur, but the finished oil will be repackaged into 1 L plastic bottles.

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. Ocular exposure is also possible. 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 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 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

In the ordinary course of events, use of the notified chemical will be limited to members of the public who practice home vehicle maintenance. In these cases any exposure to the finished oil containing the notified chemical is likely be dermal, infrequent and transient. On the basis of the above information and the low toxicity

of the notified chemical, it is considered that the notified chemical will not pose a significant hazard to public health when used as intended.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to Alkane 7:
  - Local exhaust ventilation should be in place in the repackaging facilities.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of Alkane 7:

  - 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.
  - Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to Alkane 7:
  - Chemical impervious gloves
  - Industrial overalls.

  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.

13.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(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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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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