File No: NA850

November 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

ALKANE 6

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Chevron Oronite Australia of Level 22, 385 Bourke Street, MELBOURNE VIC 3000 (ARBN 001 010 037) has submitted a standard notification statement in support of their application for an assessment certificate for Alkane 6.

2. IDENTITY OF THE CHEMICAL

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

Other Names:	Alkane-6; Polyalphaolefin; C1527-04-5.
Marketing Name:	PAO 7 & 9 cSt

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Clear, colourless liquid
Boiling Range:	>250°C
Freezing Point:	<-20°C
Density at 15°C:	0.896 g/mL
Vapour Pressure at 25°C:	<3.2 x 10^{-7} kPa
Water Solubility at 25°C:	<10 ppb - see comments below

Particle Size:	Viscous liquid, not likely to form aerosol under normal conditions
Partition Co-efficient (n-octanol/water):	Log_{10} P_{ow} >8 - see comments below
Hydrolysis as a Function of pH:	Not determined – see comments below
Adsorption/Desorption:	Not determined – see comments below
Dissociation Constant:	Not determined – see comments below
Flash Point:	>300°C
Flammability Limits:	Not determined
Autoignition Temperature:	>362°C
Explosive Properties:	Not explosive.
Reactivity/Stability:	Will react in the presence of strong oxidising agents. Stable to acid and base.

3.1 Comments on Physico-Chemical Properties

The vapour pressure provided suggests that Alkane 6 is slightly volatile (Mensink BJWG et al 1995).

The water solubility was read across from PAO 4 cSt (Rausina GA et al 1996). This is acceptable as Alkane 6 has similar constituents and a higher molecular weight and is therefore likely to be less soluble than the surrogate compound. In addition, consideration of the fully hydrocarbon chemical structure suggests that the water solubility will be very low.

Hydrolysis as a function of pH was not determined experimentally and the notifier claims that Alkane 6 should be stable under all conditions. Alkane 6 does not contain any functionality that will undergo hydrolysis under normal environmental conditions.

The partition coefficient for Alkane 6 was not determined. The notifier provided information on PAO 4 cSt, a C-10 hydrogenated dimer, as a surrogate for Alkane 6. The partition co-efficient for the surrogate chemical was determined by HPLC by comparison with polyaromatic hydrocarbon standards and it was determined that log P_{OW} >8. As Alkane 6 has a higher molecular weight than the surrogate chemical, it is anticipated that it will have a lower water solubility while the octanol solubility will be similar, so it is acceptable that the log P_{OW} of Alkane 6 be read across from the C-10 hydrogenated dimer.

Adsorption/desorption was not determined. The notifier suggests that Alkane 6 will not associate with soil or water and that, due to its very low water solubility, it will migrate slowly through soil before biodegrading. However, the high value determined for log P_{OW} (> 8) and the low water solubility indicates that Alkane 6 will probably be immobile in soils.

No dissociation constant was determined as Alkane 6 contains no functionalities that will dissociate.

4. PURITY OF THE CHEMICAL

Degree of Purity: 100%

Hazardous Impurities: None

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

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

Use & Import Volume
The proposed use of Alkane 6 in Australia is as a base fluid for the blending of synthetic automotive and industrial lubricants. The finished lubricants will be used primarily in automotive applications. It is estimated that 60% of the finished lubricant products will be sold as packaged goods to commercial outlets such as automotive fleets, trucking firms and servicing companies for cars and trucks. The remaining 40% will be sold through commercial oil jobbers, hardware, automotive and mass merchandising stores.

The notified chemical will not be manufactured in Australia. It will be imported in 200 L steel drums or in bulk in isotanks. Import volumes for the notified chemical are expected to be up to 10 tonnes per year for the next five years.

Formulation of Lubricants
Formulation of lubricants will occur at blending facilities of major lubricant manufacturers located Australia-wide.

The technological process for blending is as follows. The notified chemical is pumped from its storage tank, via hard plumbing, into a blending tank where it is mixed with, depending on product specification, additives, viscosity index improvers, pour point depressants or foam inhibitors. Blending occurs at 60°C. Computer controlled valves meter the precise delivery of components into the blending tank. The blended lubricant is pumped via hard plumbing to a finished lubricant storage tank for subsequent packaging into 1L, or 4L containers or 200 L drums. The drumming facility uses automated weigh scales to fill the 200 L drums. Bungs and labels are applied manually. Packaging into 1L and 4L containers is highly automated. Finished lubricants will contain at least 80% Alkane 6.

6. OCCUPATIONAL EXPOSURE

There is likely to be exposure of workers involved in the transfer of Alkane 6, workers involved in the blending of Alkane 6 into finished lubricants, and mechanics who may come into contact the finished lubricants while working on or repairing equipment.

Nature of Activity & Number of Workers	*Maximum Potential Exposure Duration & Personal Protective Equipment*
Transport and Storage, 20-30	Industrial standard overalls, eye protection & rubber gloves.
Sampling 1 to 2	30 minutes/day; 50 days/year. Laboratory coat, gloves & eye protection.
Analysis 1 to 2	30 minutes/day; 50 days/year. Laboratory coat, gloves & eye protection.
Cleaning 1	1 hour/day; 50 days/year. Industrial standard overalls and rubber gloves.

Dockside and Transport
Occupational exposure is not expected except in the event of a spill.

Formulation
The blending of lubricants is a highly automated, enclosed process. Worker exposure to Alkane 6 would be limited to accidental leaks and spills. Exposure is identified during the course of the following operations.

Skin contact is possible during transfer operations (hose coupling/uncoupling) of Alkane 6 into on-site storage tanks at the customers facility from the original import containers.

Once blending is complete, samples are taken from the blend tank for laboratory analysis to ensure that the specifications of the finished lubricant are met. Skin contact may occur from drips leaking from valves as they are opened and closed for sampling purposes. The lubricant is blended at 60°C, however, inhalation exposure to lubricant mist is unlikely given its low volatility.

The packaging of the 1 L and 4 L containers is highly automated and there is minimal worker exposure. However, drumming requires worker supervision (from a distance of 1 to 2 meters) and human intervention to ensure that the drum filling mechanism properly enters the drum before the drum is filled. In addition, once the drums are filled workers are required to insert the bungs and apply labels. Skin contact with Alkane 6 may occur where the lubricant has spilt onto the drum surface during these two activities.

Skin and eye contact to Alkane 6 may occur from leaks during cleaning of the blend tank, finished lubricant storage tank and packaging lines with lube oil, and from splashes from wastewater arising from the washing of the import containers.

Automobile Workshops
When changing lubricant, it is inevitable that mechanics will receive skin contact given the nature of the job and that personal protective equipment is not widely used by this trade group. Accidental eye contact may occur, particularly while mechanics are working under vehicles.

Control Measures and Worker Education and Training
The notifier states that inspections of their customers sites found that their blending facilities are well ventilated, with control systems for accidental spills and wastewater treatment. The notified chemical will be handled by employees of major Australian lubricant manufacturers. Workers involved in the above activities are reported to have received training in the handling of chemicals similar to Alkane 6.

7. PUBLIC EXPOSURE

It is expected that during transport, storage, blending and industrial use, exposure of the general public to Alkane 6 will be minimal, except in the event of an accidental spill.

Around 40% of finished lubricants will reach the public retail market, where they will be used to replace or top-up automotive lubricants, for example, engine and gearbox oils. Consequently, there is likely to be intermittent dermal exposure, with the potential for accidental eye, oral and inhalation exposure.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

No data has been provided for the likely quantity of Alkane 6 released during reformulation, repackaging and use.

There is the possibility for release of the notified chemical during reformulation and repackaging. The notifier has provided no details about the transfer of Alkane 6 from the isotanks into 200 L steel drums. However, limited losses would be expected and it is likely that any waste produced will be incinerated. Cleaning of the isotanks was not addressed, but it is likely that this will be accomplished with steam.

Blending and pumping equipment will be cleaned with lube oil that will be recycled into future blends.

Import drums will be steam cleaned, with the waste water containing Alkane 6 being sent to on-site waste water treatment facilities. Facilities would contain an API oil and water separator and it is expected that no more the 5% of the waste chemical will be emulsified in the water. The waste water is further treated with pond aeration and sand filtration before being released to sewer. Given the low water solubility of the notified chemical, it is likely that it will be present in the treated water only in very small quantities. The remaining oily portion of the waste is sent to an incinerator.

Accidental spills at the blending facilities will be contained by plant barriers. The facilities have concrete floors that allow the spilled product to be suctioned up with the remaining waste product, ending up in the waste water treatment facilities. The notifier has not detailed what would happen to the majority of the material released through accidental spills, but it is likely that this would be sent for incineration.

Accidental spills during transport and use will be contained to prevent contamination of soil, surface water and groundwater. The liquid will be adsorbed onto suitable material, and where feasible, contaminated soil removed. These will then be disposed of in accordance with local regulations. This is outlined in the Material Safety Data Sheet (MSDS).

The used lubricant products containing Alkane 6 are typically incinerated or sent to used oil recyclers. The notifier believes that the only potential for release to the environment is by individual passenger car owners and owners of equipment who do their own oil changes and do not use correct methods for disposal of used oil. Under these circumstances, it is likely that the used oil will be disposed of to landfill along with the empty oil containers. No figures have been supplied estimating the likely release of the notified chemical by these routes.

8.2 Fate

The majority of the spent oil containing Alkane 6 will be recycled or incinerated. When incinerated, Alkane 6 will form water vapour and oxides of carbon. A small amount will be released to the environment through spills and leaks, with these likely to be widely dispersed. If the notified substance is washed off road surfaces, it is expected to adsorb to adjacent soils and sediments.

There is likely to be some disposal of the lubricant products to landfill from users who do their own oil changes. Also, empty containers are also likely to be disposed to landfill. The oil should not be mobile in landfill and is unlikely to leach into the aquatic compartment. However, it may float on surface water with the potential to physically foul aquatic organisms.

No biodegradation data was provided for Alkane 6. However, biodegradation data for Alkane 5, a structurally and compositionally similar chemical to Alkane 6, is available (previously assessed as NA/256). Only 7% of Alkane 5 was found to degrade over 28 days in the CO_2 Evolution (Modified Sturm) Test (Safepharm Laboratories Limited 1995h). No inhibition of sewage sludge micro-organisms was observed. The reference substance, sodium benzoate attained 69% degradation after 14 days and therefore the test is considered valid. Alkane 5 can be considered a suitable surrogate for Alkane 6 as they have similar constituents and molecular weights. Therefore, it can be assumed that Alkane 6 will not be readily biodegradable. However, it is likely that Alkane 6 will undergo slow biodegradation under environmental conditions.

The potential for bioaccumulation was not determined. Although the molecular weight, and partition co-efficient (log P_{OW} >8) of Alkane 6 would indicate a potential for bioaccumulation (Connell 1990), the very low water solubility should reduce the availability of Alkane 6 to the aquatic compartment thus reducing the bioaccumulation potential. In support, a similar chemical was screened in a test using Semipermeable Membrane Device technology,

resulting in a maximum uptake of less than 0.001 mg/g and an estimated bioconcentration potential of less than 0.1 (Rausina GA et al 1996). In addition, exposure of Alkane 6 to aquatic organisms should not occur as any environmental release should be low and widespread throughout Australia. Therefore, significant bioaccumulation is unlikely.

9. EVALUATION OF TOXICOLOGICAL DATA

Test data on the notified chemical, Alkane 6, are not available. Instead data on Oronite Synfluid PAO 8 cSt and Alkane 5 (partial data set) previously assessed by NICNAS under the identifier of NA/256, were submitted in support of claims by the notifier for Variation to the Schedule Requirements. Both Alkane 5 and Oronite Synfluid PAO 8 cSt are closely related to the notified chemical: both are chemically and structurally similar and within the same molecular weight range. The submitted data are suitable for the toxicological assessment of Alkane 6.

For the assessment of repeated exposure, use is made of the 28-day repeat oral dose studies conducted for Alkane 2 (NA/851) and Alkane 4 (NA/849) which are both compositionally similar, but of lower molecular weight to Alkane 6.

Summary of the toxicity of Alkane 5

Tests on Alkane 5 were performed according to EC test guidelines (European Commission 1992) at Safepharm Laboratories Limited UK. These facilities comply with the OECD principles of good laboratory practice (GLP) and full test reports were submitted.

Test data on the investigation of acute inhalation toxicity, skin sensitisation, bacterial reverse mutation and induction of mouse micronuclei were not available when the assessment of Alkane 5 (NA/256) was first conducted by NICNAS, but are now included in this current assessment.

Test	*Species*	*Outcome*
Acute oral toxicity	Rat	LD_{50} > 5 000 mg/kg bw
Acute dermal toxicity	Rat	LD_{50} > 2 000 mg/kg bw
Acute inhalation toxicity	Rat	LC_{50} > 5 mg/L/4-hour
Skin irritation	Rabbit	Non irritating
Eye irritation	Rabbit	Non irritating
Skin sensitisation – non adjuvant method	Guineapig	Non sensitising
Bacterial Reverse Mutation	*S. typhimurium & E. coli*	Non mutagenic
Induction of micronuclei	Mouse	Non clastogenic

Summary of the toxicity of Oronite Gulf Synfluid 8cSt

The tests on Oronite Synfluid PAO 8 cSt were performed at Hazelton Raltech Inc USA. These facilities comply with the US EPA GLP Regulations and full test reports were submitted.

Test	*Species*	*Outcome*
Acute oral toxicity	Rat	LD_{50} > 4 168mg/kg bw
Acute dermal toxicity	Rat	LD_{50} > 2 000 mg/kg bw
Skin irritation	Rabbit	Mildly irritating
Eye irritation	Rabbit	Mildly irritating
Skin sensitisation – non adjuvant method	Guineapig	Non sensitising
Bacterial Reverse Mutation	*S .typhimurium*	Non mutagenic

9.1 Acute Toxicity

9.1.1.1 Oral Toxicity (Safepharm Laboratories Limited 1995d)

Test Substance:	Alkane 5
Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	5 000 mg/kg by gavage in a dose volume of 6.07 mL/kg
Test method:	OECD TG 401; EC Method B1
Mortality:	Nil
Clinical observations:	There were no clinical signs of systemic toxicity.
Morphological findings:	No abnormalities were noted at necropsy.
Estimated LD_{50}:	> 5 000 mg/kg
Result:	Alkane 5 was of very low acute oral toxicity to the rat.

9.1.1.2 Oral Toxicity (Hazelton Raltech Inc 1982b)

Test Substance:	Oronite Gulf Synfluid 8cSt
Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	4 168 mg/kg by gavage in a dose volume of 5.0 mL/kg bw
Test method:	Not stated
Mortality:	Nil
Clinical observations:	There were no clinical signs of systemic toxicity.
Morphological findings:	Moderate hydrometra was observed in one female. Clear, firm raised areas on all lobes of the lung were in one male. No other abnormalities were noted at necropsy.
Estimated LD_{50}:	> 4 168 mg/kg
Result:	Oronite Gulf Synfluid 8cSt was of very low acute oral toxicity to the rat.

9.1.2.1 Dermal Toxicity (Safepharm Laboratories Limited 1995b)

Test Substance:	Alkane 5
Species/strain:	Rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A single, 24-hour semi occluded dermal application to intact skin at a dose level of 2 000 mg/kg bw, dose volume of 2.43 mL/kg.
Test method:	OECD TG 402; EC Method B3.
Mortality:	Nil
Clinical observations:	No clinical signs of systemic toxicity were noted.
Dermal response:	No signs of dermal irritation were noted.
Morphological findings:	No abnormalities were noted at necropsy.

LD_{50}:	> 2 000 mg/kg bw
Result:	Alkane 5 was of low dermal toxicity to the rat.

9.1.2.2 Dermal Toxicity (Hazelton Raltech Inc 1982a)

Test Substance:	Gulf Synfluid 8cSt
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	8/sex
Observation period:	14 days
Method of administration:	A single, 24-hour occluded dermal application to intact and abraded skin at a dose level of 2 000 mg/kg bw, dose volume of 2.0 mL/kg
Test method:	Not stated
Mortality:	Nil
Clinical observations:	No clinical signs of systemic toxicity were noted.
Dermal response:	No signs of dermal irritation were noted.
Morphological findings:	Lungs were mildly reddened in two females and two males. No other abnormalities were noted at necropsy.
LD_{50}:	> 2 000 mg/kg bw
Result:	Oronite Gulf Synfluid 8cSt was of low dermal toxicity to the rat.

9.1.3. Inhalation Toxicity (Safepharm Laboratories Limited 1995c)

Test Substance:	Alkane 5
Species/strain:	Rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Test method:	OECD TG 403 limit test; EC Method B2
Method of administration:	A single 4-hour, nose only exposure to aerosolised test substance; dynamic exposure, flow rate 16 L /minute.

Atmosphere Conditions:

Nominal Concentration 40.1 mg/L
Mean achieved atmosphere concentration, 5.00 mg/L
Mean mass median aerodynamic diameter, 1.3 μm
Inspirable fraction, < 4 μm: 90.0%

Mortality: Nil

Clinical observations:
Wet fur, hunched posture, piloerection, decreased respiratory rate, ptosis and red/brown staining around the eyes were noted. Animals recovered to appear normal after 2 or 3 days.

Morphological findings:
One male showed dark patches on the lungs. No abnormalities detected in other animals.

LC_{50}: > 5.00 mg/L/ 4-hour

Result: Alkane 5 was of very low acute inhalation toxicity to the rat.

9.1.4.1 Skin Irritation (Safepharm Laboratories Limited 1995a)

Test Substance:	Alkane 5
Species/strain:	Rabbit/New Zealand white
Number/sex of animals:	4 females, 2 males
Observation period:	3 days
Method of administration:	A single 4 hour, semi occluded application of 0.5 mL of neat test substance to intact skin.
Test method:	OECD TG 404; EC Method B4.
Dermal response:	No skin reactions were observed for the duration of the study.
24, 48 & 72 hour group mean score:	Erythema/Eschar formation: 0.0; Oedema: 0.0.
Result:	Alkane 5 was non irritating to rabbit skin.

9.1.4.2 Skin Irritation (Hazelton Raltech Inc 1982d)

Test Substance:	Gulf Synfluid 8cSt
Species/strain:	Rabbit/New Zealand white
Number/sex of animals:	3/sex
Observation period:	3 days
Method of administration:	A single 24 hour, occluded application of 0.5 mL of neat test substance to abraded and intact skin on each animal. Treated sites were examined for dermal responses at 24 and 72 hours after administration.
Test method:	Not stated
Dermal response:	Individual Draize scores were not provided in the study report.
Primary dermal irritation score:	24 hours: 0.1; 72 hours: 0.0
Primary dermal irritation index (PII):	0.1
Comment:	A PII of 0.1 is classified by the study authors as mildly irritating to intact and abraded skin.
Result:	Oronite Gulf Synfluid 8cSt was mildly irritating to intact rabbit skin.

9.1.5.1 Eye Irritation (Safepharm Laboratories Limited 1995j)

Test Substance:	Alkane 5
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	6 males, 3 females
Observation period:	1, 24, 48 and 72 hours post instillation
Method of administration, Unirrigated eyes:	A single instillation of 0.1 mL of the neat test substance into the conjunctival sac of the right eye of 6 rabbits. The left eye served as the control.

Method of administration, Irrigated eyes:	A single instillation of 0.1 mL of the neat test substance into the conjunctival sac of the eye of 3 rabbits; after 30 seconds the eye was gently irrigated with 100mL of lukewarm water for one minute. The untreated eye served as the control.
Test method:	OECD TG 405; EC Method B5
Ocular response - unirrigated eyes:	Conjunctival redness noted in one treated eye 1-hour after treatment had resolved by the 24-hour observation. No iridial or conjunctival effects were noted.
Group mean scores – 24, 48 & 72 hour observation:	Corneal opacity: 0.0; Iridial lesion: 0.0; Redness of conjunctivae: 0.0; Chemosis of conjunctivae: 0.0.
Ocular response -irrigated eyes:	No corneal, iridial or conjunctival effects were noted.
Result:	Alkane 5 was non irritating to rabbit eye.

9.1.5.2 Eye Irritation (Hazelton Raltech Inc 1982c)

Test Substance:	Gulf Synfluid 8cSt
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	9 males
Observation period:	7 days post instillation
Method of administration, Unirrigated eyes:	A single instillation of 0.1 mL of the neat test substance into the conjunctival sac of the right eye of 6 rabbits. The left eye served as the control.
Method of administration, Irrigated eyes:	A single instillation of 0.1 mL of the neat test substance into the conjunctival sac of the right eye of 3 rabbits; after 30 seconds the eye was gently irrigated with 100mL of lukewarm water for one minute. The untreated eye served as the control.
Test method:	Not stated
Ocular response: -	Individual Draize scores were not provided in the study report. However, the Draize scores ranged from 0.0 to 1.3.

Primary Eye Irritation Score (PI)	Time	PI irrigated	PI unirrigated
	24 hours	1.3	1.3
	48 hours	0.0	0.0
	72 hours	0.0	0.0
	96 hours	0.0	0.0
	7 days	0.0	0.0

Comment: Gulf Synfluid 8cSt is classified by the study authors as mildly irritating

Result: Oronite Gulf Synfluid 8cSt was mildly irritating to rabbit eye.

9.1.6.1 Skin Sensitisation in Guineapigs (Hill Top Biolabs Inc 1995)

Test Substance: Alkane 5

Species/strain: Guineapig/Hartley

Number of animals: 20 test and 10 naïve control animals

Test method: Modified Buehler

Induction procedure: Day 1 to Day 21:
0.5 mL of test substance was applied every other day, three times a week for three weeks.

Challenge procedure: Day 35:
A single application of 0.5 mL of the neat test substance was applied. Grading of dermal responses occurred 24 and 48 hours post exposure

Challenge outcome: Grade 0.5 erythema (slight, patchy erythema) was observed in 12 of 20 test animals at 24 hours and 9 of 20 animals at 48 hours. The incidence and severity of these responses were comparable to control group (6 of 10 at 24 hours and 5 of 10 at 48 hours).

Result: Alkane 5 was non sensitising to guineapig skin

9.1.6.2 Skin Sensitisation in Guineapigs (Hazelton Raltech Inc 1982e)

Test Substance:	Gulf Synfluid 8cSt
Species/strain:	Guineapig/Hartley
Number of animals:	10 test, 10 positive control
Test method:	Modified Buehler
Induction procedure:	Day 1 to Day 21: 0.5 mL of test substance or positive control were applied every other day, three times a week for three weeks.
Challenge procedure:	Day 35: A single application of 0.5 mL of test substance or positive control were applied. Grading of dermal responses occurred 24 and 48 hours post exposure
Challenge outcome:	Test animals: Erythema or oedema was not observed. Positive Control animals: All animals demonstrated a positive response.
Result:	Oronite Gulf Synfluid 8cSt was non sensitising to guineapig skin

9.2 Repeated Dose Toxicity

Repeat dose toxicity testing has not been conducted on the notified chemical. Closely related, long chain, branched hydrocarbons to the notified chemical, (see NA/849 and NA/851) have been investigated in repeat oral dose studies (28-day) and demonstrate no observed adverse effect levels (NOAEL) of 1 000 mg/kg/day in rats. Being compositionally similar, the notified chemical is expected to demonstrate the same low toxicity as that observed with the substances assessed under NA/849 and NA/851.

9.3 Genotoxicity

9.3.1.1 Bacterial Reverse Mutation Assay (Safepharm Laboratories Limited 1995k)

Test Substance:	Alkane 5
Strains:	*Salmonella typhimurium*: TA100, TA1535, TA98, TA1537; *Escherichia coli*: WP2uvrA$^-$.
Auxilliary metabolic activation system:	Liver S9 fraction from rats induced with Aroclor 1254.
Concentration range:	0, 15, 50, 150, 500, 1 500, 5 000 μg/plate. Using the above concentrations, two experiments were

	conducted, each in triplicate, both in the presence and absence of metabolic activation. Appropriate strain specific positive controls were run with each experiment.
Test method:	Similar to OECD TG 471 – plate incorporation method.
Comment:	No toxicity was observed. A precipitate was observed at and above 500 μg/plate. There was no increase in the number of revertant colonies above the control, or demonstration of a dose response relationship, either in the presence or absence of metabolic activation at any test concentration. The positive control substances all produced marked increases in the frequency of revertant colonies.
Result:	Alkane 5 was non mutagenic under the conditions of the test.

9.3.1.2 Bacterial Reverse Mutation Assay (Chevron Environmental Health Center Inc 1989)

Test Substance:	PAO 8 cSt
Strains:	*Salmonella typhimurium*: TA100, TA1535, TA98, TA1537.
Auxillary metabolic activation system:	Liver S9 fraction from rats induced with Aroclor 1254.
Concentration range:	0, 100, 330, 1 000, 3 300, 10 000 μg/plate Using the above concentrations, two experiments were conducted, each in triplicate, both in the presence and absence of metabolic activation. Appropriate strain specific positive controls were run with each experiment.
Test method:	Similar to OECD TG 471 – plate incorporation method.
Comment:	No toxicity was observed. The test substance dissolved in Pluronic F-127 were well dispersed in the top agar. However, after incubation, the test substance at all dose levels was observed on the surface of the top agar. There was no increase in the number of revertant colonies above the control, or demonstration of a dose response relationship, either in the presence or absence of metabolic activation at any test concentration. The positive control substances all produced marked increases in the frequency of revertant colonies.
Result:	Oronite Synfluid PAO 8 cSt was non mutagenic under the

conditions of the test.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Safepharm Laboratories Limited 1995i)

Test Substance: Alkane 5

Species/strain: Mouse/Crl:CD-1 (ICR) BR

Experimental design: Test substance and vehicle control were administered via intraperitoneal injection, and positive control via oral administration, at the following doses:

Dose Group	*Dose Level mg/kg*	*Dose Concentration mg/mL*	*No of animals/ Kill time after dosing*
Low	1 250	125	5/sex/ 24, 48 or 72 hours
Medium	2 500	250	5/sex/ 24, 48 or 72 hours
High	5 000	500	5/sex/ 24, 48 or 72 hours
Vehicle control: Arachis oil	0	0	5/sex/ 24, 48 or 72 hours
Positive Control: cyclophosphamide	50	5	5/sex/ 24 hours

Test method: OECD TG 474; EC Method B12

Clinical observations: There were no clinical signs of toxicity. There was no mortality.

Evaluation of bone marrow slides:
1 000 polychromatic erythrocytes (PCE) were counted per slide.
There was no significant change in PCE/NCE ratio in any of the test substance dose groups when compared to the concurrent vehicle control group.
Bone marrow toxicity was not observed – the ratio of PCE to normochromatic erythrocytes was comparable to the respective control groups for each kill time and dose tested.
The positive control caused a significant increase in micronucleated PCE, 19.6

Result:
Alkane 5 is not considered clastogenic in this *in vivo* mouse micronucleus study, under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

Alkane 5 is of very low acute oral and inhalation and low dermal toxicity in rats. Alkane 5 is non irritating to the skin and eyes of rabbits. In a non-adjuvant type skin sensitisation study Alkane 5 did not cause delayed contact hypersensitivity in guineapigs.

Alkane 5 was non mutagenic in a bacterial reverse mutation assay and non clastogenic in an *in vivo* mouse micronucleus study.

Oronite Synfluid 8cSt is of very low acute oral and low dermal toxicity in rats. Oronite Synfluid 8cSt is mildly irritating to the skin and eyes of rabbits. In a non-adjuvant type skin sensitisation study Oronite Synfluid 8cSt did not cause delayed contact hypersensitivity in guineapigs. Oronite Synfluid 8cSt was non mutagenic in a bacterial reverse mutation assay.

No adverse effects related to treatment were observed in a 4-week repeat oral dose limit study in rats administered Alkane 2 or Alkane 4. For both substances the NOAEL is equal or greater than 1 000 mg/kg/day, the highest dose tested.

By analogy, Alkane 6 is expected to have low acute oral, dermal and inhalation toxicity. Alkane 6 may be mildly irritating to the eye or skin, but is not expected to cause skin sensitisation. Alkane 6 is expected to be of low toxicity upon repeated exposure and non genotoxic.

Hazard Classification
Based on results, from testing on analogue substances, which are below the thresholds for classification under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999) Alkane 6 is not classified as a hazardous substance.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicity data were supplied for Alkane 6. Instead, the notifier requested that studies carried out on Oronite Synfluid PAO 8 cSt, or Alkane 5, be used as a surrogate. The similarities between the surrogate chemicals and Alkane 6 are such that this is acceptable. The tests on Oronite Synfluid PAO 8 cSt were carried out in accordance with US EPA GLP Regulations and the tests on Alkane 5 were carried out in accordance with the UK Principles of GLP using OECD guidelines.

10.1 Summary of Effects on Biotic Systems of Synfluid PAO 8 cSt

Test	*Species*	*Results*
Acute Toxicity Semi-static, 96-hour;	Bluegill sunfish (*Lepomis macrochirus*)	LC_{50} > 100 mg/L
Acute Toxicity Semi-static, 96-hour;	Rainbow trout (*Salmo gairdneri*)	LC_{50} > 100 mg/L
Acute Immobilisation Flow through, 48-hour;	Water Flea (*Daphnia magna*)	EC_{50} = 1.83 mg/L*
Growth Inhibition Static, 96 hour.	Algae (*Selenastrum capricornutum*)	EC_{50} > 100mg/L

*nominal concentration.

10.2 Fish Acute Toxicity Test (Gulf Life Sciences Center 1983b)

A semi-static test regime was employed in this study involving a daily renewal of the test media to ensure that the concentrations of Synfluid 8 cSt remained near nominal. There were no mortalities or behavioural responses to exposure in either the rainbow trout or the bluegill sunfish exposed to 100 mg/L nominal concentration for 96 hours. The concentrations of the chemical in the test water were not performed and given the low water solubility of the test hydrocarbon, only very small quantities were dissolved with the remainder observed on the surface of the water and adhering to the sides of the test vessels. However, the test should represent the maximum saturated concentration of the test substance achievable under the conditions of the study.

10.3 Daphnia Acute Immobilisation Test (Gulf Life Sciences Center 1983a)

At each dose level, twenty daphnids (2 replicates of 10 animals) were exposed to nominal concentrations of the test substance in water of 1.0, 1.8, 3.2, 5.6 and 10.0 mg/L for 48 hours in a flow-through proportional diluter system. Under these conditions, it was determined that the EC_{50} of Synfluid 8 cSt was 1.83 mg/L, indicating that the test substance is moderately toxic to daphnia. However, given the low water solubility of the test substance, there will be undissolved test material present and this may have caused a physical response resulting in immobilisation or death of the daphnids. Chemical analysis of the test solutions was not performed (nor were observations of undissolved material provided), but the test should represent the maximum saturated concentration of the test substance achievable under the conditions of the study. Interestingly, under static conditions using a Water Accommodated Fraction (WAF) (saturated solution after removal of excess hydrocarbon), Alkane 5 (see Section 10.7) is not toxic to daphnia at the limit of its solubility, supporting a physical rather than chemical effect here.

10.4 Algal Growth Inhibition Test (Gulf Life Sciences Center 1983c)

Selenastrum capricornutum (four replicate flasks) was exposed to Synfluid 8 cSt at a nominal concentration of 1, 10 or 100 mg/L for 96 hours. The EC_{50} value was determined to be > 100 mg/L, indicating that the test material is not toxic to algae to the limit of its solubility. Chemical analysis of the test solutions was not performed and it is expected that only very small quantities of the test substance dissolved with the remainder floating on the water surface or adhering to the test vessels.

10.5 Summary of Effects on Biotic Systems of Alkane 5

Test	***Species***	***Results (loading rate of WAF)***
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
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
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

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% (72-96 hours).
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 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.

10.6 Fish Acute Toxicity Test (Safepharm Laboratories Limited 1995f)

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 responses to exposure in 20 fish exposed to 1 000 mg/L loading rate WAF for 96 hours.

10.7 Daphnia Acute Immobilisation Test (Safepharm Laboratories Limited 1995e)

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.

10.8 Alga Growth Inhibition Test (Safepharm Laboratories Limited 1995g)

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.

Samples from the test and control flasks 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 (Students t-test, $P \geq 0.05$) between the control and test groups, with only 3% inhibition of growth observed at 72 hours, 1% inhibition observed at 96 hours and 6% inhibition in the period 24 to 48 hours.

10.9 Conclusion

The ecotoxicity data supplied suggest that Alkane 6 will be non-toxic to fish and algae up to the limit of its water solubility. Based on a flow through toxicity test on Daphnia with Oronite Synfluid PAO 8 cSt as the surrogate, Alkane 6 may be moderately toxic to aquatic invertebrates. However, a toxicity test on Daphnia involving a WAF and static conditions, using Alkane 5 as the surrogate, suggests that Alkane 6 will not be toxic to aquatic invertebrates. The differences are most likely due to a physical rather than a chemical response i.e the result of the daphnids interacting with the undissolved material.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Alkane 6 is to be used as a major component of lubricants for automotive and industrial lubricants, with the main environmental exposure resulting from inappropriate disposal of waste lubricant.

It is estimated that 60% of the final lubricant products will be sold to commercial outlets such as automotive fleets where oil recovery and recycling is likely to be widely practised. The remaining 40% will be sold to the public. The extent of recovery of used oil from the public is less defined and there is likely to be some indiscriminate dumping of oil in landfills and sewer/stormwater drains. It has been estimated that 56% of used oil generated in Australia is collected (Snow 1997). Assuming no recovery of the 40% of lubricant products containing Alkane 6 sold to the public, and not taking account of oil consumption during use, up to four tonnes of Alkane 6 may be incorrectly disposed of each year. This disposal will be

widespread across Australia. The fate of oils sent to landfill is not clear, but it is thought that it may slowly migrate through the soil with some adsorption depending on the chemical nature of the hydrocarbon and the soil content (Edgehill R 1997). Alkane 6 is likely to adsorb strongly to soil. Alkane 6 is not readily biodegradable, but will be degraded by slow biological and abiotic processes.

Disposal of containers containing residual oil should not result in any significant environmental exposure. Waste oil is likely to be collected and either recycled or incinerated. When incinerated, Alkane 6 will form water vapour and oxides of carbon.

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

The available ecotoxicity data indicate that Alkane 6 is not toxic to fish or algae at the limit of its solubility. In one test, moderate toxicity to daphnia was demonstrated which was most likely due to physical effects. However, the limited release to the aquatic compartment means that Alkane 6 should only pose a minimal threat to the environment. However, the potential exists, in the advent of a sizeable release to waterways, for physical fouling of aquatic organisms by undissolved material.

Overall, the environmental hazard from the proposed reformulation and use of Alkane 6 is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment and Classification
By analogy, Alkane 6 is expected to have very low acute oral and low dermal and inhalation toxicity. It may be mildly irritating to eyes and skin, but would not be expected to cause skin sensitisation. Alkane 6 is expected to be of low toxicity upon repeated exposure and non-genotoxic. Based on the available analogue data, Alkane 6 is not classified hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

Occupational Health and Safety
Alkane 6 will be imported neat in 200 L drums or in bulk in isotanks. The main application of Alkane 6 is as a base fluid (at least 80%) for automotive lubricants.

Alkane 6 will be blended into lubricants at major lubricant manufacturers across Australia. The technological process for blending of Alkane 6 to produce the finished lubricant is a computer controlled automated enclosed system operating at 60°C. Alkane 6 may cause mild skin and eye irritation upon initial contact. Skin contact is possible during transfer operations (hose coupling/uncoupling) of Alkane 6 into on-site storage tanks at the customers facility from the original import containers. During blending operators will take samples of the lubricant for quality control purposes and skin contact is possible. Personal protective equipment, including gloves will be worn by plant operators involved, thus reducing any risk of adverse skin effects. During packaging of the finished lubricant into 200L drums, skin

contact may occur for operators involved in overseeing the filling process where manual intervention is required and during bunging and labelling of the drums. Skin contact is also identified for workers involved in steam cleaning of plant equipment. However, in both instances personal protective equipment will be worn, thus minimising any skin effects.

Automechanics may suffer repeated skin and eye contamination with the finished lubricants during servicing of vehicles. The main health risk from Alkane 6 is skin and eye irritation, as it is unlikely that gloves and eye protection are worn by this trade group.

Under normal working conditions, transport and storage workers are unlikely to be exposed to Alkane 6 and the occupational health risk posed to these workers is considered negligible.

Public Health
Individuals who maintain their automotive, recreational and/or garden equipment requiring lubricant replenishment and replacement will have contact with finished lubricants containing Alkane 6. Infrequent dermal exposure (most likely to the hands and forearms), and accidental ocular, oral and inhalation exposure could occur in these individuals. Alkane 6 comprises at least 80% of finished lubricants, but is of very low toxicity and therefore unlikely to pose a significant hazard to public health. The potential for public exposure to Alkane 6 during transport, storage, product formulation, commercial use and disposal, is considered to be low, except in the rare event of an accidental spill.

Based on the above, it is considered that Alkane 6 will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

Occupational Health and Safety Matters
To minimise occupational exposure to Alkane 6 the following guidelines and precautions should be observed:

- Workers should receive regular instruction on good occupational hygiene practices in order to minimise personal contact, and contamination of the work environment with Alkane 6 and the formulations that contain it.

- Workers should be advised of the potential for occupational dermatoses following repeated skin exposure to Alkane 6 or finished lubricants and to report any skin changes to the occupational health and safety officer at their workplace. When an occupational skin disease occurs, the employer should review work practices and opportunities for contact with the substance and instigate preventive measures to ensure other workers do not develop the same condition. Further guidance on preventing the occurrence of occupational skin diseases can be found in the NOHSC guide *Occupational Diseases of the Skin* (NOHSC 1990).

- Chemical impervious clothing and gloves are necessary to prevent skin contact - consideration should be given to the ambient environment, physical requirements and other substances present when selecting protective clothing and gloves. Good hygiene practices dictate that eye protection be worn routinely. Workers should be

trained in the proper fit, correct use and maintenance of their protective gear. PPE guidance in the selection, personal fit and maintenance of personal protective equipment can be obtained from:

Protective eyewear:	AS 1336 (SAA 1994),
	AS/NZS 1337 (SAA/SNZ 1992);
Chemical impermeable clothing:	AS 3765.2 (SAA 1990);
Impermeable gloves:	AS 2161.2 (SAA/SNZ 1998);
Occupational footwear:	AS/NZS 2210 (SAA/SNZ 1994).

- Alkane 6 is not determined to be a hazardous substance. The finished lubricant may contain hazardous ingredients making the overall finished lubricant hazardous. Therefore, workplace practices, control procedures and hazard communication products consistent with provisions of State, Territory and Commonwealth legislation based on the *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC 1994b) must be in operation.

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

Environmental Matters
Spillage of Alkane 6 should be avoided. Spillages should be cleaned up promptly and in accordance with the instructions on the notifiers MSDS.

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 1994a).

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 may 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 (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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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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