File No: NA849

November 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

ALKANE 4

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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 4.

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.

Marketing Name:	PAO 5 cSt; Alkane 4.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Clear, slightly viscous liquid, no odour
Boiling Range: (Safepharm Laboratories Limited 1995j)	165-317°C
Freezing Point:	<-20°C
Relative Density at 20°C: (Safepharm Laboratories Limited 1995j)	0.818
Vapour Pressure at 25°C: (Safepharm Laboratories Limited 1995l)	2.5×10^{-10} kPa
Water Solubility at 20°C: (Safepharm Laboratories Limited 1995j)	<0.482 mg/L

Particle Size:	Viscous liquid, not likely to form aerosol under normal conditions
Partition Co-efficient (n-octanol/water):	Log_{10} K_{ow} >3.87
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: (Safepharm Laboratories Limited 1995k)	>300°C
Flammability Limits:	Not determined
Autoignition Temperature: (Safepharm Laboratories Limited 1995k)	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

Tests were performed according to EC and OECD test guidelines (European Commission 1992), (OECD 1995-1996) at Safepharm Laboratories Limited UK. These facilities comply with the OECD principles of good laboratory practice (GLP) and full test reports were submitted. All tests were performed on the notified chemical.

The vapour pressure determined indicates that Alkane 4 is very slightly volatile (Mensink, 1995).

The water solubility was determined using the shake-flask method with analysis by gas chromatography. Due to the low water solubility of Alkane 4, it proved impractical to prepare samples at 5-times the saturation level as recommended in the experimental procedure. Instead, the test mixtures were prepared at approximately 333-times the saturation level. This deviation is not considered to have affected the integrity of the study. The water solubility was found to be below the limit of detection.

Hydrolysis as a function of pH was not determined experimentally and the notifier claims that Alkane 4 should be stable under all conditions. Alkane 4 does not contain any functionality that will undergo hydrolysis under normal environmental conditions.

The partition coefficient was determined by the shake-flask method with the concentrations determined by gas chromatography. As the water solubility of Alkane 4 was less than the limit of detection, the concentration in water could not be accurately determined, resulting in the determination of a limit value. It is expected that the partition co-efficient will be >>4.

Adsorption/desorption was not determined. The notifier considers that Alkane 4 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} (> 3.87) and the low water solubility indicates that Alkane 4 will probably be immobile in soils.

No dissociation constant was determined as Alkane 4 contains no functionalites 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 4 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.

Alkane 4 meets the US specification for mineral oils that may be used as components of non-food articles intended for use in contact with food, however, it is not known if this use will be realised in Australia.

Alkane 4 will not be manufactured in Australia. It will be imported in 200 L steel drums or in bulk in isotanks. Import volumes for Alkane 4 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. Alkane 4 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 4.

6. OCCUPATIONAL EXPOSURE

There is likely to be exposure of workers involved in the transfer of Alkane 4, workers involved in the blending of Alkane 4 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 the notified chemical 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 the notified chemical 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 the notified chemical may occur where the lubricant has spilt onto the drum surface during these two activities.

Skin and eye contact to the notified chemical 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 steam cleaning of the import containers.

Automobile Workshops
When changing lubricants, 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 have 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 blending activities are reported to have received training in the handling of chemicals similar to Alkane 4.

7. PUBLIC EXPOSURE

It is expected that during transport, storage, blending and industrial use, exposure of the general public to Alkane 4 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 4 released during reformulation, repackaging and use.

There is the possibility for release of Alkane 4 during reformulation and repackaging. The notifier has provided no details about the transfer of Alkane 4 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 4 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 the notified chemical 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 Alkane 4 by these routes.

8.2 Fate

The majority of the spent oil containing Alkane 4 will be recycled or incinerated. When incinerated, Alkane 4 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. Empty containers may be disposed of 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.

Alkane 4 was not found to be readily biodegradable. Only 6% of Alkane 4 was found to biodegrade over 28 days in the CO_2 Evolution (Modified Sturm) Test. The reference substance, sodium benzoate, attained 69% degradation after 14 days and therefore the test is considered valid. However, it is likely that Alkane 4 will undergo slow biodegradation under environmental conditions. No inhibition of sewage sludge micro-organisms was observed.

The potential for bioaccumulation was not determined. Although the molecular weight and partition co-efficient (log P_{OW} >3.87) of Alkane 4 would indicate a potential for bioaccumulation (Connell 1990), the very low water solubility should reduce the availability of Alkane 4 to the aquatic compartment, thus reducing the bioaccumulation potential. In support, a similar chemical was screened in a test using Semipermeable Membrane Device (SPMD) technology, resulting in a maximum uptake of less than 0.001 mg/g and an estimated bioconcentration factor of less than 0.1 (Rausina GA et al 1996). In addition, exposure of Alkane 4 to aquatic organisms is not expected as any environmental release should be low and widespread throughout Australia. Therefore, significant bioaccumulation is unlikely.

9. EVALUATION OF TOXICOLOGICAL DATA

Tests were performed according to EC and OECD test guidelines (European Commission 1992), OECD 1995-1996) at Safepharm Laboratories Limited UK. These facilities comply with the OECD principles of GLP and full test reports were submitted. All tests were performed on Alkane 4.

9.1 Acute Toxicity

Summary of the acute toxicity of Alkane 4

Test	*Species*	*Outcome*
Acute oral toxicity	Rat	LD_{50}> 5 000 mg/kg
Acute dermal toxicity	Rat	LD_{50}> 2 000 mg/kg
Acute inhalation toxicity	Rat	LC_{50}> 5.06 mg/L/4-hour
Skin irritation	Rabbit	Very slightly irritating
Eye irritation	Rabbit	Very slightly irritating
Skin sensitisation		
Buehler	Guineapig	Non sensitising
Magnusson & Kligman	Guineapig	Non sensitising

9.1.1 Oral Toxicity (Safepharm Laboratories Limited 1995e)

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 6.14 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 4 was of very low acute oral toxicity to the rat.

9.1.2 Dermal Toxicity (Safepharm Laboratories Limited 1995c)

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 2.46 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 4 was of low dermal toxicity to the rat.

9.1.3 Inhalation Toxicity (Safepharm Laboratories Limited 1995d)

Species/strain:	Rat/Sprague-Dawley CD
Number/sex of animals:	5/sex/group
Observation period:	14 days
Test method:	OECD TG 403; 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 Concentration:

Nominal	18.1 mg/L
Mean achieved atmosphere concentration,	5.06 mg/L
Mean mass median aerodynamic diameter,	1.2 µm
Inspirable fraction, < 4 µm:	90.1%

Mortality Nil

Clinical observations:
<u>During exposure</u>
Several animals showed wet fur and two females showed increased respiratory rate.
<u>Post exposure</u>
Upon removal from the test chamber, hunched posture and pilo-erection were common and there were incidents of increased respiratory rate, ptosis, isolated incidents of decreased respiratory rates and red/brown staining on the head.
One-hour post exposure, effects noted were confined to hunched posture, pilo-erection and three animals showed increased respiratory rate. From Day 2 onwards, all animals appeared normal.

Morphological findings: No abnormalities were detected at necropsy.

LC_{50}: > 5.06 mg/L/ 4-hour

Result: Alkane 4 was of very low acute inhalation toxicity to the rat.

9.1.4 Skin Irritation (Safepharm Laboratories Limited 1995b)

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 test substance to intact skin.
Test method:	OECD TG 404; EC Method B4.
Dermal response:	Grade 1 erythema (very slight erythema) was observed at two treated sites 30 minutes after patch removal and persisted at one treated site at the 24 hour observation. All treated sites appeared normal at the 48 hour observation time.
24, 48 & 72 hour group mean score:	Erythema/Eschar formation: 0.06; Oedema: 0.0.
Result:	Alkane 4 was very slightly irritating to rabbit skin.

9.1.5 Eye Irritation (Safepharm Laboratories Limited 1995o)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5 males, 4 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 four treated eyes 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 4 was very slightly irritating to rabbit eye.

9.1.6.1 Skin Sensitisation (Safepharm Laboratories Limited 1995m)

Species/strain:	Guineapig/Dunkin Hartley White
Number of animals:	10 test and 5 control animals
Test method:	OECD TG 406 Magnusson and Kligman Maximisation Method; EC Method B1

Induction procedure:	Intradermal Induction Test animals: Day 1: three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region: • Freund's Complete Adjuvant (FCA) in distilled water (1:1); • the test substance at 25% w/v in dried arachis oil; • the test substance at 25% w/v in a (1:1) mixture of FCA and distilled water. Topical Induction: Day 7 – A 48-hour semi occluded application of filter paper loaded with neat test substance to the treated area; Control Animals: Treated similarly to the test animals omitting the test substance from the intradermal injections and topical application.
Challenge procedure:	Test and Control animals: Day 21: A 24 hour, semi occluded application of 100% w/v of test substance to the right flank of each animal, and 75% w/v test substance in dried arachis oil, to the left flank of each animal.
Challenge Outcome:	No skin reactions were observed in test animals at the 24 or 48-hour observation period. Grade 1 erythema (discrete or patchy erythema) was observed in one control animal at the 24 hour observation period. No other reactions were noted in control animals.
Result:	Alkane 4 was non-sensitising to guineapig skin under the conditions of this adjuvant type study..

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

Species/strain:	Guineapig/Hartley
Number of animals:	10/sex (test group), 5/sex (naïve control group)
Test method:	OECD TG 406 Buehler Technique
Maximum Concentration not giving rise to irritating effects in irritation screen:	Irritancy was observed at 0.5%, the lowest concentration tested.
Induction procedure:	test animals: Days 1, 7 and 14: 0.3 mL of test substance applied, via a Hill

	Top Chamber, to the clipped skin of the left shoulder for 6 hours;
Challenge procedure:	test and naïve control animals: Day 28: same procedure as induction phase, except test substance was applied to a previously non-treated site; Grading of dermal responses occurred 24 and 48 hours post exposure
Challenge outcome:	Grade 0.5 erythema (slight, patchy erythema) was observed in 11 of 20 test animals at 24 hours and 8 of 20 animals at 48 hours. The incidence and severity of these responses were comparable to control group.
Test method:	OECD TG 406
Result:	Alkane 4 was non sensitising to guineapig skin in this non-adjuvant type study.

9.2 Repeated Dose Toxicity – Limit Test (Safepharm Laboratories Limited 1995a)

Species/strain:	Rat/Sprague-Dawley CD
Number/sex of animals:	5/sex/group
Method of administration:	Oral. Test substance administered by gavage as supplied.
Dose/Study duration:	Treatment phase: 0, or 1 000 mg/kg/day for 28 consecutive days. Recovery phase: a treatment free period of 14 days. Recovery groups were separately provided for animals of the control and 1 000 mg/kg/day test groups.
Test method:	OECD TG 407; EC Method B7 – limit test

Clinical observations
There were no deaths or clinical signs of toxicity during the treatment or recovery phase. Food and water consumption and bodyweight gain were unremarkable.

Clinical chemistry/Haematology/Urinalysis
No findings considered related to treatment were observed for clinical chemistry parameters.
A statistically significant increase in group mean neutrophil and eosinophil count was detected for treated females in comparison with controls; individual values were within the normal range of the testing laboratory, with the exception of one female which showed a general increase in leucocyte fractions. This was an isolated finding and not considered exposure related. No differences in haematology parameters of any the male groups were observed.

Organ Weights

A statistically significant reduction in group mean relative liver weights for treated females; all values were within the normal range of the testing laboratory. The reduction was not considered to be of toxicological significance because there were no morphological changes to support an effect in this organ.

Histopathology
No treatment related morphological findings were observed.

Comment
No adverse effects related to treatment at 1 000 mg/kg/day were observed in this 28-day study.

Result
The no observed adverse effect level (NOAEL) determined for this limit study is 1 000 mg/kg/day, the only dose tested.

9.3 Genotoxicity

9.3.1 Bacterial Reverse Mutation Assay (Safepharm Laboratories Limited 1995p)

Strains:	*Salmonella typhimurium*: TA100, TA1535, TA98, TA1537; *Escherichia coli*: WP2uvrA$^-$.
Auxillary 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:	OECD TG 471 – plate incorporation method.
Comment:	No toxicity was observed. Precipitation was noted at and above 1 500 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 and the activity of the S9 fraction was found to be satisfactory.
Result:	Alkane 4 was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberrations in Mammalian Cells (Safepharm Laboratories Limited 1995i)

Cells:	Human peripheral lymphocytes
Auxillary Metabolic activation system:	Liver S9 fraction from rats induced with Aroclor 1254
Dosing schedule:	Each concentration was tested in duplicate, in two independent experiments as follows: Experiment 1: *With and without metabolic activation,* Treatment time = 20 hours; 0, 39, 78.1, 156.25, 312.5, 625, 1 250*, 2 500*, 5 000*μg/mL. Experiment 2: *With and without metabolic activation,* Treatment time = 20 hours 0, 625, 1 250*, 2 500* μg/mL; Treatment time = 44 hours 0, 1 250*, 2 500, 5 000* μg/mL. *cultures selected for metaphase analysis. Appropriate clastogenic control substances were used.
Test method:	OECD TG 473; EC Method B10.
Comment:	Cytotoxicity was not observed at any concentration. The test substance did not cause any significant increases in the incidence of cells with chromosomal aberrations, polyploidy or endoreplication, at the concentrations analysed in the presence or absence of metabolic activation. Positive controls used in the test caused marked increases in the incidence of aberrant cells and the activity of the S9 fraction was found to be satisfactory.
Result:	Alkane 4 was non clastogenic under the conditions of the test.

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Safepharm Laboratories Limited 1995n)

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 or mortality.

Micronuclei score:
1 000 polychromatic erythrocytes (PCE) were counted per slide.
The number of PCE with micronuclei per 1 000 PCE was significantly increased ($p<0.05$) in the 24-hour, high dose group, test group mean 1.2 *vs* vehicle control 0.3. The testing laboratory's historical vehicle control data for the 24-hour kill time is 0.5 to 1.3, sample size not stated.
This increase occurred in the absence of a dose-response relationship and was within the historical control. No significant increases, or dose relationships were observed at any other dose or kill time.
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, 18.8.

Result:
Based on the overall findings Alkane 4 is not considered clastogenic in this *in vivo* mouse micronucleus study, under the conditions of the test.

9.4 Absorption and Metabolism (Illing HPA 2000)

In order to determine the need to undertake toxicological testing on the basis that quantities of Alkane 4 placed on the European Union market would exceed trigger levels for toxicological test requirements at levels 1 and 2, the notifier commissioned an evaluation of the available data on Alkane 4 and closely related substances on the potential gastrointestinal absorption, and metabolism of Alkane 4.

Based on structure activity relationships, the absorption of Alkane 4 is unlikely given the number of carbon atoms present. Analysis suggested no gastrointestinal absorption above C_{30-35}; Alkane 4 is above this range. The predicted partition coefficient (log P_{ow} > 3.87) and very low water solubility also suggest absorption unlikely.

By analogy with long chain branched hydrocarbons, absorbed Alkane 4 would be converted to fatty acids, with subsequent incorporation into endogenous lipid metabolism.

9.5 Overall Assessment of Toxicological Data

The notified chemical, Alkane 4, is of very low acute oral (LD_{50}>5 000 mg/kg) and inhalation (LC_{50} > 5.1 mg/L/4-hours) toxicity, and low acute dermal toxicity (LD_{50}>2 000 mg/kg) in rats. Absorption across the gastrointestinal wall is unlikely given the molecular weight of Alkane 4. Alkane 4 was very slightly irritating to rabbit eye and skin. In both adjuvant and non-adjuvant type skin sensitisation studies Alkane 4 did not cause delayed contact hypersensitivity in guineapigs.

No adverse effects related to treatment were observed in a 4-week repeat oral dose limit study in rats. The NOAEL is 1 000 mg/kg/day, the only dose tested.

Alkane 4 was non mutagenic in a bacterial reverse mutation assay and non clastogenic *in vitro* in a mammalian chromosome aberration study. In an *in vivo* mouse micronucleus study Alkane 4 caused a significant increase in the number of PCE with micronuclei following a 24-hour exposure at 5 000 mg/kg. This increase occurred in the absence of a dose-response relationship and was within the historical control of the testing laboratory. No significant increases, or dose relationships were observed at any other dose or exposure time. Under the conditions of this study Alkane 4 is not considered clastogenic *in vivo*.

Hazard Classification
Under the NOHSC *Approved Criteria for Classifying Hazardous Substances,* (NOHSC 1999) Alkane 4 would not be classified as a hazardous substance.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Tests were performed according to EC and OECD test guidelines (European Commission 1992), (OECD 1995-1996) at Safepharm Laboratories Limited UK. These facilities comply with the OECD principles of GLP and full test reports were submitted. All tests were performed on Alkane 4.

10.1 Summary of Effects on Biotic Systems

Test	*Species*	*Results*
Acute Toxicity	Rainbow trout	LLR_{50} [b] > 1 000 mg/L
Semi-static WAF [a]	(*Oncorhynchus mykiss*)	NOEC ≥ 1 000 mg/L
96 hour		
OECD TG 203		
Acute Immobilisation	Water Flea	ELR_{50} [c] > 1 000 mg/L
Static WAF [a] 48 hour	(*Daphnia magna*)	NOEC ≥ 1 000 mg/L
OECD TG 202		
Growth Inhibition	Algae	E_bLR_{50} [d] > 1 000 mg/L
Static 96 hour	(*Selenastrum capricornutum*)	$E_\mu LR_{50}$ [e] > 1 000 mg/L
OECD TG 201		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%.
e) $E_\mu LR_{50}$: effective loading rate that reduced specific growth rate by 50% (24-48 hours).
f) NOEC - no observable effect concentration.

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

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

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

10.2 Fish Acute Toxicity Test (Safepharm Laboratories Limited 1995g)

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.

10.3 Daphnia Acute Immobilisation Test (Safepharm Laboratories Limited 1995f)

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.

10.4 Algal Growth Inhibition Test (Safepharm Laboratories Limited 1995h)

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 ($P \geq 0.05$) between the control and test groups.

10.5 Conclusion

The ecotoxicity data for Alkane 4 indicate that it is non-toxic to fish, aquatic invertebrates and algae up to the limit of its water solubility. Alkane 4 was also found to be non-inhibitory to sewage sludge micro-organisms (see Environmental Fate).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Alkane 4 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 landfill and sewer/storm water 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 4 sold to the public, and not taking account of oil consumption during use, up to 4 tonnes of Alkane 4 may be improperly disposed of each year. This disposal will be widespread across Australia. The fate of oil 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 1997). Alkane 4 is likely to adsorb strongly to soil. Alkane 4 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 4 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 Alkane 4 expected to adsorb to sediments and slowly degrade.

There should be minimal release of Alkane 4 to the aquatic compartment. Alkane 4 is not toxic to aquatic organisms at the limit of its solubility and should therefore 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 4 is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment and Classification
The notified chemical, Alkane 4, is of very low acute oral and inhalation toxicity, low acute dermal and inhalation toxicity in rats. Alkane 4 was very slightly irritating to rabbit eye and skin. In both adjuvant and non-adjuvant type skin sensitisation studies Alkane 4 did not cause delayed contact hypersensitivity in guineapigs. No adverse effects related to treatment were observed in a 4-week repeat oral dose limit study in rats. The NOAEL is 1 000 mg/kg/day, the only dose tested. Alkane 4 is not considered genotoxic in *in vitro* and *in vivo* test systems.

Under the NOHSC *Approved Criteria for Classifying Hazardous Substances*, Alkane 4 would not be classified as a hazardous substance.

Occupational Health and Safety
Alkane 4 will be imported neat in 200 L drums or in bulk in isotanks. The main application of Alkane 4 is as a base fluid (at least 80%) for automotive lubricants.

Alkane 4 will be blended into lubricants at major lubricant manufacturers across Australia. The technological process for blending of Alkane 4 to produce the finished lubricant is a computer controlled automated enclosed system operating at 60°C. Alkane 4 may cause very slight skin and eye irritation upon initial contact. Skin contact is possible during transfer operations (hose coupling/uncoupling) of Alkane 4 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 the plant operators involved, thus reducing any risk of adverse skin effects. Inhalation exposure is unlikely as the process as described is unlikely to generate aerosols and ventilation systems are in place. 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 4 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 4 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 4. Infrequent dermal exposure (most likely to the hands and forearms), and accidental ocular, oral and inhalation exposure could occur in these individuals. Alkane 4 comprises at least 80% of finished lubricants, but is of very low toxicity and is therefore unlikely to pose a significant hazard to public health. The potential for public exposure to Alkane 4 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 4 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 4 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 4 and the formulations that contain it.

- 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 4 is not determined to be a hazardous substance. The finished lubricant may contain hazardous ingredients making the overall finished lubricant a hazardous substance. 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 Substance* (NOHSC 1994b) must be in operation.

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

Environmental Matters
Spillage of Alkane 4 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 Alkane 4 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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