File No: NA/256

Date: October 1996

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

ALKANE 5

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act* 1989. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 am and 12.00 noon and 2.00 pm and 4.00 pm each week day except on public holidays.

For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9565-9466 **FAX (61) (02) 9565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

ALKANE 5

1. APPLICANT

Chevron Chemical Australia of Level 22 385 Bourke St MELBOURNE VIC 3000 has applied for an assessment certificate and submitted a standard notification package for the importation of the chemical, "Alkane 5", under section 23 of the *Industrial Chemicals (Notification and Assessment) Act* 1989.

2. IDENTITY OF THE CHEMICAL

Other name(s): Polyalphaolefin; Alkane 5

Trade name(s): PAO 6 & 8 cSt (C12 content $\leq$ 10%)

PAO 7 & 9 cSt (C12 content $\leq$ 98%)

Method of detection and determination:

1. Infrared spectroscopy analysis
2. High Performance Liquid Chromatography and Gas Chromatography:
   The homopolymer is trapped on a C_{18} reverse-phase HPLC column before being eluted off with hexane, and then analysed by GC (detection limit of 10 ppb)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: clear colourless liquid

Odour: not provided

Boiling point: 420-650°C

Specific gravity/density: 0.8337 kg/m^3 at 15°C

Vapour pressure: 5.0 x 10^{-2} mm Hg at 25°C (Reid vapour pressure)

Water solubility: < 10 ppb - OECD 105 (run to SOP standards)

Partition co-efficient (n-octanol/water):	log P_{ow} > 8.0 (HPLC)
Hydrolysis as a function of pH:	stable under all conditions
Adsorption/desorption:	the PAO hydrogenated homopolymer probably will not associate with either soil or water; due to its very low water solubility, it will migrate slowly through soil before biodegrading.
Dissociation constant:	will not dissociate
Flash point:	> 180°C
Flammability limits:	will burn in the presence of enough heat and oxygen
Combustion products:	complete combustion products are carbon dioxide and water
Decomposition temperature:	> 300°C
Decomposition products:	incomplete combustion products are carbon dioxide, water, carbon monoxide, olefinic hydrocarbons, and oxygenated hydrocarbon fragments.
Autoignition temperature:	> 200°C
Explosive properties:	not known to be explosive
Reactivity/stability:	will react in the presence of strong oxidising agents. Stable to acid and base.
Particle size distribution:	viscous liquid; will not form particles.

Comments on Physico-Chemical Properties

Water solubility was determined using PAO 4 cSt (trimer fraction of the notified polyalphaolefin in NA/255 with a similar monomer composition) following the method of OECD Guideline 105. As Alkane 5 has a greater molecular weight range than the C10 trimer, it is expected to have a lower solubility (calculating water solubility using a Structural Analysis Relationship according to the method of Irmann (1)).

No test report or method was provided for the determination of the log P_{ow} for Alkane 5. However, a log P_{ow} of > 8 was determined for PAO 4 cSt using reverse phase HPLC (method given in Chromatographia, **27**, 118-122, 1989) by a comparison of polyaromatic hydrocarbon standards run with PAO 4 cSt and measured using UV spectrophotometry. The notifier has used this value as the expected log P_{ow} for Alkane 5. As Alkane 5 is expected to have a lower water solubility and equal solubility in octanol compared with PAO 4 cSt, it is agreed that its log P_{ow} will be greater than 8.

The notifier claims that Alkane 5 will not hydrolyse It is agreed that the chemical contains no functionalities that would be subject to hydrolysis, or dissociate, under the expected environmental conditions of use.

Adsorption/desorption was not determined. The notifier expects that Alkane 5 will not adsorb to soil, nor associate with water, because of its low water solubility. Further, it is expected to migrate slowly through soil before biodegrading. It is agreed that mobility through soil would be slow, but this would be due to its expected strong adsorption to soil because of its high P_{ow}.

4. PURITY OF THE CHEMICAL

Degree of purity: 100%

Toxic or hazardous impurities: none

Non-hazardous impurities (> 1% by weight): none

Additives/Adjuvants: none

5. INDUSTRIAL USE

The primary use for this hydrogenated polyalpha-olefin (PAO) homopolymer is as a base fluid to blend “synthetic” automotive and industrial lubricants. Alkane 5 is produced in the United States and imported into Australia. The estimated import volume which will be imported into Australia is approximately 300 000 kg/year.

6. OCCUPATIONAL EXPOSURE

There is likely exposure of workers involved in the transfer and transportation of the notified chemical, workers who blend the hydrogenated trimer into finished lubricants, and mechanics or technicians who may come into contact with PAO containing lubricants while working on or repairing equipment.

The most likely route of exposure for this trimer is skin and eye contact which would be minimised in manufacturing and transportation workers by engineering controls and protective clothing. However mechanics or technicians repairing equipment wear protective clothing but often may not wear gloves or eye protection.

Alkane 5 will be shipped to Australia in bulk or isotanker and stored in bulk storage tanks. The notified chemical will arrive at a typical Australian customer’s blending plant by rail car or tank truck. Alkane 5 is transferred to a storage tank through a four inch hose. One worker, wearing full protective clothing, gloves, and eye protection, spends 10 minutes fastening the end of the hose to the tank car and a further 10 minutes uncoupling the

hose when the transfer is complete. Procedures exist to ensure that there is no spillage due to loose connections between hose and tank car.

The finished automotive and industrial lubricants are prepared by pumping the notified chemical and the additive package from their storage facilities through computer controlled valves which meter the precise delivery of the components into a blending tank where more additives may be added depending on formulation to be prepared for specific uses. Exposure of workers can occur after blending during sample removal for laboratory analysis. A sample of the product is removed from the blend tank by one or two workers wearing eye protection, coveralls, and gloves to ensure that the specifications of the finished lubricant are met. Workers will be potentially exposed to an 80-100% formulation for 30 minutes, 50 days a year at both the sampling and analysis stage. During the cleaning process of the blending tank and drums, 1 worker may be exposed to an 80-100 % formulation of the notified chemical for 1 hour, 50 days a year. This exposure may be to lube oil used to clean the blending tanks or to the wastewater from the cleaning of the drums. Exposure to the wastewater will be minimal as the treatment process is part of engineering control processes to minimise exposure.

The finished products, or the notified chemical itself, are packaged into 1 L, 40 L, or 200 L drums. Workers will be potentially exposed to the finished lubricant during the packaging of the drums. The level of exposure should be minimal as the drumming facility uses automated weight scales to fill the drums and potential worker exposure occurs as the operator watches from 1-2 metres away to ensure the drum filling mechanism properly enters the drum before the drum is filled. The bungs and labels are applied by the operators. The packaging of 1 L and 4 L jugs is automated and there is minimal worker exposure. There are approximately 20-30 people in Australia who would be involved in the transportation and packaging of products containing the notified chemical.

Mechanics may be exposed to the notified chemical at a concentration of approximately 80% while changing automobile engine oil. Dermal exposure is likely to occur, and accidental eye contact may also occur, particularly while mechanics are working under vehicles. Inhalational exposure is unlikely due to the low vapour pressure of the notified chemical.

7. PUBLIC EXPOSURE

The notified chemical will be used as a base fluid to blend synthetic automotive and industrial lubricants at a level of about 80%.

The automotive and industrial lubricants will be prepared in a blending tank. There will be low potential for public exposure to the notified chemical during blending operations. The blending equipment is cleaned with steam and a typical 5 000 kg blending tank would have about 1 kg of residue which will be sent to a waste water treatment facility. After further separation of the oil from water, less than a gram will be emulsified in the water and released to the municipal sewer.

Industrial use of the lubricants in food packaging and processing equipment may result in contamination of food with the product when incidental contact with food occurs. This

type of equipment would be maintained by skilled workers and contamination should be minimal and infrequent.

The automotive engine oil containing approximately 80% of the notified chemical packaged in 4 or 1 L containers will be available to the general public. Thus, the public can be exposed to the notified chemical by skin contact during oil changes, but the exposure is short and occurs infrequently. Accidental splashing into the eye can also occur. Inhalational exposure will be negligible because of its low vapour pressure. Disposal of the used oil is not expected to result in public exposure if it is disposed of according to government regulations.

When used in automobile engine oil, the notified chemical may be decomposed in the combustion chamber, and the decomposition products may be emitted into the air via the automobile tailpipe. Complete combustion of PAO 2 cSt produces carbon dioxide and water. In the case of incomplete combustion or decomposition, a mixture of carbon dioxide, water, carbon monoxide, olefinic hydrocarbons, and oxygenated hydrocarbon fragments are produced. The notifier claimed that the decomposition products emitted from an automobile will be very limited and not distinguishable from the fuel derived combustion products, which will dominate the hydrocarbon emissions. Therefore, public exposure to the decomposition products from incomplete combustion of the notified chemical in automobile engines is expected to be low.

In the case of accidental spillage during transport, the public may be exposed to the notified chemical. However, the exposure will be minimal if the spills are contained and cleaned up by the recommended practices such as application of absorbent materials and pumping as outlined in the Material Safety Data Sheet (MSDS).

8. ENVIRONMENTAL EXPOSURE

. Release

The formulation of synthetic automotive and industrial lubricants will involve an automated blending process. The notifier estimates that on steam-cleaning of the equipment and drums, about 1 kg from a 5 tonne batch of finished product (0.02%) might be released in the waste water. After oil separation of the waste water, only 5% of the 1 kg of oil (50 g) released is expected to be left emulsified in waste water. The waste water is further treated by pond aeration, in which oil is skimmed from the surface, and sand filtration, leading to a further reduction of greater than 2% (ie < 1 g). The filling of containers is also highly automated and cleaned with lube oil. Any spillage in filling containers will be cleaned up with sawdust or rags.
Oil that can be reclaimed in the above processes will be recycled, while contaminated solids will either be burnt or landfilled. Any used drums will be recycled and steam cleaned for re-use.

. Fate

Some Alkane 5 will be combusted and destroyed in use when used as an automotive or industrial oil, while the majority will share the fate of recycled oil. Also, a minor component will be released to the environment from spills and leaks, but will be widely dispersed and expected to adsorb to soils or sediments adjacent the road or equipment. A small amount may volatilise.

The notifier estimates that about 20% of the expected volume to be used in automotive and industrial oils (ie 20% x 300 tonne = 60 tonne) will be used by home users for "do-it-your-self" purposes. It has been estimated from an ANZEC report (2) on used lubricating oil, that 35% of the oil used for automotive purposes will not be collected and could be disposed of in an inappropriate manner[1]. A worst case scenario would be if all of this uncollected oil was dumped into a sewer in some country centre. This, however, would give a concentration of only about 12 mg/L per day[2]. For a major city, the amount would only be about 115 µg/L per day. However, with its use Australia wide, and with good industrial and public practice, significant aquatic exposure to the polymer is not expected.

· *biodegradation*

Information on biodegradation was provided by the notifier (4). This indicated that PAO 6 and PAO 8, unspecified fractions of Alkane 5, were not readily biodegradable with primary degradation of 47% and 29% achieved, although ultimate degradation of only 41% and 7% after 28 d was achieved. It also indicated that for a range of polyalphaolefins, the extent of degradation of the polyalphaolefins decreased with increasing molecular weight. It would appear that Alkane 5 would generally not be readily biodegradable. Ultimate biodegradability of PAO 6 and PAO 8 ranged from 41 to 7%, and while some mineralisation was therefore shown, it was classed as not ultimately degradable.

· *bioaccumulation*

The bioaccumulation potential of Alkane 5 was not determined. The notifier claims that as its log P_{ow} is greater than 8, it is not likely to bioaccumulate because the material is practically water insoluble. Noting the literature (4), it is agreed that its low water solubility (<< 0.002 mol/m^3) and high log P_{ow} (>> 6), as well as its ready biodegradation, is likely to limit bioaccumulation.

---

1 No figures are available for how much automotive oil was collected for re-use, but an estimate of about 35% of all oil sold is not collected and possibly disposed of in an inappropriate manner. Therefore, this percentage will be specifically applied to automotive oils.

2 Given 35% of oil not collected and assuming only 20% of the imported base fluid is used as an automotive oil for home use, 21 000 kg of the additive would also not be collected (ie. 35% x 20% x 300 000 kg). This would be 58 kg/d (ie. 21 000 kg/365 d). The dilution at a rural town could reasonably be expected to be about 5 ML, while for a major city, say Melbourne, it would be 500 ML. This would give final concentrations of the oil of 12 mg/L per day and 115 µg/L per day, respectively.

9. EVALUATION OF TOXICOLOGICAL DATA

All the acute studies except for the inhalational toxicity study were performed with the notified chemical. The acute inhalational toxicity, repeated dose toxicity and genotoxicity studies were conducted with a closely related compound PAO 2. The toxicity studies on PAO 2 cSt can be used to assess the toxicity of the homopolymer, which has a relatively higher molecular weight.

9.1 Acute Toxicity

Acute studies on PAO 8 cSt were provided in a conference report. GLP status and quality assurance were not stated.

Table 1 Summary of the acute toxicity of Alkane 5 (PAO 8 cSt)

Test	Species	Outcome	Reference
Oral toxicity	rat	LD_{50} > 5 mL/kg (4 168 mg/kg)	(5,6)
Dermal toxicity	rabbit	LD_{50} > 2 000 mg/kg	(5,7)
Inhalational toxicity*	rat	LC_{50} = 1 170 mg/m^3	(5,8,9)
Skin Irritation	rabbit	non-irritant	(5,10)
Eye irritation	rabbit	mild irritant	(5,12)
Skin sensitisation	guinea pig	non-irritant	(5)

* Study performed with a closely related compound PAO 2 cSt with a lower molecular weight than the homopolymer.

9.1.1 Oral Toxicity (5,6)

Fasted Sprague Dawley (SD) rats (5/sex) were administered 5 mL/kg of undiluted PAO 8 cSt by single oral gavage and observed for 14 days. No deaths occurred. Ruffled fur and diarrhoea were observed during the first 24 hours after dosing, but all the animals appeared normal by day 2. Necropsy examination revealed 3 cases of moderate hydrometra and 3 cases of lungs with small scattered clear, firm raised areas. It was not known if these lesions were treatment-related. The oral LD_{50} of PAO 8 cSt was > 5 mL/kg (4 168 mg/kg).

In another study (6), 10 fasted SD rats (5/sex) were administered 5 000 mg/kg Alkane 5 by a single oral gavage and observed for 14 days. There were no deaths or signs of systemic toxicity. Necropsy findings were normal. The acute oral LD_{50} was greater than 5 000 mg/kg.

9.1.2 Dermal Toxicity (5,7)

One group of young adult albino NZW rabbits (4/sex) were dermally treated with 2 000 mg/kg of PAO 8 cSt under gauze patch on intact skin for 24 hours, and a second group was similarly treated on abraded skin. The observation period was 14 days. No deaths or signs of systemic toxicity were observed. Skin irritation including slight erythema and oedema at the treatment site was observed during the first 4 days of the observation period. The dermal LD_{50} of PAO 8 cSt in rabbits was > 2 000 mg/kg.

In another study (7), 10 fasted SD rats (5/sex) were dermally treated with 2 000 mg/kg Alkane 5 on the intact skin under semi-occlusive dressing for 24 hours and observed for 14 days. There were no deaths or signs of systemic toxicity. Necropsy findings were normal. The acute dermal LD_{50} was greater than 2 000 mg/kg.

9.1.3 Inhalation Toxicity (5,8,9)

An inhalation study on the notified chemical was not conducted, but studies on a closely related compound, PAO 2 cSt, was provided.

In one study (5,8) 5 groups of Charles River CD albino rats (5/sex/group) were exposed to an aerosol of SF-0203-41 (PAO 2 cSt) at 770, 940, 1 100, 1 400 or 5 100 mg/m^3 for 4 hours. The average aerosol particle size was 2.9 ± 2.07 mm. A control group was similarly exposed to air only. The animals were observed for 14 days after exposure.

Clinical signs observed during and after exposure included dyspnoea and nasal discharge. Deaths occurred within the first 2 days after exposure in all female groups and the male groups exposed to 1 100 mg/m^3 or more of test substance. The high dose groups gained less body weight during the first week after exposure, but the body weight gain was normal in the second week post-exposure. Macroscopic changes were observed in the animals that died during the study and included red nasal discharge and congested lungs.

Microscopic examination was not conducted in the rats exposed to 770 - 1 400 mg/m^3. In the 5 100 mg/m^3 group, pulmonary congestion was observed in all the animals. Mural protein casts were observed in the terminal and respiratory bronchioles. The control animals were normal. The LC_{50} for the combined sexes was 1170 mg/m^3.

In the second inhalation study (9), a group of 10 CD rats (5/sex) were exposed to an aerosol of PAO 2 cSt at 5 170 mg/m^3 (maximum practical concentration) for 1 hour. A control group (5/sex) was similarly exposed to room air only. The animals were observed for 14 days after exposure.

The average aerosol particle size was 1.9 mm with a standard deviation of 1.8. Only one treated female survived during the study and other treated animals died or were sacrificed on days 1 - 3 after exposure. Clinical signs of toxicity included reduced activity, partly closed eyes, hunched back, lateral prostration, increased respiratory rate, laboured and irregular breathing, and muzzle and abdominal staining. The surviving female was clinically normal by day 9. No clinical signs were observed in the controls.

Gross pathological examination revealed an increased incidence of fluid in the trachea, uncollapsed lungs and discolouration of the lungs in the animals that died during the study and increased lung and trachea weights in the surviving female. Microscopical examination showed acute pneumonia and/or haemorrhage in the lungs, and slight focal or multifocal degeneration and/or necrosis of the epithelium of the nasal septum in the treated animals. The surviving female had mild interstitial pneumonia of a chronic nature and slight focal hyperplasia of the respiratory epithelium. Myocardial degeneration and/or fibrosis were also observed in this animal and was considered possibly related to the treatment.

9.1.4 Skin Irritation (5,10)

Six young adult NZW rabbits (3/sex) were dermally treated with 0.5 mL of PAO 8 cSt on intact skin on the left side and abraded skin on the right side and covered with a gauze patch for 24 hours. At the end of the exposure, any residual test material was gently wiped from the skin. The skin was examined immediately after patch removal and at 72 hours after application.

The primary dermal irritation index was 0.1 at 24 hours and 0 at 72 hours using the method of Draize (11). The test substance was not a skin irritant in rabbits.

In another study (10), 6 NZW rabbits were dermally treated with 0.5 mL of Alkane 5 onto the intact skin under a 2.5 x 2.5 cm cotton gauze patch for 4 hours. The skin was examined at 30 min, 24, 48 and 72 hours after patch removal and scored according to the Draize method. No erythema or oedema was observed and the primary irritation index was 0. Alkane 5 was not a skin irritant in rabbits.

9.1.5 Eye Irritation (5,12)

Nine young adult NZW rabbits were treated with 0.1 mL of PAO 8 cSt by instillation into the conjunctival sac of the right eye. The eyes of 3 rabbits were washed with water for one minute after 20-30 seconds exposure. The eyes were examined at 24, 48, 72 and 96 hours and at 7 days after treatment and scored according to the Draize method (13). The primary eye irritation score was 1.3 at 24 hours after instillation in both washed and unwashed eyes. No irritation was observed by 48 hours after treatment. PAO 8 cSt was considered a mild eye irritant in rabbits.

In another study (12), 9 NZW rabbits received 0.1 mL of Alkane 5 into the conjunctival sac of the right eye and 3 of them were washed with water at 30 sec after treatment. The eyes were examined at 1, 24, 48 and 72 hours after instillation. Conjunctival redness was observed in one animal at 1 hour after treatment and disappeared by 24 hours. No ocular effects were seen in other rabbits. Alkane 5 was not an eye irritant in rabbits.

The notified chemical is not considered an eye irritant in rabbits based on the most recent study which was completed in March 1995 and was in compliance with the OECD guideline (1987).

9.1.6 Skin Sensitisation (13)

The skin sensitisation potential of PAO 8 cSt was studied in guinea pigs using a modified Buehler test.

A group of 10 male albino Hartley guinea pigs were induced with 0.5 mL of the test material every other day (3 times/week) for 3 weeks. The sites were examined at 24 and 48 hours after each application. The challenge dose (0.5 mL) was applied 2 weeks after the last induction dose. The reaction was examined at 24 and 48 hours after challenge. A positive control group (10 animals) was similarly treated with 2,4-dinitro-1-chlorobenzene diluted in distilled water.

Eight test animals had slight erythema and 2 had slight oedema during the induction phase. None of the test animals responded to the challenge dose. The positive control showed that the animals can be sensitised by a known skin sensitiser. PAO 8 cSt was not a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (14)

Repeated dose study on the notified chemical was not conducted, but a study on a closely related compound, PAO 2 cSt was provided.

Young adult SD rats (6/sex/group) were orally administered Oronite XS 101 (PAO 2 cSt) at 0, 200, 500 or 1 000 mg/kg/day for 29 days by gavage. Two additional groups were similarly dosed with 0 and 1 000 mg/kg/day, respectively, and recovered for two weeks after cessation of administration before being sacrificed.

No deaths or treatment-related clinical signs were observed in the control and test animals. There were no changes in body weight gain, feed consumption, haematology or clinical chemistry. Organ weights were not affected by treatment. No treatment-related macroscopic or microscopic changes were detected. The test compound was of low toxicity in rats by repeated dosing for up to 29 days.

9.3 Genotoxicity

Genotoxicity studies on the notified chemical were not conducted, but studies on a closely related compound, PAO 2 cSt , were provided.

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays (14)

Salmonella typhimurium TA 98, TA 1537, TA 100 and TA 1535 and *Escherichia coli* WP2 uvrA were cultured with 0.1 - 10 mg/plate of Oronite XS 101 (PAO 2 cSt) with and without metabolic activation using rat liver S9. At the highest concentration, the test material was suspended in the vehicle (acetone), but at all lower concentrations, the test material appeared to be miscible with the solvent. All dose levels were plated in triplicate. Solvent and positive controls were run concurrently. In the positive controls, 2-aminoanthrocene was used in the presence of S9 in all the strains. In the absence of S9, 2-nitrofluorene was used in strain T98, sodium azide in strains TA 100 and TA 1535, and ICR-191 in strains TA 1537 and WP2 uvrA.

No reproducible increases in mutant frequency were observed in the treated groups. The positive controls produced marked increases in mutant frequency in all the test strains. The test concentrations were not cytotoxic to any strain. Under the condition of the assay, PAO 2 cSt was not mutagenic in the *Salmonella typhimurium* and *Escherichia coli* reverse mutation assays.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (15)

Young adult Swiss albino mice (18-21/sex/group) were intraperitoneally administered 1 250, 2 500 or 5 000 mg/kg (the highest practical dose) of Oronite XS 101 (PAO 2 cSt), suspended in peanut oil. A vehicle control group (18/sex) received 4 000 mg/kg of peanut oil only, and a positive control group (5/sex) was treated with 0.25 mg/kg of triethylenemelamine. Bone marrow was collected from 10 animals (5/sex) from each treatment and vehicle control group at approximately 24, 48 and 72 hours after administration. Positive controls were sampled at 24 hours. Two bone marrow smears were made from each animal and 1 000 polychromatic erythrocytes were scored for micronuclei.

No clinical signs of toxicity were observed during the study. Cytotoxicity was detected in males in the positive control and at the 1 250 mg/kg dose level sampled at 24 hours and in females at the 2 500 and 5 000 mg/kg dose levels sampled at 48 hours. No significant increase in the number of micronucleated polychromatic erythrocytes was observed in the treated animals. The positive control induced micronuclei as expected. PAO 2 cSt did not cause chromosomal damage in bone marrow cells of the mouse *in vivo*.

9.4 Overall Assessment of Toxicological Data

All the acute studies except for the inhalational toxicity study were performed with the notified chemical. The acute inhalational toxicity, repeated dose toxicity and genotoxicity studies were conducted with a closely related compound PAO 2 cSt . The toxicity studies on PAO 2 cSt can be used to assess the toxicity of the homopolymer, which has a relatively higher molecular weight.

Based on the studies submitted, the notified chemical was of low acute oral toxicity in rats and low dermal toxicity in rabbits. It was not a skin irritant in rabbits or a skin sensitiser in guinea pigs but was a mild eye irritant in rabbits. Toxicity by inhalation is unlikely due to the higher viscosity of the notified chemical (7-9 cSt at 100°C) compared to the dimer (2 cSt at 100°C), the risk of aerosols being generated being negligible. The data does demonstrate however the potential for significant injury resulting from any inhalation into the respiratory tract. Based on the study on PAO 2 cSt, it is expected that repeated administration of up to 1 000 mg/kg/day for 29 days would not produce any observed adverse effects in rats. It is not expected to cause reverse mutation in bacteria or cause chromosomal damage in mouse bone marrow cells.

On the basis of the toxicity data provided, the notified chemical is not classed as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (16).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Table 2. Ecotoxicity test results for Oronite XS 101

11. Design element	Species	Test	Result
Rainbow Trout (*Oncorhynchus mykiss*)	96 hour acute	LC_{50} > 1 000 mg/L[a]	
Water Flea (*Daphnia magna*)	48 hour acute	EC_{50} = 230 mg/L[a]	
Algae (*Selenastrum capricornutum*)	72 hour	For growth stimulation (0-72 hour): EC_{50} > 1 000 mg/L[a]	

a. Result based on nominal concentrations, although test was conducted with the water soluble fraction.

Ecotoxicity studies were conducted using Oronite XS 101 (a C10 polyalphaolefin dimer with a similar monomer composition as Alkane 5) according to US EPA or OECD guidelines (Table 2). The test concentrations are nominal concentrations only, with the water soluble fraction used. Oronite XS101 was added directly to the test water to give the correct concentration if all would dissolve. The solution/ emulsion was then stirred for 20 hours, and allowed to settle for 4 hours. The required test solution was then siphoned off into test vessels, avoiding any surface film. The degree to which PAO 2 cSt did not dissolve was not recorded, although all test solutions remained clear for the duration of the test.

The results indicate that the polyolefin is practically non toxic, with the lowest EC_{50} of 230 mg/L for water flea. In fact, mortality seemed to be associated with the presence of an oily film, presumably from partitioning of the polyolefin out of solution at higher concentrations (loadings).

The notifier gave a NOEL of 19 mg/L, although the sublethal and lethal effects observed did not appear to follow a dose-response and were of a low level (mortality $\leq$ 10% at LOEL and higher concentrations). Algae toxicity was associated with all nominal concentrations, but stimulated growth and with the EC_{50} remaining above 1 000 mg/L.

Although there is some uncertainty with actual concentrations used in the tests, the EPA expects that Oronite XS 101 would be practically non-toxic up to the limit of its solubility. Since the solubility of Alkane 5 is likely to be less than Oronite XS 101 because of its greater molecular weight and size its toxicity may be higher (17). However, determining whether it is more toxic is problematic (17). Thus, the toxicity will be affected by the solubility and the log P_{ow} of each component, the degree of branching (branched alkanes less toxic than straight alkanes) and the degree of volatilisation of that component, and interactions between components.

12. ASSESSMENT OF ENVIRONMENTAL HAZARD

Alkane 5 will be used as a base for automotive and industrial oil blends. The main exposure will be from inappropriate disposal of oil. Calculations show an extremely high dilution for the polymer is still expected even if all of the 35% of oil not collected in Australia from home users was disposed of to a country sewer. Together with its

expected distribution through retail centres across Australia (ie not concentrated in one town or city), and with good industrial and public practice, significant aquatic exposure to the polymer is not expected.

Ecotoxicity tests showed that for a low molecular polyalphaolefin with a similar monomer composition as Alkane 5 (Oronite XS 101), the chemical is expected to be practically non-toxic to aquatic organisms up to the limit of its solubility.

Also, the concentration of Alkane 5 in the soil or water compartment will be further reduced as it was shown to be readily biodegradable.

13. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the data given for Alkane 5, there is low potential acute oral and dermal toxicity while there is a potential slight skin irritation and moderate eye irritation. It may cause moderate acute inhalational toxicity however there is little potential for sensitisation, repeat dose toxicity, mutation or chromosomal damage.

There exist potentially significant health risks from inhalation and eye exposure. The transfer of Alkane 5 from bulk storage to steel drums, transfer to blending tanks, sampling and analysis of Alkane 5, cleaning and packaging allows the potential for occupational exposure by splashing or spillage to an 80-100% formulation for at least 30 minutes, 50 days a year. The packaging of the finished blended lubricant is performed by automated machinery and supervised from two metres away, thereby reducing the risk of exposure. Some low exposure to residual Alkane 5 may occur during the application of labels and bungs to the drums. The cleaning of blending vessels and equipment with lube oil and the sampling and analysis of the blended lubricants has also the potential for occupational exposure from splashing or spillage. Adequate personal protection such as gloves, shoes, eye protection, protective clothing and respiratory protective devices are required at this stage to reduce the risk of inhalation or eye contact.

When lubricants containing the notified chemical are used in food packaging and processing equipment, incidental contact with food can occur, but contamination of food with the lubricants is minimal. Animal studies on a closely related compound showed that the notified chemical is expected to be of low toxicity by repeated oral administration and is not genotoxic. Infrequent and slight contamination of food with the notified chemical is not considered a significant hazard to public health.

When used in automotive engine oil which is available to the public through retailers, public exposure can occur. During oil changes, the user may be dermally exposed to the notified chemical, but the contact would be short and infrequent. Animal studies showed that the notified chemical is of low dermal toxicity and not a skin irritant in rabbits. Thus, short dermal exposure to the notified chemical should not have significant health effects. Any accidental splashing into the eye is not expected to result in serious damage to the eyes. In animal studies, the notified chemical was a mild irritant in rabbits and the effects disappeared within 48 hours after treatment. Therefore, public use of the engine oil

containing approximately 80% of the notified chemical is not expected to result in significant adverse health effects provided contact with eyes can be avoided.

The main occupational health risk posed to automobile mechanics is skin irritation, following repeated exposure to the notified chemical in engine oil. As previously discussed, accidental eye contact is likely to cause discomfort, but no serious damage to eyes.

The incomplete combustion products emitted from automobiles are similar to those from the combustion of gasoline, but the levels are very low and not distinguishable from the fuel derived combustion products, which will dominate the hydrocarbon emissions. Such use of the notified chemical is not expected to pose a health hazard to the public.

Alkane 5 will not pose a significant hazard to public health when used in the proposed manner.

14. RECOMMENDATIONS

To minimise occupational exposure to Alkane 5 the following guidelines and precautions should be observed:

- The appropriate respiratory device should be selected and used in accordance with Australian/New Zealand Standard (AS/NZS) 1715 (18) and should comply to AS/NZS 1716 (19) if ventilation is inadequate;
- Eye protection should be selected and fitted in accordance with Australian Standard (AS) 1336 (20) and used in accordance with AS/NZS 1337 (21);
- Industrial clothing must conform to the specifications detailed in AS 2919 (22) and AS 3765.1 (23);
- Industrial gloves should conform to the standards detailed in AS 2161 (24) and AS 3765.1 (23);
- All occupational footwear should conform to the standards detailed in AS/NZS 2210 (25);
- Particular care should be taken to avoid spillage or splashing of the notified chemical;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees;
- Automobile engine oil containing decene/dodecene hydrogenated trimer should carry the following warning statements:

  Avoid contact with eyes
  Wash hands after use.

15. MATERIAL SAFETY DATA SHEET

The MSDS for Alkane 5 was provided in an acceptable format (26).

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act* 1989, secondary notification of Alkane 5 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. If conditions of use are varied, greater exposure of the public to the product may occur. In such circumstances further information may be required to assess the hazards to public health.

17. REFERENCES

1. Lyman, WJ, Reehl, WF & Rosenblatt, DH, 1982, Handbook of Chemical Property Estimation Methods. McGraw-Hill Book Company, New York. p 2- 39.

2. Australian and New Zealand Environment Council, 1991, Used lubricating oil: Generation, recovery and reuse in Australia. Prepared by Technisearch Ltd for the Waste and Resources Committee (WRAC).

3. Cisson, CM, Rausina, GA & Stonebraker, PM, (submitted to Lubrication Science). Human health and environmental hazard characterisation of lubricating oil additives.

4. Connel, DW, 1989, General Characteristics of organic compounds which exhibit bioaccumulation, Chapter 3, in Connel DW (ed) "Bioaccumulation of xenobiotic compounds". CRC Press, Boca Raton, USA. p 56.

5. Guiney, PD, 1982*, Acute toxicity assessment of polyalphaolefin (PAO) synthetic fluids*. Symposium On Synthetic And Petroleum Based Lubricants, American Chemical Society, Las Vegas, , p 381-391.

6. Driscoll, R, 1995, *Alkane 5 (C1527-04-5): acute oral toxicity in the rat.* Safepharm Laboratories Ltd (Derby, UK), Project No: 703/14.

7. Driscoll, R, 1995, *Alkane 5 (C1527-04-5): acute dermal toxicity in the rat.* Safepharm Laboratories Ltd (Derby, UK), Project No: 703/15.

8. Ulrich, CE, 1982, *SF-0203-41: Acute inhalation toxicity (LC_{50}) study in rats*. International Research and Development Corporation, Study No. 107-006.

9. Salame, R, 1994, : *An evaluation of the acute toxicity of an inhaled nebulised aerosol formulation of Oronite Synfluid PAO 2 cSt (C1234-01-1) in the albino rat (safety test).* Bio-Research Laboratories Ltd, Project No: 90907.

10 Driscoll, R, 1995, *Alkane 5 (C1527-04-5): primary skin irritation test in the rabbit*. Safepharm Laboratories Ltd (Derby, UK), Project No: 703/16.

11. Draize, JH, 1959, Paper, Assoc. Food Drug Officials, US, Topeka, Kansas, p 49.

12. Driscoll R, 1995*, Alkane 5 (C1527-04-5): primary eye irritation test in the rabbit.* Safepharm Laboratories Ltd (Derby, UK), Project No: 703/17.

13. Cooper, PN, Rogers, BC. and Wong, ZA, 1989, *Four-week repeated-dose toxicity study in rats with Oronite XS 101 (KWA 88-01217).* Chevron Environmental Health and Toxicology, Report No: CEHC 3050.

14. Myers, M, Machado, ML and Wong, ZA, 1989*, Microbial/microsome reverse mutation plate incorporation assay with Oronite XS 101 (KWA 88-01217).* Chevron Environmental Health and Toxicology, Report No: CEHC 3048.

15. Wing, CD, Machado, ML and Wong, ZA, 1989, *Micronucleus assay in mouse bone marrow erythrocytes with Oronite XS 101 (KWA 88-01217).* Chevron Environmental Health and Toxicology, Report No: CEHC 3049.

16. Worksafe Australia, 1994, *Approved Criteria For Classifying Hazardous Substances [NOHSC:1008(1994)],* AGPS, Canberra.

17. Peterson, DR 1994. Calculating the aquatic toxicity of hydrocarbon mixtures. Chemosphere **29**, 2493-2506.

18. Standards Australia, Standards New Zealand, 1994, *Australian/New Zealand Standard 1715-1994 Selection, Use and Maintenance of Respiratory Protective Devices.* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

19. Standards Australia, 1991, *Australian Standard 1716-1991 Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Australia.

20. Standards Australia , 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment.*, Standards Association of Australia Publ. Sydney, Australia.

21. Standards Australia, Standards New Zealand 1992, *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

22. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.

23. Standards Australia, 1990, *Australian Standard 3765-1990 Clothing for Protection Against Chemical Hazards, Part 1 Protection Against General or Specific Chemicals, Part 2 Limited Protection Against Specific Chemicals,* Standards Association of Australia Publ., Sydney, Australia.

24. Standards Australia, 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney, Australia.

25. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

26. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.