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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

GTL Base Oil

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Sasol Chevron Consulting Limited (ABN 46 096 439 404)
Level 15, QV1 Building
250 Georges Terrace
Perth WA 6000

The Shell Company of Australia Limited (ABN 46 004 610 459)
8 Redfern Road
East Hawthorn VIC 3123

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name, other names, CAS number, molecular formula, structural formula, molecular weight, spectral data, manufacture/import volume, identity of sites, identity of analogues.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Acute dermal toxicity, acute inhalation toxicity, repeat dose toxicity, genotoxicity, biodegradability, acute fish toxicity, acute *Daphnia* toxicity, and acute algal toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US, Canada, Korea, European Union

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
GTL Base Oil
FTBO Distillates
F-T Base Oil

MOLECULAR WEIGHT
MW < 1000 Da, with the majority < 500 Da

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

The notified chemical is a complex mix of hydrocarbons. The level of aromatic hydrocarbons is very low (< 1%) and benzene is essentially absent (< 0.1%).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear, colourless, slightly viscous liquid with petroleum odour.

Property	Value	Data Source/Justification
Pour point	< -20°C	Measured
Boiling Point	314-379°C at 100.6 to 101.2 kPa	Measured
Density	809 kg/m^3 at 20°C	Measured
Vapour Pressure	2.8 x 10^{-6} kPa at 25°C	Measured
Viscosity	2-7 x 10^{-6} m^2/s (2-7 cSt) at 100°C ≥ 4 x 10^{-6} m^2/s (≥ 4 cSt) at 40°C	MSDS Value given in CAS definition
Water Solubility	< 1 mg/L at 20°C	Measured. The notified chemical is a mixture of hydrocarbons. Individual components have solubilities below 0.01 mg/L.
Hydrolysis as a Function of pH	Not determined	The hydrocarbon components in the notified chemical have no hydrolysable functionality.
Partition Coefficient (n-octanol/water)	log Pow > 6.5 at 20°C	Measured (HPLC)
Adsorption/Desorption	log K_{oc} > 5.6	Measured (HPLC screening method)
Dissociation Constant	Not determined	No dissociable functionality
Particle Size	Not determined	Notified chemical is a liquid
Flash Point	187°C at 101.3 kPa	Measured
Flammability in air	Not determined	Based on the flash point the notified chemical is not expected to form a flammable vapour/air mixture
Autoignition Temperature	348°C	Measured
Explosive Properties	Not expected to be explosive	Estimated based on chemical structure

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

The viscosity data provided in the MSDS only indicates the viscosity values at 100°C. According to the Approved Criteria (NOHSC, 2004) substances with < 7 × 10^{-6} m^2/s (7 cSt) at 40°C viscosity should be classified for aspiration hazard (R65 – Harmful: May cause lung damage if swallowed). The notified chemical will be imported into Australia in 4 different grades based on viscosity. Therefore, depending on the viscosity of the notified chemical (i.e. where the viscosity is < 7 × 10^{-6} m^2/s (7 cSt) at 40°C), it should be classified as hazardous with the risk phrase, 'Harmful: May cause lung damage if swallowed (R65)'.

Based on the measured flash point the notified chemical is not classified as flammable, but would be considered to be a C2 combustible liquid [NOHSC:1015(2001)].

Reactivity
The notified chemical is not expected to react with water or air, and is considered to be stable under normal use conditions.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be manufactured overseas from natural gas using the Fischer-Tropsch process. The notified chemical (100%) will be imported into Australia as four different grades, based on viscosity (extra extra light-"XXL"- 2cSt; extra light- "XL"- 2.9cSt; light-"L"- 4.5cSt and medium-"M"- 7cSt).

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	500-1,000	500-1,000	500-1,000	500-1,000	500-1,000

PORT OF ENTRY

The port of entry is likely to be any major Australian port where a petroleum refinery or a major lube blending facility is located, eg Adelaide, Perth, Sydney, etc.

IDENTITY OF RECIPIENTS
Lubricant manufacturers around Australia.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as bulk oil and transported by tank truck to formulation sites. The blended lubricant products containing the notified chemical will be packaged in 200 L drums, 20 L pails, 4 L jugs or 1 L cans, and will be transported by truck.

USE
The notified chemical will be used as a base stock for lubricants used in passenger car engines and automatic transmission fluids (ATF).

OPERATION DESCRIPTION
The notified chemical is not manufactured in Australia. It is imported as the bulk oil and transported to customer sites where it is formulated into automatic transmission fluids (ATF) for passenger cars or low viscosity multigrade passenger car engine oils.

ATF and Lubricant reformulation
At the reformulation sites 10 cm hoses are connected to the tank truck and storage vessels and the notified chemical is transferred via a pumping system. An air back flush system is used to prevent spillage. The notified chemical is then transferred (usually via hard piping) to the blending vessel as required. The blending process is largely enclosed, except for sampling for quality control purposes. After blending the finished product (containing > 80% notified chemical) is transferred (usually via hard piping) to a storage tank for subsequent packaging into drums or small containers (1 and 4 L). The drumming facility uses automated weight scales to fill the drums. The operator watches (from about 3-6 feet away) to ensure the drum filling mechanism properly enters the drum before the drum is filled, and then attaches the bungs and labels. The small container packaging is a fully automated process. The operator watches (from about 3-6 feet away) to ensure the filling mechanism properly enters the container before it is filled.

End use- ATF
The small containers of ATF containing > 80% notified chemical will be sold to the public who will use it to top off the ATF reservoir in the engine compartment of their cars. The 200 L drums will be sold to workplaces such as automotive repair shops, automobile dealer service centres, service stations, and quick lubes. In these workplaces transmissions are dismantled and rebuilt and the finished ATF product is added to transmissions using pneumatic delivery equipment. The bulk finished ATF is transported in tank trucks to large taxi, courier, delivery and other automotive fleet operations. The bulk ATF unloading at these sites involves the connection of a 4-inch line to the truck and removal of the line after completion of the transfer. A vacuum back flush removes the lubricant from the unloading hoses, which are then capped to prevent spillage. The ATF product is transferred from the on-site storage tank to the transmission reservoir using pneumatic delivery equipment.

End use- Lubricants
The small containers of lubricant > 80% notified chemical will be sold to the public who will use it to top off the engine oil sump in the engine compartment of their cars. The 200 L drums will be sold to workplaces such as automotive repair shops, automobile dealer service centres, service stations, and quick lubes. In these workplaces the finished lubricant product is added to engines using pneumatic delivery equipment. The bulk finished lubricants are transported in tank trucks to large taxi, courier, delivery and other automotive fleet operations. The bulk lubricant unloading at these sites involves the connection of a 4-inch line to the truck and removal of the line after completion of the transfer. A vacuum back flush removes the lubricant from the unloading hoses, which are then capped to prevent spillage. The lubricant product is transferred from the on-site storage tank to the engines using pneumatic delivery equipment.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Lubricant/ATF reformulation	15	10 hours/day	240 days/year
Transport	50-100	1 hour/shipment	240 days/year
Repair Shop mechanics	5000	8 hours/day	240 days/year
Engine mechanics	2000	8 hours/day	240 days/year
Drum Cleaning	20	8 hours/day	240 days/year

EXPOSURE DETAILS

Transport

Dermal and accidental ocular exposure may occur due to drips, spills and splashes during the connection and disconnection of transfer hoses. This exposure is likely to be minimised by the engineering controls (vacuum back flush and hose caps) and the use of personal protective equipment (coveralls, gloves and safety glasses).

ATF/Lubricant Reformulation

While the blending of ATF and lubricants is a highly automated and enclosed process, there is some potential for exposure of workers involved in blending operations using the notified chemical. Dermal and accidental ocular exposure to the notified chemical (neat or >80% concentration) may occur due to drips, spills and splashes during quality control sampling and analysis, as well as during drum filling if worker intervention is required. This exposure is likely to be minimised by the use of personal protective equipment, including protective clothing, gloves and safety glasses. Inhalation of the notified chemical vapour is unlikely given its low volatility. Although oil mists of the notified chemical may be generated, exposure is expected to be limited due to the enclosed nature of the blending operation.

Use

Dermal exposure to the finished products (>80% notified chemical) may occur during commercial and industrial applications, although this will be minimised by the pneumatic delivery system and the expected use of personal protective equipment (coveralls, gloves). However, personal protective equipment may not be used in all workplaces, particularly the smaller repair shops. Inhalation exposure is expected to be limited under normal operating conditions.

6.1.2. Public exposure

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

Both finished ATF and finished lubricants (containing >80% of the notified chemical) will reach the public retail market, where they will be used to replace or top-up automotive ATF/lubricants. Consequently, there is likely to be intermittent dermal exposure, with the potential for accidental eye, oral and inhalation exposure.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical and analogue chemicals are summarised in the tables below. Analogue data is listed only for endpoints for which there were no data on the notified chemical. The analogue chemicals are petroleum-derived base oils, as well as petroleum-derived fractions in which the alkanes are within the defined carbon range of the notified chemical. Details of these studies can be found in Appendix B.

Notified chemical

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 > 5000 mg/kg bw low toxicity

Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Guinea pig, skin photosensitisation – adjuvant test.	no evidence of photosensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro micronucleus	non genotoxic

Analogue chemicals

Endpoint	*Result and Assessment Conclusion*
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity (Analogues 1-4)
Rat, acute inhalation toxicity	LC50 = 1.71 to > 5.5 mg/L/4 hour for analogues with varying viscosities
Rat, repeat dose oral toxicity – 28 days	NOEL = 1000 mg/kg bw/day (Analogues 2 and 3)
Genotoxicity – in vivo mouse micronucleus	non genotoxic (Analogues 2-4)

Toxicokinetics, metabolism and distribution

The toxicokinetics of the notified chemical is likely to be very similar to the toxicokinetics of analogous petroleum derived hydrocarbons. These hydrocarbons have been shown to absorb to a limited extent through the intestinal tract, mainly through the small intestine. The level of absorption depends on the molecular weight, with hydrocarbons at the higher end of the range present in the notified chemical not being absorbed to any significant extent. Once absorbed these hydrocarbons have been shown to distribute to the lymph nodes, liver, spleen and adipose tissue of the rat. Metabolism of the absorbed hydrocarbons involves oxidation to the alcohol, and then to the fatty acid. Unabsorbed hydrocarbons are excreted in the faeces.

Acute toxicity

The notified chemical was found to be of low toxicity via the oral route, based on a study conducted in rats. As discussed in Section 4, the notified chemical may present an aspiration hazard if swallowed, dependent on the viscosities of the different grades at 40°C. The CONCAWE product dossier (1997) for lubricating oil base stocks (petroleum derived analogues) states that aspiration of low viscosity base oils (i.e. below about 7 cSt at 40°C), either directly or as a result of vomiting following ingestion, could give rise to rapidly developing and potentially fatal chemical pneumonitis.

Based on studies conducted on analogue chemicals the notified chemical is expected to be of low toxicity via the dermal route.

Acute inhalation studies on aerosols of the analogue chemicals gave differing results, with the differences appearing to be dependent on the viscosities of the test substances.

Analogue	*LC50 (mg/L)*	*Viscosity (cSt) at 100°C*
2	1.71 (females), > 5.06 (males)	2.4
3	> 5	~ 5.0
4	> 5	5.7
5	< 5	1.7
6	> 4	> 5 (estimated)
7	> 5.5	> 5 (estimated)
8	> 5.4	2.4
9	2.18	2.2

The higher viscosity (≥ 5 cSt at 100°C) analogues (Analogues 3, 4, 6 and 7) were found to be of low toxicity via the inhalation route whereas 3 out of 4 of the lower viscosity (~2 cSt at 100°C) analogues (Analogues 2 , 5 and 9) were found to be harmful by inhalation (LC50 < 5 mg/L/4 hour). Analogue 8 being the exception in the latter. It should be noted that Analogue 9 is a naphthenic distillate that contains a relatively high proportion of aromatic content as compared to the notified chemical that is a paraffinic distillate, so the acute inhalation toxicity observed in this case may be a result of the aromatic content or the low viscosity, or a combination of the both, hence the result on this analogue may not be a good indicator of the toxicity of the notified chemical. As noted previously, it is known that there is a correlation with viscosity of base oils with toxicity with low viscosity base oils (i.e. below about 7 cSt at 40°C) possibly presenting an aspiration hazard that could potentially lead to death. Given this it may be surmised that the acute inhalation toxicity observed with Analogues 2 and 5 (8.3 and 5.1 cSt at 40°C, respectively) may in part be a result of the aspiration effect as observed with low viscosity base oils. It has been reported that inhalation of mineral oils cause reactions largely limited to the lung, which appear to be

primarily non-specific responses to the aerosol, rather than systemic toxicity (Dalbey and Biles, 2003). Nevertheless, the mortalities observed in the acute inhalation studies with the low viscosity Analogues 2 and 5 indicate a potential for harm following aerosol inhalation.

The notified chemical will be introduced in four different grades, with viscosities ranging from 2 to 7 cSt at 100°C. It is likely that at least for the lower viscosity grades of the notified chemical similar adverse effects to those seen for Analogues 2 and 5 after inhalation exposure to aerosols would be predicted. However, given no acute inhalation toxicity was observed for the higher viscosity analogues (> 5 cSt at 100°C) and considering a correlation with viscosity of base oils with toxicity, no adverse effects are expected with the high viscosity grades of the notified chemical (≥ 5 cSt at 100°C). Hence, based on weight of evidence it is recommended only the low viscosity imported grades of the notified chemical (< 5 cSt at 100°C) should be classified as R20: Harmful by inhalation.

Irritation and Sensitisation
The notified chemical was found to be only slightly irritating after four hour exposures to rabbit skin and eye. Based on studies conducted in guinea pigs there was no indication that the notified chemical would be a skin sensitiser or photosensitiser.

Repeated Dose Toxicity
A number of repeat dose studies (oral, dermal and inhalation) have been conducted on analogue chemicals of varying purities and carbon ranges. Based on the weight of evidence the notified chemical is expected to have low systemic toxicity, although adverse effects could arise with repeated inhalation exposure to significant amounts of the oil mist i.e. approximately 100 mg/m^3 (Concawe, 1997).

Mutagenicity
The notified chemical was found to be non-mutagenic to bacteria and non-clastogenic to human lymphocytes when tested in vitro. In vivo murine micronucleus studies conducted on analogue chemicals found no indication of genotoxicity, although it was not clear from these studies whether the test substances were reaching the target organ (bone marrow).

Classification
Based on the analogue data for inhalation toxicity the notified chemical is classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with risk phrase, 'Harmful by inhalation (R20)' where the viscosity of the notified chemical is < 5 cSt at 100°C. In addition the notified chemical should also be classified as hazardous with risk phrase, 'Harmful: May cause lung damage if swallowed (R65)' where the viscosity of the notified chemical is < 7 x 10^{-6} m^2/s (7 cSt) at 40°C.

The analogous petroleum derived base oil is classified as a carcinogen (category 2). However, this classification is based on the amount of aromatic hydrocarbons (including benzene), which are present as impurities due to the fact that the base oil is refined from a natural source. The notified chemical is derived from the 'Gas-to-Liquid' process, which is a synthetic process that produces aliphatic hydrocarbons. Therefore the aromatic content of the notified chemical is much lower (< 1%, essentially no benzene). The notified chemical is therefore considered to not require classification as a carcinogen.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The toxicological profile indicates that the notified chemical is harmful after inhalation of aerosols and may pose an aspiration hazard based on its viscosity. However, inhalation exposure to oil mists is expected to be limited under normal operating conditions due to the enclosed processes. Oral exposure is not expected, except in the case of an accident involving equipment failure. Dermal and accidental ocular exposure to the notified chemical may occur during transport, reformulation and use, although this is likely to be minimised by the engineering controls and personal protective equipment expected to be in use in the majority of workplaces. Therefore, the risk to workers involved in reformulation, use, transport and storage or disposal of the notified chemical is not considered to be unacceptable.

6.3.2. Public health
DIY enthusiasts may be exposed to the notified chemical in reformulated lubricants and ATFs, but this exposure is likely to be infrequent (a few times a year). The generation of aerosols during public use of the notified chemical in reformulated products is not expected, and therefore exposure to oil mists is unlikely.

Accidental oral exposure may occur, either as a result of an accident when using the end products or to children after accidental ingestion. The aspiration hazard would depend on the viscosity of the reformulated product. Labelling of the reformulated lubricants may therefore be required to ensure they are kept out of the reach of children, as well as a direction to not induce vomiting. Liquid hydrocarbons are listed in the Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), and as such labelling requirements apply.

Therefore, although the notified chemical has been identified as an inhalation hazard, due to the expected low exposure, the risk of adverse health effects is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be synthesised overseas and imported into Australia. Environmental exposure to the notified chemical is expected to be limited to small amounts (a few grams) that remain on the surface of hoses used to transfer the notified chemical at lubricant blending facilities.

RELEASE OF CHEMICAL FROM USE

Small amounts of waste are expected to be produced at lubricant blending facilities. These will undergo on-site treatment as outlined below.

Environmental exposure from use as engine or transmission lubricants would be from drips while adding the finished oil to the engine or from the engine itself. It is not possible to estimate these losses, though they are expected to be small.

Used oil will be disposed of in a manner consistent with local and federal regulations. Most likely this will be burning fuel or by used oil recycling. In the case of used oil recycling, a recycling company such as Safety Kleen converts the used oil to fresh lubricant plus asphalt.

A survey by the Australian Institute of Petroleum (AIP 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases could be expected to be disposed of responsibly - either to oil recycling or incineration. The remaining 14% are removed by “do it yourself” (DIY) enthusiasts, and in these cases some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. A recent report estimated that DIY activities account for between 7 to 10% of the unaccounted used oil (MEINHARDT 2002).

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997) only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed to landfill, 5% is disposed of into stormwater drains and the remaining 50% unaccounted for.

Consequently, assuming that oil removed by professional mechanics is disposed of appropriately (i.e. sent for recycling or possibly burning as workshop heating oil), negligible release of the notified chemical should result from these professional activities.

Assuming that 14% of the used oil is removed by the DIY enthusiasts it is possible to have 20% collected for recycling, 25% buried or disposed to landfill, 5% disposed into stormwater drains and 50% unaccounted for.

Since automatic transmission fluid changes are likely to be carried out by specialists, and will be disposed of more appropriately, an amount less than 1% of the total import volume of the notified substance could be expected to enter the aquatic environment via disposal into the storm water system. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified chemical in high concentrations is very unlikely except as a result of transport accidents.

RELEASE OF CHEMICAL FROM DISPOSAL

Used oil from oil changes and engine or transmission maintenance will be disposed of at used oil recycling centres. Residues in small containers used by the general public will be disposed of to landfill, where they are expected to remain immobile and degrade slowly. Residues in larger drums used by commercial establishments will be removed when the drums are cleaned, usually with steam, and discharged to on-site wastewater treatment facilities. These residues will undergo oil-water separation, pond aeration, bio-disk and sand filtration before discharge of the aqueous effluent to sewer. Residual oily waste will be incinerated or disposed of at used oil recycling centres.

The main route of environmental exposure to the notified chemical is expected to be illegal disposal into stormwater drains. Less than 1% of the notified chemical is expected to be disposed of in this way.

7.1.2 Environmental fate

As the base oils are hydrophobic hydrocarbons with low volatility, they are expected to partition to solid media such as soils and sediments, where they will slowly biodegrade. Aquatic and atmospheric exposures are expected to remain minimal.

The individual components of the notified chemical are not expected to be readily biodegradable. Biodegradation of an analogue hydrocarbon in a modified Sturm test was only 5%. The test substance is identified as Analogue 1 in the table below. Details of this test can be found in Appendix C.

Biodegradability data for petroleum derived base oils have been compiled by Peter Fisk Associates (2005a) as tabulated below. The foregoing reference should be consulted for details regarding the origins of these tests.

Test substance	*Method*	*Result*
Analogue 12	OECD 301D	18% after 28 days
Analogue 12	OECD 301D	6% after 28 days
Analogue 12	OECD 301D	28% after 28 days
Analogue 12	OECD 301D	25% after 28 days
Analogue 12	OECD 301D	17% after 28 days
Analogue 12	OECD 301D	29% after 28 days
Analogue 11	OECD 301D	2% after 28 days
Analogue 1	OECD 301D	66% after 28 days
Analogue 1	OECD 301B	5% after 28 days
Analogue 2	OECD 301B	51% after 28 days
Analogue 2	OECD 301D	15% after 28 days
Analogue 2	Not stated (anaerobic test)	Not biodegradable
Analogue 2	OECD 301B	4% after 28 days
Analogue 2	Not stated	Nil (104% recovery)
Analogue 2	Not stated	Nil (106% recovery)
Analogue 10	OECD 301B	6% after 28 days
Analogue 3	OECD 301B	6% after 28 days
Analogue 4	OECD 301B	7% after 28 days

The notified chemical should be inherently biodegradable. The biodegradability of the individual components of the notified chemical has been predicted in accordance with the methods described by Peter Fisk Associates (2005b). The lighter fractions are expected to be readily biodegradable but not meeting the 10 day window. Heavier fractions (majority by mass) are predicted to be inherently biodegradable. This conclusion is consistent with the established behaviour of analogue lubricant oil basestocks derived from petroleum, which have a very similar chemical composition apart from their much higher aromatic hydrocarbon content (CONCAWE, 1997).

The notified substance is not expected to be significantly bioaccumulated by aquatic organisms, based on the established behaviour of petroleum derived analogues, including the very low absorption of large hydrocarbon molecules through biological membranes, and the very low levels of exposure expected for dissolved residues of the notified chemical.

7.1.3 Predicted Environmental Concentration (PEC)

The notified chemical would be expected to float and spread following accidental introduction into aquatic environments, with adsorption to sediment the major fate process.

A worst case estimated PEC might be calculated if it is assumed that 1% of the notified chemical (maximum 10 tonnes) is released into stormwater drains in a single metropolitan area with a geographical footprint of 500 km^2 and an average annual rainfall of 500 mm, all of which drains to stormwater. With a maximum annual release into this localised stormwater system of 10000 kg and the annual volume of water drained from this region estimated to be approximately 250 x 10^6 m^3, the resultant PEC is approximately 40 µg/L. It should be stressed that this result is very much a worst case scenario, and that in reality releases of the chemical would be very much more diffuse than indicated here, and also at significantly reduced levels.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on petroleum derived analogues of the notified chemical are summarised in the table below. These acute studies were conducted on water accommodated fractions (daphnid test) or oil in water dispersions (fish and algal test). Results should be interpreted as loadings rather than concentrations. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL50 > 1000 mg/L	Nontoxic to limit of water solubility
Daphnia Toxicity	EL50 = 190 mg/L	Some toxicity near the limit of water solubility
Algal Toxicity	EL50 > 100 mg/L	Nontoxic to limit of water solubility

7.2.1 Predicted No-Effect Concentration

The PNEC was calculated from the daphnid test. Although the algal test returned a lower limit of 100 mg/L for the median effect concentration, the extent of inhibition at this limit was very low at 0.62%.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment			
Lowest median effect concentration	190		mg/L
Assessment Factor	100		
Mitigation Factor		1.00	
PNEC:	1900		µg/L

7.3. Environmental risk assessment

The risk quotient, or the ratio of the PEC to the PNEC, is 0.02, indicating a low risk to the environment under the conservative assumptions used to establish the PEC.

The notified chemical is not expected to present a risk to the environment, except when spilt in large quantities to water, as aquatic exposure is expected to be minimal, and the notified chemical is practically nontoxic to fish, aquatic invertebrates and algae.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

Symbols: Xn: Harmful

Risk Phrases: R20: Harmful by inhalation (Note: This risk phrase only applies where the viscosity of the notified chemical is < 5 cSt at 100°C)
R65: May cause lung damage if swallowed (Note: This risk phrase only applies where the viscosity of the notified chemical is < 7 x 10^{-6} m^2/s (7 cSt) at 40°C)

Safety Phrases: S2: Keep out of reach of children
S23: Do not breathe mists
S51: Use only in well-ventilated areas
S62: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label

And

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Acute Inhalation Toxicity	Category 4	Harmful if inhaled (mist)
Aspiration Hazards	Category 1*	May be fatal if swallowed and enters airways

* Only applies where the kinematic viscosity of the notified chemical is ≤ 20.5 mm^2/s at 40°C

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the expected minimal aquatic exposure and absence of aquatic toxicity, and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following hazard classification and safety phrases for the notified chemical:

Risk Phrases:

- Xn: R20: Harmful by inhalation (Note: This risk phrase only applies where the viscosity of the notified chemical is < 5 cSt at 100°C)
- Xn: R65 May cause lung damage if swallowed (Note: This risk phrase only applies where the viscosity of the notified chemical is < 7 x 10^{-6} m^2/s (7 cSt) at 40°C)

Safety Phrases:

- S2: Keep out of reach of children
- S23: Do not breathe mists
- S51: Use only in well-ventilated areas
- S62: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label

- Use the following risk phrases for products/mixtures containing the notified chemical (depending on the viscosity of the notified chemical used):
  - ≥25%: R20: Harmful by inhalation
  - ≥10%: R65 May cause lung damage if swallowed

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Local and/or general ventilation indoor to control airborne levels

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid generation of aerosols (oil mists)
  - Use only in well ventilated areas
  - If swallowed, do not induce vomiting, seek medical advice immediately
  - Workers must have adequate education and training before handling the notified chemical.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Respiratory protection, if significant inhalation is expected

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- The notified chemical as introduced should be handled consistent with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- Suppliers of the notified chemical to the public should meet all requirements for "Hydrocarbons, liquid" in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)

Disposal

- The notified chemical should be disposed of by landfill.

Storage

- The notified chemical as introduced should be stored consistent with provisions of State and Territory legislation regarding the Storage of Combustible and Flammable Liquids.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a base stock for lubricants, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 1,000 tonnes, or is likely to increase, significantly;
  - if the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour Point < -20°C

Method	BS 2000: Part 15 (equivalent to ISO 3016) EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	No pour point was determined down to a temperature of -20°C
Test Facility	Safepharm Laboratories (2006a)

Boiling Point 314-379°C at 100.6 to 101.2 kPa

Method	ASTM D 86, Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure
Remarks	The initial determination of the boiling point range was determined in the SafePharm Laboratories using the distillation method according to EC Directive 92/69/EEC A.2 Boiling Temperature. In this initial test approximately 82 to 84% of the test material boiled in the range of 198 to 361°C. The remainder of the test material was considered to have a boiling temperature greater than 361°C. However it was considered by the test laboratory that this method was not appropriate for test materials of this nature. Therefore the boiling point range was determined at Shell Research Ltd (non-GLP, but conducted in the presence of a Study Director and management from SafePharm) using the ASTM D 86 method. This method uses specific apparatus that controls heating rate, temperature of the condenser and temperature of the collection vessel. These parameters are very specific for a particular petroleum product type and can have a significant effect on the boiling temperatures obtained. During this test the temperature of the vapour was shown to drop after 90% recovery. This was considered to be due to thermal cracking of the test material above 379°C. The value at 90% recovery was therefore used as the final boiling point.
Test Facility	Safepharm Laboratories (2006a)

Density 809 kg/m^3 at 20°C

Method	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	The density was determined using the pycnometer method.
Test Facility	Safepharm Laboratories (2006a)

Vapour Pressure 2.8 x 10^{-6} kPa at 25°C

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	The vapour pressure was determined using the vapour pressure balance method followed by linear regression analysis to calculate the vapour pressure at 25°C. The test material did not change in appearance under the conditions of the test.
Test Facility	Safepharm Laboratories (2006b)

Water Solubility < 1 mg/L at 20°C

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method. Analysis relied on monitoring the total organic carbon content, as the test substance was a complex and essentially insoluble mixture. The measured solubility was less than the limit of quantification (1 mg/L). The column elution method was not used because of the likelihood that the oily test substance would clog up the column.
Test Facility	Safepharm Laboratories (2006a)

Partition Coefficient (n-octanol/water) log Pow > 6.5 at 20°C

Method	EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	HPLC Method. All components of the test substance eluted after the reference substance (DDT).

Test Facility Safepharm Laboratories (2006a)

Adsorption/Desorption – screening test log K_{oc} > 5.6 at 40°C

Method EC Directive 2001/59/EEC C.19.
Remarks HPLC screening method. All components of the test substance eluted after the reference substance (DDT).
Test Facility Safepharm Laboratories (2006a)

Flash Point 187°C at 101.3 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.
Remarks The flash point was determined using the closed cup equilibrium method.
Test Facility Safepharm Laboratories (2006b)

Autoignition Temperature 348°C

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks No significant protocol deviations.
Test Facility Safepharm Laboratories (2006b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

Choice of analogue data

For endpoints where information was available on the notified chemical only this data was considered. Analogues 1-9 are alkanes derived from petroleum, each with varying carbon ranges, which together cover the carbon range of the notified chemical. For most endpoints data from the CONCAWE product dossier (1997) for lubricating oil base stocks (petroleum derived distillates) was also considered.

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 420 Acute Oral Toxicity: Fixed Dose Procedure. EC Directive 2004/73/EC B.1 bis Acute Oral Toxicity – Fixed Dose Procedure
Species/Strain	Rat/ Sprague-Dawley CD
Vehicle	None, test substance administered as supplied
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1 female	5000	0
2	4 females	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	There were no clinical observations indicating systemic toxicity, and all animals showed the expected gains in bodyweight over the study period.
Effects in Organs	No abnormalities were noted at necropsy.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Safepharm Laboratories (2007a)

B.2. Acute toxicity – dermal

A study conducted on Analogue 1 (a low molecular weight alkane derived from petroleum), which was GLP compliant, did not indicate whether it was in accordance with OECD/EC Guidelines, although the method appears similar. No signs of systemic toxicity were observed. Skin irritation was observed in both control and treated animals, although the irritation was more severe and persistent in the treated animals with cracking, scabs and scarring also being observed. The LD50 is considered to be > 2000 mg/kg bw (Chevron, 1989).

Studies conducted on the Analogues 2-4 (petroleum derived alkane fractions) were all conducted in accordance with OECD TG 402 Acute Dermal Toxicity, and were GLP compliant. In all studies no signs of local or systemic toxicity were observed at any point and so the LD50s were considered to be > 2000 mg/kg bw (Safepharm Laboratories 1995a-c).

The CONCAWE product dossier (1997) for lubricating oil base stocks (petroleum derived analogues) lists the results from 10 studies on base oil distillates, but does not give details of how the studies were conducted. In all studies the LD50 was > 2000 mg/kg bw.

B.3. Acute toxicity – inhalation

The following table summarises the acute inhalation toxicity studies on analogues of the notified chemical. These analogues together span the carbon range of the notified chemical.

Analogue	*Dose(mg/L)*	*Exposure*	*Viscosity (cSt) at 100°C*	*LC50 (mg/L)*	*Reference*
2	1.0, 2.6 and 5	4 hr nose only	2.4	1.71 (females); > 5.06 (males)	Safepharm Laboratories (1995f)
3	5	4 hr nose only	~ 5.0	> 5	Safepharm Laboratories (1995d)
4	5	4 hr nose only	5.7	> 5	Safepharm Laboratories (1995e)
5	5	1 hr whole body	1.7	< 5	Bioresearch Labs, 1994
6	4.026	4 hr whole body	> 5 (estimated)	> 4	Exxon Biomedical Sciences, 1988a
7	5.530	4 hr whole body	> 4 (estimated)	> 5.5	Exxon Biomedical Sciences, 1988b
8	5.399	4 hr whole body	2.4	> 5.4	Exxon Biomedical Sciences, 1988c
9	1.0, 1.5, 2.5, 3.5, 5.0	4 hr whole body	2.2	2.18	API, 2003

C*omments on studies where acute inhalation toxicity was observed:*

The study on Analogue 2 used a nose only four hour exposure to 0, 1, 2.6 and 5 mg/L of the test substance (concentrations determined gravimetrically). Toxic effects, including deaths were observed at all doses. At necropsy, all animals that died during the study showed swollen and abnormally dark lungs, as well as dark livers. Several animals also showed reddening of the intestine. The LC50 for females was 1.71 mg/L, while for males it was > 5 mg/L (Safepharm Laboratories, 1995f).

The study on Analogue 5 was a limit dose test (5 mg/L) and used a whole-body, one hour exposure. Toxic effects were observed in all animals and 9/10 animals died 1 to 3 days after exposure. Reduction in body weights, increased lung and trachea weight, increased incidence of fluid in the trachea and uncollapsed, discoloured lungs as well as lesions in the lungs, nasal cavities and possibly in the heart were also observed (Bioresearch Labs, 1994).

Analogue 9 is a naphthenic distillate that contains a relatively high proportion of aromatic content relative to the notified chemical and other analogues. Hence, the results of this study may not be an indicator of the toxicity of the notified chemical, as any contribution of the aromatic content to toxicity is unknown. In the study a group of 5 male and 5 female Sprague-Dawley rats were whole of body exposed for 4 hours to an aerosol of Analogue 9 at a target concentration of 5 mg/L (API, 1987a). Four additional groups were then exposed to target concentrations of 1, 1.5, 2.5 and 3.5 mg/L. A group exposed only to chamber air served as the control. At gross necropsy, dark red lungs were described for some animals. Mortality and the incidence of dark red lungs are shown in the following table (the numbers of animals with dark red lungs per number examined are given in parentheses).

Summary of survival and clinical findings in rats exposed to Analogue 9 by inhalation		
Target Concentration (mg/L)	Mortality (Incidence of Dark Red Lungs)	
	Male	Female
0	0/5 (0/5)	0/5 (0/5)
1.0	1/5 (1/5)	1/5 (1/5)
1.5	0/5 (0/5)	0/5 (0/5)
2.5	3/5 (3/5)	3/5 (3/5)
3.5	5/5 (5/5)	5/5 (5/5)
5.0	5/5 (5/5)	5/5 (5/5)

Histological examination revealed that affected animals exhibited diffuse pulmonary congestion and perivascular oedema which was mostly moderate or marked in degree. There was widespread damage to alveolar walls resulting in fibronecrotic debris but the larger airways were relatively unaffected. None of the surviving animals exhibited the above acute changes. However, most of the surviving animals exposed to 2.5 mg/L and above exhibited chronic inflammatory changes that were not seen in the controls and only seen occasionally in animals exposed at the 1.5 mg/L level and to a lesser degree of severity. The LC50 for combined sexes was estimated to be 2.18 mg/L.

B.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None, test substance administered as supplied
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations. GLP compliant.
RESULTS	
Remarks - Results	Very slight erythema was observed in 1 animal only at the 24 and 48 hour observation points. This had cleared by 72 hours.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	Quintiles (1997a)

B.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	No significant protocol deviations. GLP compliant.
RESULTS	
Remarks - Results	Very slight conjunctival redness was observed in 2 animals at 1 hour after dosing. These reactions had cleared by 24 hours after dosing.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Quintiles (1997b)

B.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Magnusson and Kligman Maximisation test EC Directive 92/69/EC B.6 Skin Sensitisation - Magnusson and Kligman Maximisation test

Species/Strain	Guinea pig/ Dunkin-Hartley
PRELIMINARY STUDY	Maximum non-irritating concentration: topical: 50% in cottonseed oil Minimally irritating concentration: topical: undiluted (100%)
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 50% in cottonseed oil topical: undiluted (100%)
Signs of Irritation	Intradermal: All test and control animals exhibited a moderate degree of skin irritation to the injection sites. Topical: All test and control animals exhibited minimal skin irritation at the test sites.
CHALLENGE PHASE	
1st challenge	topical: 50% in cottonseed oil
2nd challenge	Not required
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS	
Remarks - Results	There were no reactions indicative of sensitisation to the test substance following the challenge exposure. There were no deaths or test substance-related clinical signs of toxicity or remarkable body weight changes during the study.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Quintiles (1997c)

B.7. Skin photosensitisation

TEST SUBSTANCE	Notified chemical
METHOD	Method based on Ichikawa et al, 1981
Species/Strain	Guinea pig/ Dunkin-Hartley
PRELIMINARY STUDY	Maximum non-photoirritating concentration (MNIC): 3.125% in cottonseed oil Minimally photoirritating concentration: 6.25% in cottonseed oil
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Topical induction Concentration: 6.25% in cottonseed oil
Signs of Irritation	Discrete or patchy erythema was observed in 1 animal after the 2nd induction (Day3) and on a second animal after the 2nd-5th inductions (Day 3, 5, 8 and 10).
CHALLENGE PHASE	
1st challenge	3.125% in cottonseed oil (MNIC) and 1.562% in cottonseed oil (50% MNIC)
2nd challenge	Not required
Remarks - Method	The procedures used are based on the publication of Ichikawa et al (1981). The topical induction procedure (four intradermal injections of 1:1 Freund's Complete Adjuvant/Water, followed by topical application of the test article in cottonseed oil) was performed on 5 occasions throughout the study (Days 1, 3, 5, 8 and 10) and approximately 30 minutes after each application the treated area was exposed to 10 J/cm^3 of UV-A light for 20-25 minutes. The animals received the challenge

	applications to both left and right flanks, followed by 10 J/cm^3 of UV-A light to the right flank only, on Day 24. GLP compliant.
RESULTS	
Remarks - Results	There were no reactions indicative of photosensitisation to the test substance following the challenge exposure. There were no deaths or test substance-related clinical signs of toxicity or remarkable body weight changes during the study.
CONCLUSION	There was no evidence of reactions indicative of skin photosensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Quintiles (1997d)

B.8. Repeat dose toxicity

Repeat dose studies (28 day, oral gavage, Sprague-Dawley rats) have been conducted on Analogues 2 and 3. These studies were conducted in accordance with OECD TG 407 and were GLP compliant. Both studies were limit dose studies and no treatment-related effects were observed. The NOEL for each analogue was determined to be 1000 mg/kg bw/day (Safepharm Laboratories, 1995g-h).

The CONCAWE product dossier (1997) summarises the results from a number of repeat dose studies conducted on petroleum derived base oils of varying viscosity and refining history. In the majority of feeding studies on highly refined mineral oils, which are likely to be the most relevant to the notified chemical due to the low impurity (including aromatics) content, these oils were found to be of low systemic toxicity after chronic exposure. Adverse systemic effects (microgranulomas/granulomas in liver and lymph nodes) were seen in some of the studies conducted in rats. These effects were mainly observed for low viscosity oils and appeared to be species specific (most severe in Fischer 344 rats compared to Sprague-Dawley rats, and absent in Long Evans rats and dogs). In recent reports it has been concluded that the relevance of these effects to humans is questionable, as they are morphologically different from the changes observed in the lymph nodes and livers of humans exposed to mineral oils (Carlton et al, 2001).

The CONCAWE product dossier (1997) also summarises the results of several sub-acute studies via the dermal route. The studies have been carried out in New Zealand white rabbits for up to 28 days. In most cases dosing was for 3 days per week, and dose levels ranged from 200 mg/kg up to 5 g/kg. In the studies systemic effects were rarely seen, with only one oil (a hydrotreated, heavy naphthenic distillate) showing liver effects. The studies conducted on the more highly refined oils showed no systemic effects.

Fourteen-day subchronic inhalation toxicity studies have been conducted on Analogues 6 and 8 (Exxon Biomedical Sciences, 1991a and 1991b). In each study three groups of 10 rats (5 per sex) were exposed for 6 hours per day for a total of 10 days to a liquid droplet aerosol of the test substance at concentrations of 55, 511 and 1507 mg/m^3 and 50, 513 and 1480 mg/m^3 for Analogue 6 and 8, respectively. In each study, there were no deaths in any of the test groups. The toxicologically significant effects were limited to dose related microscopic changes in the lungs and nasal cavities that were largely attributed to the mild irritating effect of the test substance. There was no evidence of systemic toxicity at all doses tested.

B.9. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction derived from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 15-5000 µg/plate b) Without metabolic activation: 15-5000 µg/plate

Vehicle	Tetrahydrofuran
Remarks - Method	No significant protocol deviations. GLP compliant. In a preliminary toxicity study the notified chemical was found to be non-toxic to the strains of bacteria used (TA100 and WP2uvrA) up to a dose of 5000 µg/plate.

RESULTS

Remarks - Results	The oily precipitate which formed at and above 1500 µg/plate did not prevent scoring of the revertant colonies. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any dose level, either with or without metabolic activation. The positive control chemicals induced marked increases in the frequency of revertant colonies, thereby confirming the validity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Safepharm Laboratories (2006c)

B.10. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	Modified Draft OECD TG 487 In vitro Micronucleus Test in Human Lymphocytes.
Species	Human
Cell Type	Lymphocytes
Metabolic Activation System	S9 fraction derived from phenobarbitone/β-naphthoflavone induced rat liver
Vehicle	Acetone
Remarks - Method	The method from Draft OECD TG 487 was modified to more closely resemble the OECD TG 473 for the chromosome aberration test. In particular the exposure groups from OECD TG 473 were adopted in preference to those suggested in the draft OECD TG 487. In a preliminary toxicity study the maximum dose tested was 2500 µg/mL as there were difficulties in formulating the test material at higher concentrations in the vehicle. A cloudy precipitate was generally observed as a greasy/oily layer at and above 625 µg/mL. The test material induced no evidence of toxicity in any of the exposure groups. The selection of the maximum dose level for the main study was based on the onset of the greasy/oily precipitate and was limited to 640 µg/mL.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	0*, 20, 40, 80, 160*, 320*, 640*	4 h	20 h	48 h
Test 2	0*, 20, 40, 80, 160*, 320*, 640*	20 h	20 h	48 h
Present				
Test 1	0*, 20, 40, 80, 160*, 320*, 640*	4 h	20 h	48 h
Test 2	0*, 20, 40, 80, 160*, 320*, 640*	4 h	20 h	48 h

*Cultures selected for binucleate analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				

Test 1	>2500	> 640	640	Negative
Test 2		> 640	80	Negative
Present				
Test 1	> 2500	>640	640	Negative
Test 2		> 640	160	Negative

Remarks - Results

The notified chemical did not induce any statistically significant increases in the frequency of cells with micronuclei, in either the absence or presence of metabolic activation.

The positive control chemicals induced statistically significant increase in the frequency of cells with micronuclei, thereby confirming the validity of the test system.

CONCLUSION

The notified chemical was not clastogenic or aneugenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

Safepharm Laboratories (2006d)

B.11. Genotoxicity – in vivo

Murine bone marrow micronucleus studies conducted on the petroleum derived Analogues 2, 3 and 4 were all conducted in accordance with OECD TG 474 and were GLP compliant. None of these analogues induced a toxicologically significant increase in the incidence of micronucleated polychromatic erythrocytes when tested up to the maximum recommended dose of 5000 mg/kg bw. However there was no indication in these studies of whether the test substances were reaching the bone marrow (Safepharm Laboratories, 1995i-k).

The CONCAWE product dossier (1997) states that a range of seven solvent extracted paraffinic and naphthenic base oils (carbon ranges not indicated) were tested in mouse lymphoma and bone marrow cytogenetics assays. All the oils were negative in the mouse lymphoma assay, and only one was positive in the cytogenetic tests. This positive result could not be explained, as similar oils of higher and lower viscosities were inactive.

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sewage sludge microorganisms.
Exposure Period	29 days.
Auxiliary Solvent	None.
Analytical Monitoring	Production of carbon dioxide.
Remarks - Method	Sodium benzoate was used as the positive control. The test substance was non-inhibitory to microorganisms used in the study, as demonstrated by incubation of a mixture with sodium benzoate (41% degradation after 28 days).
RESULTS	Not readily biodegradable (5% degradation).

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0%	2	43%
14	7%	14	69%
29	5%	29	101%

Remarks - Results	The degradation of sodium benzoate met the validation criterion of 60% after 14 days.
CONCLUSION	Not readily biodegradable.
TEST FACILITY	Safepharm Laboratories (1995l).

C.1.2. Bioaccumulation

The notified substance is not expected to be significantly bioaccumulated by aquatic organisms, based on the established behaviour of petroleum derived analogues, including the very low absorption of large hydrocarbon molecules through biological membranes, and the very low levels of exposure expected for dissolved residues of the notified chemical.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 12
METHOD	OECD TG 203 Fish, Acute Toxicity Test –semi-static.
Species	Rainbow trout (*Oncorhynchus mykiss*).
Exposure Period	96 hours.
Auxiliary Solvent	None (oil in water dispersion).
Water Hardness	190 mg $CaCO_3$/L.
Analytical Monitoring	Not conducted.
Remarks – Method	The test medium was stirred continuously to produce a uniform dispersion which was renewed daily. The propellor stirrers aerated the test medium.
RESULTS	No mortalities or other adverse reactions.

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	n/a	10	0	0	0	0	0
0	n/a	10	0	0	0	0	0
1000	n/a	10	0	0	0	0	0
1000	n/a	10	0	0	0	0	0

LL50 > 1000 mg/L at 96 hours (oil in water dispersion).
NOEC 1000 mg/L at 96 hours.
Remarks – Results

CONCLUSION Nontoxic to limit of water solubility.

TEST FACILITY Huntingdon Research Centre (1992).

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue 11

METHOD Committee on Methods for Toxicity Tests with Aquatic Organisms. Methods of Acute Toxicity Tests with Fish, macroinvertebrates and Amphibians. 1975. US EPA Ecol Res Ser 660/3-75-009 – semi-static.
Species *Daphnia magna*
Exposure Period 48 hours *[acute study]*
Auxiliary Solvent None (water accommodated fraction from oil in water dispersion).
Water Hardness 180 mg $CaCO_3$/L
Analytical Monitoring Not conducted.
Remarks - Method The test substance was dispersed in water by stirring for 20 hours. Test media were siphoned off after the dispersion had been allowed to settle for 4 hours, and renewed after 24 hours. A persistent oily film was seen on the surface at higher test concentrations (250, 500 and 1000 mg/L).

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
0	n/a	20	0	0
32	n/a	20	0	0
65	n/a	20	0	2
130	n/a	20	0	1
250	n/a	20	0	13
500	n/a	20	0	20
1000	n/a	20	0	20

EL50 > 1000 mg/L at 24 hours (water accommodated fraction).
190 mg/L at 48 hours.
NOEC < 32 mg/L at 48 hours.
Remarks - Results The NOEC was less than the lowest concentration tested as abnormal effects (surfacing or tending to the bottom of the test vessel) were seen after 48 hours in all of the treated test concentrations.

CONCLUSION Some toxicity near the limit of water solubility, possibly from physical effects.

TEST FACILITY ABC Laboratories (1988).

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Analogue 13
METHOD	The *Selenastrum capricornutum* Printz, Algal Assay Bottle Test. US EPA (July 1978) EPA 600/9-78-018.
Species	*Selenastrum capricornutum* Printz.
Exposure Period	96 hours.
Concentration Range	Nominal: 1, 10 and 100 mg/L.
Auxiliary Solvent	None.
Water Hardness	Not stated.
Analytical Monitoring	Not conducted.
Remarks - Method	Test media were prepared by adding the test substance (100 mg/L) to algal assay media followed by dilution as appropriate.. Algal cultures were counted four times with a Coulter Counter to determine cell numbers at 96 hours. Untreated controls were also cunted at 48 hours to confirm logarithmic growth.
RESULTS	Results were based on growth rate. Biomass was not recorded.

Growth rate 0 mg/L at 96 h	*Growth rate 100 mg/L*
1.62	1.61

Remarks - Results	The EC50 for the positive control (zinc chloride) was 0.53 mg/L.
CONCLUSION	Nontoxic to limit of water solubility (0.62% inhibition after 96 hours at 100 mg/L as oil in water dispersion).
TEST FACILITY	Gulf Life Sciences Centre (1983).

C.2.4. Inhibition of microbial activity

An analogue of the notified chemical was non-inhibitory to microorganisms used in the ready biodegradability study (C1.1) as demonstrated by incubation of a mixture with sodium benzoate.

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