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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

GTL Diesel

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 the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

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

The Shell Company of Australia Limited (ABN: 46 004 610 459)
8 Redfern Road
East Hawthorn
Melbourne 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 names(s), Other names(s), CAS number, Molecular formula, Structural formula, Molecular weight, Spectral data, Import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
The applicant has applied for variation to the schedule of data requirements for toxicological and ecotoxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Unites States; Canada, Korea, European Union

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
GTL Diesel, GTL Distillate fuel, GTL gas oil, F-T diesel, F-T gas oil, F-T distillate

OTHER NAME(S)
Distillates (Fischer-Tropsch), branched and linear

MOLECULAR WEIGHT
<500 Da

ANALYTICAL DATA
Reference NMR, IR and GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 100% (Complete mixture)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-20°C (<253°K)	Measured
Boiling Point	278°C (mean value) at 101.3 kPa	Measured
Density	780 kg/m^3 at 20°C	Measured
Vapour Pressure	5.4 x 10^{-4} kPa at 25°C	Measured
Viscosity	<7 cSt @ 40°C	Estimated (MSDS)
Water Solubility	<0.001 g/L (1.0 x 10^{-3} g TOC/L) at 20°C	Measured
Hydrolysis as a Function of pH	Not tested, but expected to be stable.	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 method).
Adsorption/Desorption	log K_{oc} > 5.63 at 40°C	Measured (HPLC method).
Dissociation Constant	Not determined.	No dissociable functionality.
Particle Size	Not applicable	The notified chemical is a liquid
Flash Point	94 ± 2°C at 101.33 kPa	Measured
Flammability Limits	Upper: 6% Lower: 1%	Analogue data
Autoignition Temperature	208 ± 5°C	Measured
Explosive Properties	Not explosive	Estimated

DISCUSSION OF PROPERTIES

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

The value provided for viscosity indicates that the notified chemical meets the criterion for classification as a aspiration hazard (ie < 7 × 10^{-6} m^2/s). Therefore, the notified chemical is classified as hazardous (with risk phrase R65 Harmful: May cause lung damage if swallowed) under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Reactivity

The notified chemical is not expected to react with air or water.

Dangerous Goods classification

Based on the available data, the notified chemical is not classified as a Dangerous Goods according to the Australian Dangerous Goods Code (NTC, 2007). It is classified as a C1 combustible liquid (NOHSC, 2001)

5. INTRODUCTION AND USE INFORMATION

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

GTL Diesel will be imported into Australia in bulk quantities by sea.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30,000-100,000	30,000-100,000	30,000-100,000	100,000-170,000	100,000-170,000

PORT OF ENTRY

Any major Australian port where a petroleum refinery is located.

IDENTITY OF RECIPIENTS Australian refineries

TRANSPORTATION AND PACKAGING

The notified chemical will be imported in bulk by ship and transported in bulk through pipelines. Barge or truck transport is also used. It is first transported from the ports of entry to the refinery, and then to customers.

USE
Fuel for diesel power cars, truck, off road equipment, agriculture, power plants and marine applications.

OPERATION DESCRIPTION
The notified chemical will be imported by ship and transferred by pipeline directly into a GTL Diesel storage tank at a refinery, using an ISO 14001 procedure that allows for virtually no losses. A vacuum back flush removes fuel from the unloading hoses, which are then further capped to prevent any fuel spillage. Only a few grams that reside on the surface of the hoses is allowed to dry.

From its storage tank, GTL diesel is managed in two possible ways through pipelines:

- Blended at 1-10% into regular refinery produced diesel.
- Sold directly into specific markets that require low emissions diesel fuel, such as National Parks, public transit bus lines or other areas where control of emissions is required due to environmental sensitivity.

Up to 35% of the diesel fuel will be distributed to non-Chevron oil companies by marine barge (80%) or truck (20%). The remaining fuel (up to 70%) is moved directly from the refinery to end users by truck (80%) or by barge (20%). There is no rail or drum distribution of diesel fuel from refinery to end users. Of the 80% distributed by truck from distribution centers, over 50% goes to commercial end users such as trucking fleets, marine, agriculture and construction companies, less than 20% to retail truck stops and service stations, approximately 10% to government and military and less than 20% to railroads.

The loading of trucks occurs at the distribution center where the diesel is loaded with no spills or leaks expected. Trucks are dried drain and are not cleaned. Marine barges are not cleaned. The trucks will deliver fuel to tankage located at commercial trucking fleets, marine tugs or small ships, agriculture users, railroads, service stations, truck stops and construction companies. Workers will also be involved in fuelling vehicles and in the maintenance and cleaning of equipment and pipelines.

Blended diesel fuel is analyzed to ensure that physical and chemical specifications are met. This analysis is performed in a chemical laboratory. Remaining diesel fuel left over from the analysis is disposed of into a waste drum, which is recycled back to the refinery.

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*
Unloading	1	1–8 hrs/shipment	1-2 times per year
Sampling and Analysis	1	10 min/shipment	1-2 times/week
Truck & Barge Distribution	5000	1 hour	240 days/week
End-use fuelling	>10,000	10-30 minutes	200 days/year

* Other categories of workers may also have occupational exposure to GTL Diesel.

EXPOSURE DETAILS
The main routes of occupational exposure are dermal, ocular and inhalation. Occupational exposure is possible during import, loading/unloading, transport, and handling of the fuel containing notified chemical.

During importation and unloading, worker exposure is expected to be low as fuel is transferred across in pipelines using a standard procedure that allows virtually no losses and recommends wearing PPE. A vacuum back flush removes fuel from the unloading hoses, which are then further capped to prevent any fuel spillage. Only a small quantity (few grams) that is left on hoses is allowed to dry.

Worker exposure is also expected to be low during initial transfer of GTL Diesel from the storage tank to the

refinery, as transfer will occur by pipeline.

At refineries, GTL diesel fuel is either blended at 1-10% into regular refinery produced diesel or sold directly into specific markets. Although details of handling at the refinery during blending are not available, exposure is expected to be low during blending, which will be carried out mainly through pipelines.

Exposure to GTL Diesel fuel is expected to be low during sampling and analysis of blended GTL Diesel fuel at the refinery, as a worker wearing appropriate PPE performs this in a chemical laboratory. Remaining diesel fuel left over from the analysis is disposed of into a waste HC drum, which is recycled back to the refinery.

During transportation by marine barge, exposure is expected to be low as loading and unloading consists of attaching hoses to the truck and storage vessels for product transfer. A special air back flush system is used to prevent spillage during transfer. Dermal exposure to drips and spills is possible during the connection and disconnection of transfer hoses. Marine barge are not cleaned. Similarly, exposure is also expected to be limited to during transportation by trucks as loading and unloading is done with minimal spills or leaks. The drivers usually wear gloves and long sleeves shirts when unloading the fuel. Trucks are drain dried and not cleaned.

Personnel from commercial trucking fleet, marine tugs or small ships, agriculture users, railroads, service stations, truck stops and construction companies may be exposed to GTL Diesel during handling and fueling of the vehicles. Maintenance on refinery plant and pipelines may also lead to worker exposure. As most of the notified chemical will be combusted as a fuel, exposure is expected to be minimal during end-use/combustion.

MEASURED/ESTIMATED EXPOSURE

Inhalation Exposures:

Measured inhalation exposure data is available from surveys of industry in the EU for gas oils, including automotive fuels for diesel engines, railway engine gas oil, and heating oils (distillate fuel oils). The highest inhalation exposure value (median value) (expressed as total hydrocarbon) during the use of gas oils was observed during domestic heating oil tank cleaning (190 mg/m^3) with lower levels measured during deliveries (100 mg/m^3), top loading (85 mg/m^3), gantry operator & refinery laboratory worker (7 mg/m^3), waste water treatment plant operator (6 mg/m^3), on-site analysers operator (5 mg/m^3), tank farm operator (4 mg/m^3), drivers (2 mg/m^3), production operator (1 mg/m^3), and area near diesel pumps (0.9 mg/m^3) (CONCAWE 2006).

To supplement the exposure information available from EU company surveys and from the literature, a number of jobs and activities were targeted for exposure monitoring. The company staff undertook the exposure monitoring surveys, but sample analysis was centralised. A well-established sampling and analytical procedure was adopted and an analytical laboratory was selected from several that had returned satisfactory responses to a quality assurance questionnaire. Gas oil vapour exposure (mg/m^3) was measured as total hydrocarbons and expressed as n-dodecane equivalents. The maximum exposure value (median value) was observed during loading-unspecified (10 mg/m^3) followed by top loading and rail car loading (6 mg/m^3), tank farm operator-sampling, tank farm operator-filter changing and refuelling-heavy goods vehicle (5 mg/m^3), jetty crew (3 mg/m^3), bottom loading and deliveries (2 mg/m^3), and full shift (1 mg/m^3). As a reasonable worst case scenario, the maximum value was observed during loading-unspecified and top loading (74 mg/m^3), deliveries (33 mg/m^3), rail car loading (28 mg/m^3), tank farm operator-filter changing (20 mg/m^3), tank farm operator-sampling (11 mg/m^3), and refuelling-heavy goods vehicle (11 mg/m^3) (CONCAWE 2006).

Dermal Exposures:

There is at present no reliable and widely accepted analytical approach to quantify dermal exposure to complex petroleum substances such as gas oils, including automotive fuels for diesel engines, railway engine gas oil, and heating oils (distillate fuel oils). Therefore, exposure estimates used in the gas oils risk assessment were based on modelling approaches. The Technical Guidance Document (TGD) by the European Chemical Bureau, provides criteria to be used when characterising the intensity, frequency and duration of dermal exposure, both in terms of number of events per work shift and in qualitative descriptive terms. The estimates are combined with the assumed exposed surface, of which typical numbers are also included in the TGD (ranging from the palm of one hand-210 cm^2-to both hands and forearms-2000 cm^2).

The daily dermal exposures (mg/day-) to gas oils were estimated during manufacturing, distribution operations and retail (service stations). During manufacturing, the maximum daily dermal exposure value (420 mg.day^{-1}) was observed for tank farm/off-site operator and for rail car operator while the minimum daily dermal exposure value (42 mg.day^{-1}) was observed for production/on-site operator, mechanical maintenance, laboratory technician, and for jetty crew. During distribution operations, the maximum daily dermal exposure value (420 mg.day^{-1}) was observed for terminal operator and for rack operator while the minimum daily dermal exposure value (42 mg.day^{-1}) was observed for road tanker driver and for mechanic. During retail (service stations), the maximum daily dermal exposure value (42 mg.day^{-1}) was observed for pump calibration while the minimum daily dermal exposure value (21 mg.day^{-1}) was observed for refuelling attendant, forecourt cleaner, and for mechanic (CONCAWE 2006).

Summary Exposure levels:
The following table presents exposure estimates for some of the main categories of users of gas oils, using reasonable worst-case values for inhalation exposures (CONCAWE 2006).

Job/Task	Frequency	Duration (minutes)	Inhalation level (mg/m^3)	Inhalation dose (mg/day)*	Dermal dose (mg/day)
Refinery tank farm operator	5 days/week	480	18	180	420
Road tanker driver	5 days/week	480	6	60	42
Refuelling vehicle**	Once a week	5	11	1	21

*On the basis of breathing volume of 10m^3 per 8 hours work shift, the measured full-shift exposure levels were converted to provide an inhalation dose in mg/day. Similarly, short-term exposures such as consumer car refuelling were also converted.
** May be more frequent for some workers

6.1.4. Public exposure
The notified chemical is intended for use as a fuel for diesel power cars, trucks, off road equipment, agriculture, power plants and marine applications. Therefore, the general public will be directly exposed (dermal, inhalation) to the notified chemical when vehicle and equipment users fuel their vehicles at service stations and truck stops. Overall, direct exposure to the notified chemical in blended diesel is expected to be low, similar to the estimates above for occupational refueling and similar to that for currently used diesel fuels.

There are no measurements available for indirect exposure via the environment (the amounts to which members of the general public are exposed via air, water and food) for gas oils (diesel fuels) (CONCAWE 2006). However, the general population may be exposed through exposure to contaminated air, soil, water and via the food chain, as many components of diesel are commonly found in urban air.

6.2. Human health effects assessment

6.2.1. Studies on GTL Diesel
The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of the studies conducted on the notified chemical can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw, low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – In Vitro Micronucleus Test	non genotoxic

6.2.2. Studies on Analogues
Analogue data has also been provided for a number of petroleum derived streams that together cover the carbon range of the notified chemical. Analogue data is assessed only for the endpoints in which there was no data available on the notified chemical. The study reports for the analogues have not been reviewed by NICNAS as such and only summaries are presented in this report.

Description of Surrogate Test Substances

GTL Diesel is a complex combination of hydrocarbons obtained from a feedstock derived from the catalytic hydrogenation of carbon monoxide (the Fischer-Tropsch Process), optionally followed by one or more of the following processes: hydrotreatment, hydroisomerisation, hydrocracking. GTL Diesel is virtually free of aromatic hydrocarbons and the sulphur and nitrogen compounds present in petroleum derived diesel. GTL Diesel also contains no poly cyclic aromatic hydrocarbons. The presence of significant amounts of polycyclic aromatic compounds in the petroleum derived diesel (unless severely treated) results in the petroleum derived equivalents being classified as carcinogenic.

The petroleum derived analogues identified are:

- GTL Kerosine
- Analogues 1, 2 and 3 (petroleum derived alkanes, with narrow carbon ranges)
- Gas oils, including: straight-run middle distillate, light catalytic cracked distillate, steam-cracked gas oil, hydrodesulphurised middle distillate, diesel fuel, and hydrotreated straight-run middle distillate.

Summary of Acute Dermal Toxicity of Analogues

TEST SUBSTANCE	GTL kerosine	Analogue 1	Analogue 2	Gas oils
DERMAL LD_{50} (mg/kg bw)	>2000 (rat)	>2000 (rat)	>2000 (rat)	>2000 (rabbit)
REFERENCE	Huntingdon Life Sciences (1997a)	Chevron (1989a)	Safepharm (1995a)	CONCAWE (1996)
REMARKS - RESULTS	The LD50 value was >2000 mg/kg bw/d. The value for gas oil is from eight studies conducted on different gas oils.			
CONCLUSION	The notified chemical is expected to be of low toxicity via the dermal route.			

Summary of Acute Inhalation Toxicity of Analogues

TEST SUBSTANCE	GTL kerosine	Analogue 2	Analogue 3	Gas oils
INHALATION LC_{50} (mg/L, rat, 4 hour)	>5.0	1.71 (females) >5.06 (males)	<5.17 (1 hour value)	1.8 to 7.64
REFERENCE	Illing (2006)	Safepharm (1995b)	Bio-Research (1994)	CONCAWE (1996)
REMARKS - RESULTS	The LC50 value ranged from 1.71 to >7.4 mg/L.			

For GTL Kerosine, the value was estimated from 'read across' data for Straight run kerosine, Hydrodesulphurised kerosine, Cracked kerosine, and Alkanes (C12-C26).

For Analogue 2, the animals were exposed using a nose only exposure system and males were tested at the highest dose (5.06 mg/L) only (Safepharm 1995c).

In another study, a single 1-hour whole-body aerosol exposure to 5.17 mg/L of Analogue 3 to rats resulted in the death of 9 of the 10 treated animals up to 14 days after treatment. 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. The LC50 (1 hour value) was <5.17 mg/L (Bio-Research 1994).

For petroleum derived gas oils, there were six studies reported. The value was 1.8 mg/L for straight-run middle distillate (API 83-11), 4.8 mg/L for light catalytic cracked distillate (API 83-07), 4.65 mg/L for light catalytic cracked distillate (API 83-08), >2.7 mg/L for steam-cracked gas oil, and 4.6 mg/L for hydrodesulphurised middle distillates (API 81-09) and 7.64 mg/L for hydrodesulphurised middle distillates (API 81-10).

CONCLUSION	The notified chemical is expected to be harmful via inhalation.

Summary of Skin Irritation of Analogues

TEST SUBSTANCE	GTL kerosine	Analogue 1	Analogue 2	Gas oils
SKIN IRRITATION	Slight	Slight	Slight	Non-irritant to severe irritant
REFERENCE	Huntingdon Life Sciences (1997b)	Chevron (1989b)	Safepharm (1995c)	CONCAWE (1996)
REMARKS - RESULTS	No to well-defined erythema was observed at 24 through 72 hrs and was cleared by day 7. Flaky skin was observed up to day 7 and was cleared by Day 14. For gas oils, cracked gas oil caused severe irritation in two studies whereas straight run gas oil was non-irritant. Cracked oil contains considerably more aromatic material and less paraffin and therefore, the results for the cracked oils are not suitable for 'read across' to GTL Diesel (llling 2006).			
CONCLUSION	The notified chemical is expected to be slightly irritating to the skin.			

Summary of Eye Irritation of Analogues

TEST SUBSTANCE	GTL kerosine	Analogue 1	Analogue 2	Gas oils
EYE IRRITATION	Slight	Slight	Non-irritant	Non-irritant
REFERENCE	Huntingdon Life Sciences (1997c)	Chevron (1989c)	Safepharm (1995d)	CONCAWE (1996)
REMARKS - RESULTS	For gas oils, only one study (cracked heating oil) indicated that the material was mild irritant. Other nine studies on gas oils indicated that the materials tested were non-irritant.			
CONCLUSION	The notified chemical is expected to be slightly irritating to the eyes.			

Summary of Skin Sensitisation of Analogues

TEST SUBSTANCE	GTL kerosine	Analogue 1	Analogue 2	Gas oils
SKIN SENSITISATION	Inadequate evidence	Negative	Negative	Negative
REFERENCE	Huntingdon Life Sciences (1997d)	Hill Top Biolabs (1995)	Safepharm (1995e)	CONCAWE (1996)
REMARKS - RESULTS	For gas oils, there were nine studies on skin sensitisation. All studies gave negative results.			
CONCLUSION	The notified chemical is not expected to be a skin sensitiser.			

6.2.3. Summary of Human Health Effects

Toxicokinetics, metabolism and distribution.

The notifier has not submitted any information on toxicokinetics, metabolism and distribution of GTL Diesel. The notified chemical has a measured log Kow of >6.5 and chemicals with log Kow >5 can pass through the stratum corneum but is limited by low water solubility in their ability to enter the bloodstream. However the irritating /defatting effects of chemical are likely to enhance dermal penetration.

In addition, some information is also available on hydrocarbons in general. Hydrocarbons are absorbed through the lung and the gastro-intestinal tract. They are widely distributed and excreted in urine or in exhaled air, depending on volatility. They are metabolised by ω- or ω-1 oxidation to the alcohol and then to the fatty acid. Fatty acids derived from hydrocarbons are likely to enter intermediary metabolism (including β-oxidation) and be excreted in bile urine and exhaled air (as carbon dioxide) (Illing 2006).

Acute toxicity.
The notified chemical was of low acute oral toxicity in rats. Acute dermal and inhalation toxicity studies were not conducted on the notified chemical. However, based on acute dermal and inhalation toxicity studies of analogues, the notified chemical is expected to have low acute dermal toxicity and to be harmful via inhalation.

Irritation and Sensitisation.
Acute skin and eye irritation and skin sensitisation studies were not conducted on the notified chemical. However, based on the studies of analogues, the notified chemical is expected to be slightly irritating to the skin and eyes and is not expected to be a skin sensitiser.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).
There are no repeat dose toxicity studies available on the notified chemical, nor for the analogue GTL Kerosine. Repeat dose toxicity studies on other non-GTL analogues, therefore will be used for this endpoint.

In a limit dose oral toxicity study on Analogue 2, the test material was administered to rats for twenty-eight consecutive days at a dose level of 1000 mg/kg bw/day by gavage. There were no treatment related effects observed on clinical observations, body weight, food consumption, water consumption, haematology, blood chemistry, organ weights, and at necropsy and histopathology. The No Observed Effect Level (NOEL) was therefore, considered to be 1000 mg/kg bw/day (Safepharm 1995f).

Groups of rats were exposed to atmospheres containing both aerosol and vapour of two hydrodesulphurised middle distillates (gas oils). The animals were exposed 6 hrs/day for 5 days/week over 4 weeks at average concentrations of 0.023 and 0.024 mg/L for samples 81-09 and 81-10, respectively. No treatment-related effects were evident from body weight measurements, or from haematology, clinical chemistry or organ weight data. Mild sub-acute inflammatory changes were found in the nasal tissues of all animals to API 81-09. Increased leukocyte counts were found in all animals exposed to API 81-10, which may have been stress-related (CONCAWE 1996).

Groups of rats were exposed to diesel fuel aerosols having a mean particle size of one micron at concentrations in the range 0.5 to 6 mg/L for 2 to 6 hrs. It was estimated that about 15-20% of the diesel fuel was in the vapour phase. Single exposures resulted in a concentration-related decrease in respiratory frequency during exposure. There was also decreased responsiveness in a startle reflex assay just after exposure but this returned to normal, one week after exposure. An influx of granulocytes into the lungs was observed for several days after treatment. Repeated exposures (a total of 9) with varying aerosol concentrations, durations and frequencies resulted in an increase in free pulmonary cells, a reduction in respiration rate, increase in lung weight and a reduction in lung volume (CONCAWE 1996).

In a follow up study, groups of rats were exposed to aerosol concentrations varying from 1.33 to 6 mg/L for either (a) 3 times per week for 2 hrs over 3 weeks, or (b) once per week for a total of 6 hrs over 9 weeks. No evidence of neurotoxicity was evident from a number of tests such as startle response or forelimb gripstrength. However, significant effects were found in the lungs, including an increase in, and focal accumulation of free cells, and thickening and hypocellularity of alveolar walls. Pulmonary function tests revealed decreased total lung capacity and increased functional lung capacity. The wet and dry lung weights were significantly increased. Animals studied 2 weeks after the exposure ended, showed no evidence of reversal of the lung condition. Overall, frequency of exposure was considered to be the most important factor contributing to toxicity.

Five 28 days repeat dose dermal toxicity studies were reported for petroleum derived gas oils. In these studies, the test materials were applied to clipped rabbit skin, three times/week for 4 weeks. The main effect noted was significant skin irritation at the treatment sites reflected in erythema, oedema, discharge and swelling. These effects were dose-related in terms of incidence and severity. Microscopic examination of the treated skin revealed moderate to severe acanthosis and hyperkeratosis (CONCAWE 1996).

Mutagenicity:
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation test and also showed no evidence of clastogenicity to human lymphocytes *in vitro*, either with or without metabolic activation. Based on these results, the notified chemical is not suspected to be genotoxic.

Similarly, the analogue chemical GTL Kerosine was also was found to be non-mutagenic in a bacterial reverse mutation test and also showed no evidence of clastogenicity to human lymphocytes *in vitro*, either with or without metabolic activation.

Carcinogenicity:
The notifier has not submitted any information on the carcinogenicity of the GTL Diesel.

The carcinogenicity of gas oils has been evaluated in a series of mouse skin painting studies. All materials, which have been tested, have caused the development of skin tumours. However, a feature of all the reported studies has been the occurrence of severe skin irritation and in many of the studies a long latency period before tumours developed. It was, therefore, difficult to assess the extent to which the severe irritation has influenced the tumourogenicity that was observed (CONCAWE 1996).

Further studies were conducted on straight run and a cracked gas oils to determine the influence of dermal irritation on the carcinogenic activity of middle distillates. The results showed that at non-irritant doses, straight run gas oil was not carcinogenic, but at irritant doses, weak carcinogenic activity was demonstrated. However, in the case of the diluted cracked gas oil, carcinogenic activity was demonstrated, irrespective of the occurrence of skin irritation (CONCAWE 1996). The carcinogenic activity of the cracked gas oil has been attributed to the fraction rich in aromatic hydrocarbon, particularly components distilling above 370ºC. Further studies examined the tumour initiating/promoting activity of six oil gas samples in mice. These studies demonstrated that the blend of a straight run and fluid-bed catalytically cracked stock was a tumour initiator and a promoter. However, diesel fuel (DGMK, No. 22) was neither an initiator nor a promoter (CONCAWE 1996).

In a review on the available data on distillate fuel, The International Agency for Cancer Research (IARC) concluded that there is inadequate evidence for the carcinogenicity of diesel fuels in humans. However, marine diesel fuel is possibly carcinogenic to humans (API 2003).

The relevance of analogue studies for this endpoint is not clear, as GTL Diesel is virtually free of aromatic hydrocarbons and also contains no polycyclic aromatic hydrocarbons, and components of gas oils are suspected to have human carcinogenic potential.

Toxicity for reproduction/development:
The notifier has not submitted any information on the reproductive/development toxicity of the GTL Diesel.

In a teratology study, pregnant rats were exposed to 102 or 402 ppm of commercially available diesel fuel vapour on days 6 through 15 of pregnancy. The only sign of maternal toxicity was a reduction in food consumption at the highest exposure concentration. No foetotoxic or teratogenic effects were observed in the study.

Development toxicity studies have been carried out in rats on six gas oils (Light cycle oil, coker light gas oil, vacuum tower overheads, heavy coker gas oil, heavy vacuum gas oil, heavy atmospheric gas oil) applied to the skin daily on days 0 through 19 of gestation. The dose levels varied for each gas oil but ranged from 8 up to 1000 mg/kg bw/day. With the exception of coker light gas oil, all other materials tested caused foetotoxicity (increased resorptions, reduced litter weight, reduced litter size), at doses which also caused material toxicity (mainly reduced weight gain, but also increased liver weight, reduced thymus weight).

Observations on Human Exposure.
Human Experience:
A population-based case-control study detected an excess of lung cancer in workers exposed to diesel fuel. The population was small and the reported odds ratio was 1.6 with 95% confidence interval of 1.1 – 2.4. However, no account was taken of the concurrent exposure to diesel exhaust, which may have occurred (Siemiatycki et al., 1987, cited in CONCAWE 1996).

Inhalation exposure:
High inhalation exposure, for example where temperatures are high and ventilation is poor, may result in health effects such as central nervous and respiratory system depression with eventual loss of consciousness. In some cases, a mist may be generated at concentrations well above 5 mg/m^3, which could irritate the mucous membranes of the upper respiratory tract (CONCAWE 1996).

Ingestion:
Ingestion of gas oil (diesel fuels) is an unlikely event in normal use, but could occur during accidental spillage or loss of containment. The taste and smell will usually limit ingestion to small amounts. Although gas oils (diesel fuels) are of low acute oral toxicity, spontaneous vomiting may occur, with the associated risks of aspiration of gas oils into lungs. Ingestion may also give rise to irritation of the mouth, throat and gastrointestinal tract (CONCAWE 1996).

Skin contact:
In common with other low viscosity hydrocarbons, gas oils (diesel fuels) will remove natural fat from the skin; repeated or prolonged exposure can results in drying and cracking, irritation and dermatitis. Some individuals may be especially susceptible to these effects. Excessive exposure under conditions of poor personal hygiene may also lead to oil acne and folliculitis and with some products, development of warty growth may occur and these may become malignant subsequently (CONCAWE 1996).

Eye contact:
Accidental eye contact with liquid gas oil may cause mild, transient stinging and/or redness. Exposure to high concentrations of vapour of mist or vapour may also cause slight eye irritation (CONCAWE 1996).

Aspiration:
Aspiration of gas oil (diesel fuel) into the lungs, either directly or as a consequence of vomiting following ingestion, may result in damage to lung tissue. Breathing difficulties may arise and a potentially fatal chemical pneumonitis may follow (CONCAWE 1996).

Classification
The notified chemical has not been tested for a number of health effects and therefore, analogue data were used for the description of some of its health effects.

Based on the analogue data for inhalation toxicity and for skin irritation studies, and on the viscosity of the notified chemical, the notified chemical is classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with risk phrases of R20, R65, and R66.

It is noted that Diesel Fuels (CAS No. 68334-30-5) is classified as Carc. Cat. 3 with a risk phrase R40 (Limited evidence of a carcinogenic effect) and a Note N. Note N states that the classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen. Based on the method of manufacture and composition, a carcinogenicity classification would not apply to GTL diesel.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified chemical was of low acute oral toxicity in rats and is expected to be of low acute dermal toxicity and harmful via inhalation. The notified chemical is expected to be slightly irritating to the skin and eyes and not a skin sensitiser. No evidence of carcinogenicity was available. The notified chemical is classified as hazardous substance, with the risk of harmful by inhalation, lung damage if swallowed and skin dryness or cracking following repeated dermal exposure, based on the analogues data and the viscosity of the notified chemical.

In addition, inhalation exposure to high levels of the notified chemical may cause central nervous system effects such as headache, dizziness, nausea, vomiting, weakness, loss of coordination, blurred vision, drowsiness, confusion, or disorientation. At extreme exposure, these effects may include respiratory depression, tremors or convulsion, loss of consciousness, coma or death. Therefore, restriction of airborne concentrations to low levels in the workplace situation is important and should minimise the risk of adverse health effects from inhalation exposure to the notified chemical. Inhalation exposure to airborne concentrations of the notified chemical can also be minimised by the use of the notified chemical in well-ventilated areas. However, if significant inhalation exposure is expected, respiratory protection is warranted. Similarly, minimisation of dermal exposure is important, in order to avoid adverse health effects.

The main potential for occupational exposure is during importation, loading/unloading, blending, sampling and analysis, transportation, and handling of the fuel containing notified chemical. The main routes of occupational exposure are dermal, ocular and inhalation. Considering the use of engineering controls and PPE during these procedures, the risk to workers is expected to be low and is considered acceptable. However, certain occupational scenarios have the potential for higher exposure e.g., some loading procedures, maintenance of pipes and equipment, use in confined spaces or elevated temperatures. In these occupational situations, multiple controls would be needed to ensure safe use.

6.3.2. Public health

The main potential for public exposure (dermal, inhalation) to the notified chemical would be when users of diesel vehicles fuel their vehicles at service stations and truck stops. However, exposure to the public will be infrequent (once a week), only for a brief period (maximum 15 minutes) and will be in the open area. Therefore, considering the overall exposure, the hazards of the notified chemical, and that, based on its composition, GTL diesel is expected to be less toxic than the currently available diesel, the risk to public health is not considered unacceptable.

Although most of the notified chemical will be combusted as a fuel, the general population may be exposed at low levels through exposure to contaminated air, soil, water and via the food chain, as many components of diesel are commonly found in urban air. However, the risk of indirect exposure of the general public to the notified chemical through media such as drinking water is also expected to be low, considering low water solubility, readily biodegradability, a very high log K_{oc} and a high log Kow.

Where GTL diesel is available to the public, accidental ingestion could lead to serious health effects through aspiration. Liquid hydrocarbons including diesel (distillate) are included in Schedule 5 of the Uniform Standard for the Scheduling of Drugs and Poisons (SUSDP). Controls include requirements for packaging and first aid instructions.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be transferred to diesel storage tanks at refineries using a pipeline from the ship in which it is imported. Unloading hoses are back flushed before disconnection and capped. The few grams that remain on the surface of the hoses will evaporate to the atmosphere and disperse. Small amounts (about 5 g) removed from each load for analysis will be recycled.

RELEASE OF CHEMICAL FROM USE

Less than 1% of the notified chemical is expected to be released during use. Small amounts (expected to be less than a gram per operation) will be spilt on the ground during vehicle refuelling, and will largely evaporate to the atmosphere and disperse. Most of the notified chemical will be combusted as fuel.

RELEASE OF CHEMICAL FROM DISPOSAL

If the notified chemical needs to be disposed of, this will be by incineration.

7.1.2 Environmental fate

The notified chemical is a mixture of hydrophobic and volatile hydrocarbons, and can therefore be expected to partition mainly to the atmosphere following spillage to soil or water. Spills to water will spread on the surface and evaporate, with limited adsorption to sediment. Residues spilt on land that do not evaporate and remain sorbed to soil will have low mobility and can be expected to degrade. Atmospheric vapours will be susceptible to oxidation, mainly by hydroxyl radicals.

Testing (see Appendix C for details) has shown the notified chemical to be readily biodegradable. Degradation occurred more rapidly than for petroleum derived analogues, reflecting the higher content of linear hydrocarbons and lower levels of aromatic compounds.

No bioaccumulation studies were performed on the notified chemical. As lipophilic substances, the individual components in the notified chemical have the potential to bioaccumulate, but this potential may not be realised *in vivo* because of their degradability. In practice, significant bioaccumulation in fish is not expected because of the low aquatic exposure. Spills to water are expected to largely partition to the atmosphere, with limited dissolution in the water column.

7.1.3 Predicted Environmental Concentration (PEC)

A PEC in water cannot be calculated, as release to water is expected to be restricted to accidental spills, and such releases will largely partition to the atmosphere.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL50 > 1000 mg/L (WAF)	Nontoxic to fish, daphnids and green algae, up to the limit of water solubility.
Daphnia Toxicity	EL50 > 1000 mg/L (WAF)	
Algal Toxicity	EL50 > 1000 mg/L (WAF)	

The results from toxicity testing are expressed as loading rates. They indicate that the notified substance is nontoxic to fish, daphnids and green algae, to the limit of water solubility. Because of the volatility and poor water solubility of the notified substance, test organisms were exposed to water accommodated fractions in sealed vessels.

7.2.1 Predicted No-Effect Concentration

A predicted no-effect concentration cannot be calculated as the aquatic toxicity endpoints are water accommodated fractions, with no measurement of actual exposure concentrations. The notified chemical is not harmful to aquatic life at concentrations up to the solubility limit

7.3. Environmental risk assessment

It is neither meaningful nor necessary to determine an environmental risk quotient as the notified chemical is not expected to be released into aquatic ecosystems in ecotoxicologically significant amounts. No PEC or PNEC can be calculated.

The notified chemical is not expected to present a risk to the environment, as aquatic exposure is expected to be limited, and the notified chemical is nontoxic to fish, aquatic invertebrates and algae up to the limit of water solubility.

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
R65: May cause lung damage if swallowed
R66: Repeated exposure may cause skin dryness or cracking

Safety Phrases: S2: Keep out of reach of children
S23: Do not breathe mists
S24/25: Avoid contact with skin and eyes
S36/37: Wear suitable protective clothing and gloves
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
Skin irritation	Category 3	Causes mild skin irritation

For environment purposes, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is inapplicable. Classification in Category Chronic 4 (may cause long lasting harmful effects to aquatic life) merits consideration, as the notified chemical consists of poorly soluble substances for which no acute toxicity is recorded at levels up to the solubility limit and which have a log K_{ow} > 4. However, the ready biodegradability of the notified chemical constitutes evidence of rapid degradation in the environment, thus showing classification to be unnecessary. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

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 limited 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:
  - Xn: R20: Harmful by inhalation
  - Xn: R65 May cause lung damage if swallowed.
  - Xn: R66 Repeated exposure may cause skin dryness or cracking.
  - S2: Keep out of reach of children
  - S23: Do not breathe mists

- S24/25: Avoid contact with skin and eyes
- S36/37: Wear suitable protective clothing and gloves
- 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:
  - ≥25%: R20: Harmful by inhalation
  - ≥10%: R65 May cause lung damage if swallowed
  - ≥10%: R66 Repeated exposure may cause skin dryness or cracking

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following 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:
  - Use only in well ventilated areas
  - If swallowed, seek medical advice immediately
  - Avoid skin and eye contact
  - 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:
  - Safety glasses
  - Gloves
  - Coveralls
  - 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 incineration.

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 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 fuel for diesel power cars, truck, off road equipment, agriculture, power plants and marine applications, or is likely to change significantly;
- the amount of chemical being introduced has increased from 170,000 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

All physical and chemical properties were tested using 100% pure notified chemical.

Melting Point/Freezing Point -20°C (<253 K)

Method	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	The true freezing temperature of the test material, that at which it completely solidifies, has been determined to be less that 253 K However, on cooling, the test material became increasingly opaque and viscous from approximately 275 K, resulting in a white, opaque, 'slush-like' state on completion of each test.
Test Facility	SafePharm Laboratories Ltd. (2006a)

Boiling Point 278°C (mean value) at 101.3 kPa

Method	EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	It was difficult to generate a significant head of sample vapour due to the complexity of the test material resulting in only limited quantities of each individual component being present. Therefore, for each determination, the upper limit for the boiling temperature range has been reported as the maximum recorded vapour pressure. Mean 50% distillation value was 278°C, overall boiling temperature range was 76 to 304°C, and the mean mid-90% distillation range was 195 to 302°C.
Test Facility	SafePharm Laboratories Ltd. (2006a)

Density 780 kg/m^3 at 20.0 ± 0.5°C

Method	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using the pycnometer method.
Test Facility	SafePharm Laboratories Ltd. (2006a)

Vapour Pressure 5.4 x 10^{-4} kPa at 25°C

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined using a vapour pressure balance method.
Test Facility	SafePharm Laboratories Ltd. (2006b))

Water Solubility <0.001 g/L (1.0 x 10^{-3} g TOC/L) at 20 ± 0.5°C

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Determination was carried out using the flask method. Due to the test material being a complex mixture of hydrocarbons, and is also being essentially insoluble in water, analysis of the sample solution was performed monitoring the total organic carbon (TOC) content of the sample solution.
Test Facility	SafePharm Laboratories Ltd. (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. The limit value of 6.5 is based on the retention time of the reference substance (DDT).
Test Facility	SafePharm Laboratories Ltd. (2006a)

Adsorption/Desorption – screening test log K_{oc} > 5.63 at 40°C

Method	EC Directive 2001/59/EC C19 (HPLC Screening Method).
Remarks	The limit value of 5.63 is based on the retention time of the reference substance (DDT).
Test Facility	SafePharm Laboratories Ltd. (2006a)

Flash Point 94 ± 2°C at 101.33 kPa

Method	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	Determined using a closed cup equilibrium method.
Test Facility	SafePharm Laboratories Ltd. (2006b)

Autoignition Temperature 208 ± 5°C

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Aliquots of test material were injected into the flask (heated in a flask heater) using a syringe and the flaks observed for signs of ignition over a 300 second period. The procedure was repeated, varying the sample size, as necessary, until the lowest temperature at which the ignition, if any occurred within 300 seconds of insertion, was determined. The atmospheric pressure was in the range of 100.65 to 102.35 kPa.
Test Facility	SafePharm Laboratories Ltd. (2006b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Method EC Directive 2004/73/EC-Method B1 *bis* Acute Toxicity (Oral)
Species/Strain	Female Rat/ Sprague-Dawley CD (Crl:CD® (SD) IGS BR)
Vehicle	None (undiluted)
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 F	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	There were no signs of toxicity and there were no deaths. All animals showed expected gains in bodyweight over the study period.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	

CONCLUSION	The notified chemical is of low toxicity *via* the oral route.
TEST FACILITY	SafePharm Laboratories Ltd. (2006c)

B.2. 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.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 0, 15, 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 0, 15, 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. Plate incorporation method.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 5000			
Test 1		> 5000	≥ 1500	Negative
Test 2		> 5000	≥ 1500	Negative
Present	> 5000			
Test 1		> 5000	≥ 1500	Negative
Test 2		> 5000	≥ 1500	Negative

Remarks - Results	No significant increases in the frequency of relevant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.

All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was shown to be satisfactory.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY SafePharm Laboratories Ltd. (2006d)

B.3. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 487 Draft proposal for a New Guideline: In Vitro Micronucleus Test
(Guideline closely resembles the OECD TG 473 In vitro Mammalian Chromosome Aberration Test)

Species/Strain Human
Cell Type/Cell Line Lymphocyte cells
Metabolic Activation System Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-naphthoflavone
Vehicle Minimal Essential Medium (MEM)
Remarks – Method No significant protocol deviations.
The dose level range for preliminary toxicity was 19.5 to 5000 µg/mL. The maximum dose was based on the maximum recommended dose level. The test material induced no evidence of toxicity in any of the exposure groups.

The selection of the maximum dose level was based on the onset of the oily precipitate and the precipitate was observed to form a greasy layer at and above 625 µg/mL. Therefore, the maximum exposure of the cells was limited to 1250 µg/mL in all exposure groups for both experiments.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 39, 78.1, 156.25, 312.5*, 625*, 1250*, MMC 0.2*	4 hr	28 hr
Test 2	0*, 39, 78.1, 156.25, 312.5*, 625*, 1250*, DC 0.075*	20 hr	28 hr
Present			
Test 1	0*, 39, 78.1, 156.25, 312.5*, 625*, 1250*, CP 5*	4 hr	28 hr
Test 2	0*, 39, 78.1, 156.25, 312.5*, 625*, 1250*, CP 5*	4 hr	28 hr

*Cultures selected for metaphase analysis.
MMC = Mitomycin C, DC = Demecolcine, CP = Cyclophosphhamide

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000 µg/mL	> 1250 µg/mL	> 650 µg/mL	Negative
Test 2	> 5000 µg/mL	> 1250 µg/mL	> 650 µg/mL	Negative
Present				
Test 1	> 5000 µg/mL	> 1250 µg/mL	> 650 µg/mL	Negative
Test 2	> 5000 µg/mL	> 1250 µg/mL	> 650 µg/mL	Negative

Remarks – Results All vehicle (solvent) controls had frequencies of cells with micronuclei within the range expected for normal human lymphocytes.
The positive control materials induced statistically significant increases in the frequency of cells with micronuclei, indicating the satisfactory

	performance of the test and of the activity of the metabolising system. The test material was non-toxic and did not induce any statistically significant increase in the frequency of cells with micronuclei, in either of the two experiments, using a dose range that induced the lowest moderately precipitating dose level.
CONCLUSION	The notified chemical was not clastogenic and non-aneugenic to human lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Ltd. (2006e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Sasol SPD™ Diesel.
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Return water from sewage treatment facility that treats mainly domestic sewage.
Exposure Period	28 days
Auxiliary Solvent	Test samples were adsorbed onto glass fibre filters.
Analytical Monitoring	Oxygen consumption.
Remarks - Method	

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	10	1	10
12	60	10	90

Remarks - Results	Biodegradation exceeded 70% at 28 days, and had yet to reach a plateau.
CONCLUSION	The notified chemical can be considered to be readily biodegradable.
TEST FACILITY	Sasol (2008)

C.1.2. Bioaccumulation

No bioaccumulation studies were performed on the notified chemical. As lipophilic substances, the individual components in the notified chemical have the potential to bioaccumulate, but this potential may not be realised *in vivo* because of their degradability. In practice, significant bioaccumulation in fish is not expected because of the low aquatic exposure.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	SMDS gas oil.
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – semi-static.
Species	Fathead minnow (*Pimephales promelas*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	143 mg $CaCO_3$/L
Analytical Monitoring	Not conducted.
Remarks – Method	Fish were exposed to water accommodated fractions, drawn off from preparations (loading rate 1000 mg/L) that had been stirred for 72 hours in sealed vessels with only a small headspace and allowed to settle for 1-2 hours. Fish were exposed in sealed vessels, with daily renewal of the test medium.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*

Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	n/a	7	0	0	0	0	0
1000	n/a	7	0	0	0	0	0

LL50	> 1000 mg/L at 96 hours.
NOEC	1000 mg/L at 96 hours.
Remarks – Results	No toxic symptoms were observed in any of the fish.

CONCLUSION Nontoxic to fish, up to the limit of water solubility.

TEST FACILITY Shell (2002).

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE SMDS gas oil.

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	240 mg $CaCO_3$/L
Analytical Monitoring	Not conducted.
Remarks - Method	Daphnids were exposed to water accommodated fractions, drawn off from preparations (loading rate 1000 mg/L) that had been stirred for 72 hours in sealed vessels with only a small headspace and allowed to settle for 1-2 hours. Daphnids were exposed in sealed vessels, with no renewal of the test medium.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	n/a	10	0	0
Control	n/a	10	0	0
1000	n/a	10	0	0
1000	n/a	10	0	0

EL50	> 1000 mg/L at 48 hours
NOEC	1000 mg/L at 48 hours
Remarks - Results	No effects were seen in any daphnids exposed to the gas oil fraction. Some daphnids were slower moving than control organisms in concurrent range-finding testing when exposed to petroleum-derived diesel (10 and 100 mg/L).

CONCLUSION Nontoxic to daphnids, up to the limit of water solubility.

TEST FACILITY Shell (2001)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE SMDS gas oil.

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Raphidocelis subcapitata*
Exposure Period	72 hours
Concentration Range	Limit test using water accommodated fraction at loading of 1000 mg/L
Auxiliary Solvent	None

Water Hardness	240 mg $CaCO_3$/L
Analytical Monitoring	Not conducted
Remarks - Method	Algae were exposed to water accommodated fractions, drawn off from preparations (loading rate 1000 mg/L) that had been stirred for 72 hours in sealed vessels with only a small headspace and allowed to settle for 1-2 hours. The test was conducted in sealed vessels, with no renewal of the test medium.
RESULTS	There was no effect from exposure to the water accomodated fraction on the growth rate and biomass production in this algal species.
Remarks - Results	Growth rate in controls met validity criteria. Elevations of pH were observed in all cultures as the test proceeded, as a consequence of good algal growth.
CONCLUSION	Nontoxic to green algae, up to the limit of water solubility
TEST FACILITY	Shell (2001)

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