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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

GTL Kerosine

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, and 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 Kerosine, F-T Kerosine

OTHER NAME(S)
Kerosine (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	Measured
Boiling Point	157 to 268°C at 101.2 kPa	Measured
Density	742 kg/m^3 at 20°C	Measured
Vapour Pressure	1.78 x 10^{-1} kPa at 25°C	Measured
Viscosity	4 x 10^{-6} m^2/s (4 cSt) @ 20°C	Estimated (MSDS)
Water Solubility	<1.0 x 10^{-3} g TOC/L at 20°C	Measured
Hydrolysis as a Function of pH	Stable.	The hydrocarbon components in the notified chemical have no hydrolysable functionality.
Partition Coefficient (n-octanol/water	log Pow = 3.17 - > 6.5 at 20°C	Measured.
Adsorption/Desorption	log K_{oc} = 2.21 - > 5.63 at 40°C	Measured.
Dissociation Constant	Not determined.	No dissociable functionality.
Particle Size	The notified chemical is a liquid	N/A
Flash Point	44 ± 2°C at 101.33 kPa	Measured
Flammability	Upper: 6% Lower: 0.6%	Analogue data on non-GTL kerosine (CONCAWE 1995)
Autoignition Temperature	232 ± 5°C	Measured
Explosive Properties	Lower Explosivity Limit - 1% by volume	Analogue data on non-GTL kerosine (CONCAWE 1995)

DISCUSSION OF PROPERTIES

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

The value given for the viscosity indicates that the notified chemical meets the criterion for classification as a aspiration hazard (i.e. < 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

The notified chemical is classified as a Class 3 flammable liquid according to the Australian Dangerous Goods Code (NTC, 2007). The IMO/MDG/ADG code for Kerosene is UN1223.

5. INTRODUCTION AND USE INFORMATION

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

GTL Kerosine 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	10,000-30,000	10,000-30,000	10,000-30,000	30,000-100,000	30,000-100,000

PORT OF ENTRY

Any major Australian port where a petroleum refinery is located e.g., Sydney, Perth, Adelaide, Melbourne etc.

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 jet and turbo power airplanes and helicopters.

OPERATION DESCRIPTION
The notified chemical will be imported by ship and transferred by pipeline directly into a kerosine storage tank at a refinery. A vacuum back flush system removes fuel from the ship unloading hoses, which is further automatically capped on removal to prevent fuel spillage. The few grams that reside on the outside of the hoses is allowed to evaporate.

From the storage tank, the notified chemical will be blended at approximately 10% in normal straight run or hydrocracked kerosine produced at the refinery and sent by pipeline to airports, where it is stored in above ground storage tanks. From the storage tanks, the fuel is sent by pipeline to an underground hydrant system at each gate location where airplanes are parked and fueled.

Using a special small pump cart, a hose is connected by a skilled trade worker to the ground based hydrant from the cart (which contains a pump) and then by a second hose to the wing of the airplane. The airplanes are then fueled. Disconnection uses a similar vacuum back flush procedure, which results in minimal losses of fuel. Any fuel, which is spilled to the cement tarmac, is lost to evaporation.

Sampling and analysis occurs throughout the blending and distribution system. Only small samples are taken by employees. Also 20-50 times per day a "white bucket" analysis at the airport storage site occurs to check for water contamination. One to two kilograms of fuel is drawn and checked for water. After checking for water, the fuel is sent to a special recycling operation, which filters and dries the fuel before returning it for use.

There is some non-pipeline distribution of kerosine as well. Approximately 7% of kerosine is sold to other oil companies (80% by barge, 20% by truck). Marine barges are not cleaned. The trucks are off loaded to above ground storage tanks and drain dried. Spills and leaks are not recovered, as the fuel evaporates into the atmosphere. All trucks are dedicated to fuel operations and are rarely cleaned.

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	<10	1–8 hrs/shipment	1-2 times per year
Sampling and Analysis	<10	10 min/shipment	1-2 times/week
Sampling for water	<10	10 min	20-50 times per day
Aircraft refuellers	>100	1-8 hrs/day	200 days/year

*Other categories of workers may also have occupational exposure to GTL Kerosine (CONCAWE 2007)

EXPOSURE DETAILS
The main routes of occupational exposure are *via* dermal, ocular and inhalation. Aspiration is not expected to occur under normal scenarios but could occur with accidental release of the notified chemical. Occupational exposure is possible during import, transport and handling of the fuel containing notified chemical.

During importation and unloading, worker exposure is expected to be minimal 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. The few grams that reside on the outside of the hoses is allowed to evaporate.

Worker exposure is also expected to be low during initial transfer of GTL Kerosine from GTL storage tank to the refinery, as transfer will occur by pipeline. At the refinery, GTL jet fuel will be blended at approximately

10% in normal straight or hydrocracked kerosine produced at a refinery. Although details of how GTL jet fuel will be handled at refinery during blending are not available, exposure is expected to be low during blending as blending will be done mostly through pipeline.

From the large storage tanks at airports, the fuel is sent by pipeline to an underground hydrant system at each gate location where airplanes are parked and fueled. Exposure is expected to be low during this process. Exposure is also expected to be low during non-pipeline distribution of GTL Kerosine.

Exposure is expected to be low during refueling of planes at the airport. This procedure is performed by a skilled trade worker wearing PPE and involves connecting/disconnecting hoses and using a special small pump cart. Disconnection uses a similar vacuum back flush procedure, which results in minimal losses of fuel. Any fuel, which is spilled to the cement tarmac, is lost to evaporation.

Exposure to GTL jet fuel is expected to be low during sampling and analysis, which occurs throughout the blending and distribution system. During blending, a worker wearing appropriate PPE performs the test in a chemical laboratory and remaining jet fuel left over from the analysis is disposed of into a waste HC drum, which is recycled back to the refinery. During storage at airport sites, a worker wearing PPE performs a 'white bucket' analysis to check for water contamination. After checking for water, the sampled fuel is sent to a special recycling operation, which filters and dries the fuel before returning it for use.

MEASURED/ESTIMATED EXPOSURE

Information on levels of human exposure in the EU resulting from kerosene vapours during manufacture, distribution and the use of petroleum products (known collectively as kerosines) is available. The data indicated that worker exposure levels are generally low and that a wide range of control measures are in place, and that occurrences of elevated exposure occurred but appear to be infrequent. More elevated exposure may occur during maintenance tasks when kerosene-containing equipment is opened (CONCAWE 2007).

The maximum inhalation exposure value (arithmetic mean, expressed as total hydrocarbon) to kerosene was observed during aircraft refuelling and associated operations by yard operator when filter testing (77 mg/m^3) followed by overwing loading (18.4 mg/m^3). During manufacturing /refinery operations, the value observed was 28 mg/m^3 during maintenance (turnaround) while during road tanker distribution operations, the value observed was 16 mg/m^3 by top loader (CONCAWE 2007).

The published data indicated that measured kerosene inhalation exposure (arithmetic mean) (expressed as total hydrocarbon) was highest during fuel tank entry (267 mg/m^3), followed by aircraft tan repairs (161 mg/m^3) and aircraft maintenance (2.8 mg/m^3). This data on inspection and maintenance operations inside fuel tanks of aircraft indicated that inhalation and dermal exposures may be high when kerosene fuel residues were still present and that in these circumstances, control of exposure relies heavily on PPE (CONCAWE 2007).

Both miliary and commercial aircraft workers are at risks of inhalation toxicity from jet fuels, as air-craft refuelling results in the production of significant amounts of aerosolised jet fuel, despite vapour ventilation (Hays et al., 1995, cited in Harris et al., 2007).

6.1.2. Public exposure

The notified chemical is to be used as a fuel for jet and turbo power airplanes and helicopters and will not be directly available to the public. Therefore, the general public is not expected to be exposed to the notified chemical. The fueling of commercial or private jet and turbine powered airplanes or helicopters is always done by skilled workers.

However, general population may be exposed through exposure to contaminated air, soil, water and via the food chain, as many components of kerosine are commonly found in urban air.

6.2. Human health effects assessment

6.2.1. Studies on GTL Kerosine

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
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	limited evidence of sensitisation
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 kerosine streams that together cover the carbon range of the notified chemical. Analogue data is used 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 and only summaries are presented in this report.

Description of GTL Kerosine Analogues

GTL kerosine is a process stream made up from existing substances and can be defined as 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 process: hydrotreatment, hydroisomerization, hydrocraking. It consists predominately of branched and linear aliphatic hydrocarbons and little if any aromatic material (Illing 2006).

With conventional kerosene, hydrodesulphurisation may be employed to remove sulphur components and hydrogenation may be employed to remove sulphur and nitrogen components as well as olefins. Because of the way in which it is manufactured, GTL kerosine is unlikely to contain sulphur and nitrogen, so hydrodesulphurised or hydrotreated petroleum derived kerosines are the most appropriate comparison substances for GTL kerosene. Furthermore, all kerosine contain less than 0.01% by mass of benzene and petroleum derived kerosine contains less than 0.01% by mass of n-hexane (CONCAWE 1995 , Illing 2006).

Several analogues to GTL kerosine have been identified, which are as follows:

Analogue	CAS #	Description
Straight run kerosine (API 83-09)	8008-20-6	A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon number predominantly in the range of C9-C16 and boiling in the range of approximately 150 ºC to 290 ºC.
Hydrodesulphurised kerosine (API 81-07)	64742-81-0	A complex combination of hydrocarbons obtained from a petroleum stock by treating with hydrogen to convert organic sulphur to hydrogen sulphide. It consists of hydrocarbons having carbon number predominantly in the range of C9-C16 and boiling in the range of approximately 150 ºC to 290 ºC.
Cracked Kerosine	68477-39-4	A complex combination of hydrocarbons obtained by distilling cracked stripped steam-cracked distillates. It consists of hydrocarbons having carbon numbers in the range of C8-C10 and boiling in the range of approximately 129 ºC to 194 ºC.
Deodorised kerosine (Hydrotreated light)	64742-47-8	A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C16 and boiling in the range of approximately 150 ºC to 290 ºC.

Jet Fuel A	--	--
Alkanes, C12-26, branched and linear	90622-53-0	Branched & linear, boiling in the range of approximately 240 °C to 360°C.

Summary of Acute Inhalation Toxicity of Analogues

TEST SUBSTANCE	Straight run kerosine (API 83-09	Hydrodesulphurised kerosine (API 81-07)	Cracked Kerosine	Alkanes (C12-C26)
INHALATION LC_{50} (mg/L, rat, 4 hour)	>5.0	>5.2	>7.5	>5.6, >8.7, >5.8

REMARKS - RESULTS	The LC50 value ranged from >5.0 to >8.7 mg/L for 4 hrs exposure. There were four acute inhalation toxicity studies for Alkanes (C12-26) in the IUCLID. In one study, exposure time was for 8 hrs and this study is not included here. The acute inhalation toxicity values for other studies were >5.6 mg/L (n-C10-C12), >8.7 mg/L (n-C12-14), and >5.8 mg/L (n-C14-C16).
CONCLUSION	The notified chemical is of low toxicity via inhalation
REFERENCE	CONCAWE 1995: Straight run kerosine, hydrodesulphurised kerosine, and cracked kerosine. IUCLID 2000a: Alkanes C12-26.

Repeat Dose Toxicity of Analogues

There are no repeat dose toxicity studies available on the notified chemical. Therefore, repeat dose toxicity studies on analogues will be used for the present assessment and a summary is presented below:

Oral exposure

Deodorised kerosine (Hydrotreated kerosene)

Male and female Sprague Dawley rats received 0, 100, 500 or 1000 mg/kg bw/d Exxsol D80 (hydrotreated kerosine), 7 days/week for 13 weeks by gavage. The study included groups allowed a 4-week recovery period post dosing. The study was conducted in accordance with OECD Guideline 409 and was subjected to Good Laboratory Practice audit. There was no treatment-related mortality and no significant effects on mean body weight or food intake. Clinical chemical changes recorded affected all but in the lowest dose group, they were for glucose, blood urea nitrogen, aspartate aminotransferase, alanine aminotransferase and cholesterol. Male rats in the 500 and 1000 mg/kd/d groups had increased relative liver weights and increased relative and absolute kidney weights. Relative testes weights were also significantly elevated in the top dose males. In females, absolute and relative liver weights were elevated at 1000 mg/kg bw/d and relative liver weight was elevated at 500 mg/kg bw/d. Histological effects indicative of alpha-2-globulin induced kidney damage were seen in male rats at all doses; hepatocyte hypertrophy occurred in male rats at 1000 mg/kg bw/d and females at 500 and 1000 mg/kg bw/d. None of these effects were seen in the recovery groups. The LOAEL was 100 mg/kg bw/d (IUCLID 2000b).

Dermal exposure

Hydrodesulphurised kerosine

Groups of 5 male and 5 female rabbits (New Zealand white) were exposed by the dermal route to undiluted test substance at 200, 1000 or 2000 mg/kg, 3 times a week for 28 days. The study was conduced to an American Petroleum Institute protocol and was subjected to GLP audit. One high dose animal died and six others were sacrificed due to severe dermal reactions. Three middle dose and one low dose animal were also sacrificed due to dermal reactions. The dermal effects were indicative of severe irritation at the high dose level and moderate irritation at the middle and low dose levels. Significant erythema and oedema were found at the treatment sites. Liver lesions were found in high dose animals (IUCLID 2000c).

In another study, groups of 12 male and female rats (Sprague-Dawley) were used. The test material was applied to the shorn intrascapular region of the rats at doses of 165, 330 or 495 mg/kg bw/d. Dosing was continued daily for five consecutive days each week, five days a week for 13 weeks. In addition, a group of 12 male and 12 female rats of similar age were administered mineral oil at a dose rate of 1 mL/kg bw/d; these animal served as vehicle control. An additional 12 rats/sex/group in the vehicle control and high dose group were maintained for a 4-week recovery period following dosing for 13 weeks. All animals survived until scheduled termination. There were no test substance-related effects on survival, clinical observations, neurobehavioral signs or opthalmological findings. The only clinical observations during the study were related to skin irritation at the application site. There was a generally dose-related increase in the incidence and severity of erythema, oedema, epidermal scaling, scab formation, thickening of the skin and ulceration at the treated site. Males seemed to be more sensitive than females. Growth rates were unaffected by treatment. Functional Observation Battery (FOB) screen did not demonstrate any substance-related effects. At necropsy, no substance-related observations were made for males in any group. In the females, there was a suggestion of possible treatment-related effect, which occurred in 7 rats across all groups and consisted of skin crusts or ulceration at the site of application of test material. Haematological and serum clinical parameters were unaffected by treatment. The only organ weight effects noted were an increase in spleen/body weight and spleen/brain weight ratios in the high dose group females at the 13 week necropsy and an increase in absolute spleen weight in the same dose group females after the 4 weeks recovery period. Since there were no associated microscopic or clinical chemical findings, these differences were not considered to be of biological relevance. There were no treatment-related microscopic changes in the tissues examined with the exception of the findings in the skin. The skin observations were minimal in nature with a severity score less than 1 or on 1 to 4 scale. The findings included acanthosis, ulceration, parakeratosis, chronic active inflammation and hyperkeratosis. The males were affected at all doses. However, the effects indicated very little irritation. Recovery group animals revealed complete in the females and minimal hyperkeratosis in the high dose group males. No effects were found in the animals subjected to detailed neuropathological examination (API 2003).

Straight run kerosine (API 83-09)
Undiluted test material was applied to the shorn dorsal skin of each of five male and female rabbits at doses of 200, 1000 and 2000 mg/kg bw/d, three times weekly until 12 doses had been applied. (28 days exposure period). Five animals of each sex served as sham treated controls. Clinical signs observed in the study were considered to be treatment –related included: thinness, nasal discharge, lethargy, soiled anal area, anal discharge, wheezing. One control male was found in a moribund state and was sacrificed on day 21 of the study. One female control was found dead on day 11 of the study. One 1000 mg/kg bw/d male was found dead on day 15. A male and a female in the highest dose groups were found dead on days 10 and 24 respectively and were considered to be treatment-related. Treatment-related mean body weight losses were observed in the high dose groups. The skin irritation showed that irritation was dose related and was greatest in the highest dose group. Other dermal findings included cracked, flaky and/or leathery skin, crusts and/or hair loss. These findings only occurred in the treated groups and appeared with greater frequency as the dose level increased. No treatment-related changes were seen in the clinical chemistry. There were no haematological findings in the female groups. In males, reductions in RBC values were significantly decreased in all treatment groups. Reductions in haemoglobin and haematocrit values were seen only in the mid and high dose groups. The authors concluded that the increases in relative heart weights for the mid and high dose males and females were treatment-related. Increased absolute and relative spleen weights for females were also considered to be treatment-related. Gross necropsy findings were confined largely to the skin. Enlarged spleens in the female groups were also noted. Microscopically, slight to moderate proliferative and slight to moderately severe inflammatory changes were present in the treated skin of all male and female animals in the high dose group. These changes were accompanied by an increase in granulopoiesis of the bone marrow in 5/6 males and 3/4 females. 4/6 high dose group males also had multifocal or diffuse tubular hypoplasia of a few of the seminiferous tubules of both testes. The degree of spermatogenesis was similar to controls in one animal, was absent in two animals and was slightly reduced in three animals. These testicular changes were considered to be secondary to the skin and/or weight changes (API 2003).

Jet Fuel A
In a single dose study with Jet Fuel A, rabbits were dermally treated with 6.4 g/kg bw/d, 5 days/week for 2 weeks. This resulted in severe skin damage at the treatment areas together with depression and weight loss associated with anorexia. Tissue damage observed in the liver (mottled necrosis and centrilobular degeneration). Kidney and bladder (hyperplasia) was considered to secondary to the severe skin irritancy (CONCAWE 1995).

General
A hydrotreated, straight-rune kerosine (CAS No. 64742-81-0), when applied non occluded three times per week to mouse skin for 3 weeks, produced degenerative skin changes, including necrosis and hyperplasia. These effects were well advanced after one week (CONCAWE 1995).

Three kerosine samples (two hydrotreated, straight-run kerosines and a blend of 70% hydrocraked kerosine and 30% hydrotreated straight-rune kerosine) were applied 3 times at 3 days intervals to mouse skin. All produced inflammation, necrosis of the hair follicles and degenerative changes in the skin surface (CONCAWE 1995).

In a 13 week dermal study, 2 samples of kerosines (a straight-run hydrotreated kerosine and 70/30 blend of hydrocracked/straight-run hydrotreated kerosine) were applied at various dilutions to find a level that did not cause skin irritation. A 25% solution of the kerosines in white oil, applied at 50 µL twice per week, was non-irritant surface (CONCAWE 1995).

Inhalation exposure
Hydrodesulphurised kerosine
In a limit dose study on petroleum derived hydrodesulphurised kerosine (API 81-07), groups of 20 male and 20 female rats (Sprague-Dawley) received either 0 or 0.024 mg/L 6h/d, 5 d/week for 4 weeks. The study was conduced to an American Petroleum Institute protocol and was subjected to GLP audit. Organ weights, clinical chemistry and haematology were normal. Apart from minor sub-acute inflammation of the respiratory mucosa, no treatment related effects were reported (IUCLID 2000c).

Deodorized kerosine
In a study on deodorized kerosine, 25 male rats/group were exposed to 0, 0.02, 0.048 or 0.10 mg/L test substance vapour for 6 h/d, 5d/w for 13 weeks. The study was not subject to GLP audit. No significant treatment related effects were identified although two rats died, one at the middle dose level and one at the high dose level. Another rat in the high dose group was found with pleural adhesions with abscess bronchopneumonia. A parallel study with dogs (Beagles) also failed to show any significant results (IUCLID 2000c).

Carcinogenicity
A number of studies have been reported on the dermal carcinogenicity of kerosines. In these studies, repeated dermal applications of kerosines caused moderate to severe skin damage (including necrosis) as well as an incidence of tumours after long latency periods. It should be noted that in those studies in which tumours developed, moderate to severe skin irritation was also observed (CONCAWE 1995).

Because 3, 7 ring polycyclic aromatic compounds (PACs), the components of petroleum hydrocarbon mixtures generally regarded as being responsible for, or associated with dermal carcinogenicity, are either absent from kerosine or present only in extremely low concentrations, a non-genotoxic mechanism is the most likely explanation for the late development of tumours in the long-term studies. CONCAWE, therefore, carried out a program of studies that examined the effects of skin irritation on the tumorigenicity of kerosine. In this study, it was found that in the absence of skin irritation, kerosine did not induce skin tumours (CONCAWE 1995).

In a review of the available information on the carcinogenicity of middle distillates fuels, it was concluded that the tumorigenicity activity of fuels was secondary to skin irritation. In addition, initiation/promotion studies on kerosines have shown them to have weak promoting but not initiating activity (CONCAWE 1995, API 2003). Support for the possibility of a non-genotoxic mechanism appears to be provided by: (a) the general lack of activity of kerosines in genotoxicity assays, (b) the results of initiation/promotioan studies, and (c) CONCAWE preliminary studies on the role of irritancy in production of skin tumours (CONCAWE 1995).

IARC reviewed the data on the carcinogenicity of jet fuel and concluded: There is inadequate evidence for the carcinogenicity in humans of jet fuel. There is inadequate evidence for the carcinogenicity in experimental animals of jet fuel. The IARC overall evaluation was that Jet fuel is not classifiable as to its carcinogenicity to humans (API 2003).

Developmental toxicity
Pregnant rats (Sprague-Dawley) rats were exposed to atmospheres containing either 0.76 or 2.6 mg/L (106 or 365 ppm) of kerosine vapours for 6 hrs per day on days 6 to 15 of gestation. No adverse effects were observed in the dams or their progeny. A similar study was conducted with Jet Fuel A, in which pregnant rats ((Sprague-Dawley) were exposed to Jet Fuel A vapours at 0, 103 and 395 ppm on days 6-15 of gestation. No adverse effects were reported in the dams or their offspring (CONCAWE 1995, API 2003).

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 Kerosine. However, some information is 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). Absorption through skin could also be facilitated by the defattening effect of the notified chemical, as normal protective ability of skin would be lessened with exposure to the notified chemical.

Acute toxicity:
The notified chemical was of low acute oral and dermal toxicity in rats. An acute inhalation toxicity study was not conducted on the notified chemical. The notified chemical is expected to be of low acute inhalation toxicity, based on the acute inhalation toxicity studies of the analogues.

The MSDS of the notified chemical states that excessive or prolonged breathing of this material 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. CONCAWE (1995) states that the signs seen after high doses via different routes are indicative of central nervous system depression.

Irritation and Sensitisation:
The notified chemical was found to be slightly irritating to the skin and eyes of rabbits in acute studies. Exfoliation in a skin irritation study on rabbits, from Day 7 until termination on Day 16, reflected a recovery process from the drying effect of the notified chemical. Occluded topical application of the notified chemical in a skin sensitisation study also resulted in slight erythema, eschar formation, exfoliation, yellow staining, loss of flexibility and oedema. Irritation of the upper respiratory tract by vapour and aerosol has also been observed in conventional kerosine (CONCAWE 1995).

In a number of repeat dose dermal toxicity studies on analogues, the main clinical observations during the study were also related to skin irritation at the application site. There was a generally dose-related increase in the incidence and severity of erythema, oedema, necrosis, hyperplasia, epidermal scaling, scab formation, thickening of the skin and ulceration at the treated site.

While atypical skin reactions were observed during the challenge phase of the sensitisation study in guinea pigs, the results indicated that the notified chemical may have potential to cause skin sensitisation in guinea pigs. However, the incidence of significant responses was below the threshold for classification as a skin sensitiser.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).
There are no repeat dose toxicity studies available on the notified chemical. Therefore, repeat dose toxicity studies on analogues will be used for the present assessment.

In an oral toxicity study, rats received 0, 100, 500 or 1000 mg/kg bw/d Exxsol D80 (hydrotreated kerosine) for 13 weeks by gavage. The LOAEL was 100 mg/kg bw/d, based on clinical chemical changes and kidney damage. None of the effects were seen in the 4-week recovery group post dosing.

In a number of dermal toxicity studies on analogues, the main clinical observations during the study were related to skin irritation at the application site. There was a generally dose-related increase in the incidence and severity of erythema, oedema, necrosis, hyperplasia, epidermal scaling, scab formation, thickening of the skin and ulceration at the treated site. There were mainly no test substance-related effects on survival, clinical observations, neurobehavioral signs or opthalmological findings and growth rates were unaffected, however, treatment-related mean body weight losses, tissue damage in some other organs and deaths were observed in the high dose groups in some studies.

In a 13-week dermal study, two samples of kerosines (a straight-run hydrotreated kerosine and 70/30 blend of hydrocracked/straight-run hydrotreated kerosine) were applied at various dilutions to find a level that did not cause skin irritation. A 25% solution of the kerosines in white oil, applied at 50 µL twice per week, was non-irritant to the surface.

In a limit dose inhalation study at a low exposure level, rats received either 0 or 0.024 mg/L 6h/d hydrodesulphurised kerosine, 5 d/week for 4 weeks. Apart from minor sub-acute inflammation of the respiratory mucosa, no treatment related effects were reported.

In an inhalation study on deodorized kerosene, also at low exposure levels, rats were exposed to 0, 0.02, 0.048 or 0.10 mg/L test substance vapour for 6 h/d, 5d/w for 13 weeks. No significant treatment related effects were identified although two rats died, one at the middle dose level and one at the high dose level. Another rat in the high dose group had pleural adhesions with abscess bronchopneumonia.

A parallel inhalation study with dogs (Beagles) on hydrodesulphurised kerosine failed to show any significant results.

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.

Carcinogenicity:
In a number of dermal carcinogenicity studies, kerosine caused moderate to severe skin damage (including necrosis) as well as an incidence of tumours after long latency periods. Further studies that examined the effects of skin irritation on the tumorigenicity of kerosine found that in the absence of skin irritation, kerosine did not induce skin tumours and a non-genotoxic mechanism is the most likely explanation for the late development of tumours in the long-term studies.

Support for the possibility of a non-genotoxic mechanism appears to be provided by: (a) the general lack of activity of kerosines in genotoxicity assays, (b) the results of initiation/promotioan studies, and (c) CONCAWE preliminary studies on the role of irritancy in production of skin tumours, (d) absence of carcinogenic aromatic material, and especially polycyclic aromatic compounds.

Furthermore, IARC reviewed the data on the carcinogenicity of jet fuel and concluded that there is inadequate evidence for the carcinogenicity of jet fuel in humans and experimental animals and that Jet fuel is not classifiable as to its carcinogenicity to humans.

Toxicity for reproduction/development
Information is not available for the effects of the notified chemical on reproduction. However, in developmental toxicity study in rats, no adverse effects were reported in the dams or their offspring up to 365 ppm and 395 ppm of kerosine and Jet Fuel A vapours, respectively.

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

Based on the analogues data for repeat dose toxicity, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with risk phrase R66: Repeated exposure may cause skin dryness or cracking.

Based on the viscosity and chemical class of the notified chemical, it is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with risk phrase R65: May cause lung damage if swallowed.

It is noted that Kerosine (CAS No. 8008-20-6) and its other derivatives are also classified as a hazardous substances and are listed on HSIS with a risk phrase R65.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified chemical was of low acute oral and dermal toxicity in rats and is expected to be of low acute inhalation toxicity. The notified chemical was found to be slightly irritating to the skin and eyes of rabbits in acute toxicity studies. Vapours and aerosols of the notified chemical are also expected to be irritating to the upper respiratory tract. There was inadequate evidence of skin sensitisation in a guinea pig adjuvant study. It is likely that the notified chemical is not a carcinogen. The notified chemical is classified as hazardous substance, with the risk of 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.

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.

Exposure to the notified chemical is likely during importation, blending, laboratory testing, and handling of the fuel containing notified chemical. Engineering controls and PPE are expected to be used during these procedures to minimise exposure. Scenarios with high exposure include those with poor ventilation or confined spaces, those where aerosols are generated, and those maintenance processes where equipment containing kerosine is opened.

Considering the health effects of the notified chemical, the restriction of airborne concentrations to low levels in the workplace situation is important to 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, dermal exposure to the notified chemical should also be minimise to avoid adverse health effects.

The notified chemical is classified as a Class 3 flammable liquid and therefore is a flammable hazard. Flammable and explosive concentrations in air may be generated. Because of low conductivity of kerosine, electrostatic charges may be generated during pumping and tank filling operations. Therefore, considering physico-chemical hazards, precautions are needed during all situations involving the storage, handling and use of the notified chemical in order to ensure safe use (CONCAWE 1995).

There is at present no Australian occupational exposure limit for conventional kerosines. However, the American Conference of Government Industrial Hygienists set a Threshold Limit Value (TLV) for 8-hour time-weighted average (TWA) inhalation exposure to kerosine vapour of 200 mg/m^3, total hydrocarbons, with a skin notation. The skin notation implies that dermal uptake may contribute significantly to the body burden. The TLV is not applicable in situations where kerosene or jet fuel exposure contains appreciable amounts of the aerosol (CONCAWE 2007).

Therefore, considering the use, controls in place and the health effects of the notified chemical, the risk to workers is expected to be low. Furthermore, based on its composition, GTL kerosine is likely to be less toxic than the conventional kerosene.

6.3.2. Public health

The notified chemical will not be directly available to the public. Therefore, public exposure to the notified chemical is expected to be low and the risk to public health is also considered to be low. 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 kerosine are commonly found in urban air. Considering that GTL kerosine is expected to be less toxic than the currently available kerosine, the risk to public health from the notified chemical through indirect exposure is considered to be lower than the currently available kerosine.

Kerosene is listed in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). However, this listing is related to public/home use of kerosene and does not apply to the present application, as the notified chemical will be used only for industrial purpose.

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 kerosine 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. A few grams will be spilt on the ground during aircraft refuelling, and will largely evaporate to the atmosphere and disperse. Atmospheric exposure will also occur when aircraft dump fuel in emergency situations so as to meet maximum structural landing weight limits. This normally occurs at sufficient elevation to ensure evaporation of the jettisoned fuel before it reaches the ground. 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 slowly degrade. Atmospheric vapours will be susceptible to oxidation, mainly by hydroxyl radicals.

There are no biodegradation data for the notified chemical, but analogue data are available in the 2003 SIDS (Screening Information Data Sets) dossier prepared by the OECD for multi-constituent C9-C13 aliphatic hydrocarbon solvents (dearomatised). The test was conducted in accordance with OECD Guideline 301F (manometric respirometry) and showed that 70% biodegradation was achieved in 28 days, but that the 10 day window criterion was not met. The notified chemical can therefore be expected to be degradable in the environment, although the strict criterion of ready biodegradability is unlikely to be met.

The biodegradability of the individual components of the notified chemical has been predicted in accordance with the methods described by Peter Fisk Associates (2006a). The linear hydrocarbons are expected to be readily biodegradable, and most of the branched hydrocarbons (majority by mass) readily biodegradable but not meeting the 10 day window. Minor components with higher levels of branching (vicinal dimethyl substitution) are predicted to be inherently biodegradable.

No bioaccumulation studies were performed on the notified chemical. 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 minimal 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

No ecotoxicity data were submitted for the notified chemical. Data for analogue chemicals have been compiled by Peter Fisk associates (2006b) as tabulated below. The analogue chemical is C8-C13 mixed paraffins (normal, iso- and cyclic) as evaluated in 2003 in the OECD SIDS dossier. Test media were the water accommodated fractions obtained after mixing with dilution water and settling of the mixture. Results are reported as loadings.

Test	*Result*	*Assessment Conclusion*
OECD 203. Rainbow trout. Test media were water accommodated fractions, drawn off after mixing with dilution water for 70-73 hours and settling for 1-2 hours.	LL50 > 1000 mg/L	Nontoxic to the limit of water solubility.
OECD 202. *Daphnia magna*. Test media were water accommodated fractions, drawn off after mixing with dilution water for 43 hours and settling for 1-2 hours.	EL50 > 1000 mg/L	Nontoxic to the limit of water solubility.
OECD 201 sealed test. Green alga *Raphidocelis subcapitata*. Test media were water accommodated fractions, drawn off after mixing with dilution water for 25 hours in sealed vessels and settling for 1 hour.	EL50 > 1000 mg/L	Nontoxic to the limit of water solubility.

The analogue test data indicate that the notified chemical is likely to be nontoxic to fish, aquatic invertebrates and algae, to the limit of water solubility.

The property summary review prepared by Peter Fisk Associates (2006b) also refers to preliminary results of testing with the notified chemical in green algae, which produced the same outcome (EL50 > 1000 mg/L) as the analogue chemical.

Further evidence that the notified chemical is likely to be nontoxic to the limit of water solubility was provided in the form of QSAR estimates for non-polar narcotics (Peter Fisk Associates, 2006b). The QSAR estimates, which considered linear:branched ratios of 1:4 and 4:1, indicate that the notified substance would not be acutely toxic to fish, invertebrates or algae at a loading rate of 100 mg/L. Chronic toxicity was predicted for fish and invertebrates (NOELs of 0.008 and 0.056 mg/L, respectively) but not for algae (NOEL > 100 mg/L).

7.2.1 Predicted No-Effect Concentration

An upper limit for the PNEC can be calculated from the analogue data as outlined below.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
	1000	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	10000	µg/L

7.3. Environmental risk assessment

Risk quotients cannot be calculated as aquatic exposure is expected to remain minimal.

The notified chemical is not expected to present a risk to the environment, as aquatic exposure is expected to be minimal, 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: R65: May cause lung damage if swallowed
R66: Repeated exposure may cause skin dryness or cracking.

Safety Phrases: S2: Keep out of the reach of children
S23: Do not breathe fumes or vapour
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***
Skin irritation	Category 3	Causes mild skin irritation
Aspiration Hazards	Category 1	May be fatal if swallowed and enters airways
Flammable liquids	Category 3	Flammable liquid and vapour

For environment purposes, the classification of the notified chemical for acute toxicity, using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003), is inapplicable as the median acute effect concentrations in fish, daphnids and algae are well above 100 mg/L on a lethal loading basis. This means that the notified substance cannot be categorised as hazardous to the aquatic environment based on its acute toxicity. It could arguably be categorised as Chronic 4, based on the predicted chronic NOELs below 1 mg/L, although it should be noted that the notified chemical is expected to degrade rapidly in the environment.

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

  - S2: Keep out of the reach of children
  - S23: Do not breathe fumes or vapour
  - 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:
  - ≥10%: R65 May cause lung damage if swallowed
  - ≥10%: R66 Repeated exposure may cause skin dryness or cracking

- The notified chemical should be classified as follows under the ADG Code:
  - Class 3 Flammable Liquid; packaging group II

Health Surveillance

- As the notified chemical is a health hazard (may cause lung damage if swallowed, repeated exposure may cause skin dryness or cracking), employers should carry out health surveillance for any worker who has been involved in its handling.

Material Safety Data Sheet

- Any MSDS for the notified chemical should contain the following warning or similar in the Hazards Identification section of the MSDS: "Excessive or prolonged breathing of this material may cause central nervous system effects".

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:
  - Use only in well ventilated areas
  - Avoid generation of aerosols
  - 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 is warranted if significant inhalation exposure is expected, such as in scenarios with poor ventilation or confined spaces, those where aerosols are generated, and those maintenance processes where equipment containing kerosine is opened.

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

- Where appropriate, workplace monitoring of atmospheric levels should be carried out to confirm that controls are sufficient to reduce exposure.

- Employers should take precautions to the control the flammability risks of the notified chemical at workplaces.

- 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.

Disposal

- The notified chemical should be disposed of by incineration.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - Store in a well ventilated area away from sources of ignition

Emergency procedure

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

Transport and Packaging

- The notified chemical is a Dangerous Good (Class 3, Flammable Liquid) under the ADG code. All relevant requirements for transport, packaging, labelling and storage should be complied with.

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(1) of the Act; if
  - GTL kerosine is intended for domestic uses.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from fuel for jet and turbo power airplanes and helicopters., or is likely to change significantly;

- the amount of chemical being introduced has increased from 100,000 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.

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	Determined using BS4633: Method for the determination of Crystallizing Point. The test material did not change in appearance during cooling.
Test Facility	SafePharm Laboratories Ltd. (2006a)

Boiling Point 157 to 268°C at 101.2 kPa

Method	EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Determined using the distillation method at atmospheric pressure. The boiling temperature range of the test material was determined to be 98 to 217°C at 101.96 to 102.76 kPa. However, 75% of the test material (5 to 80%) distillation distilled over a significantly reduced range of 138 to 199 °C. As the distillation approached completion, due to the complex nature of the test material resulting in only limited quantities of each individual component being present, it was difficult to maintain a head of test material vapour in the distillation apparatus, irrespective of repeatedly increasing the heater setting. This resulted in erratic rising and falling temperature and therefore, the upper limit of the boiling temperature range has been reported as the maximum recorded vapour temperature during each determination Comment: It is also stated that the standard method used for the determination of boiling temperature is not appropriate for test material of this nature. The determination of boiling temperatures for petroleum products uses a specific method, which is referred in ASTM D86 (Standard Test Method for Determination of Petroleum Products at Atmospheric Pressure). Therefore, A non-GLP, UKAS approved determination was also conducted in the presence of a Study Director and management of Safepharm Laboratories at Shell Research Ltd, using the specific ASTM D 86 method. The determination performed at Shell Research Ltd gave a boiling temperature range of 157 to 268°C at 101.2 kPa. It was also stated that the overall definitive temperature range is to be quoted using the results obtained following the method of ASTM D 86. The data generated by Safepharm Laboratories Ltd. is to be used as supporting data as this is the method referenced in Annex V.
Test Facility	SafePharm Laboratories Ltd. (2006a)

Density 742 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 1.78 x 10^{-1} kPa at 25°C

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined using an isoteniscope system in which the sample's vapour pressure was measured using a mercury in glass manometer. The temperature of the sample (93-147°C) was regulated by use of a silicone oil bath.
Test Facility	SafePharm Laboratories Ltd. (2006b)

Water Solubility <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 also being essentially insoluble in water, analysis of the sample solutions was performed monitoring the total organic carbon (TOC) content of the sample solutions only.

Test Facility SafePharm Laboratories Ltd. (2006a)

Partition Coefficient (n-octanol/water log Pow = 3.17 - > 6.5 at 40°C

Method EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC Method. The bulk of the test material (96.7%) was shown to have a log Pow > 6.5 by fraction collection and gas chromatographic analysis. The limit value of 6.5 is based on the retention time of the reference substance (DDT).

Test Facility SafePharm Laboratories (2006a)

Adsorption/Desorption log K_{oc} = 2.21 - > 5.63 at 40°C
– screening test

Method EC Directive 2001/59/EC C19 (HPLC Screening Method).

Remarks The bulk of the test material (90.7%) was shown to have a log Koc > 5.63 by fraction collection and gas chromatographic analysis. The limit value of 5.63 is based on the retention time of the reference substance (DDT).

Test Facility SafePharm Laboratories (2006a)

Flash Point 44 ± 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 232 ± 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 flask 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 100.29 to 101.02 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	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.
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. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/ Sprague-Dawley CD
Vehicle	Maize oil
Remarks - Method	No significant protocol deviations

RESULTS

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

LD50	> 5000 mg/kg bw
Signs of Toxicity	There were no systemic sign of toxicity and there were no deaths. All animals achieved anticipated bodyweight gains.
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	Huntingdon Life Sciences (1997a)

B.3. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test
Species/Strain	Rat/ Sprague-Dawley CD
Vehicle	None (undiluted)
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no signs of dermal irritation.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity. 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 dermal route
TEST FACILITY	Huntingdon Life Sciences (1997b)

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	6
Vehicle	None (undiluted)
Observation Period	16 Days
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.9	1	72 hours	0
Oedema	0.2	1	72 hours	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	Very slight erythema was apparent at the test site of each animal during the first 72-hours after bandage removal and in one animal up to Day 7. Very slight oedema was apparent in one animals during the first 72-hours after bandage removal. Exfoliation was evident at all test sites from Day 7 until termination on Day 16. The exfoliation observed at termination of the study probably reflected a recovery process from a drying effect of the test material. The control sites did not show any response to the control procedure.
CONCLUSION	The notified chemical is slightly irritating to the skin
TEST FACILITY	Huntingdon Life Sciences (1997c)

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	6
Observation Period	72 h initially and then at Day 8
Remarks - Method	A sentinel animal was initially treated with the test material. In the absence of severe irritation response in this animal, the remaining five animals were treated.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.4	1.0	72 h	0.0
Conjunctiva: chemosis	0.0	0.0	0.0	0.0
Corneal opacity	0.0	0.0	0.0	0.0
Iridial inflammation	0.0	0.0	0.0	0.0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	Slight erythema was apparent in the treated eye of four animals during the first 24-hours after instillation, persisting in one animal to the 48-hour examination and in another animal to the 72-hour assessment. Iritis was also apparent in the treated eye of one animal at the 1-hour examination. There was no ocular reaction to treatment in the remaining two animals. The treated eye of all animals was overtly normal at the Day 8 examination.
CONCLUSION	The notified chemical is slightly irritating to the eye
TEST FACILITY	Huntingdon Life Sciences (1997d)

B.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation - Magnusson Kligman. EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson Kligman.
Species/Strain	Guinea pig/Dunkin-Hartley strain
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 50% Kerosine in paraffin oil
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 20
INDUCTION PHASE	Induction Concentration: intradermal: 50% Kerosine in paraffin oil topical: 100% (notified chemical as supplied)
Signs of Irritation	Intradermal injection of 50% Kerosine in adjuvant gave rise to moderate erythema and oedema. No dermal response was evident following a similar administration of 50% Kerosine in paraffin oil. Occluded topical (induction) application of the notified chemical as supplied gave rise to slight erythema, eschar formation, exfoliation, yellow staining, loss of flexibility and oedema.
CHALLENGE PHASE	
1st challenge	intradermal: topical: 50% Kerosine in paraffin oil

2nd challenge	topical: 10% Kerosine in paraffin oil
Remarks - Method	No significant protocol deviations. Sodium lauryl sulphate pretreated in challenge phase.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge (50% kerosine in paraffin oil)		*2nd challenge (10% kerosine in paraffin oil)*	
		24 h	*48 h*	*24 h*	*48 h*
*Test Group**	50% & 10% Kerosine in paraffin oil	13/19 (3)	14/19 (0)	5/19 (5)	7/19 (2)
	Paraffin Oil only	0/19 (0)	0/19 (0)	-	-
Control Group	50% & 10% Kerosine in paraffin oil	9/20 (0)	7/20 (0)	0/20	2/20
	Paraffin Oil only	0/20	2/20	-	-

* One animal was found dead on Day 2.
(n) Number of animals showing a reaction more marked than the most severe evident amongst the control animals.

Remarks - Results	Challenge application of 50% Kerosine in paraffin oil gave rise to a positive response (slight erythema or a more marked reaction) in 17 test and 11 control animals. Challenge application of 10% Kerosine in paraffin oil caused a positive response in 9 test and 2 control animals. Challenge application of paraffin oil alone caused a positive response in 2 control animals. At the 50% challenge, effects were seen in some animals of both the control and test groups, ranging from slight erythema to severe erythema with eschar formation. At the 10% challenge, the effects were generally of less severity, with slight erythema in some animals in both test and control groups and severe erythema with eschar in two animals of the test group. For both the 50% and 10% challenges, the incidence of effects was higher in the test group than the control group.
CONCLUSION	There was limited evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences (1997e)

B.7. 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	*Test Substance Concentration (µg/plate) Resulting in:*

Activation	*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

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

TEST FACILITY SafePharm Laboratories Ltd. (2006d)

B.8. Genotoxicity – bacteria (Summary)

TEST SUBSTANCE Notified chemical

METHOD Method is not stated in the summary provided.
Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA
Metabolic Activation System Metabolic activation system was used. However, details are not stated.
Concentration Range in Main Test a) With metabolic activation: 50, 158, 500, 1580, 5000 µg/plate
b) Without metabolic activation: 50, 158, 500, 1580, 5000 µg/plate
Vehicle Tween 80
Remarks - Method An independent repeat of the study was performed to confirm the results. Negative and positive controls were used to demonstrate the sensitivity and activity of the test system.

RESULTS

Remarks – Results None of the bacterial strains showed a positive response to treatment with the notified chemical with or without S9 at any concentration.

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

TEST FACILITY Huntingdon Life Sciences (1996)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 487 Draft proposal for a New Guideline: In Vitro Micronucleus Test
(Guideline closely resemble 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 selection of the maximum dose level was based on the onset of the oily precipitate and therefore, the maximum exposure of the cells was

limited to 1250 µg/mL in the 4-hr exposure groups both with and without metabolic activation. For the 20-hr exposure group without S9 in Experiment 2, the maximum dose (312.5 µg/mL) was limited by toxicity.

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*, 9.75*, 19.5*, 39*, 78.1, 156.25, 312.5, 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.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 1250 µg/mL	> 1250 µg/mL	> 1250 µg/mL	Negative
Test 2	> 312.5 µg/mL	> 39 µg/mL	> 625 µg/mL	Negative
Present				
Test 1	> 1250 µg/mL	> 1250 µg/mL	> 1250 µg/mL	Negative
Test 2	> 1250 µg/mL	> 1250 µg/mL	> 1250 µg/mL	Negative

Remarks - Results

The positive control materials induced statistically significant increases in the frequency of cells with micronuclei. The metabolic activation system was therefore shown to be functional and the test method itself was operating as expected.
The test material did not induce any statistically significant increase in the frequency of cells with micronuclei in either the absence or presence of a metabolising system, in either of two separate experiments.

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)

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