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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

GTL Naphtha

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.

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

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FULL PUBLIC REPORT

GTL Naphtha

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Sasol Chevron Consulting Limited (ABN: 46 096 439 404)

Level 15, QV1 Building, 250 Georges Terrace

Perth WA 6000

The Shell Company of Australia Limited (ABN: 46 004 610 459)

8 Redfern Road

East Hawthorn, VIC 3123

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Chemical name, other names, CAS number, molecular formula, structural formula, molecular weight, spectral data, import volume, the identity of the manufacturer and the identity of analogues.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: biodegradation, bioaccumulation, acute toxicity to fish, acute toxicity to aquatic invertebrates, algal growth inhibition, acute dermal toxicity, acute inhalation toxicity, eye irritation, skin irritation, skin sensitisation, repeated-dose toxicity and in vitro chromosomal aberration.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

United States of America, Canada, Korea and the European Union

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) GTL Naphtha F-T Naphtha

MOLECULAR WEIGHT < 500 Da

ANALYTICAL DATA

Reference NMR and IR spectra were provided.

3. COMPOSITION

The notified chemical is a complex mixture of hydrocarbons with a high paraffinic content. The notified chemical contains hexane at a concentration between 5 and 20%.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear, colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	<-20°C	Measured
Boiling Point	62-181°C at 100.8 kPa	Measured
Density	$701 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C}$	Measured
Viscosity	$0.98 \text{ cSt} (9.8 \times 10^{-7} \text{ m}^2/\text{s}) \text{ at } 40^{\circ}\text{C}$	Provided by notifier, source not specified.
Vapour Pressure	4.4 kPa at 25°C	Measured
Water Solubility	<1 mg TOC/L at 20 ± 0.5 °C	Measured
Hydrolysis as a Function of pH	Not determined.	The notified chemical does not contain hydrolysable functionality.
Partition Coefficient (n-octanol/water)	$\log P_{OW} = 4.40 \text{ to } > 6.50 \text{ at } 20^{\circ}\text{C}$	Measured
Adsorption/Desorption	$\log K_{oc} = 2.05 \text{ to } > 5.63$	Measured
Dissociation Constant	Not determined.	No acid or base groups are present and the water solubility is very low.
Flash Point	-18°C at 101.3 kPa	Measured
Flammability	Upper: 6%	Provided by notifier, source not
-	Lower: 1%	specified.
Autoignition Temperature	256°C	Measured

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 (ie $< 7 \times 10^{-6} \text{ m}^2/\text{s}$). 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

Expected to be stable under normal conditions of use. However, it is highly flammable and is expected to burn vigorously if involved in a fire.

Dangerous Goods classification

Based on the available data the notified chemical is classified as follows according to the Australian Dangerous Goods Code (FORS, 1998): Class 3 Flammable Liquid; packaging group II

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS The notified chemical will not be manufactured in Australia.

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	30,000-100,000	30,000-100,000

PORT OF ENTRY

The notified chemical will be imported through major ports throughout Australia, including but not limited to Sydney, Melbourne, Adelaide and Perth.

IDENTITY OF RECIPIENTS

Australian ethylene producers.

TRANSPORTATION AND PACKAGING

The notified chemical will be transported by ship, barge or rail car and off loaded to an on-site storage tank at an appropriate ethylene cracker site.

USF

The notified chemical will be used as a feedstock in ethylene crackers for the production of polyethylene and alpha-olefins.

OPERATION DESCRIPTION

Once the notified chemical has been transported to an ethylene cracker site hoses will be connected to the transport tank and it will be off loaded into on-site storage tanks. A vacuum back flush system will remove the notified chemical from the unloading hoses, which will be further automatically capped on removal to prevent spillage. The few grams of notified chemical that may reside on the surface of the hoses will be allowed to evaporate.

Once in the storage tank, quality control samples will be taken and analysed. The notified chemical will be fed from the storage tank to the ethylene crackers through a pipeline. The produced ethylene will be used to prepare low and high-density polyethylene, alpha-olefins and poly-alpha-olefins. The by-products from the ethylene cracker (various C₃, C₄ and higher olefins, methane, hydrogen and low MW aromatics such as benzene, toluene and ethylbenzene) are separated, purified and marketed. The ethylene crackers tubes are decoked (cleaned) approximately every 30 days by burning off the coke using steam and air in different proportions and at different temperatures for 12-48 hours. The hydrocarbon waste produced during de-coking (which contains ~100 kg of the notified chemical per reactor) is captured with all of the separated materials then incinerated.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	Number/ site	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Unloading	1-2	1-8	3
Sampling and analysis	1-2	0.2	3
Cleaning	1-2	Intermittent	12

EXPOSURE DETAILS

Transport

During transport of the notified chemical to the on-site storage tanks workers are not expected to be exposed to the notified chemical except in the event of a spill or leak.

Industrial Use

While the use of the notified chemical as an ethylene feedstock is an automated and enclosed process, there is still some potential for exposure of workers. Dermal, and accidental ocular exposure to drips, spills and splashes may occur during the connection and disconnection of transfer hoses and during quality control sampling. This exposure is expected to be minimised by the use of personal protective equipment (including gloves, coveralls, eye protection and hard hat) and by the engineering controls (vacuum back flush and hose caps). Inhalation exposure to notified chemical vapours may also occur during these processes, especially as the notified chemical has a high vapour pressure (4.4 kPa at 25°C) and will readily evaporate if spilt.

6.1.2. Public exposure

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

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical and analogues are summarised in the table below. Analogue data has been provided for a number of petroleum derived naphtha streams that together cover the carbon range of the notified chemical (More detailed information on the analogues can be found in Appendix B). Analogue data is listed only for the endpoints in which there was no data on the notified chemical. All tests followed GLP unless otherwise mentioned. Details of the studies conducted on the notified

chemical can be found in Appendix B. The full study reports for the analogues have not been reviewed by NICNAS.

Endpoint	Test Substance	Result and Assessment Conclusion	Source
Rat, acute oral toxicity	Notified chemical	oral LD50 > 5000 mg/kg bw	Safepharm
•		low toxicity	Laboratories
		·	(2006c)
Rat, acute dermal toxicity	Analogue 1	LD50 > 2000 mg/kg bw	API (2003)
,	C	low toxicity	,
Rabbit, acute dermal	Analogue 3	LD50 > 3160 mg/kg bw	IUCLID (2000)
toxicity	C	low toxicity	,
•	Analogue 4	LD50 > 2000 mg/kg bw	IUCLID (2000)
	Č	low toxicity	,
Rat, acute inhalation	Analogue 1	LC50 > 5 mg/L/4 hour	API (2003)
toxicity	Č	low toxicity	, ,
-	Analogue 3	LC50 > 12 mg/L/6 hour	IUCLID (2000)
	Č	low toxicity	, ,
	Analogue 4	LC50 > 5.24 mg/L/4 hour	IUCLID (2000)
	-	low toxicity	, ,
Rabbit, skin irritation	Analogue 1	moderately irritating	API (2003)
	Analogue 3	slightly irritating	IUCLID (2000)
	Analogue 4	moderately irritating	IUCLID (2000)
Rabbit, eye irritation	Analogue 1	non-irritating	API (2003)
•	Analogue 3	slightly irritating	IUCLID (2000)
	Analogue 4	slightly irritating	IUCLID (2000)
Guinea pig, skin	Analogue 1	no evidence of sensitisation	API (2003)
sensitisation – adjuvant test.	Analogue 4	no evidence of sensitisation	IUCLID (2000)
Rat, repeat dose inhalation toxicity – 90 days.	Analogue 2	NOAEL < 2220 ppm	API (2003)
Rat, repeat dose inhalation toxicity, 21 days	Analogue 4	NOAEL > 9.88 mg/L	IUCLID (2000)
Rabbit, repeat dose dermal	Analogue 1	NOAEL > 2000 mg/kg bw/day	API (2003)
toxicity – 28 days.	Analogue 4	NOAEL = 1000 mg/kg bw/day	IUCLID (2000)
, ,	S	LOAEL = 2000 mg/kg bw/day	()
Mutagenicity – bacterial	Notified chemical	non mutagenic	Safepharm
reverse mutation	_	G	Laboratories (2006d)
Genotoxicity – in vitro	Notified chemical	non genotoxic	Safepharm
micronucleus test			Laboratories (2006e)
Genotoxicity – in vivo cytogenetic assay	Analogue 1	non genotoxic	API (2003)
Developmental and reproductive effects	Analogue 2	NOAEL Parental > 24700 mg/m ³	API (2003)
1		NOAEL F1 offspring > 24700 mg/m ³	

Toxicokinetics, metabolism and distribution.

The notified chemical is likely to be absorbed through the lung and the gastro-intestinal tract (Illing 2006). However no effects were seen in the acute oral toxicity study therefore absorption via the gastro-intestinal tract is not confirmed. The notified chemical is expected to be metabolised by ω - or ω -1 oxidation to the alcohol and then to the fatty acid. These fatty acids are then likely to enter intermediary metabolism (including β -oxidation) and be excreted in bile urine and exhaled air (Illing 2006).

Acute toxicity.

The notified chemical is considered to be of low acute toxicity via the oral route based on tests on the notified chemical conducted in rats.

In the acute dermal toxicity study using Analogue 1, apart from skin irritation no clinical signs of toxicity were observed. Skin irritation ranged from slight to severe for erythema and oedema, slight to moderate for atonia and coriaceousness (leathery texture) and slight to moderate for desquamation and fissuring. Subcutaneous haemorrhage, blanching and eschar were also observed.

The acute dermal toxicity study using Analogue 3 was not performed to GLP guidelines. Three rabbits of each sex were exposed to a single dose for 24 hours, no deaths were recorded and clinical signs were reported to be minimal.

The acute dermal toxicity study using Analogue 4 was similar to OECD guideline 402. No deaths were recorded, slight to severe dermal irritation was observed. No systemic effects were evident.

All 10 animals in the acute inhalation study using Analogue 1 survived the test but exhibited languid behaviour and a hunched appearance during exposure

The acute inhalation study using Analogue 3 was not performed to GLP standards. There were no deaths and no significant bodyweight changes, clinical findings or necropsy findings.

In the acute inhalation study using Analogue 4 that was similar to OECD guideline 403, there were no deaths, but languid behaviour and squinted eyes were observed during exposure. There was also minimal incidences of rhinorrhea. Gross post mortem and histopathological findings were not significant.

The notified chemical contains a number of hydrocarbons that are classified as R67: Vapours may cause drowsiness and dizziness.

Based on toxicity data for the notified chemical and read across data, the notified chemical is considered to be of low acute toxicity via the oral and dermal routes. The notified chemical is also considered to be of low toxicity via inhalation but may cause effects on the central nervous system.

Irritation and Sensitisation.

A skin irritation test using Analogue 1 with a 24 hour occlusive exposure and 6 subjects gave a primary irritation index (PII) value of 3.9 and had effects (both erythema and oedema) that were still present at the end of the 14 day study although the effects had decreased from the maximum seen at 96 hours.

The skin irritation study using analogue three was not performed to GLP guidelines. Three rabbits of each sex were treated with 0.5 mL of the test substance for four hours using a semi-occluded patch. Mean draize scores for erythema of between 1 and 2 and for oedema between 0 and 1, were recorded at 24, 48 and 72 hours.

The skin irritation study using Analogue 4 was conducted using six New Zealand white rabbits, which were exposed to 0.5 mL of the test substance for 24 hours to both abraded and non-abraded skin areas using an occluded dressing. The PII was 4.9 indicating the test substance was moderately irritating.

No pain response or corneal or iridal irritation was seen in an eye irritation test using Analogue 1 where 0.1 mL of undiluted test material was applied to one eye in each of the 9 test subjects.

The eye irritation study using Analogue 3 was not performed to GLP guidelines. Six albino rabbits had 0.1 mL of the test substance applied to one eye. Apart from slight irritancy detected at 1 and 4 hours no irritation was observed.

The eye irritation study using Analogue 4 showed slight eye irritation one hour after application but scores were zero at 24, 48 and 72 hours. Nine New Zealand white rabbits were treated with 0.1 mL of the test substance, three had their eyes washed with water after being treated.

Analogue 1 was tested for skin sensitisation using the Buehler method. At challenge one of ten test subjects showed slight erythema as did one control subject. The positive and negative controls gave satisfactory responses, confirming the validity of the test system.

Analogue 4 was tested for skin sensitisation using a closed patch test closely following the Buehler method outlined in OECD guideline 406. It was concluded that the test substance was not sensitising.

Based on read across data, the notified chemical is considered to be moderately irritating to skin, a slight eye

irritant and is not considered to cause sensitisation by skin contact.

Repeated Dose Toxicity (sub chronic).

In a 90 day repeat dose inhalation toxicity study on Analogue 2, groups of 12 male and 12 female rats underwent whole body exposures to 668, 2220 and 6646 ppm for six hours per day, five days per week for 13 weeks, followed by a 28 day recovery period. No mortalities were recorded during the study. Both sexes in the high dose group showed an increased incidence of red facial staining. Haematological and clinical chemical measurements were unaffected except for a 5% decrease in haemoglobin and haematocrit and a 7% decrease in erythrocytes, however these changes were considered toxicologically unimportant as they were within the historical range for the control. Kidney weights were increased in males at all dose levels and liver weights were also increased for the high doses male and female test groups. The NOEL for subchronic toxicity was determined to be 2220 ppm and for neurotoxicity was determined to be 6646 ppm.

In a 21 day repeat dose inhalation toxicity study on Analogue 4, groups of 20 animals (male and female) were exposed to 1.13, 3.48 and 9.88 mg/L for six hours a day, five days per week for 21 days. No treatment related effects considered relevant in humans were observed.

A 28 day repeat dose dermal toxicity study was conducted using Analogue 1 at doses of 200, 1000 and 2000 mg/kg bw/day. No mortalities were recorded during the study. Weight gains of treated animals over the course of the study were similar to controls except for females in the high dose group, where the weight gain was significantly reduced, this was considered to be a treatment related effect. There were no remarkable findings in haematological data. Minimal to moderate irritation was seen in the skin of all animals treated with the test substance.

A 28 day repeat dose dermal toxicity study was also conducted using Analogue 4 at doses of 200, 1000 and 2000 mg/kg bw/day. All animals treated with the test substance showed slight to severe skin irritation and animals in the high dose group showed a significant decrease in their bodyweight. No treatment related trends were evident from the haematology, clinical chemistry parameters and organ weight data.

The notified chemical is stated to contain $\geq 5\%$ n-hexane which is classified as R48/20: Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Mutagenicity.

The notified chemical was negative in an Ames test and an *in vitro* micronucleus test. The notified chemical is not considered to be mutagenic or genotoxic.

In the in vivo cytogenetic assay on Analogue 1 (API 2003) no evidence of genotoxicity was observed. In the cytogenetics assay 5 of 18 male and 4 of 18 female test subjects receiving 3000 mg/kg bw died within 3 days. Weight losses of 10 and 9% were seen in male and female test subjects respectively, other signs of toxicity included piloerection, crusty eyes and noses and excess lacrimation. The positive and negative controls gave satisfactory responses, confirming the validity of the test system.

Toxicity for reproduction.

Analogue 2 was tested in an adaptation of the Reproduction/Developmental Toxicity Screening Test (OECD 421). No animals died during the study, body and organ weights were unaffected and there were no treatment related histopathological findings. No reduction in the fertility of the test subjects was observed. No significant increase in developmental effects was observed when compared to the controls.

Although the tests on Analogue 2 indicated that the notified chemical may not be a reproductive toxin, the notified chemical is stated to contain $\geq 5\%$ n-hexane which is classified as Toxic to Reproduction Category 3 R62 Possible risk of impaired fertility.

Classification

Based on the read across data for skin irritation test and the viscosity of the notified chemical, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

As the notified chemical has not been tested for its health effects as a whole for a number of endpoints, the notified chemical is also classified as hazardous under the Approved Criteria for Classifying Hazardous

Substances (NOHSC, 2004) based on the presence of hexane (CAS No. 110-54-3) at \geq 5% and other hydrocarbons.

The analogue petroleum derived naphtha streams are classified as Carc Cat 2, R45 may cause cancer. However this classification need not apply if it can be shown that the substance contains less than 0.1% w/w benzene. As the notified chemical contains less than 0.1% w/w benzene, classification with the risk phrase R45 is not required.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Due to the presence of hexane in the notified chemical it is classified as R48/20 danger of serious damage to health by prolonged exposure through inhalation. Inhalation exposure to the notified chemical during the connection and disconnection of transfer hoses should be reduced by the engineering controls present. The presence of hexane and information on its exposure standard are included in the MSDS provided. Management of airborne concentrations below the recommended occupational standard should minimise the risk of adverse health effects.

There is also a risk to the occupational health and safety of workers from dermal exposure to the notified chemical as it is classified as a skin irritant. Dermal exposure to the notified chemical is most likely to occur during the connection and disconnection of transfer hoses, however engineering controls and the use of PPE should reduce this. In addition, the high vapour pressure of the notified chemical is likely to limit dermal uptake of the chemical (especially for the shorter chain hydrocarbons) due to evaporation from the skin.

The notified chemical is classified under the Australian Dangerous Goods Code as a Class 3 Flammable Liquid; packaging group II. The risk to workers is greatest during the connection and disconnection of transfer hoses, however engineering controls should reduce this.

Overall, although the notified chemical is classified as hazardous the low exposure expected from the proposed use ensures that the risk to the occupational health and safety of workers is not considered to be unacceptable.

6.3.2. Public health

The notified chemical will be available only to industrial end users. The unlikely but potential public exposure through accidents during importation, transportation or storage is assessed as very low and hence the risk to the public health from the notified chemical is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be synthesised overseas and will be imported into Australia. Therefore, environmental release within Australia will not occur at this stage.

RELEASE OF CHEMICAL FROM USE

The notified chemical is a site-limited intermediate used for the production of polyethylene and alpha-olefins. A vacuum back flush system removes the notified chemical from the unloading hoses, which is further automatically capped on removal to prevent spillage. It is estimated by the notifier that only a few grams that reside on the surface of the hoses will be allowed to evaporate. Practically all notified chemical will be consumed in the synthesis process.

RELEASE OF CHEMICAL FROM DISPOSAL

Due to the nature of the notified chemical and the dedicated handling equipment used to transfer the notified chemical from import containers to receiving vessels, only a very small quantity is expected to be released in effluents or in fugitive emissions. Due to the volatile nature of the notified chemical and its low water solubility, releases are expected to ultimately partition to air.

7.1.2 Environmental fate

No studies of the biodegradability of the notified chemical were available. Brief details of biodegradation studies are available for two related substances (Girling, AE and Fisk, PR, 2006).

Biodegradation studies of Analogue 5 reported 89% and 98% degraded in 28 days. The study was conducted to OECD Guideline 301F (CEFIC-HSPA 2002).

A biodegradation study of Analogue 6 reported 10% degraded in 28 days. This was a closed bottle study, not appropriate to poorly soluble substances (Exxon Biomedical Sciences, Inc. 1988).

Measured data for representative individual components have also been sought (Girling, AE and Fisk, PR, 2006). Data for "various components" were found in the public domain, and are in agreement with the degradabilities that have been assigned when predicting the biodegradability of the substance.

The results of modelling show that 67.5% of the mass of the substance would be considered readily biodegradable, passing the 10-day window, 22.5% would be readily biodegradable not passing the 10-day window and 10% would be inherently biodegradable.

Girling, AE and Fisk, PR (2006) indicate that a reasonable conclusion that can be drawn from both the test and predicted data is that, overall, the notified chemical should be considered to be readily biodegradable. The test data also support the view that the substance passes the 10-day window criterion for ready biodegradability. The measured data found in the literature for Analogue 1 supports this conclusion.

The predicted log $K_{\rm OW}$ values of the chemical components of the notified chemical range from 2.3 to 5.3 with approximately 80% of the mass having values > 3.0. In the absence of a measured bioconcentration factor (BCF) a log $K_{\rm OW}$ value that is > 3.0 is taken as an indicator of bioaccumulation potential. The components would therefore be expected to have the potential to bioaccumulate. However, Girling, AE and Fisk, PR (2006) state that the bioaccumulation potential may not be realised because of the high degradability potential of the component hydrocarbons.

7.1.3 Predicted Environmental Concentration (PEC)

As release to the aquatic compartment is not expected, it is not possible to calculate an aquatic Predicted Environmental Concentration.

7.2. Environmental effects assessment

There are no measured aquatic toxicity data for the notified chemical. However there are data for related commercial substances. These data are summarised in the table below. It should be noted that the original study reports have not been reviewed and have been reproduced from the supplied paper (Girling, AE and Fisk, PR, 2006).

Analogue	Result (mg/L)	Method	Reference
3	96 h LC ₅₀ = 10-18	Oncorhynchus mykiss. Data summarises valid acute toxicity data using Water Accommodated Fraction (WAF) method and covers 8 studies.	
4	96 h $LL_{50} = 27$	Menidia beryllina. Test solutions were prepared using a Water Accommodated Fraction (WAF) methodology.	CONCAWE (2001)
3	48 h EC ₅₀ = 4.5-32	Daphnia magna. Data summarises valid acute toxicity data for LBPN's using Water Accommodated Fraction (WAF) method and covers 6 studies.	CONCAWE (2001)
4	$48 \text{ h EL}_{50} = 2.0$	Mysidopsis bahia. Test solutions were prepared using a Water Accommodated Fraction (WAF) methodology.	CONCAWE (2001)
5	$48 \text{ h LC}_{50} = 2.0$	Mysidopsis bahia. Semi-static test.	Adema (1987)
6	96 h $LC_{50} = 2.6$	Chaetogammarus marinus. Semi static test in closed vessels.	Exxon Chemical International Inc. (1988)
3	72 h $EL_{50} = 3.1 - 30000$	Selenastrum capricornutum. Data summarises valid acute toxicity data using Water Accommodated Fraction (WAF) method and covers 11 studies.	CONCAWE (2001)
5	$72 \text{ h EC}_{50} = 6.5 \text{ (NOEC} = 0.1)$	OECD 201. <i>Selenastrum capricornutum</i> . Closed vessels. Included chemical analysis and GLP.	Springborn Laboratories Inc. (1993)

The results obtained by measurement in acute tests with related substances, and by prediction using QSAR methodology (Girling, AE and Fisk, PR, 2006) are consistent for fish and invertebrates. Both sets of data give lowest LL₅₀ or EL₅₀ values that are in the range of 1-10 mg/L. The predicted acute EL₅₀ value for algae of 0.55 mg/L falls just below the lowest measured values that are in the range of 1-10 mg/L.

7.2.1 Predicted No-Effect Concentration

Using the most sensitive endpoint identified (Algae EL₅₀), the PNEC has been calculated using an assessment factor of 100.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Algae EL ₅₀	0.55	mg/L
Assessment Factor	100	
PNEC:	5.5	μ g/L

7.3. Environmental risk assessment

While the notified chemical's aquatic hazard is classified as being Acute Category 1, there will be limited, if any, aquatic release during use, and based on the proposed use pattern and expected negligible environmental exposure, the notified chemical is not considered to pose a risk to the environment.

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:

- Xi: R38 Irritating to skin.
- Xn: R48/20 Danger of serious damage to health by prolonged exposure through inhalation.
- Xn: R62 (category 3) Possible risk of impaired fertility.
- Xn: R65 May cause lung damage if swallowed.
- Xn: R67 Vapours may cause drowsiness and dizziness.
- S3 Keep in a cool place
- S9 Keep container in a well-ventilated place
- S16 Keep away from sources of ignition No smoking
- S24 Avoid contact with skin
- S36/37 Wear protective clothing and suitable 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
Specific Target Organ Toxicity – Single Exposure	Category 3	May cause drowsiness and dizziness
Flammable liquids	Category 2	Highly flammable liquid and vapour
Environment	Acute Category 1	Very toxic to aquatic life

The above classification of the notified chemical using the GHS does not take into account the presence of hexane.

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 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 health and physico-chemical hazard classification and safety phrases for the notified chemical:
 - Xi: R38 Irritating to skin.
 - Xn: R48/20 Danger of serious damage to health by prolonged exposure through inhalation.
 - Xn: R62 Possible risk of impaired fertility.
 - Xn: R65 May cause lung damage if swallowed.
 - Xn: R67 Vapours may cause drowsiness and dizziness.
 - S3 Keep in a cool place
 - S9 Keep container in a well-ventilated place
 - S16 Keep away from sources of ignition No smoking
 - S24 Avoid contact with skin
 - S36/37 Wear protective clothing and suitable 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:
 - Conc \geq 20%: R38; R67; R65
 - $\geq 15\%$ Conc < 20%: R67; R65
 - $\geq 10\%$ Conc < 15%: R65

The risk phrases R62 and R48/20 should be assigned based on the hexane content of the product/mixture.

- 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 (including danger of serious damage to health by prolonged exposure through inhalation and possible risk of impaired fertility), employers should determine whether health surveillance is required for any worker where the workplace risk assessment identifies a significant risk to health.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
 - Vacuum back flush system to remove the notified chemical from the unloading hoses

- Local and/or general ventilation 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 skin 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.

- 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 cool, well ventilated area away from sources of ignition

Emergency procedures

• 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(2) of the Act; if

- the function or use of the chemical has changed from a feedstock in ethylene crackers, 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.

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

 $< -20^{\circ}C$

Freezing Point

Method EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks No significant protocol deviations. GLP compliant.

No change in the appearance of the test material was observed.

Test Facility Safepharm Laboratories (2006a)

62-181°C at 100.8 kPa **Boiling Point**

Method ASTM D 86, Standard Test Method for Distillation of Petroleum Products at Atmospheric

Pressure

Remarks The initial determination of the boiling point range was determined in the SafePharm

> Laboratories using the distillation method according to the EC Directive 92/69/EEC A.2 Boiling Temperature. In this initial test approximately 96% of the test material boiled in the range of 59 to 154°C. However, it was considered by the test laboratory that this was

not appropriate for test materials of this nature.

Therefore, the boiling point range was determined at Shell Research Ltd (non-GLP) using the ASTM D 86 method. This method uses specific apparatus that controls heating rate, temperature of the condenser and temperature of the collection vessel. These parameters are very specific for a particular petroleum product type and can have a significant effect

on the boiling temperature obtained.

Test Facility Safepharm Laboratories (2006a)

701 kg/m³ at 20°C **Density**

Method EC Directive 92/69/EEC A.3 Relative Density. Remarks No significant protocol deviations. GLP compliant.

The density was determined using the pycnometer method.

Test Facility Safepharm Laboratories (2006a)

4.4 kPa at 25°C Vapour Pressure

Method EC Directive 92/69/EEC A.4 Vapour Pressure. No significant protocol deviations. GLP compliant. Remarks

The vapour pressure was determined using an isoteniscope system at 48.2 – 79.5°C and

linear regression.

The test was conducted without prior degassing in order to minimise the loss of volatile

components.

Test Facility Safepharm Laboratories (2006b)

Water Solubility <1 mg TOC/L for C_{4-10} at $20\pm0.5^{\circ}C$

Method EC Directive 92/69/EEC A.6 Water Solubility.

Due to the test material being a very complex mixture of hydrocarbons, and it also being Remarks

essentially insoluble in water, analysis of the sample solutions was performed monitoring the TOC content of the sample solutions only. The preliminary water solubility test indicated that the solubility was less than 1x10⁻² g/L. However, due to the physical nature of the test material, it was not possible to use the column method; experience has shown that liquid test materials coated onto glass beads cause these beads to adhere together

forming a plug within the column and thus preventing water circulation.

Mixtures of test material and water were added to three separate flasks to obtain a nominal loading concentration of 0.10 g/L of solution. After shaking at approximately 30°C and subsequently standing for 20°C for 24 h, the contents of the flasks were centrifuged. Each supernatant was then sampled excluding excess, undissolved test material and was analysed using a Shimadzu TOC-5050A instrument to determine the

total organic carbon (TOC) content in solution. No significant protocol deviations. GLP

compliant.

Test Facility Safepharm Laboratories (2006b)

Partition Coefficient (n-

 $\log P_{OW} = 4.40 \text{ to } > 6.50 \text{ at } 20^{\circ}\text{C}$

octanol/water)

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

Remarks HPLC Method. 0.5124 g was diluted to 10 mL with methanol. Peaks from the notified

chemical eluted after the reference substances Naphthalene, Phenanthrene, Triphenylamine and DDT. By percentage are normalisation, 60.2% of the test material

had a Pow value greater than 6.50.

Test Facility Safepharm Laboratories (2006b)

Adsorption/Desorption

 $\log K_{oc} = 2.05 \text{ to } > 5.63$

- screening test

Method Remarks EC Directive 67/548/EEC C19.

HPLC Method. Peaks from the notified chemical eluted after the reference substances Atrazine, Linuron, Naphthalene, Endosulfan-diol, Fenthion, α-Endosulfan, Phenanthrene,

Diclofop-methyl, DDT.

The test material was known to primarily be a complex mixture of alkanes and therefore a majority of the components were not anticipated to absorb in the UV region. Preliminary assessment of the test material therefore used a refractive index (RI) detector. Unfortunately, unlike the partition coefficient, fraction collection and GC analysis indicated that negligible components were successfully eluted when maintaining an isocractic mobile phase, in this case at a ratio of 55:45 v/v methanol:water as required by the method guideline. A gradient increase in the methanol content of the mobile phase composition was therefore required at a time greater than the retention time of the highest calibration standard to elute a majority of the test material. This requirement for a gradient method invalidated the use of the RI detector. This is since the detector baseline is adversely affected by the continuing shift in the refractive index of the mobile phase caused by the gradient. Therefore the sample was monitored in the far UV region, possibly detecting trace levels of aromatics, and the elution of the test material confirmed by fraction collection and subsequent GC analysis.

With the exception of the component at a GC retention time of approximately 5.1 minutes, all the major components of the test material were positively detected in the analysed fractions. The absence of this single component was noted but concluded not to impact on the validity of the test. This was since a significant majority of the test material, greater than 90%, had been successfully detected and quantified.

The retention time limit value used for the calculation of the adsorption coefficient for those components identified in the collected fractions represent the start of the amended 100% methanol mobile phase. All these components share a common adsorption coefficient value, that of greater than the highest calibration standard. The method guideline states that the measurement of adsorption coefficient be performed on the ionised and unionised form of the test material. However, in the absence of any dissociating groups, the test material being a mixture of alkanes, the determination was performed at an approximately neutral pH only, on the test material in an unionised form.

The adsorption coefficient of the test material has been determined to be $\log K_{oc} = 2.05$ to >5.63. By fraction collection and subsequent GC analysis, 91.4% of the test material had a $\log K_{oc}$ >5.63, calculated from GC normalisation data.

Test Facility

Safepharm Laboratories (2006b)

Flash Point

-18°C at 101.325 kPa

Method

EC Directive 92/69/EEC A.9 Flash Point.

Remarks No significant protocol deviations. GLP compliant.

The closed cup method was used.

Test Facility Safepharm Laboratories (2006b)

Autoignition Temperature 256°C

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks No significant protocol deviations. GLP compliant.

Test Facility Safepharm Laboratories (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 B.1bis Acute Toxicity (Oral) Fixed Dose

Species/Strain Rat/Sprague-Dawley CD (Crl : CD® (SD) IGS BR) Vehicle Test substance was used as supplied. GLP compliant.

Remarks - Method No significant protocol deviations. A preliminary test was done on one

> female rat in which there were no deaths at a dose rate of 5000 mg/kg bodyweight, an additional four fasted female rats were then treated at this

dose rate.

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	1 female	5000	0
2	4 females	5000	0
LD50 Signs of Toxicity		leaths or test substan	ce-related clinical signs or study period.

Effects in Organs There were no remarkable necropsy findings.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Safepharm Laboratories (2006c)

B.2. Genotoxicity – bacteria

Notified chemical TEST SUBSTANCE

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test

using Bacteria.

Plate incorporation procedure

Species/Strain S. typhimurium: TA1535, TA1537, TA98, TA100

E. coli: WP2uvrA-

Metabolic Activation System

S9 fraction derived from Phenobarbital/β-napthoflavone induced rat liver

Concentration Range in Main Test

a) With metabolic activation: $0.5 - 5000 \,\mu g/plate$ b) Without metabolic activation: 1.5 - 5000 μg/plate

Vehicle

Acetone; test substance applied as solution

Remarks - Method No significant protocol deviations. GLP compliant.

RESULTS

Metabolic	Test	Substance Concentrati	ion (µg/plate) Resultii	ng in:
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect
	Preliminary Test	Main Test		
Absent				
Test 1	500	500	5000	Negative
Test 2		500	5000	Negative
Present				
Test 1	1500	500	5000	Negative
Test 2		500	5000	Negative

Remarks - Results

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any dose level, either with or without metabolic activation.

A visible reduction in the background lawn was seen in the Salmonella tester strains, with and without metabolic activation and predominantly in the base-pair substitution strains.

The positive and negative controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions

of the test.

TEST FACILITY Safepharm Laboratories (2006d)

Genotoxicity - in vitro

TEST SUBSTANCE Notified chemical

METHOD Draft OECD TG 487 In vitro Micronucleus Test.

Species/Strain Human

Cell Type/Cell Line Peripheral lymphocytes

Metabolic Activation System

Vehicle

Remarks - Method

S9 fraction derived from Phenobarbital/β-napthoflavone induced rat liver Not specified

The draft guideline OECD TG 487 In vitro Micronucleus Test was modified to more closely resemble the guideline OECD TG 473 In vitro Mammalian Chromosome Aberration Test. The modification made was the adoption of the exposure groups from the OECD 473 guideline in preference to those suggested in the draft OECD 487 guideline.

The maximum treatment concentration (1250 µg/mL) was chosen based on a preliminary toxicity study in which above this concentration the notified chemical formed an oily layer on top of the culture medium.

GLP compliant.

Metabolic	Test Substance Concentration (µg/mL)	Exposure	Expression	Selection
Activation		Period	Time	Time
Absent				
Test 1	0*, 39, 78.1, 156.25, 312.5*, 625*, 1250*	4 hours	16 hours	28 hours
Test 2	0*, 4.88, 9.75*, 19.5*, 39*, 78.1, 117.2	20 hours	0 hours	28 hours
Present				
Test 1	0*, 39, 78.1, 156.25, 312.5*, 625*, 1250*	4 hours	16 hours	28 hours
Test 2	0*, 39, 78.1, 156.25, 312.5*, 625*, 1250*	4 hours	16 hours	28 hours

^{*}Cultures selected for metaphase analysis.

RESULTS

Metabolic	Tes	st Substance Concentra	ution (µg/mL) Resultin	g in:
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect
	Preliminary Test	Main Test		
Absent				
Test 1	>1250	>1250	>1250	Negative
Test 2	156.25	78.1	>117.2	Negative
Present				
Test 1	>1250	>1250	>1250	Negative
Test 2	>1250	>1250	>1250	Negative

Remarks - Results

In both experiments in the absence and presence of metabolic activation, no biologically relevant increase in the number of cells carrying structural chromosome aberrations was observed.

The positive and negative controls gave satisfactory responses,

confirming the validity of the test system.

CONCLUSION The notified chemical was not clastogenic to human lymphocytes treated

in vitro under the conditions of the test.

TEST FACILITY Safepharm Laboratories (2006e)

B.4. Analogues

The identities of the petroleum derived analogues considered for each of the endpoints where no information was available on the notified chemical are listed in the table below:

Ana- logue	Substance	Class	CAS No	Description	Reference
1	Light alkylate naphtha	Naphthas in the range C5-C10	64741- 66-8	Paraffinic naphtha streams are obtained by alkylation (catalytic reaction), isomerization (catalytic conversion) and solvent extraction. They contain mostly saturated hydrocarbons, generally in the range C5 to C10 and boil in the range of 90 to 160°C.	API (2003)
2	Light alkylate naphtha distillate (LAN-D)	Naphthas in the range C4-C10	Not specified	A distillate fraction of light alkylate naphtha. The composition is as follows; Carbon number Volume % 4 3.25 5 33.3 6 18.61 7 9.81 8 31.14 9 3.21 10 0.39 The composition of the test substance used in the reproduction/developmental toxicity screening	API (2003)
3	Heavy hydrodesulphurized naphtha	Naphthas in the range C7-C12	64742- 82-1	contained only C4 and C5 hydrocarbons A complex combination of hydrocarbons obtained from a catalytic hydrodesulfurization process. It consists of hydrocarbons having carbon numbers predominantly in the range of C7 through C12 and boiling in the range of approximately 90°C to 230°C (194°F to 446°F).	IUCLID (2000)
4	Naphtha (petroleum), heavy thermal cracked	Naphthas in the range C6-C12	64741- 83-9	A complex combination of hydrocarbons from distillation of the products from a thermal cracking process. It consists predominantly of unsaturated hydrocarbons having carbon numbers predominantly in the range of C6 through C12 and boiling in the range of approximately 65°C to 220°C (148°F to 428°F).	IUCLID (2000)`
5	Naphtha (petroleum), hydrotreated light	Naphthas in the range C4-C11	64742- 49-0	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 C4 through C11 and boiling in the range of approximately minus 20°C to 190°C (-4°F to 374°F).	
6	Naphtha (petroleum), hydrotreated heavy	Naphthas in the range C6-C13	64742- 48-9	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 C6 through C13 and boiling in the range of approximately 65°C to 230°C (149°F to 446°F).	
7	Low boiling point Naphtha	Naphthas in the range C4-C11	64742- 49-0 and 64742- 89-8	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 C4 through C11.	CONCAWE (2001)
8	Solvent Naphtha, petroleum, light aliphatic	Naphthas in the range C5-C10	64742- 89-8	A complex combination of hydrocarbons obtained from the distillation of crude oil or natural gasoline. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C5 through C10.	CONCAWE (2001)
9	Alkylated Naphtha		Not assigned but in	Naphtha (petroleum) solvent refined light (Substance contains benzene)	Adema (1987) and Springborn Laboratories Inc.

10	Norda -		IUCLID for 64741- 81-0	Norther (catalogue) or house of and links (Substance	(1993)	
10	Naphtha		64742- 48-9	Naphtha (petroleum) solvent refined light (Substance contains benzene)	Exxon Chemical International Inc.	
					(1988)	
Various Components		Hexane (confidential IUCLID), 2-methylpentane (confidential IUCLID), 2-methylbutane (Solano-				
		Serena, 2000) and n-decane (Verschueren, 1983; Wakeham, 1986)				

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