File No: SN/23

November 2014

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)**

# PUBLIC REPORT

## GTL Gasoil

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

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

This 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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**Director**
**NICNAS**

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# SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

| ASSESSMENT REFERENCE | APPLICANT(S) | CHEMICAL OR TRADE NAME | HAZARDOUS CHEMICAL | INTRODUCTION VOLUME | USE |
|---|---|---|---|---|---|
| SN/23 | The Shell Company of Australia Ltd | GTL Gasoil | Yes | ≤ 585,000 tonnes per annum | Diesel fuel, drilling fluid and solvent applications |

*ND = not determined

# NOTE

Since the finalisation of this Report, the applicant The Shell Company of Australia Limited has changed its name and address details. Current details as of February 2020 are:

Viva Energy Australia Pty Ltd (ABN 46 004 610 459)
Level 16, 720 Bourke Street
Docklands VIC 3008

# CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

| *Hazard classification* | *Hazard statement* |
|---|---|
| Flammable Liquids (Category 4) | H227 – Combustible liquid |
| Aspiration Hazard (Category 1) | H304 - May be fatal if swallowed and enters airways |

In Australia, additional non-GHS hazard statements apply (see *Guidance on the Classification of Hazardous Chemicals Under the WHS Regulations* for further information; SWA, 2012a). Based on the available information, the following additional (non-GHS) hazard statement is also recommended:

AUH066 – Repeated exposure may cause skin dryness and cracking

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

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

**Human health risk assessment**
Provided that control measures (e.g. containment and/or adequate ventilation and appropriate PPE, such as coveralls, impervious gloves and respiratory protection, as applicable) are in place to minimise worker exposure, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

**Environmental risk assessment**
On the basis of the PEC/PNEC ratio and the assessed use patterns, the notified chemical is not considered to pose an unreasonable risk to the environment.

**Recommendations**

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Aspiration Hazard (Category 1): H304 - May be fatal if swallowed and enters airways
  - AUH066 - Repeated exposure may cause skin dryness and cracking

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

(Material) Safety Data Sheet

- The (M)SDS of the notified chemical should reflect the hazards associated with the notified chemical (as indicated above).

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical itself (and if hazards are relevant for products containing the notified chemical):
  - Enclosed, automated processes, where possible
  - Local and/or general ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical itself (and if hazards are relevant for products containing the notified chemical):
  - Use only in well ventilated areas
  - If swallowed, seek medical advice immediately
  - Avoid skin contact
  - Avoid inhalation
  - Workers should have adequate education and training before handling the notified chemical.

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical itself (and if hazards are relevant for products containing the notified chemical):
  - Gloves
  - Coveralls
  - Respiratory protection, if significant inhalation exposure is expected and/or during spray application.

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012b) or relevant State or Territory Code of Practice.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- As liquid hydrocarbons are included in Schedule 5 of the SUSMP, any labelling and/or packaging requirements for products containing the notified chemical, which are available to the public, should be adhered to.

- Cosmetic products containing the notified chemical should be formulated in a manner that addresses the hazards of the notified chemical.

- The notified chemical should not be used in products available to the public that are intended to be applied by spray.

- When used as a fuel for domestic heating purposes, the notified chemical should be stored in tanks that are installed, maintained and used in accordance with relevant local council and/or state or territory requirements and any obligations under the Building Code of Australia.

Disposal

- The notified chemical should be disposed of to landfill.
- The notified chemical in fuel should be disposed of in accordance with local regulations for recycling, re-use or recovery of calorific content.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012c) or relevant State or Territory Code of Practice.

Emergency procedures

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

**Regulatory Obligations**

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

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

(1) Under Section 64(1) of the Act; if
  - the notified chemical is expected to be used in products available to the public, that are intended to be applied by spray;
  - the concentration of the notified chemical is intended to exceed 45% in mascaras, 20% in face creams and 10% in roll-on deodorants;
  - the notified chemical is intended to be used in applications associated with hydraulic fracturing or coal seam gas operations;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from diesel fuel, drilling fluid or solvent applications, or is likely to change significantly;

- the notified chemical is proposed to be used in cosmetic products other than mascaras, face creams and roll-on deodorants;
- the amount of chemical being introduced has increased from 585,000 tonnes per annum, or is likely to increase, significantly;
- 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 (M)SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

# ASSESSMENT DETAILS

## 1. APPLICANT AND NOTIFICATION DETAILS

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

Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* [the IC(NA) Act], as STD/1270, with the Summary Report of the assessment published in the *Chemical Gazette* of 2nd October, 2008.

The Director of NICNAS was informed of additional proposed uses of the notified chemical. Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical formerly known as GTL Diesel.

In accordance with Section 65 of the IC(NA) Act, a notice requiring the secondary notification of GTL Diesel was published in the *Chemical Gazette*. The notice of 7th February, 2012 stipulated that the following data were required to undertake further assessment of GTL Diesel:

Any changes in the following data items from that submitted in the original notification:

a. proposed uses and concentrations of the chemical;
b. import quantity (and transportation and packaging);
c. operation description;
d. occupational, public and environmental exposure associated with the proposed uses (including introduction, reformulation, use, recovery and disposal);
e. physico-chemical properties; and
f. any additional toxicity or ecotoxicity data that is available.

This report, SN/23, represents the revised assessment for GTL Diesel which will now be known as GTL Gasoil. Where additional data has been provided, it has been incorporated into the report (if necessary) and the implications of the data for the health and environmental risks of the notified chemical considered.

NOTIFICATION CATEGORY
Secondary notification.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, impurities, use details, import volume and identities of analogue chemicals.

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)
STD/1270 (Marketing name GTL Diesel)

NOTIFICATION IN OTHER COUNTRIES
Unites States; Canada, Korea, European Union, China, New Zealand, Philippines

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
GTL, Gasoil, GTL Diesel, GTL Distillate fuel, GTL gas oil, F-T diesel, F-T gas oil, F-T distillate, Saraline 98V, Saraline 185V, Saraline 200, Sarasol 100, Sarasol 200, Shell GTL Fluid G65, Shell GTL Fluid G75, Shell GTL Fluid G85.

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

MOLECULAR WEIGHT
< 500 Da

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

## 3. COMPOSITION

DEGREE OF PURITY 100% (Complete mixture)

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid

*Original notification*

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point/Freezing Point | -20 °C (< 25 3°K) | Measured |
| Boiling Point | 278 °C (mean value) at 101.3 kPa | Measured |
| Density | 780 kg/$m^3$ at 20 °C | Measured |
| Vapour Pressure | 5.4 x $10^{-4}$ kPa at 25 °C | Measured |
| Viscosity | 5.50 x $10^{-6}$ $m^2$/s at 20 °C<br>3.42 x $10^{-6}$ $m^2$/s at 40 °C | Measured |
| Water Solubility | < 0.001 g/L (1.0 x $10^{-3}$ g TOC/L) at 20 °C | Measured |
| Hydrolysis as a Function of pH | Not tested, but expected to be stable. | The hydrocarbon components in the notified chemical have no hydrolysable functionality. |
| Partition Coefficient (n-octanol/water) | log Pow > 6.5 at 20 °C | Measured (HPLC method). |
| Adsorption/Desorption | log $K_{oc}$ > 5.63 at 40 °C | Measured (HPLC method). |
| Dissociation Constant | Not determined | No dissociable functionality. |
| Flash Point | 94 ± 2 °C at 101.33 kPa | Measured |
| Flammability Limits | Upper: 6%<br>Lower: 1% | Analogue data |
| Autoignition Temperature | 208 ± 5 °C | Measured |
| Explosive Properties | Not explosive | Estimated |

*Secondary notification*

| Property | Value | Data Source/Justification |
|---|---|---|
| Vapour Pressure | 0.1 kPa at 25 °C | Measured, Grabner method, study not available. |

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

The viscosity of the notified chemical (3.42 x $10^{-6}$ $m^2$/s at 40 °C) indicates that the notified chemical is an aspiration hazard according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* and the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). See Section 6.2 for further details regarding the health hazard classification.

While the measured flash point of the notified chemical is 94 ± 2 ºC at 101.33 kPa, the notifier indicated that the flash point is variable (> 60 °C, with a typical value of 80-95 ºC).

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

***Physical hazard classification***
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

| ***Hazard classification*** | ***Hazard statement*** |
|---|---|
| Flammable Liquids (Category 4) | H227 – Combustible liquid |

## 5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical 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* | *tonnes* | *tonnes* | *tonnes* | *tonnes* |
| *Original notification* | 30,000-100,000 | 30,000-100,000 | 30,000-100,000 | 100,000-170,000 | 100,000-170,000 |
| *Maximum total (based on secondary notification)* | 30,000-100,000 | 30,000-100,000 | 30,000-100,000 | 100,000-170,000 | < 415,000 |

PORT OF ENTRY
*Original notification*
Any major Australian port where a petroleum refinery is located.

*Secondary notification*
Dampier, Freemantle, Perth, Brisbane, Melbourne and Sydney.

IDENTITY OF RECIPIENTS
*Original notification*
Australian refineries

*Secondary notification*
The Shell Company of Australia and/or their distributors.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in bulk by ship and transported in bulk through pipelines. Barge or truck transport will also be used.

USE
The notified chemical was originally notified for use as a fuel for diesel power cars, trucks, off road equipment, agriculture, power plants and marine applications.

Under the secondary notification, the notified chemical is also proposed to be used: as a drilling fluid for oil and gas operations (~37% of the additional import volume); in solvent applications (~62% of the additional import volume; broad range of solvent applications, both industrial and in products available to the public, e.g. use in cosmetics); and as domestic heating fuel (~1% of the additional import volume).

OPERATION DESCRIPTION

*Original Notification: Use in fuel*

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

From its storage tank, the notified chemical will be managed in two possible ways through pipelines:

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

The notified chemical will be distributed from the refinery to end users by truck or by marine barge. There will be no rail or drum distribution of diesel fuel from refinery to end users. Approximately 50% of the imported volume will go to commercial end users such as trucking fleets, marine, agriculture and construction companies, < 20% to retail truck stops and service stations, approximately 10% to government and military and < 20% to railroads.

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

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

*Secondary Notification:*

*Drilling fluid for oil and gas operations*

The majority of the notified chemical (~90% of the import volume for oil and gas operations) will be used as a synthetic base fluid stock for Non-Aqueous Drilling Fluid (NADF) mud formulations. A small proportion of the notified chemical (~10% of the import volume for oil and gas operations) may be used in water-based muds.

At drilling fluid formulation sites, the notified chemical will be blended with water, emulsifiers, fluid loss additives, viscosity modifiers and barium sulphate in high shear mixers and then pumped to onsite storage tanks, via automated processes. The finished drilling fluid (mud) product will contain 33-50% notified chemical.

The drilling fluid containing the notified chemical will be used in both on-shore (35%) and off-shore (65%) operations. During drilling, the fluid (mud) containing the notified chemical at 33-50% will be circulated down a borehole. The drill mud will remove drill cuttings away from the drill bit and out of the wellbore to a solids control system. After separation from the drill cuttings, the drill fluid will be recycled.

*Solvent applications*

The notified chemical will be used for a broad range of solvent applications. The products will contain the notified chemical at up to 100% concentration. A general operation description is provided below.

In the event of reformulation prior to distribution to the end-users, the notified chemical will be transported to various sites for reformulation processes. The procedures for incorporating the notified chemical into the end-use products will vary depending on the nature of the product formulated. In general, it is expected that the notified chemical will be transferred via automated or manual means from storage containers into the blending apparatus. The end use products will then be transferred into containers of various sizes and transported/sold to end users. The majority of products containing the notified chemical will be used by professionals/industry, but a small proportion (~4% of the additional import volume for solvent uses) may also be used by members of the public. Further information on products that may contain the notified chemical is provided below (with products that may be available for use by members of the public denoted by an asterisk).

*Coatings/Inks/Adhesives**
The notified chemical may be used in coatings, inks and adhesives at up to 50% concentration. The products may be applied by roller, brush or by spray. Spray applications will only occur in industrial settings. The majority of the spray applications are expected to be fully automated (i.e. robotic). Any manual spray applications are expected to be conducted by professionals only and occur in spray booths and/or other adequately ventilated areas. Coatings and adhesives available to the public will not be available as products that are intended to be applied by spray.

*Cleaning agents and household products**
The notified chemical may be used as a component of various cleaning and household products (e.g. all-purpose cleaners) at up to 25% concentration. In an industrial setting, the products may be applied in a number of ways, such as by high or low pressure spray or manual wiping. Any spray applications are expected to be conducted by professionals only and occur in adequately ventilated areas. Cleaning and household products containing the notified chemical at up to 25% concentration, which are available to consumers, will not be available in spray form.

*Lubricants*, metal working fluids and functional fluids**
The notified chemical may be used as a component of lubricants (e.g. for small equipment, bicycles and locks), metal working fluids (for use during the machining and grinding of metal parts to prolong the life of the tools, carry away debris and provide surface protection) and functional fluids (for use in closed systems, e.g. hydraulic fluids, brake fluids, cooling liquids, cable oils and transformer oils) at up to 100% concentration. In an industrial setting, products may be applied in a number of ways, such as by spray or by hand. Any spray applications are expected to be conducted by professionals only and to occur in adequately ventilated areas. Lubricants, metal working fluids and functional fluids containing the notified chemical at up to 100% concentration, which are available to consumers, will not be available in spray form.

*Binders and release agents*
The notified chemical may be used as a binder and release agent in products (such as concrete mould oils for use in the construction industry) at up to 100% concentration. The notified chemical may be applied (by brush, roller or spray) to act as a lubricating barrier to prevent castings (e.g. preformed concrete, metal or synthetic castings) from releasing to the pattern.

*Roads construction*
The notified chemical may be used in road construction applications at up to 53% concentration (e.g. for cutting road grade bitumen to provide temporary reductions in viscosity). Products containing the notified chemical may be applied by brush, roller or spray.

*Water treatment*
The notified chemical may be used in water treatment processes (to dissolve out impurities from water streams or as a carrier in water treatment chemicals) at up to 100% concentration.

*Laboratories*
The notified chemical may be used as a solvent in laboratories at up to 100% concentration.

*Mining*
The notified chemical may be used as a carrier of chelating agents in solvent metal extraction processes at up to 95% concentration (i.e. the metal-chelating agent complex will be removed from the water phase and the metal extracted).

*Explosives*
The notified chemical may be used in the production of slurry explosives at up to 4% concentration. The notified chemical may be mixed with other ingredients (including explosive components and other additives) to produce a doughy mixture. The resulting mixture will be shaped by extrusion and cut into specific lengths for use as explosives.

*Polymer processing and rubber manufacture and processing*
The notified chemical may be used in the processing of polymers using injection moulding processes or in the manufacture of rubber articles (e.g. to improve the dispersion of fillers and flow characteristics of the rubber compound during processing) at up to 100% concentration.

*Cosmetics**
The notified chemical is proposed to be used as an ingredient in specific cosmetic products. These include mascara (at up to 45% concentration), face creams (at up to 20% concentration) and roll-on anti-perspirant deodorants (at up to 10% concentration). The notified chemical will not be used in other type of cosmetics, or in products that will be applied by spray.

iii) Domestic heating fuel
The notified chemical will be used as a domestic heating fuel at up to 100% concentration. Heating fuel containing the notified chemical (at up to 100% concentration) will be delivered directly from a local distribution terminal to end users' domestic storage tanks. The external, domestic vented storage tanks will be maintained and refilled by professionals. The fuel oil may be burned in a number of domestic oil heaters, including boilers and combustion furnaces. Exhausts from the burnt oil will be expelled directly into the atmosphere from the house (e.g. via flue).

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

*Original Notification: Use in fuel*

CATEGORY OF WORKERS

| *Category of Worker** | *Number* | *Exposure Duration (hours/day)* | *Exposure Frequency* |
|---|---|---|---|
| Unloading | 1 | 1-8 hours/shipment | 1-2 times/year |
| Sampling and Analysis | 1 | 10 minutes/shipment | 1-2 times/week |
| Truck & Barge Distribution | 5000 | 1 hour | 240 days/year |
| End-use fuelling | > 10,000 | 10-30 minutes | 200 days/year |

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

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

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

Worker exposure is also expected to be low during initial transfer of GTL Diesel from the storage tank to the refinery, as transfer will occur by pipeline.

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

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

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

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

MEASURED/ESTIMATED EXPOSURE

*Inhalation Exposures:*

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

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

*Dermal Exposures:*

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

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

*Summary Exposure levels:*

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

| Job/Task | Frequency | Duration (minutes) | Inhalation level ($mg/m^3$) | Inhalation dose (mg/day)* | Dermal dose (mg/day) |
|---|---|---|---|---|---|
| Refinery tank farm operator | 5 days/week | 480 | 18 | 180 | 420 |
| Road tanker driver | 5 days/week | 480 | 6 | 60 | 42 |

| | | | | | |
|---|---|---|---|---|---|
| Refuelling vehicle** | Once a week | 5 | 11 | 1 | 21 |

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

*Secondary Notification:*

*Drilling fluid for oil and gas operations*
Workers involved in the transport and storage of the notified chemical would only be exposed to the chemical (at up to 100% concentration) in the unlikely event of an accidental spill or container rupture.

Workers involved in the reformulation of the notified chemical into the drilling fluid (containing 33-50% notified chemical) may be exposed to the notified chemical (at up to 100% concentration) via the dermal, ocular and inhalation routes during transfer processes, quality control analysis and cleaning and maintenance of equipment. Operations are expected to be conducted in enclosed and/or ventilated environments and PPE is expected to be used to minimise worker exposure.

Workers involved in drilling operations may be exposed to the notified chemical (at up to 50% concentration) via the dermal, ocular and inhalation routes during transfer processes, manipulation of the drill and when the drill bit is replaced or removed from the hole.

*Solvent applications*
Workers involved in transport and storage of the notified chemical would only be exposed to the chemical (at up to 100% concentration) in the unlikely event of an accidental spill or container rupture.

While the notified chemical will be used for a broad range of solvent applications, regardless of the application, workers involved in reformulation processes may be exposed to the notified chemical at up to 100% concentration via the dermal, ocular and inhalation routes during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. It is expected that reformulation processes will be conducted in enclosed and/or ventilated environments and all workers handling the notified chemical will use appropriate PPE (the (M)SDS advises the use of skin and eye protection and respiratory protection, if ventilation is inadequate).

Workers involved in end-use applications of industrial products containing the notified chemical may be exposed to the chemical at up to 100% concentration. The primary route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray. Appropriate PPE (including skin and eye protection and respiratory protection, if ventilation is inadequate), is expected to be worn by workers to minimise exposure to the notified chemical.

In the case of exposure of workers to products that will also be available to members of the public (e.g. cosmetic and cleaning products), such workers may use some PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

*Domestic heating fuel*
Workers involved in transport and storage of the notified chemical would only be exposed to the chemical (at up to 100% concentration) in the unlikely event of an accidental spill or container rupture.

Workers involved in the distribution and filling of domestic heating fuel tanks may be exposed to the chemical at up to 100% concentration. The primary route of exposure would be dermal, while ocular and inhalation exposure is also possible. Appropriate PPE (including skin and eye protection and respiratory protection, if ventilation is inadequate), is expected to be worn by workers to minimise exposure to the notified chemical.

### 6.1.2. Public Exposure

*Original Notification:*
The notified chemical is intended for use as a fuel for diesel power cars, trucks, off road equipment, agriculture, power plants and marine applications. Therefore, the general public will be directly exposed (dermal, inhalation) to the notified chemical when vehicle and equipment users fuel their vehicles at service stations and truck stops.

Overall, direct exposure to the notified chemical in blended diesel is expected to be low, similar to the estimates above for occupational refueling and similar to that for currently used diesel fuels.

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

*Secondary Notification:*
It is expected that a small percentage of the additional total import volume of the notified chemical for solvent uses (~4%) will be sold to the public (e.g. in coatings, lubricants and cosmetic and cleaning products). Therefore, there may be widespread and repeated exposure of the public to the notified chemical, particularly from use of cosmetic and cleaning products, which will contain the notified chemical at up to 45% concentration. The primary route of exposure would be dermal, although ocular and inhalation exposure is also possible.

While the concentration of the notified chemical in other products available to the public may be higher than in cosmetic and/or cleaning products (e.g. lubricants, which may contain the notified chemical at up to 100% concentration), the use of such products is expected to be infrequent. Furthermore, good hygiene practices are expected to be in place and, if used on a regular basis, some PPE may be used (e.g. gloves) to minimise repeated exposure to the notified chemical.

When the notified chemical is being used for domestic heating fuel purposes it is expected that it will be stored in above ground purpose-designed fuel tanks, which will be installed, maintained and used in accordance with relevant local Council and/or State or Territory requirements and any obligations under the Building Code of Australia. Once the fuel has been burned, exhausts are expected to be released directly to the atmosphere (e.g. via a flue), with no exhausts released into the house. If used in this manner, exposure to the public to the notified chemical is expected to be significantly less than the exposure to the notified chemical from other fuel-based uses (e.g. from automotive exhausts).

## 6.2. Human health effects assessment

*Original notification:*

### 6.2.1. Studies on GTL Diesel

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

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

### 6.2.2. Studies on Analogues

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

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

The petroleum derived analogues identified are:

- GTL Kerosine
- Analogues 1, 2 and 3 (petroleum derived alkanes, with narrow carbon ranges)

- Gas oils, including: straight-run middle distillate, light catalytic cracked distillate, steam-cracked gas oil, hydrodesulphurised middle distillate, diesel fuel, and hydrotreated straight-run middle distillate.

**Summary of Acute Dermal Toxicity of Analogues**

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

**Summary of Acute Inhalation Toxicity of Analogues**

| TEST SUBSTANCE | GTL kerosine | Analogue 2 | Analogue 3 | Gas oils |
|---|---|---|---|---|
| INHALATION LC50 (mg/L, rat, 4 hour) | > 5.0 | 1.71 (females) > 5.06 (males) | < 5.17 (1 hour value) | 1.8 to 7.64 |
| REFERENCE | Illing (2006) | Safepharm (1995b) | Bio-Research (1994) | CONCAWE (1996) |
| REMARKS – RESULTS | The LC50 value ranged from 1.71 to 7.64 mg/L. | | | |
| | For GTL Kerosine, the value was estimated from 'read across' data for Straight run kerosine, Hydrodesulphurised kerosine, Cracked kerosine, and Alkanes (C12-C26). | | | |
| | For Analogue 2, the animals were exposed using a nose only exposure system and males were tested at the highest dose (5.06 mg/L) only (Safepharm 1995c). | | | |
| | In another study, a single 1-hour whole-body aerosol exposure to 5.17 mg/L of Analogue 3 to rats resulted in the death of 9 of the 10 treated animals up to 14 days after treatment. Reduction in body weights, increased lung and trachea weight, increased incidence of fluid in the trachea and uncollapsed, discoloured lungs as well as lesions in the lungs, nasal cavities and possibly in the heart were also observed. The LC50 (1 hour value) was < 5.17 mg/L (Bio-Research 1994). | | | |
| | For petroleum derived gas oils, there were six studies reported. The value was 1.8 mg/L for straight-run middle distillate (API 83-11), 4.8 mg/L for light catalytic cracked distillate (API 83-07), 4.65 mg/L for light catalytic cracked distillate (API 83-08), > 2.7 mg/L for steam-cracked gas oil, and 4.6 mg/L for hydrodesulphurised middle distillates (API 81-09) and 7.64 mg/L for hydrodesulphurised middle distillates (API 81-10). | | | |
| CONCLUSION | The notified chemical is expected to be harmful via inhalation. | | | |

**Summary of Skin Irritation of Analogues**

| TEST SUBSTANCE | GTL kerosine | Analogue 1 | Analogue 2 | Gas oils |
|---|---|---|---|---|
| SKIN IRRITATION | Slight | Slight | Slight | Non-irritant to severe irritant |
| REFERENCE | Huntingdon Life Sciences (1997b) | Chevron (1989b) | Safepharm (1995c) | CONCAWE (1996) |

| | |
|---|---|
| REMARKS – RESULTS | No to well-defined erythema was observed at 24 through 72 hrs and was cleared by day 7. Flaky skin was observed up to day 7 and was cleared by Day 14.<br>For gas oils, cracked gas oil caused severe irritation in two studies whereas straight run gas oil was non-irritant. Cracked oil contains considerably more aromatic material and less paraffin and therefore, the results for the cracked oils are not suitable for 'read across' to GTL Diesel (llling 2006). |
| CONCLUSION | The notified chemical is expected to be slightly irritating to the skin. |

**Summary of Eye Irritation of Analogues**

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

**Summary of Skin Sensitisation of Analogues**

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

### 6.2.3. Summary of Human Health Effects

*Toxicokinetics, metabolism and distribution.*

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

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

*Acute toxicity.*

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

*Irritation and Sensitisation.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Secondary Notification*
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, with a brief discussion of the studies below. There were a number of studies (on the notified chemical or analogue chemicals) that were submitted for the human health endpoints that were not considered previously. These were not assessed as part of the secondary notification (and/or the study details are not included in Appendix B), as the studies were not considered to impact on the previous assessment of the chemical.

| *Endpoint* | *Result and Assessment Conclusion* |
|---|---|
| Rat, acute inhalation toxicity | LC50 > 5mg/L; low toxicity |
| Genotoxicity – in vivo chromosome aberration | non genotoxic |
| Rat, reproductive toxicity - 2 generation study | NOAEL = 750 mg/kg bw/day |

Acute toxicity:
An acute inhalation study was conducted in rats at 5.11(group 1) and 5.61(group 2) mg/L notified chemical. All animals exhibited increased respiratory rate with some instances of laboured respiration. One day after exposure one female and one male were found dead in group 1 and one female was found dead in group 2. Abnormally dark or dark patches were observed on lungs at necropsy in animals that died during the study. Gaseous distension was also noted in the stomach and the large intestine of animals that died during the study. Pale and/or dark patches were noted on lungs at necropsy of surviving animals. Histopathology of the lungs in surviving animals showed congestion, haemorrhage, edema, alveolar macrophages, acute alveolar inflammation, and acute perivascular inflammation. As less than half of the animals died at each dose level, the LC50 was determined to be > 5 mg/L. While the effects noted do not warrant classification given the high dose level, irreversible damage was caused to the lungs of rats with continuing inflammation 14 days after acute exposure. Irreversible damage from exposure to lower dose levels is unknown and thus, the notified chemical is considered to still have the potential for significant lung damage from inhalation.

Genotoxicity:
A mammalian chromosome aberration test was conducted on the notified chemical in male rats (treated at up to 2000 mg/kg bw). There were no premature deaths or clinical signs noted in any animals at any dose tested. There were no significant decreases in the mean mitotic index, or significant increases in the frequency of aberrations in any of the treatment groups. This result is supported by the negative result from an *in vitro* chromosome aberration test conducted on the notified chemical (study details not provided in Appendix B).

Repeat dose and reproductive toxicity:
In a two-generation reproductive toxicity study, rats were administered the notified chemical by gavage at 0, 50, 200 or 750 mg/kg bw/day and mated to produce subsequent generations. The study authors concluded there were no significant adverse treatment related systemic effects or effects on reproductive performance or on the pups.

Treatment related effects in the kidneys (F1 generation males treated at 750 mg/kg bw/day; the kidneys of animals treated at lower doses were not evaluated) were attributed to α2-microglobulin accumulation and, in the absence of associated effects, were not considered by the study authors to be adverse, as the effect is considered to be a rodent-specific effect following exposure to hydrocarbons and is not relevant to humans. Effects in the lungs of treated animals (P and F1 male and female rats treated at 750 mg/kg bw/day; the lungs of animals treated at lower doses were not evaluated), were considered to be secondary to aspiration of the test substance. It is also noted that there were a number of premature mortalities that were attributed to aspiration of the test substance. Based on the lack of adverse treatment-related effects, the NOAEL for reproductive, foetal and parental systemic toxicity was established by the study authors as 750 mg/kg bw/day.

It is noted that additional (2) 90 day repeated dose oral (gavage) toxicity studies were provided on analogues of the notified chemical (study details not provided in Appendix B). These studies formed part of the basis for the selection of doses that were tested in the abovementioned reproductive toxicity study. However, the relevance of the effects for read-across purposes to the potential toxicity of the notified chemical is uncertain due to significant differences in the carbon chain lengths between the notified chemical and analogue chemicals. In particular, adverse effects (on blood chemistry parameters and organ weights) were noted at low doses (NOAEL ≤ 200 mg/kg bw/day) in the study of a chemical of significantly lower alkyl chain length (narrow range), while in a study of a chemical of similar chain length (and significantly higher, i.e. broad range) to the notified chemical, the NOAEL was established as 1000 mg/kg bw/day, based on the lack of adverse effects at the highest dose tested.

***Health hazard classification***

Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

| ***Hazard classification*** | ***Hazard statement*** |
|---|---|
| Aspiration Hazard (Category 1) | H304 - May be fatal if swallowed and enters airways |

In Australia, additional non-GHS hazard statements apply (see *Guidance on the Classification of Hazardous Chemicals Under the WHS Regulations* for further information; SWA, 2012a). Based on the available information, the following additional (non-GHS) hazard statement is also recommended:

AUH066 – Repeated exposure may cause skin dryness and cracking

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrases:

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

### 6.3. Human health risk characterisation

#### 6.3.1. Occupational health and safety

*Original Notification:*

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

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

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

*Secondary notification*
The risks to workers involved in reformulation tasks, the end-use of the notified chemical as a drilling fluid for oil and gas applications and the distribution and filling of domestic heating fuel tanks is expected to be similar to the risks identified for workers above. Containment measures are expected to be in place and appropriate PPE (including respiratory protection, if inhalation exposure is likely), is expected to be worn by workers to minimise exposure to the notified chemical. A new inhalation toxicity study submitted with the secondary notification has warranted the removal of the R20 classification instated with STD/1270 (which was based on analogue data), however, irreversible damage caused in the study on the notified chemical continues to warrant caution and PPE by workers to reduce inhalation exposure, where possible. Based on its viscosity, the notified chemical is also an aspiration hazard and may be harmful if swallowed.

Additional considerations for workers involved in specific end use applications of the notified chemical (or products containing the notified chemical), namely, spray applications when used in solvent applications and use in cosmetic products, are as follows:

Solvent applications (application by spray)
There may be widespread and frequent worker exposure to the notified chemical at up to 100% concentration in a variety of solvent applications, with the greatest risk to workers associated with spray applications. While the notified chemical is an aspiration hazard, and may be harmful if inhaled, spray applications are expected to be conducted in spray booths and/or other adequately ventilated areas and exposure of workers is expected to be limited by the use appropriate PPE, including respiratory protection.

Cosmetics
Beauty care professionals will handle the notified chemical at ≤ 45% concentration in mascara and ≤ 20% in face creams, similar to public use. Therefore, the risk to workers who regularly use products containing the notified chemical is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis. For details of the public health risk assessment see Section 6.3.2.

Overall, provided that control measures (e.g. containment and/or adequate ventilation and appropriate PPE, such as coveralls, impervious gloves and respiratory protection, as applicable) are in place to minimise exposure of workers to the notified chemical, the risk to the health of workers is not considered to be unreasonable.

### 6.3.2. Public health

*Original notification*
The main potential for public exposure (dermal, inhalation) to the notified chemical would be when users of diesel vehicles fuel their vehicles at service stations and truck stops. However, exposure to the public will be infrequent (once a week), only for a brief period (maximum 15 minutes) and will be in the open area.

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

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

*Secondary notification*
Members of the public may experience widespread and repeated exposure to the notified chemical (at ≤ 45% concentration), particularly through the use of specific cosmetic and cleaning products. Spray products containing the notified chemical will not be available to the public. The notified chemical has the potential to cause skin dryness and cracking with repeated exposure. However, this effect is expected to depend on the formulation of the products containing the notified chemical (i.e. concentration and identities of other components of the formulation) and it is expected that reformulators will take this into account when formulating products that are expected to be repeatedly used by members of the public (e.g. cosmetics). Based on the information available, systemic toxicity effects are not expected from repeated exposure of members of the public to products containing the notified chemical.

Regarding use of the notified chemical for domestic heating fuel purposes, no direct exposure is anticipated, as exhausts are expected to be expelled directly to the atmosphere (e.g. through a flue or similar vent). In addition, the storage tanks containing the notified chemical will be installed, maintained and used in accordance with relevant local Council and/or State or Territory requirements and any obligations under the Building Code of Australia. Therefore, the risk to the public from use of the notified chemical for domestic heating purposes is not considered to be unreasonable.

Overall, the risk to public health from use of the notified chemical in the proposed manner is not considered to be unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia; therefore no release to the local environment is expected during this activity. Releases to the environment may occur following accidental spills during import, transport or storage. Notified chemical that is spilled is expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations.

The notified chemical will be transferred to diesel storage tanks at refineries using a pipeline from the ship in which it is imported. Unloading hoses will be back flushed before disconnection and capped. The few grams that will 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.

The notified chemical may be released to the environment during reformulation. Equipment used during reformulation that is contaminated with residues of the notified chemical is expected to be rinsed with an appropriate solvent. The solvent rinsate containing the notified chemical is expected to be collected and disposed of according to local regulations. Empty import containers with residues of the notified chemical are expected to be recycled.

RELEASE OF CHEMICAL FROM USE

*Original Notification: Use in Fuel*

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

*Secondary Notification*

The notified chemical is reported to have a number of uses with varying degrees of release to the environment. The uses for the notified chemical are listed in the table below along with their expected percentage releases to air, wastewater and soil. The level of environmental exposure has been divided into three categories based on information provided by the notifier. The environmental releases were reported to be interpreted from the Generic Exposure Scenarios outlined in the European Union's Technical Guidance Documents and the OECD Emission Scenario Documents. In this case, low exposure uses are considered to have < 1% release to air and < 1% release to wastewater after risk management measures; potentially moderate exposure uses are considered to have > 1% release to air and < 5% release to wastewater after risk management measures; and potentially high exposure uses are considered to have > 1% release to air and > 5 % release to wastewater after risk management measures. Risk management measures are measures undertaken by users to try to minimise release of the notified chemical to the environment. These include control measures such as ventilation and extraction fans, bunding to prevent release through drainage systems, on-site wastewater treatment and spray booths. Collected wastes containing the notified chemical are expected to be disposed of according to local regulations.

| Conservative Exposure Category | Uses | Expected environmental releases after risk management measures | | |
|---|---|---|---|---|
| | | Air | Wastewater | Soil |

| | | | | |
|---|---|---|---|---|
| Low | Lubricants | 0.003 – 0.01%* | 0.0001% | 0.10% |
| | Metal working fluids | 0.6% | 0.0001% | 0% |
| | Functional fluids | 0.01% | 0.0001% | 0.1% |
| | Explosives | 0.01% | 0.0001% | 0.01% |
| | Intermediates | 0% | 0.001% | 0.1% |
| | Domestic heating fuel | Release from this use is expected to be similar to the previously assessed release during use as a fuel. The notified chemical is expected to be combusted during use. | | |
| Moderate | Coatings/inks/adhesives | 9.8 – 98%* | 0.002% | 0% |
| | Cleaning agents and household products | 30 – 100%* | 0.00001% | 0% |
| | Binders and release agents | 20% | 0.00001% | 0% |
| | Polymer processing | 2% | 0% | 0.001% |
| | Rubber manufacture and processing | 1% | 0.001% | 0.01% |
| | Roads construction | 95% | 1% | 4% |
| | Laboratory chemicals | 2.5% | 2% | 0.01% |
| High | Drilling fluid for oil and gas operations[1] | 0% | 10% | See [1] |
| | Water treatment | 5% | 95% | 0% |
| | Mining | 5% | 50% | 5% |
| | Cosmetics | A worst-case assumption is applied to chemicals in cosmetics where 100% of the notified chemical is released to sewer during use. | | |

*The higher value for the release of the notified chemical to air is assumed for products that are used by members of the public with limited access to risk management measures.

[1]The majority of the notified chemical used in drilling fluids for conventional oil and gas operations off-shore as a component of drilling mud is expected to be separated from drilling cuttings after use and reused in the drilling muds. Approximately 10% of the notified chemical used for conventional oil and gas drilling is expected to be used in Water-Based Muds (WBM) and be disposed of directly to the ocean through a continuous discharge during drilling. Of the notified chemical used in Non-Aqueous Drilling Fluids (NADF), up to 10% of the notified chemical is expected to remain as part of the drill cuttings, which are expected to be treated on-site and consequently disposed of to the ocean or returned to shore for disposal according to local regulations. The remaining NADF is expected to be recovered and reused in drilling muds. Drilling muds containing the notified chemical used on-shore are expected to be disposed of according to local regulations, most likely buried or disposed of to a licensed landfill. The use of the notified chemical in WBM is expected to result in the greatest release to the environment as risk management measures will be in place to prevent the release of NADFs. Drill cuttings contaminated with NADFs are also expected to sink and be incorporated into the sediment. Therefore, only the 10% of the notified chemical used in WBMs in conventional oil and gas drilling operations is expected to be released to the environment at significant concentrations.

RELEASE OF CHEMICAL FROM DISPOSAL

After use in fuels, if the notified chemical needs to be disposed of, it is expected to be disposed of in accordance with local regulations for recycling, re-use or recovery of calorific content.

As a solvent used by industry, the notified chemical is expected to be disposed of according to local regulations.

Residues of the notified polymer in the empty end-use containers are likely either to share the fate of the container and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling.

### 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 release to soil or water. Release of the notified chemical to water will spread on the surface and evaporate, with limited adsorption to sediment. The notified chemical on land that does not evaporate and remains sorbed to soil will have low mobility and can be expected to degrade. Atmospheric vapours will be susceptible to oxidation, mainly by hydroxyl radicals.

Testing has shown the notified chemical to be readily biodegradable (see Appendix C for details; note, there were a number of studies on the notified chemical that were submitted for the environmental endpoints, that were not considered previously and were not assessed as part of the secondary notification (and/or the study details are not included in Appendix C), as the studies were not considered to impact on the previous assessment of the chemical). Degradation occurred more rapidly than for petroleum derived analogues, reflecting the higher content of linear hydrocarbons and lower levels of aromatic compounds. One study indicated that the notified chemical is not readily biodegradable; however, the reliability of the test is uncertain as markedly different results were observed between an initial biodegradation test and the final biodegradation test. The notified chemical has also been found to be biodegradable in soils.

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

The notified chemical that is released to sewer is expected to biodegrade and be efficiently removed by sewage treatment plant (STP) processes. The SimpleTreat model (European Commission 2003) predicts that at least 97% of the notified chemical is expected to be removed from the aqueous stream during STP processes assuming a Henry's law constant (log H) of 5 and n-octanol/water partition coefficient (log Pow) of 6. However, these values are both greater than the assumed log H and log Pow, therefore removal from STP may be greater.

### 7.1.3 Predicted Environmental Concentration (PEC)

As release to water is expected to be minimal for the low and moderate exposure uses and the original notification use in fuels, and any releases will largely partition to the atmosphere, a predicted environmental concentration (PEC) for the aquatic compartment has not been calculated for these uses.

The PEC was calculated for uses where significant exposure to the aquatic environment is likely to occur. Use of the notified chemical in off-shore Water-Based Muds (WBM) is expected to result in direct release of the notified chemical to the ocean. The notified chemical is reported to be used in drilling fluids that will be continuously discharged. In the CHARM model (Thatcher et al., 2005, p. 22), the PEC for drilling chemicals in seawater resulting from continuous discharge of WBM ($PEC_{water,cont}$/ mg $L^{-1}$) is calculated using the following equation:

$$PEC_{water,cont} = \frac{M}{T \times V_t} \times 10^3$$

In this equation, $PEC_{water,cont}$ is related to the amount of chemical discharged (M/ kg), the volume of water passing the platform ($V_t$/ $m^3.d^{-1}$), and the time needed to drill a section (T/ days). The specific values for volume of water passing the platform and the time needed to drill a section have not been provided for operations under Australian conditions. Hence, the default values for $V_t$ ($3.6 \times 10^8$ $m^3.d^{-1}$) and T (16 d) as specified in the CHARM model for the continuous discharge scenario have been used for this calculation (Thatcher et al., 2005, p. 46). The notifier predicts that up to 10% of the notified chemical used in drilling fluids may be used as part of WBM and released to the ocean. A total of up to 1500 T of the notified chemical is expected to be used at each well. As a worst-case scenario, 1500 T is assumed to be used in WBM. Based on the default CHARM values and the worst case continuous discharge of 1 500 000 kg of notified chemical, the $PEC_{water,cont}$ for the notified chemical is calculated to be 0.26 mg/L.

The $PEC_{water,batch}$ calculated above is based on a theoretical worst-case in which all of the mass of notified chemical discharged with a batch of mud is present in seawater within a radius of 500 m from the discharge point. However, based on the apparent insolubility of notified chemical in water, a significant fraction of the discharged mass of this chemical is expected to remain associated with the insoluble minerals and other solids discharged overboard. This fraction of the notified chemical is therefore expected to deposit on the sea floor beneath the discharge point along with the mud and cuttings. The concentration of the notified chemical in sediment ($PEC_{sediment}$) is therefore of potential significance.

An estimate of the $PEC_{sediment}$ can be made in accordance with the CHARM model (Thatcher et al., 2005, p. 30). The $PEC_{sediment}$ is related to the $PEC_{water,cont}$, the sediment-water partition coefficient and the fraction of the substance in sediment that is degraded in one year. As the notified chemical is considered to be biodegradable in seawater (see Appendix C), it is likely that a large fraction of the notified chemical will be degraded in one year. Therefore, if not 0 mg/kg, $PEC_{sediment}$ is expected to be very low.

The PECs for other uses that are expected to result in the nationwide release of the notified chemical to sewer are calculated below. The proportion of chemical expected to be released to sewer, and the number of days release is expected to occur, are estimates provided by the notifier based on exposure information from EU Technical Guidance Documents and OECD emission estimations. Using SimpleTreat (European Commission 2003), at least 97% of the notified chemical is calculated to be removed from the aqueous waste stream during STP processes. The individual use PECs were then combined to determine a total PEC for riverine and marine environments.

***Predicted Environmental Concentration (PEC) for the Aquatic Compartment***

| *Use* | *Water treatment* | *Mining* | *Cosmetics* | |
|---|---|---|---|---|
| Total Annual Import/Manufactured Volume | < 50,000 | < 5,000 | < 5,000 | kg/year |
| Proportion expected to be released to sewer | 95% | 50% | 100% | |
| Annual quantity of chemical released to sewer | < 47,500 | < 2,500 | < 5,000 | kg/year |
| Days per year where release occurs | 300 | 20 | 365 | days/year |
| Daily chemical release: | < 158.33 | < 125 | < 13.699 | kg/day |
| Water use | 200 | 200 | 200 | L/person/day |
| Population of Australia (Millions) | 22.613 | 22.613 | 22.613 | million |
| Removal within STP | 97% | 97% | 97% | Mitigation |
| Daily effluent production: | 4,523 | 4,523 | 4,523 | ML |
| Dilution Factor - River | 1 | 1 | 1 | |
| Dilution Factor - Ocean | 10 | 10 | 10 | |
| PEC - River: | < 1.05 | < 0.83 | < 0.09 | µg/L |
| PEC - Ocean: | < 0.11 | < 0.08 | < 0.01 | µg/L |
| Total PEC – River | | | < 1.97 | µg/L |
| Total PEC - Ocean | | | < 0.20 | µg/L |

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 637 mg/kg (dry wt). Biosolids are applied to agricultural soils however due to the potential of the notified chemical to volatilise and degrade in soils, it is unlikely that the notified chemical will be present in soils at ecotoxicologically significant concentrations.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 $L/m^2$/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 $kg/m^3$). Using these assumptions, irrigation with a concentration of 1.97 µg/L may potentially result in a soil concentration of approximately 13.1µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 65.7 µg/kg and 131.5 µg/kg, respectively. However, due to the potential for the notified chemical to volatilise and biodegrade, these are likely to be the maximum values.

### 7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of the majority of these studies can be found in Appendix C. As noted above, there were a number of studies on the notified chemical that were submitted for the environmental endpoints, that were not considered previously and were not assessed as part of the secondary notification (and/or the study details are not included in Appendix C), as the studies were not considered to impact on the previous assessment of the chemical.

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| ***Acute Toxicity*** | | |
| Fish Toxicity (96 h) | LL50 > 1000 mg/L* | Not harmful to fish, daphnids or green algae, up to the limit of water solubility on an acute basis. |
| Marine Fish Toxicity (96 h) | LC50 = 75 500 mg/L[$] | |
| Invertebrate Toxicity (48 h) | EL50 > 1000 mg/L* | |
| Marine Invertebrate Toxicity (96 h) | LC50 > 1000 mg/L* | |
| Algal Toxicity (72 h) | EL50 > 1000 mg/L* | |
| Marine Algal Toxicity (72 h) | EL50 > 1000 mg/L* | |
| ***Chronic Toxicity*** | | Not harmful to fish, invertebrates or algae, up to the limit of water solubility on a chronic basis. |
| Fish Toxicity (33 d) | NOEL = 100 mg/L* | |
| Invertebrate Toxicity (21 d) | NOEL = 32 mg/L* | |
| Algal Toxicity (72 h) | NOEL = 1000 mg/L* | |
| Marine Algal Toxicity (72 h) | NOEL = 1000 mg/L* | |
| ***Toxicity to soil organisms*** | | |
| Plants (22 d) | EC50 > 1000 mg/kg (Growth) | Not expected to be harmful to soil dwelling organisms |
| Earthworms (14 d) | LC50 > 1000 mg/kg | |

*Tests prepared using a water accommodated fraction (WAF)
[$]Test organisms were exposed to the suspended particle phase
[#] Sediment was spiked with the notified chemical

The notified chemical is not expected to be harmful to aquatic organisms on an acute or chronic basis. Therefore, the notified chemical is not formally classified under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009).

### 7.2.1 Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the low or moderate exposure uses as there is expected to be limited release of the notified chemical to the aquatic environment from these uses.

The marine PNEC, calculated for the use of the notified chemical in off-shore WBM drilling fluids, was determined by using the endpoint for the most sensitive species from the reported results (NOEL, Invertebrates, 21 d). A freshwater chronic endpoint was deemed suitable for calculation of the marine PNEC because it is the most conservative scenario. An assessment factor of 10 was used as full study reports were available for acute and chronic ecotoxicological endpoints for three trophic levels.

| Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment | | |
|---|---|---|
| NOEL (Invertebrate, 21 d) | 32 | mg/L |
| Assessment Factor | 10 | |
| PNEC: | 3200 | µg/L |

As the notified chemical is biodegradable in seawater and the $PEC_{sediment}$ is not expected to be significant and is therefore much less than the endpoint for the most sensitive species, the $PNEC_{sediment}$ was not calculated.

The freshwater PNEC, calculated for uses where release to sewer is expected, was determined by using the endpoint for the most sensitive species from the reported results (NOEL, Invertebrates, 21 d). An assessment factor of 10 was used as full study reports were available for acute and chronic ecotoxicological endpoints for three trophic levels.

| Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment | | |
|---|---|---|
| NOEL (Invertebrate, 21 d) | 32 | mg/L |
| Assessment Factor | 10 | |
| PNEC: | 3200 | µg/L |

The terrestrial PNEC has not been calculated as the notified chemical is not expected to be harmful to organisms in the soil and the notified chemical is not expected to be present at ecotoxicologically significant concentrations. The notified chemical is also expected to volatilise and degrade in soil, further reducing exposure to organisms in the soil.

### 7.3. Environmental risk assessment

For the low and moderate exposure uses of the notified chemical, an environmental risk quotient has not been determined as the notified chemical is not expected to be released into aquatic ecosystems in ecotoxicologically significant amounts and the PEC or PNEC have not been calculated.

For the use of the notified chemical in WBM drilling fluids, the risk quotient (Q) is calculated below:

| *Risk Assessment* | *$PEC_{water}$ µg/L* | *PNEC µg/L* | *Q* |
|---|---|---|---|
| Q - Ocean: | 260 | 3200 | 0.081 |

As the notified chemical is biodegradable in seawater, it is not expected to accumulate in marine sediment at ecotoxicologically significant amounts. Therefore, the Q for the notified chemical used in WBM drilling fluids cannot be calculated for marine sediments.

The Q for the uses where the notified chemical is released to sewer is calculated as follows:

| *Risk Assessment* | *PEC µg/L* | *PNEC µg/L* | *Q* |
|---|---|---|---|
| Q - River: | < 1.97 | 3200 | < 0.001 |
| Q - Ocean: | < 0.20 | 3200 | < 0.001 |

The Qs for the assumed discharge scenarios have been calculated to be << 1 for the river and ocean compartments. The notified chemical is readily biodegradable in freshwater and biodegradable in seawater. It is therefore not expected to be persistent. The majority of the notified chemical is likely to partition to the atmosphere where it will disperse and oxidise. The notified chemical is not expected to be harmful to organisms in the soil as it is expected to volatilise and degrade in soil. It is therefore not expected to persist in the environment at ecotoxicologically significant concentrations. Therefore, the notified chemical is not expected to pose an unreasonable risk to the environment based on its assessed use patterns.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

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

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

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

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

**Density** 780 kg/$m^3$ at 20.0 ± 0.5°C

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

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

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

**Viscosity** 5.50 x $10^{-6}$ $m^2$/s at 20 °C
3.42 x $10^{-6}$ $m^2$/s at 40 °C

| | |
|---|---|
| Method | OECD TG 114 Viscosity of Liquids. |
| Remarks | Determined using the capillary viscometer method. |
| Test Facility | Harlan (2010a) |

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

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

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

| | |
|---|---|
| Method | EC Directive 92/69/EEC A.8 Partition Coefficient. |
| Remarks | HPLC Method. The limit value of 6.5 is based on the retention time of the reference substance (DDT). |
| Test Facility | SafePharm Laboratories Ltd. (2006a) |

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

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

**Flash Point** 94 ± 2ºC at 101.33 kPa

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

**Autoignition Temperature** 208 ± 5ºC

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

# APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

## B.1. Acute toxicity – oral

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

RESULTS

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

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

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

## B.2. Acute toxicity – inhalation

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 436 Acute Inhalation Toxicity- Acute toxic Class Method |
| Species/Strain | Rat/ Wistar |
| Vehicle | None |
| Method of Exposure | Oro-nasal exposure. |
| Exposure Period | 4 hours |
| Physical Form | liquid aerosol |
| Remarks - Method | No significant protocol deviations |

RESULTS

| *Group* | *Number and Sex of Animals* | *Concentration <mg/L>* | | *Mortality* |
|---|---|---|---|---|
| | | *Nominal* | *Actual* | |
| I | 3M/3F | 15.3 | 5.61 | 2/6 |
| II | 3M/3F | 11.7 | 5.11 | 1/6 |

| | |
|---|---|
| LC50 | 5 mg/L/4 hours |
| Signs of Toxicity | In group 1 all animals exhibited increased respiratory rate with instances of laboured respiration. In group 2 the same effects were observed except there was only one isolated incident of laboured respiration. One day after exposure one female and one male were found dead in group 1 and one female was found dead in group 2. All surviving animals exhibited increased respiratory rate, hunched posture and piloerection. In group 1, isolated occurrences of laboured respiration, splayed gait, tip-toe gait and ptosis were noted in one female. In group 2, there were occasional instances of laboured respiration tip-toe gait and red/brown staining around the eyes and an isolated instance of red/brown staining around the snout was also |

| | |
|---|---|
| | noted. These effects gradually receded and surviving animals had recovered by days 8 to 9 for group 1, and days 7 to 8 for group 2.<br>All animals exhibited body weight losses one day post exposure. With the exception of one female in group 1 who gained no weight from days 1-3 post exposure, reasonable body weight development was noted in all surviving animals. |
| Effects in Organs | Abnormally dark or dark patches were observed on lungs at necropsy in animals that died during the study. Gaseous distension was also noted in the stomach and the large intestine of animals that died during the study.<br>Histopathology of the lungs revealed the following in animals who survived to scheduled necropsy: minimal to moderate congestion; minimal to slight haemorrhage; minimal to moderate edema; minimal to slight alveolar macrophages; minimal acute alveolar inflammation; minimal acute perivascular inflammation. In animals that died one day after exposure the following were noted: moderate congestion; slight haemorrhage; minimal to slight alveolar macrophages; slight acute alveolar inflammation. |
| Remarks - Results | The LC50 value was estimated to be > 5mg/L. |
| CONCLUSION | The notified chemical is of low toxicity via inhalation. |
| TEST FACILITY | Harlan (2013) |

**B.3. Genotoxicity – bacteria**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 471 Bacterial Reverse Mutation Test.<br>EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. |
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA98, TA100<br>*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<br>b) Without metabolic activation: 0, 15, 50, 150, 500, 1500, 5000 µg/plate |
| Vehicle | Acetone |
| Remarks - Method | No significant protocol deviations. Plate incorporation method. |

RESULTS

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

| | |
|---|---|
| Remarks - Results | No significant increases in the frequency of relevant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.<br>All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was shown to be satisfactory. |

| | |
|---|---|
| CONCLUSION | The notified chemical was not mutagenic to bacteria under the conditions of the test. |
| TEST FACILITY | SafePharm Laboratories Ltd. (2006d) |

**B.4. Genotoxicity – in vitro**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 487 Draft proposal for a New Guideline: In Vitro Micronucleus Test<br>(Guideline closely resembles the OECD TG 473 In vitro Mammalian Chromosome Aberration Test) |
| Species/Strain | Human |
| Cell Type/Cell Line | Lymphocyte cells |
| Metabolic Activation System | Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-naphthoflavone |
| Vehicle | Minimal Essential Medium (MEM) |
| Remarks – Method | No significant protocol deviations.<br>The dose level range for preliminary toxicity was 19.5 to 5000 µg/mL. The maximum dose was based on the maximum recommended dose level. The test material induced no evidence of toxicity in any of the exposure groups.<br><br>The selection of the maximum dose level was based on the onset of the oily precipitate and the precipitate was observed to form a greasy layer at and above 625 µg/mL. Therefore, the maximum exposure of the cells was limited to 1250 µg/mL in all exposure groups for both experiments. |

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

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

RESULTS

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

| | |
|---|---|
| Remarks – Results | All vehicle (solvent) controls had frequencies of cells with micronuclei within the range expected for normal human lymphocytes.<br>The positive control materials induced statistically significant increases in the frequency of cells with micronuclei, indicating the satisfactory performance of the test and of the activity of the metabolising system.<br>The test material was non-toxic and did not induce any statistically significant increase in the frequency of cells with micronuclei, in either of the two experiments, using a dose range that induced the lowest moderately precipitating dose level. |

| | |
|---|---|
| CONCLUSION | The notified chemical was not clastogenic and non-aneugenic to human lymphocytes treated *in vitro* under the conditions of the test. |
| TEST FACILITY | SafePharm Laboratories Ltd. (2006e) |

**B.5. Genotoxicity – in vivo**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 475 Mammalian Bone Marrow Chromosome Aberration Test.<br>EC Directive 440/2008/EC B.11 Mutagenicity - In vivo Mammalian Bone Marrow Chromosome Aberration Test. |
| Species/Strain | Rat: Wister Han (RCCHan$^{TM}$WIST) |
| Route of Administration | Oral – gavage |
| Vehicle | Arachis oil |
| Remarks - Method | A range finding study was not conducted as the notified chemical had an acute oral LD50 of > 5000 mg/kg bw in rats (see above). Therefore, the maximum recommended dose of 2000 mg/kg bw was used for this study. In addition, the study was conducted in male rats only.<br><br>Positive (Cyclophosphamide) and negative (vehicle) controls were run in parallel with the test substance. |

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Sacrifice Time hours* |
|---|---|---|---|
| I (vehicle control) | 7M | 0 | 24 |
| II (low dose) | 7M | 500 | 24 |
| III (mid dose) | 7M | 1000 | 24 |
| IV (high dose) | 7M | 2000 | 24 |
| V(high dose) | 7M | 2000 | 48 |
| VI (positive control, CP) | 5M | 25 | 24 |

CP=cyclophosphamide.

| | |
|---|---|
| RESULTS | |
| Doses Producing Toxicity | No premature deaths or clinical signs were noted in animals of any of the treatment groups. |
| Genotoxic Effects | There were no significant decreases in the mean mitotic index, or significant increases in the frequency of aberrations in any of the treatment groups.<br><br>The positive and negative control groups showed satisfactory results confirming the validity of the test system. |
| CONCLUSION | The notified chemical was not clastogenic under the conditions of this in vivo mammalian bone marrow chromosome aberration test. |
| TEST FACILITY | Harlan (2011a) |

**B.6. Toxicity to reproduction – two generation study**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | Similar to OECD TG 416 Two-Generation Reproduction Toxicity Study |
| Species/Strain | Rat: Crl:CD(SD) |
| Route of Administration | Oral – gavage |
| Exposure Information | Exposure period – female: ~70 days prior to mating; during mating, gestation, lactation and then until euthanasia.<br>Exposure period – male: ~70 days prior to mating, during mating and then until euthanasia. |

| | |
|---|---|
| Vehicle | Corn oil |
| Remarks - Method | P generation rats were administered the test substance at 0, 50, 200 or 750 mg/kg bw/day (25 rats/sex/dose) by oral gavage for approximately 10 weeks. The animals were then mated over 2 weeks to produce the F1 generation (pregnancy detected by vaginal smear). Females were fed their premating dietary concentration during the mating period, gestation, lactation and weaning.<br><br>The F1 generation was culled on day 4 postpartum (to give 5 pups/sex/litter), then weaned on postpartum day 21, and F1 adults (28 rats/sex/dose) selected. F1 adults were administered the test substance for approximately 10 weeks before mating to produce the F2 generation. The F2 generation were culled on day 4 postpartum (to give 5 pups/sex/litter) and maintained until weaning then sacrificed and subject to necropsy (up to 3/sex/litter).<br><br>Reproductive, macroscopic and microscopic investigations were conducted on P and F1 generations at the control and high dose, and the low and intermediate dose where necessary to examine possible treatment related effects. Sacrificed weanling pups were examined for gross abnormalities, anogenital distance, body weight and macroscopic and microscopic investigations.<br><br>Dose selection was based on the results of 90 day repeated dose oral toxicity studies on analogue chemicals. |

| *Weeks on study* | *P* | *F1* | *F2* |
|---|---|---|---|
| 0-10 | - premating exposure | | |
| 11-12 | - mating period | | |
| 13-15 | - exposure continues | - litter born and culled on day 4 postpartum to 10/sex/litter | |
| 16-18 | - exposure continues | - litters weaned 21 days postpartum<br>- adult population selected (28/sex/dose)<br>- weanlings necropsied (10/sex/dose) | |
| | - Males sacrifice and necropsy | -F0 males sacrificed and necropsied | |
| 19 | - Females sacrifice and necropsy | - premating exposure begins | |
| 20-29 | | - exposure continues | |
| 30-31 | | - mating period | |
| 32-34 | | Gestation – exposure continues | - litter born and culled on day 4 postpartum to 10/sex/litter |
| 35-37 | | Lactation – exposure continues | - litters weaned 21 days postpartum<br>- weanlings necropsied (28/sex/dose) |
| 38 | | - sacrifice and necropsy | |

- Study periods are a general guide only and some animals

| *Generation* | *Group* | *Number and Sex of Animals* | *Dose mg/kg bw/day* |
|---|---|---|---|
| P,F1 | control | P-25/sex, F1-28/sex | 0 |
| P,F1 | low dose | P-25/sex, F1-28/sex | 50 |
| P,F1 | mid dose | P-25/sex, F1-28/sex | 200 |
| P,F1 | high dose | P-25/sex, F1-28/sex | 750 |

RESULTS

*Mortality and Time to Death*

There were no treatment related mortalities during the study. There were 19 incidental deaths (4 P males, 6 P females, 5 F1 males and 4 F1 females) that were considered by the study authors to be unrelated to treatment. Eleven deaths were attributed to gavage error and/or aspiration of the test substance into the lungs. Two P females were euthanized after being injured by their mating partner, 1 P male was euthanised due to lesions attributed to ear tag irritation, and 2 females died (1 euthanised/1 found dead) due to dystocia. Three animal deaths could not be definitively determined at necropsy (1 P male treated with 50 mg/kg bw/day, and 1 F1 male and 1 F1 female treated with 750 mg/kg bw/day).

*Effects on Parental (P) animals:*

There were no treatment related clinical signs of toxicity or effects on mean body weights observed in treated P generation adults. There were no significant treatment related effects on the reproductive performance or gestation length and parturition in P generation animals, or on andrology parameters and sperm morphology in males.

Treatment related histopathological lesions (chronic interstitial/alveolus inflammation) were noted in the lungs of all P generation animals of both sexes treated with 750 mg/kg bw/day. There was also an increase in absolute and relative lung weights (~38% and ~33% for males and ~14% and ~13% for females, respectively) in these animals compared to controls. The study authors considered these effects to be secondary to aspiration of the test substance (the lungs from the animals of the low and mid dose groups were not evaluated).

Renal tubule mineralisation was noted in 7/23 P generation males treated with 750 mg/kg bw/day. The study authors considered the effect to be non-adverse, noting that the lesion may be due to artificial change and was not seen in F1 males and females treated with vehicle or 750 mg/kg bw/day, or P generation females receiving 750 mg/kg bw/day.

*Effects on 1st Filial Generation (F1)*

There were no treatment related effects on F1 litter parameters, postnatal survival, physical condition, mortality, pup body weights or anogenital distance. Additionally, there were no statistically significant microscopic or macroscopic findings in F1 pups.

In F1 male adults treated with 750 mg/kg bw/day, there were statistically significant increases in the mean age of attainment of balanopreputial separation and the number of abnormal sperm. The study authors concluded that the reproductive effects were non-adverse as the percentage of abnormal sperm and attainment of balanopreputial separation values were within the historical control ranges and there were no corresponding microscopic findings noted in the testes. In addition, mating and fertility indices in this group, while found to be slightly lower than control animals, were not statistically significant and were within historical control ranges.

There were no treatment related clinical signs of toxicity or effects on mean body weights in treated F1 generation adults. The same treatment related histopathological lesions (chronic interstitial/alveolus inflammation) and increased weights were noted in the lungs of F1 adults, as for P generation animals. The study authors considered these effects to be secondary to aspiration of the test substance. The lungs of the low and mid dose animals were not examined.

Increased renal tubule degeneration/necrosis and renal tubule hyaline droplets were noted in F1 generation adult males treated with 750 mg/kg bw/day. There were no significant changes in kidney weights in these animals. The study authors noted that the effect is likely due to test substance-induced $\alpha_2\mu$-globulinergic nephropathy, which is known to occur in rats exposed to hydrocarbons (the kidneys of from the animals of the low and mid dose groups were not evaluated).

*Effects on 2nd Filial Generation (F2)*

There were no treatment related effects on F2 litter parameters, postnatal survival, physical condition, mortality, pup body weights or anogenital distance. Additionally, there were no statistically significant microscopic or macroscopic findings in F2 pups.

Remarks – Results

Similar toxicity was observed across the P and F1 adult generations. In males there were significant effects in andrology parameters, however, these were within historical ranges.

Reproductive performance and foetal outcomes were not affected at any dose level in both generations, thus the test substance was not considered to be a reproductive toxicant.

CONCLUSION
The parental and reproductive NOAEL was determined by the study authors to be 750 mg/kg bw/day, based on the lack of adverse effects from the test substance at this dose.

TEST FACILITY RTI (2011)

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

## C.1. Environmental Fate

### C.1.1. Ready biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test. |
| Inoculum | Return water from STP |
| Exposure Period | 28 days |
| Auxiliary Solvent | Test samples were adsorbed onto glass fibre filters |
| Analytical Monitoring | Oxygen consumption |
| Remarks - Method | Method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. |

RESULTS

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

| | |
|---|---|
| Remarks - Results | Biodegradation exceeded 70% at 28 days, and had yet to reach a plateau. |
| CONCLUSION | The notified chemical can be considered to be readily biodegradable. |
| TEST FACILITY | Sasol (2008) |
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 301 B Ready Biodegradability: $CO_2$ Evolution. |
| Inoculum | Activated sludge |
| Exposure Period | 28 days |
| Auxiliary Solvent | Test samples adsorbed onto glass fibre filters |
| Analytical Monitoring | Not reported |
| Remarks - Method | Method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. |

RESULTS

| *Test substance* | | *Aniline* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 7 | 14.1 | 7 | 42.9 |
| 14 | 23.5 | 14 | 69.8 |
| 28 | 39.5 | 28 | 73.8 |

| | |
|---|---|
| Remarks - Results | Relevant test validity criteria were met. However, there was a significant difference between an initial test (8.4%) and the final test (39.5%), which was attributed to the bioavailability of the test substance in each test. Therefore, the reliability of the test is uncertain. |
| CONCLUSION | The notified chemical cannot be considered to be readily biodegradable. |
| TEST FACILITY | Supervision and Test Centre (2009) |

### C.1.2. Biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |

| | |
|---|---|
| METHOD | OECD TG 306 Biodegradability in Seawater – Closed Bottle. |
| Inoculum | Filtered seawater with standard nutrient reagents |
| Exposure Period | 28 days |
| Auxiliary Solvent | Surfactants used to emulsify sample |
| Analytical Monitoring | Not reported |
| Remarks - Method | Unclear as to whether good laboratory practice (GLP) was used. |

RESULTS

| *Test substance* | | *Sodium acetate* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 28 | 63 | 28 | 69 |

| | |
|---|---|
| Remarks - Results | Unclear as to whether test validity criteria were met. Biodegradation exceeded 60% at 28 days. This method is not suitable for assessing ready biodegradability. |
| CONCLUSION | The notified chemical can be considered as biodegradable in seawater. |
| TEST FACILITY | NEERI (2005) |

**C.1.3. Degradation**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 307 Aerobic and Anaerobic Transformation in Soil. |
| Exposure Period | 51 days |
| Auxiliary Solvent | Acetone |
| Analytical Monitoring | GC-FID |
| Remarks - Method | The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. |
| RESULTS | |
| DT50 | 11.4 days at 20 ± 2°C |
| Remarks - Results | Method is not ideal for complex substances, and therefore results may not be indicative of degradation. However, bound residues do not appear to be a specific concern and therefore should reflect degradation for the majority. Relevant test validity criteria were met. |
| CONCLUSION | The notified chemical can be considered as degradable in soil. |
| TEST FACILITY | Harlan Laboratories (2010b) |

**C.2. Ecotoxicological Investigations**

**C.2.1. Acute toxicity to fish**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 203 Fish, Acute Toxicity Test – Semi Static. |
| Species | *Pimephales promelas* (Fathead minnow) |
| Exposure Period | 96 hours |
| Auxiliary Solvent | None |
| Water Hardness | 143 mg $CaCO_3$/L |
| Analytical Monitoring | Not reported |
| Remarks – Method | Water temperature was not within method guidelines, however no stress to fish was observed. Unclear as to whether good laboratory practice (GLP) was used. Unfiltered water accommodated fractions (WAF) were prepared by stirring for 72 hours in sealed vessels with only a small headspace, with |

the aqueous phases used as the test solution. Test solution was renewed daily.

RESULTS

| *Concentration mg/L Nominal* | *Number of Fish* | *Mortality* | | | | |
|---|---|---|---|---|---|---|
| | | *3 h* | *24 h* | *48 h* | *72 h* | *96 h* |
| Control | 7 | 0 | 0 | 0 | 0 | 0 |
| 1000 | 7 | 0 | 0 | 0 | 0 | 0 |

| | |
|---|---|
| LL50 | > 1000 mg/L at 96 hours (WAF) |
| NOEC | 1000 mg/L at 96 hours |
| Remarks – Results | Unclear as the whether relevant test validity criteria met. No toxicity symptoms were observed in any of the fish. |

CONCLUSION The notified chemical is not expected to be harmful to fish.

TEST FACILITY Shell (2002)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test – Static.

| | |
|---|---|
| Species | *Mugil persia* (Mullet) |
| Exposure Period | 96 hours |
| Auxiliary Solvent | None |
| Water Hardness | Not reported |
| Analytical Monitoring | Not reported |
| Remarks – Method | Unclear as to whether good laboratory practice (GLP) was used. Fish were exposed to 'suspended particle phase', which was prepared by mixing a 1:9 solution of drilling mud containing the notified chemical and seawater for 30 minutes, settling for 1 hour, and removing the aqueous phase. |

RESULTS

| | |
|---|---|
| LC50 | 75500 mg/L at 96 hours |
| Remarks – Results | Unclear as to whether relevant test validity criteria met. |

CONCLUSION The notified chemical is not expected to be harmful to fish.

TEST FACILITY NEERI (2005)

**C.2.2. Chronic toxicity to fish**

TEST SUBSTANCE Notified chemical

METHOD OECD TG 210 Fish, Early-life Stage Toxicity Test.

| | |
|---|---|
| Species | *Pimephales promelas* (Flathead Minnow) |
| Exposure Period | 33 days |
| Auxiliary Solvent | None |
| Water Hardness | 140 mg $CaCO_3$/L |
| Analytical Monitoring | Total Organic Carbon (TOC) analysis |
| Remarks – Method | The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. Used water accommodated fraction (WAF). |

RESULTS

| *Concentration mg/L Nominal* | *Number of Eggs* | *Number of Live Larvae 33 days* |
|---|---|---|

| | | |
|---|---|---|
| Control | 2 × 30 | 55 |
| 10 | 2 × 30 | 52 |
| 32 | 2 × 30 | 53 |
| 100 | 2 × 30 | 54 |

NOEL 100 mg/L at 33 days
Remarks – Results

CONCLUSION The notified chemical is not expected to be harmful to fish in the long term.

TEST FACILITY Harlan (2009a)

**C.2.3. Acute toxicity to aquatic invertebrates**

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia sp*. Acute Immobilisation Test - Static.
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness 240 mg $CaCO_3$/L
Analytical Monitoring Not reported.
Remarks - Method The method was conducted according to test guidelines. Unclear as to whether good laboratory practice (GLP) was used. Unfiltered water accommodated fractions (WAF) were prepared by stirring for 72 hours in sealed vessels with only a small headspace, with the aqueous phases used as the test solution.

RESULTS

| *Concentration mg/L* | | *Number of D. magna* | *Number Immobilised* | |
|---|---|---|---|---|
| *Nominal* | *Actual* | | *24 h* | *48 h* |
| Control | n/a | 2 × 10 | 0 | 0 |
| 1000 | n/a | 2 × 10 | 0 | 0 |

EL50 > 1000 mg/L at 48 hours (WAF)
NOEL 1000 mg/L at 48 hours
Remarks - Results Relevant test validity criteria were met.

CONCLUSION The notified chemical is not expected to be harmful to aquatic invertebrates.

TEST FACILITY Shell (2001)

TEST SUBSTANCE Notified chemical

METHOD Ministry of Agriculture, Fisheries and Food (MAFF) Method.
Species *Acartia tonsa* (Copepod)
Exposure Period 96 hours
Auxiliary Solvent None
Water Hardness mg $CaCO_3$/L
Analytical Monitoring Not reported.
Remarks - Method WAF used, prepared with seawater

RESULTS
LC50 > 1000 mg/L at 96 hours
NOEC 130 mg/L at 96 hours
Remarks - Results

CONCLUSION The notified chemical is not expected to be harmful to aquatic invertebrates.

TEST FACILITY Springborn Smithers Laboratories (2006a)

**C.2.4. Chronic toxicity to aquatic invertebrates**

TEST SUBSTANCE Notified chemical

METHOD OECD TG 211 *Daphnia magna* Reproduction Test.
Species *Daphnia magna*
Exposure Period 21 days
Auxiliary Solvent None
Water Hardness 140 – 170 mg $CaCO_3$/L
Analytical Monitoring Not reported
Remarks - Method The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. Filtered water accommodated fractions (WAF) were used as the test solutions, and were renewed three times per week.

RESULTS

Survival of parental daphnids and number of offspring released per female daphnid at 21 days (*Daphnia magna*)

| Nominal Loading (mg/L) | A | B | C | D | E | F | G | H | I | J | Number of Adult Daphnids Immobilized | Percent Survival |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Number of Offspring Released per Daphnid | | | | | | | | | | | | |
| Control | 68 | 53 | 55 | 57 | 70 | 61 | 66 | 64 | 57 | 51 | 0 | 100 % |
| 10 | 75 | 66 | 60 | 10 | 69 | 31 | 62 | 58 | 33 | 52 | 3 | 70 % |
| 32 | 0 | 17 | 64 | 65 | 60 | 58 | 72 | 60 | 67 | 54 | 2 | 80 % |
| 100 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 0 % |

LOEL 100 mg/L at 21 days (WAF)
NOEL (reproduction) 32 mg/L at 21 days (WAF)
Remarks - Results Relevant test validity criteria were met.

CONCLUSION The notified chemical is not expected to be harmful to aquatic invertebrates with long term effects.

TEST FACILITY Harlan (2011b)

**C.2.5. Algal growth inhibition test**

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test - Static.
Species *Raphidocelis subcapitata*
Exposure Period 72 hours
Concentration Range 1000 mg/L
Auxiliary Solvent None
Water Hardness 240 mg $CaCO_3$/L
Analytical Monitoring Not reported
Remarks - Method The method was conducted according to test guidelines. Unclear as to whether good laboratory practice (GLP) was used. Unfiltered water accommodated fractions (WAF) were prepared by stirring for 72 hours in sealed vessels with only a small headspace, with the aqueous phases used as the test solution.

RESULTS

| | *Growth* | |
|---|---|---|
| *$E_rL50$* | | *$NOE_rL$* |

| *mg/L at 72 h* | *mg/L at 72 h* |
|---|---|
| > 1000 | 1000 |

| | |
|---|---|
| Remarks – Results | Unclear as to whether all relevant test validity criteria were met. |

CONCLUSION The notified chemical is not expected to be harmful to algae.

TEST FACILITY Shell (2001)

TEST SUBSTANCE Notified chemical

METHOD SOP E209.

| | |
|---|---|
| Species | *Skeletonema costatum* |
| Exposure Period | 72 hours |
| Concentration Range | Nominal: 45, 100, 220, 450, 1000 mg/L |
| Auxiliary Solvent | None |
| Water Hardness | Not reported |
| Analytical Monitoring | Not reported |
| Remarks - Method | Method based on ISO 10253:2006 Water quality – Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum*. Test conducted using good laboratory practice (GLP). Unfiltered water accommodated fractions (WAF) were prepared via aspiration for 20 to 24 hours and used as test solutions. |

RESULTS

| *Biomass* | | *Growth* | |
|---|---|---|---|
| *$E_bL50$* | *$NOE_bL$* | *$E_rL50$* | *$NOE_rL$* |
| *mg/L at 72 h* | *mg/L at 72 h* | *mg/L at 72 h* | *mg/L at 72 h* |
| > 1000 | 1000 | > 1000 | 1000 |

| | |
|---|---|
| Remarks - Results | The NOEL was not reported but was extracted from the available results. |

CONCLUSION The notified chemical is not expected to be harmful to algae.

TEST FACILITY Chemex (2006)

**C.2.6. Inhibition of microbial activity**

TEST SUBSTANCE Notified chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

| | |
|---|---|
| Inoculum | Activated sewage sludge |
| Exposure Period | 3 hours |
| Concentration Range | Nominal: 10, 32, 100, 320, 1000 mg/L |
| Remarks – Method | The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. |

RESULTS

| | |
|---|---|
| EC50 | > 1000 mg/L at 3 hours |
| NOEC | 1000 mg/L at 3 hours |
| Remarks – Results | Oxygen uptake of the control did not meet the test validity criteria. All other relevant test validity criteria were met. |

CONCLUSION The notified chemical is not expected to harmful to microbial activity.

TEST FACILITY Harlan (2009b)

**C.2.7. Inhibition of nitrogen transformation**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 216 Soil Microorganisms: Nitrogen Transformation Test. |
| Exposure Period | 28 days |
| Concentration Range | Nominal: 100, 180, 320, 560, 1000 mg/kg |
| Remarks - Method | The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. |
| RESULTS | |
| EC50 | 320 mg/kg at 28 days |
| NOEC | 180 mg/kg at 28 days |
| Remarks - Results | Relevant test validity criteria were met. |
| CONCLUSION | The notified chemical is not expected to be harmful to nitrogen transforming activity of soil microorganisms. |
| TEST FACILITY | Harlan (2010c) |

**C.2.8. Acute toxicity to plants**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 208 Terrestrial (Non-Target) Plant Test: Seedling Emergence and Seedling Growth Test. |
| Species | *Glycine max* (Soybean) |
| Exposure Period | 22 days |
| Concentration Range | Nominal: 100, 180, 320, 560, 1000 mg/kg |
| Remarks - Method | The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. |

RESULTS

| *Emergence* | | *Growth* | |
|---|---|---|---|
| *EC50* | *NOEC* | *EC50* | *NOEC* |
| *mg/kg at 22 days* | *mg/kg at 22 days* | *mg/kg at 22 days* | *mg/kg at 22 days* |
| > 1000 | 1000 | > 1000 | 1000 |

| | |
|---|---|
| Remarks - Results | Unclear as to whether test validity criteria were met. |
| CONCLUSION | The notified chemical is not expected to be harmful to plants. |
| TEST FACILITY | Harlan (2011c) |
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 208 Terrestrial (Non-Target) Plant Test: Seedling Emergence and Seedling Growth Test. |
| Species | *Lycoperisicon esculentum* (Tomato) |
| Exposure Period | 21 days |
| Concentration Range | Nominal: 100, 180, 320, 560, 1000 mg/kg |
| Remarks - Method | The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. |

RESULTS

| *Emergence* | | *Growth* | |
|---|---|---|---|
| *EC50* | *NOEC* | *EC50* | *NOEC* |
| *mg/kg at 21 days* | *mg/kg at 21 days* | *mg/kg at 21 days* | *mg/kg at 21 days* |

| | | | |
|---|---|---|---|
| > 1000 | 1000 | > 1000 | 1000 |

Remarks - Results: Unclear as to whether test validity criteria were met.

CONCLUSION: The notified chemical is not expected to be harmful to plants.

TEST FACILITY: Harlan (2011c)

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 208 Terrestrial (Non-Target) Plant Test: Seedling Emergence and Seedling Growth Test.

Species: *Sinapis alba* (Mustard)
Exposure Period: 21 days
Concentration Range: Nominal: 100, 180, 320, 560, 1000 mg/kg
Remarks - Method: The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations.

RESULTS

| *Emergence* | | *Growth* | |
|---|---|---|---|
| *EC50* | *NOEC* | *EC50* | *NOEC* |
| *mg/kg at 21 days* | *mg/kg at 21 days* | *mg/kg at 21 days* | *mg/kg at 21 days* |
| > 1000 | 1000 | > 1000 | 1000 |

Remarks - Results: Unclear as to whether test validity criteria were met. Statistically significant difference found between control group and mustard group for emergence; however considered to be a factor of the statistically analysis. A slight reduction in vigour was observed at 320, 560 and 1000 mg/kg. Significant increase in growth observed at 560 mg/kg.

CONCLUSION: The notified chemical is not expected to be harmful to plants.

TEST FACILITY: Harlan (2011c)

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 208 Terrestrial (Non-Target) Plant Test: Seedling Emergence and Seedling Growth Test.

Species: *Avena sativa* (Oat)
Exposure Period: 21 days
Concentration Range: Nominal: 100, 180, 320, 560, 1000 mg/kg
Remarks - Method: The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations.

RESULTS

| *Emergence* | | *Growth* | |
|---|---|---|---|
| *EC50* | *NOEC* | *EC50* | *NOEC* |
| *mg/kg at 21 days* | *mg/kg at 21 days* | *mg/kg at 21 days* | *mg/kg at 21 days* |
| > 1000 | 1000 | > 1000 | 1000 |

Remarks - Results: Unclear as to whether test validity criteria were met. A slight reduction in vigour was observed at 1000 mg/kg. Significant increase in growth observed at 100 mg/kg.

CONCLUSION: The notified chemical is not expected to be harmful to plants.

TEST FACILITY: Harlan (2011c)

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 208 Terrestrial (Non-Target) Plant Test: Seedling Emergence and Seedling Growth Test. |
| Species | *Lolium perenne* (Perennial ryegrass) |
| Exposure Period | 21 days |
| Concentration Range | Nominal: 100, 180, 320, 560, 1000 mg/kg |
| Remarks - Method | The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. |

RESULTS

| *Emergence* | | *Growth* | |
|---|---|---|---|
| *EC50* | *NOEC* | *EC50* | *NOEC* |
| *mg/kg at 21 days* | *mg/kg at 21 days* | *mg/kg at 21 days* | *mg/kg at 21 days* |
| > 1000 | 1000 | 990 | 560 |

| | |
|---|---|
| Remarks - Results | Unclear as to whether test validity criteria were met. |
| CONCLUSION | The notified chemical is not expected to be harmful to plants. |
| TEST FACILITY | Harlan (2011c) |

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