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(STD/1335)

May 2012

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

**FULL PUBLIC REPORT**

**Infineum 6399**

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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

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**Director  
NICNAS**

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## **FULL PUBLIC REPORT**

This assessment report is for an extension of current assessment certificate for Infineum 6399. Based on the submission of new information by the extension notifier, some sections of the current assessment report for IMCD Australia Limited have been modified. These modifications have been made under the heading '*Extension Application*' in the respective sections.

## **SUMMARY**

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

| ASSESSMENT REFERENCE | APPLICANT                | CHEMICAL OR TRADE NAME | HAZARDOUS SUBSTANCE | INTRODUCTION VOLUME   | USE                          |
|----------------------|--------------------------|------------------------|---------------------|-----------------------|------------------------------|
| EX/173 (STD/1335)    | United Terminals Pty Ltd | Infineum 6399          | No                  | < 65 tonnes per annum | An additive for diesel fuels |

## **CONCLUSIONS AND REGULATORY OBLIGATIONS**

### **Hazard classification**

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

### **Human health risk assessment**

Under the conditions of the occupational settings described, 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 reported use pattern, the notified chemical is not considered to pose a risk to the environment.

### **Risk assessment relating to extension applicant**

The use and environmental fate described in the extension application are not expected to impact the outcomes of the current human health and environment risk assessment and recommendations.

### **Recommendations**

#### **CONTROL MEASURES**

##### **Occupational Health and Safety**

- Employers should implement the following safe work practices to minimise occupational exposure when handling the notified chemical at high concentrations i.e. the imported additive:
  - Avoid eye contact
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure when handling the notified chemical at high concentrations i.e. the imported additive:
  - Protective eyewear

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]

workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

#### Disposal

- The notified chemical should be disposed of to landfill or thermally decomposed during container reconditioning.

#### Emergency procedures

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

### Regulatory Obligations

#### *Secondary Notification*

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

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

- (1) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from an additive for diesel fuels, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 65 tonnes, 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.

No additional secondary notification conditions are stipulated.

#### *Material Safety Data Sheet*

The MSDS of products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

#### *Extension Application*

The extension applicant has provided an MSDS of a product containing the notified chemical which was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

**Infineum 6399****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Current Holder of the Assessment Certificate (STD/1335)

IMCD Australia Limited (ABN: 44 000 005 578)

1st Floor, 372 Wellington Road,

MULGRAVE VIC 3170

Applicant for Extension of the Current Assessment Certificate

United Terminals Pty Ltd (ABN: 73 129 440 955)

200 Hoddle street,

Abbotsford VIC 3067

## NOTIFICATION CATEGORY

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

## EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formula, molecular weight, spectra data, purity, details of use, import volumes, identity of recipients and methods of detection and determination.

## VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

## PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

## NOTIFICATION IN OTHER COUNTRIES

The notified chemical has been approved for inclusion on the national inventories in the following countries: Korea, US, Canada, China and Japan. The notified chemical is currently undergoing notification in the Philippines.

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Infineum 6399 will be imported into Australia as a component of a commercial fuels additive package. It will not be imported in isolation. The trade name of the new product has not yet been finalised.

## OTHER NAME(S)

Infineum 6399, WASA 6399

## MOLECULAR WEIGHT

&gt; 1000 Da

## ANALYTICAL DATA

Reference NMR, IR and UV spectra were provided.

**3. COMPOSITION**

DEGREE OF PURITY &gt; 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (&gt;1% by weight) None

ADDITIVES/ADJUVANTS None

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Cream coloured waxy/brittle solid

| Property                                | Value                              | Data Source/Justification   |
|---|------------------------------------|---|
| Melting Point/Freezing Point            | 51.8°C                             | Measured  |
| Boiling Point                           | Not determined                     | Starts to decompose at 300°C  |
| Density                                 | 948 kg/m <sup>3</sup>              | Measured  |
| Vapour Pressure                         | $5.85 \times 10^{-4}$ Pa at 20°C   | Measured  |
| Water Solubility                        | < 1.0 µg/L at 20°C                 | Measured.   |
| Hydrolysis as a Function of pH          | Not Determined                     | Measurement unfeasible due to the low water solubility. Hydrolysis is unlikely given the extremely low water solubility, despite of the existence of hydrolysable function groups in the notified chemical. |
| Partition Coefficient (n-octanol/water) | log Pow > 6.5 at 40°C              | Estimated.  |
| Adsorption/Desorption                   | log K <sub>oc</sub> = 6.62 at 40°C | Estimated.  |
| Dissociation Constant                   | PK <sub>a</sub> = ~ 4              | Predicted based on the existence of dissociable functional groups in the notified chemical. Measurement not feasible due to the insolubility in water.  |
| Particle Size                           | Not determined                     | Waxy solid  |
| Flash Point                             | 169°C at 101 kPa                   | Measured  |
| Flammability                            | Not determined                     | Not expected to be flammable based on measured flash point.   |
| Autoignition Temperature                | Not determined                     | Not expected to autoignite under normal conditions of use.  |
| Explosive Properties                    | Not expected to be explosive       | The structural formula contains no explosives.  |
| Stability Testing                       | Thermally stable up to 297°C.      | Measured  |

#### DISCUSSION OF PROPERTIES

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

#### Reactivity

Starts to decompose at 300°C, but expected to be stable under normal conditions.

#### 5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured within Australia. The notified chemical will be imported at a concentration of < 50 wt % in a new fuel additive package in bulk vessels or 205 L steel drums.

#### Extension Application

The notified chemical will be imported in diesel fuels at approximately 200 ppm.

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

#### Current Certificate Holder

| Year   | 1    | 2    | 3    | 4    | 5    |
|--------|------|------|------|------|------|
| Tonnes | < 20 | < 20 | < 50 | < 50 | < 50 |

#### Extension Application

| Year   | 1  | 2  | 3  | 4  | 5  |
|--------|----|----|----|----|----|
| Tonnes | 15 | 15 | 15 | 15 | 15 |

#### PORT OF ENTRY

Melbourne, Sydney and Brisbane.

#### IDENTITY OF MANUFACTURER/RECIPIENTS

The notifier expects the notified chemical to be used by a number of formulators of diesel fuels.

#### Extension Applicant

United Terminals Pty Ltd

#### TRANSPORTATION AND PACKAGING

The product containing the notified chemical will be brought into Australia in bulk vessels and 205 L drums. These containers will be transported by road for delivery to customer facilities or refineries. The finished diesel fuels containing the notified chemical at < 500 ppm will be distributed to service stations by road tankers. At the service stations, the diesel fuels will be transferred to underground tanks for storage.

#### USE

The notified chemical will be used as an additive in finished diesel fuels.

The notified chemical will be imported at a concentration of < 50 wt % in a new fuel additive package. The notified chemical will be blended with diesel fuels and other additives within Australia to form finished fuels where it will be present at a concentration of < 500ppm.

#### Extension Application

The use of the notified chemical will be same as that for the current assessment certificate. However, no reformulation will take place in Australia.

#### OPERATION DESCRIPTION

##### *Reformulation*

At the reformulation sites the additive package containing the notified chemical will be blended with diesel fuel and other additives typically in batches of 10,000-100,000 litres, to form the finished diesel fuels. The transfer of the imported additive package containing the notified chemical into the blend tanks is automated apart from the connection and disconnection of the flexible transfer hoses. Blending of the additives will be conducted in a closed system and on completion of the blending the container, transfer hoses and pump are cleaned of additive by flushing with diesel fuel.

##### *End use*

The finished fuels containing the notified chemical (at < 500 ppm) are then pumped out for distribution to service stations around Australia by road tanker. At the service stations, the diesel fuel will be transferred to underground tanks. When required, the diesel fuel would be pumped directly into automobile fuel tank.

#### Extension Application

The imported diesel fuels containing the notified chemical at approximately 200 ppm will be used in the same way as for the current assessment certificate.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

##### EXPOSURE DETAILS

Transport and dock workers will be exposed to the notified chemical only in the event of a spill due to an accident or leaking drum.

##### *Reformulation*

During reformulation, dermal and ocular exposure to the additive package containing the notified chemical at a concentration of < 50 wt % is possible during the connection and disconnection of the vessels containing it to the transfer hoses. Inhalation exposure is likely to be negligible due to the low vapour pressure of the notified chemical and the automation of the reformulation process. Exposure is expected to be reduced by engineering controls such as flushing of the transfer hoses and containers with diesel and the use of PPE such as gloves, safety glasses, overalls and safety shoes.

##### *End use*

Worker exposure to the notified chemical at concentrations of < 500 ppm could occur during handling and fueling of vehicles or equipment that are powered by diesel. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible. Maintenance on refinery plants and pipelines may also lead to worker exposure. Exposure during end use is expected to be minimized by the low (< 500 ppm) concentrations of the notified chemical in the finished diesel fuel and through good hygiene practices.

##### Extension Application

As only finished diesel containing the notified chemical at approximately 200 ppm concentration will be imported under the extension application, potential exposure will be limited to transportation, storage and end-use applications only.

#### 6.1.2. Public exposure

The additive package containing the notified chemical at a concentration of < 50 wt % will not be sold to the public and hence exposure would only occur in the event of an accident during transportation.

The public will be directly exposed (dermal and ocular) to the notified chemical when filling vehicles and equipment with finished diesel fuels containing it. Overall, direct exposure to the notified chemical in blended diesel is expected to be low due to the low concentration (< 500 ppm).

##### Extension Application

The public will be exposed to diesel fuel containing approximately 200 ppm notified chemical (as above).



## 6.2. Human health effects assessment

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

| <i>Endpoint</i>   | <i>Result and Assessment Conclusion</i> |
|---|---|
| Rat, acute oral toxicity                                      | oral LD50 > 2000 mg/kg bw; low toxicity |
| Rat, acute dermal toxicity                                    | LD50 > 2000 mg/kg bw; low toxicity      |
| Rabbit, skin irritation                                       | non-irritating                          |
| Rabbit, eye irritation  | slightly irritating                     |
| Mouse, skin sensitisation – Local lymph node assay            | no evidence of sensitisation            |
| Rat, repeat dose oral toxicity – 28 days.                     | NOAEL > 1000 mg/kg bw/day               |
| Mutagenicity – bacterial reverse mutation                     | non mutagenic                           |
| Genotoxicity – in vitro Mammalian Chromosome Aberration Test. | non genotoxic                           |
| Genotoxicity – in vitro Mammalian Cell Gene Mutation Test.    | non genotoxic                           |
| Reproduction/Developmental Toxicity Screening Test            | NOAEL > 1000 mg/kg bw/day               |

### *Toxicokinetics, metabolism and distribution.*

Based on the high molecular weight (> 1000 Da) and the lipophilicity of the notified chemical (water solubility < 1.0 µg/L at 20°C; log Pow > 6.5 at 40°C) dermal absorption is unlikely.

### *Acute toxicity.*

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

### *Irritation and Sensitisation.*

Based on a test conducted on rabbits the notified chemical is considered to be non-irritating to the skin and slightly irritating to the eye. The notified chemical was found to be a non-sensitiser in a local lymph node assay in mice.

### *Repeated Dose Toxicity.*

In a 28-day repeat dose oral toxicity study conducted on rats no test substance related effects were observed at all dose levels tested. Therefore, the No Observed (Adverse) Effect Level (NO(A)EL) was established as > 1000 mg/kg bw/day, based on the highest dose level examined.

### *Mutagenicity and Carcinogenicity.*

The notified chemical was found to not be mutagenic using a bacterial reverse mutation test, and not clastogenic to human lymphocytes and mouse L5178Y TK+/- 3.7.2c cells *in vitro*.

### *Toxicity for reproduction.*

In a reproduction toxicity study conducted on rats administered orally (gavage) no test substance related effects were observed at all dose levels tested. Therefore, the No Observed (Adverse) Effect Level (NO(A)EL) was established as > 1000 mg/kg bw/day, based on this being the highest dose tested.

### **Health hazard classification**

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

## 6.3. Human health risk characterisation

### 6.3.1. Occupational health and safety

Occupational dermal and ocular exposure to the notified chemical for reformulation workers may occur during handling of the drums or bulk vessels, transfer of the additive package ( $\leq 50\%$ ) into the blend tank, cleaning and maintenance of the equipment. Dermal and ocular exposure may also occur in the end use where diesel ( $< 500$  ppm notified chemical) or equipment powered by it is used.

Workers most at risk of irritancy will be reformulation workers handling the notified chemical at high concentrations i.e. in the imported additive. Given the engineering controls in place and proposed use of PPE including eye protection, the potential for exposure to the notified chemical should be minimised and therefore the risk to workers is not considered unreasonable.

#### Extension Application

As only finished diesel containing the notified chemical at approximately 200 ppm concentration will be imported under the extension application, exposure will be limited and therefore the risk to workers is not considered unreasonable.

### 6.3.2. Public health

The public will only be exposed to the notified chemical when it is present in diesel fuel ( $< 500$  ppm). Due to the low concentration of the notified chemical in the diesel and the low hazard of the notified chemical the risk to the public is not considered unreasonable.

#### Extension Application

The risk to the public from exposure to diesel fuel containing approximately 200 ppm of the notified chemical is not considered unreasonable (as above).

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1 Environmental Exposure

##### RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported at a concentration of  $< 50$  wt % in a new fuel additive package in bulk vessels or 205 L steel drums for further blending with diesel fuels and other additives to form finished fuels. Fugitive emissions during transport and blending are considered to be negligible. Transfer to blending operation occurs in closed pipes and vessels, where the new chemical will be blended with diesel fuel and automatically pumped out for distribution by road tanker. If incidental spillage of the additive package occurs during normal blending procedures, it will be contained and soaked up with earth or sand before being transported off-site to an approved industrial facility for appropriate disposal to landfill. It would not be released to the environment.

Empty containers will be removed to a safe place to await appropriate recycling or disposal. Approximately 1% unused residues left inside "empty" containers will be either decomposed during the reconditioning of the containers forming water and oxides of carbon and nitrogen, or disposed of as consumer container residues.

##### RELEASE OF CHEMICAL FROM USE

The end use of the chemical will be as an additive in diesel fuel. There could be minor spills at petrol stations, which would mostly fall to the ground. Release of the new chemical to the atmosphere is unlikely to occur, particularly as the vapour pressure of the new chemical is negligible and its viscosity at ambient temperatures is high. In automotive engines, the notified chemical will be consumed together with the diesel fuel to generate primarily water and oxides of carbon and nitrogen.

##### RELEASE OF CHEMICAL FROM DISPOSAL

No significant release of the notified chemical from formulation to end use is expected. Any significant spill would most likely be disposed of to landfill.

#### 7.1.2 Environmental fate

The notified chemical is considered to be readily biodegradable based on the study provided. The potential for bioaccumulation is expected to be low based on the modelling results. For the details of the environmental fate

studies please refer to Appendix C.

Most of the notified chemical will share the fate of the diesel fuel containing it and be consumed in automotive engines. Residues in containers are not significant and are expected to be removed and treated properly, and most likely will be thermally decomposed to recover the calorific value at the container reconditioning facility. For the limited disposal to landfill, the notified chemical is expected to bind to organic matter based on the high estimated log K<sub>oc</sub> of 6.62, and undergo degradation processes via biotic and abiotic pathways. Either way, the notified chemical will be finally decomposed into small molecules of water and oxides of carbon and nitrogen.

### 7.1.3 Predicted Environmental Concentration (PEC)

The calculation of PEC is not conducted due to the minimal release estimated based on the reported use pattern.

## 7.2. Environmental effects assessment

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

| <i>Endpoint</i>                     | <i>Result</i>                | <i>Assessment Conclusion</i>                                 |
|-------------------------------------|------------------------------|--|
| Fish Toxicity                       | LL50 > 100 mg/L WAF, nominal | Not toxic to fish up to the limit of the water solubility    |
| Daphnia Toxicity                    | EL50 > 100 mg/L WAF, nominal | Not toxic to daphnia up to the limit of the water solubility |
| Algal Toxicity                      | EL50 > 100 mg/L WAF, nominal | Not toxic to algae up to the limit of the water solubility   |
| Inhibition of Bacterial Respiration | IC50 > 1000 mg/L             | Not toxic to sludge micro-organisms                          |

The notified chemical is not considered toxic to the aquatic life up to the limit of its water solubility.

### 7.2.1 Predicted No-Effect Concentration

Calculation of PNEC for the notified chemical is not necessary given its property of no toxicity to aquatic life up to the limit of water solubility.

## 7.3. Environmental risk assessment

The Risk Quotient (RQ, PEC/PNEC) has not been determined given no significant release of the notified chemical to environment is expected from the reported use pattern. In case any release occurs to the environment, it readily biodegrades and therefore will not be a concern to the aquatic compartment.

Based on the above, the notified chemical is not expected to pose any unreasonable risk to the environment from the proposed application.

### Extension Application

Considering that the notified chemical will share the fate of the diesel fuel and be consumed in automotive engines, the proposed increase in volume under the extension application is not expected to impact on the current environmental risk assessment.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES****Melting Point/Freezing Point** 51.8°C

Method OECD TG 102 Melting Point/Melting Range.  
 Remarks No significant protocol deviations. GLP compliant.  
 Test Facility Wildlife International (2008a)

**Boiling Point** Not determined

Method OECD TG 103 Boiling Point.  
 US EPA OPPTS 830.7220, Boiling Point/Boiling Range  
 Remarks The notified chemical starts to decompose at 300°C.  
 No significant protocol deviations. GLP compliant.  
 Test Facility Wildlife International (2008b)

**Density** 948 kg/m<sup>3</sup>

Method OECD TG 109 Density of Liquids and Solids.  
 US EPA OPPTS 830.7300, Density/Relative Density/Bulk Density  
 Remarks Bulk density was measured using a Quantachrome Ultrapycnometer 1000 helium pycnometer.  
 The temperature at which the test was conducted was not recorded. GLP compliant.  
 Test Facility Wildlife International (2008c)

**Vapour Pressure**  $5.85 \times 10^{-4}$  Pa at 20°C

Method OECD TG 104 Vapour Pressure.  
 US EPA OPPTS 830.7950 Vapour Pressure  
 Remarks Spinning rotor gauge method used. Hexachlorobenzene was used as the reference substance, for which the tested vapour pressure was  $1.35 \times 10^{-3}$  Pa. This result is consistent with the literature value.  
 The mean calculated vapour pressure for the new chemical at 20°C was  $5.85 \times 10^{-4}$  Pa, with a range of  $4.96 \times 10^{-4}$  to  $7.61 \times 10^{-4}$  Pa.  
 Test Facility Wildlife International (2008d)

**Water Solubility** < 1 µg/L at 20°C

Method OECD TG 105 Water Solubility.  
 US EPA OPPTS 830.7860.  
 Remarks Column Elution Method. Samples were collected separately at water flow rate of 1.0 mL/min and 0.5 mL/min at 20°C, and the concentrations were tested. For both cases the concentration was below the method limit of quantitation of 1 µg/L.  
 Test Facility Wildlife International (2008e)

**Partition Coefficient (n-octanol/water)** log P<sub>ow</sub> > 6.5

Method OECD TG 117 Partition Coefficient (n-octanol/water).  
 US EPA OPPTS 830.7570.  
 Remarks HPLC Method. The column temperature was maintained at 40 ± 0.8°C. The column dead time was determined to be 0.893 min by injecting thiourea. The notified chemical eluted as six peaks. All the six peaks eluted after the reference standard DDT that has the highest log P<sub>ow</sub> of 6.5.  
 Test Facility Wildlife International (2008f)

**Adsorption/Desorption** log K<sub>oc</sub> = 6.62  
– screening test

|                          |   |
|--------------------------|---|
| Method                   | OECD TG 121 Estimation of the Adsorption Coefficient ( $K_{OC}$ ) on Soil and on Sewage Sludge Using High Performance Liquid Chromatography (HPLC).   |
| Remarks                  | The column temperature was maintained at 40°C. The column dead time was determined to be 1.836 min by injecting thiourea. The notified chemical eluted as five peaks. The corresponding log $K_{OC}$ for the notified chemical ranged from unretained to an extrapolated value of 6.94. The weighted mean log $K_{OC}$ of the notified chemical was calculated to be 6.62.  |
| Test Facility            | Wildlife International, Limited (2008g)   |
| <b>Flash Point</b>       | 169°C at 101 kPa  |
| Method                   | US EPA OPPTS 830.6315 Flammability;<br>D93-90 Flash Point by Pensky-Martens Closed Tester   |
| Remarks                  | The flash point was determined using a PetroLab, Inc. Model PMA 2 flash point tester following the procedure presented in method D 93-90 of the American Society of Testing and Materials, Flash Point by Pensky-Martens Closed Tester.<br>No significant protocol deviations. GLP compliant.   |
| Test Facility            | Wildlife International (2008h)  |
| <b>Stability Testing</b> | Thermally stable up to 297°C.   |
| Method                   | OECD TG 113 Screening Test for Thermal Stability and Stability in Air.<br>US EPA OPPTS 830.6316 Explodability   |
| Remarks                  | Under the conditions specified, the thermal analysis determined one endothermic region with an average onset temperature of 36.1°C, consistent with phase transition (i.e., melting). An exothermic region prior to the boiling point of the test substance was also identified with an average onset temperature of 297°C, consistent with thermal decomposition. Therefore, the test substance was determined to be thermally stable below 297°C.<br>No significant protocol deviations. GLP compliant. |
| Test Facility            | Wildlife International (2008i)  |

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

### B.1. Acute toxicity – oral

|                  |   |
|------------------|---|
| TEST SUBSTANCE   | Notified chemical   |
| METHOD           | OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. |
| Species/Strain   | Rat/Albino CrI : CD (SD) Female                             |
| Vehicle          | Corn oil  |
| Remarks - Method | No significant protocol deviations.<br>GLP compliant.       |

#### RESULTS

| <i>Group</i> | <i>Number and Sex<br/>of Animals</i> | <i>Dose<br/>mg/kg bw</i> | <i>Mortality</i> |
|--------------|--------------------------------------|--------------------------|------------------|
| I            | 3 Female                             | 2000                     | 0                |
| II           | 3 Female                             | 2000                     | 0                |

|                   |   |
|-------------------|---|
| LD50              | > 2000 mg/kg bw   |
| Signs of Toxicity | There were no deaths.<br>Clinical findings consisted of abnormal excretion (feces smaller than normal and/or decreased defecation). No other abnormal physical signs were noted during the study. |
| Effects in Organs | There were no remarkable necropsy findings.   |
| Remarks - Results | Body weight gains were as expected.   |

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

TEST FACILITY WIL (2008a)

### B.2. Acute toxicity – dermal

|                  |   |
|------------------|---|
| TEST SUBSTANCE   | Notified chemical                                     |
| METHOD           | OECD TG 402 Acute Dermal Toxicity – Limit Test.       |
| Species/Strain   | Rat/Sprague-Dawley CD (CrI : CD (SD) IGS BR)          |
| Vehicle          | Arachis oil was used to moisten the test substance.   |
| Type of dressing | Semi-occlusive.                                       |
| Remarks - Method | No significant protocol deviations.<br>GLP compliant. |

#### RESULTS

| <i>Group</i> | <i>Number and Sex<br/>of Animals</i> | <i>Dose<br/>mg/kg bw</i> | <i>Mortality</i> |
|--------------|--------------------------------------|--------------------------|------------------|
| I            | 5 per sex                            | 2000                     | 0                |

|                              |  |
|------------------------------|--|
| LD50                         | > 2000 mg/kg bw  |
| Signs of Toxicity - Local    | There were no test substance-related dermal reactions.   |
| Signs of Toxicity - Systemic | There were no deaths or test-substance related clinical signs. There were no signs of systemic toxicity. |
| Effects in Organs            | No abnormalities were noted at necroscopy  |
| Remarks - Results            | Body weight gains were as expected.  |

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

TEST FACILITY Safepharm (2008a)

**B.3. Irritation – skin**

|                    |   |
|--------------------|---|
| TEST SUBSTANCE     | Notified chemical   |
| METHOD             | OECD TG 404 Acute Dermal Irritation/Corrosion.<br>EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).   |
| Species/Strain     | Rabbit/New Zealand White  |
| Number of Animals  | 3 Male  |
| Vehicle            | Test substance administered as supplied   |
| Observation Period | 72 Hours  |
| Type of Dressing   | Semi-occlusive.   |
| Remarks - Method   | The pH of a 10% aqueous solution of the notified chemical was determined prior to the commencement of the study and found to be 8.3 immediately on preparation and 8.4 after 10 minutes.<br>No significant protocol deviations.<br>GLP compliant. |
| Remarks - Results  | A single 4-hour, semi-occluded application of the test material to the intact skin of the three rabbits produced no evidence of skin irritation.  |
| CONCLUSION         | The notified chemical is non-irritating to the skin.  |
| TEST FACILITY      | Safepharm (2008b)   |

**B.4. Irritation – eye**

|                    |   |
|--------------------|---|
| TEST SUBSTANCE     | Notified chemical   |
| METHOD             | OECD TG 405 Acute Eye Irritation/Corrosion.<br>EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation). |
| Species/Strain     | Rabbit/New Zealand White  |
| Number of Animals  | 3 (1 female and 2 male)   |
| Observation Period | 72 Hours  |
| Remarks - Method   | No significant protocol deviations.<br>GLP compliant.   |

**RESULTS**

| <i>Lesion</i>                 | <i>Mean Score*</i><br><i>Animal No.</i> |     |     | <i>Maximum Value</i> | <i>Maximum Duration of Any Effect</i> | <i>Maximum Value at End of Observation Period</i> |
|-------------------------------|---|-----|-----|----------------------|---------------------------------------|---|
|                               | 1                                       | 2   | 3   |                      |                                       |   |
| <i>Conjunctiva: redness</i>   | 0.7                                     | 0.3 | 0.3 | 2                    | < 72 hours                            | 0   |
| <i>Conjunctiva: chemosis</i>  | 0.3                                     | 0   | 0   | 2                    | < 48 hours                            | 0   |
| <i>Conjunctiva: discharge</i> | 0                                       | 0   | 0   | 2                    | < 24 hours                            | 0   |
| <i>Corneal opacity</i>        | 0                                       | 0   | 0   | 0                    | 0                                     | 0   |
| <i>Iridial inflammation</i>   | 0                                       | 0   | 0   | 0                    | 0                                     | 0   |

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

|                   |  |
|-------------------|--|
| Remarks - Results | No corneal or iridial effects were noted.<br>A single application of the test material to the non-irrigated eye of the 3 rabbits produced moderate conjunctival irritation 1 hour after treatment. Two treated eyes appeared normal at the 48 hour observation and the remaining treated eye appeared normal at the 72 hour observation. |
| CONCLUSION        | The notified chemical is slightly irritating to the eye.   |
| TEST FACILITY     | Safepharm (2008c)  |

**B.5. Skin sensitisation – mouse local lymph node assay (LLNA)**

|                  |   |
|------------------|---|
| TEST SUBSTANCE   | Notified chemical   |
| METHOD           | OECD TG 429 Skin Sensitisation: Local Lymph Node Assay<br>EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)  |
| Species/Strain   | Mouse/CBA/Ca (CBA/CaOlaHsd) Female  |
| Vehicle          | Butanone  |
| Remarks - Method | A preliminary screening test was conducted on 1 mouse with 50% w/w of the test substance in butanone. No signs of systemic toxicity were noted. Residual test material was noted post dose on day 2, with fur loss noted on day 3 and for the remainder of the test.<br>$\alpha$ -Hexylcinnamaldehyde (85% in butanone) was used as the positive control.<br>GLP compliant. |

**RESULTS**

| <i>Concentration<br/>(% w/w)</i> | <i>Proliferative response<br/>(DPM/lymph node)</i> | <i>Stimulation Index<br/>(Test/Control Ratio)</i> |
|----------------------------------|--|---|
| <i>Test Substance</i>            |  |   |
| 0 (vehicle control)              | 735 ( $\pm$ 169)                                   |   |
| 10                               | 1554 ( $\pm$ 454)                                  | 2.12  |
| 25                               | 1733 ( $\pm$ 322)                                  | 2.36  |
| 50                               | 2021 ( $\pm$ 537)                                  | 2.75  |
| <i>Positive Control (% v/v)</i>  |  |   |
| 10                               |  | 2.86  |
| 25                               |  | 5.74  |

|                   |   |
|-------------------|---|
| Remarks - Results | There were no deaths and no signs of systemic toxicity were noted in the test or control animals.<br>Residual test material on the ears and fur loss was noted post dose on day 2 and for the remainder of the test in all animals treated with concentrations of 25 and 50% of the notified chemical.<br>Body weight changes of the test animals were comparable to those seen in the control animals.<br>A stimulation index of less than 3 was observed for all concentrations of the test material. |
| CONCLUSION        | There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.  |
| TEST FACILITY     | Safepharm (2008d)   |

**B.6. Repeat dose toxicity**

|                         |  |
|-------------------------|--|
| TEST SUBSTANCE          | Notified chemical  |
| METHOD                  | OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.<br>EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral). |
| Species/Strain          | Rat/Crl:CD(SD)   |
| Route of Administration | Oral – gavage  |
| Exposure Information    | Total exposure days: 28 days<br>Dose regimen: 7 days per week<br>Post-exposure observation period: 14 days                             |
| Vehicle                 | Corn oil   |



## Remarks - Method

At the time of randomization male rats weighed only 153 to 185 g.  
One female animal in the control group did not have the histological processing performed on the adrenal glands.  
GLP compliant.

## RESULTS

| <i>Group</i>       | <i>Number and Sex<br/>of Animals</i> | <i>Dose<br/>mg/kg bw/day</i> | <i>Mortality</i> |
|--------------------|--------------------------------------|------------------------------|------------------|
| control            | 5 per sex                            | 0                            | 0                |
| low dose           | 5 per sex                            | 100                          | 0                |
| mid dose           | 5 per sex                            | 300                          | 0                |
| high dose          | 5 per sex                            | 1000                         | 0                |
| control recovery   | 5 per sex                            | 0                            | 0                |
| high dose recovery | 5 per sex                            | 1000                         | 0                |

*Mortality and Time to Death*

There were no unscheduled deaths during the study.

*Clinical Observations*

Incidental findings of red/yellow material around the mouth, nose, eyes and anogenital regions, fur loss, scabbing and soft faeces were noted during the study. These isolated, incidental external changes were considered of no toxicological importance.

*Behavioural Assessment* – There were no significant treatment-related changes.

*Functional Performance Tests* – Mean rotarod performance for female animals in the high dose group (mean 48.1 with standard deviation 40.47) was significantly lower than the control animals (mean 120 with standard deviation 0) during the third week of the study. However the pretest measurements on the high dose group were of a similar value (mean 46.7 with standard deviation 46.0) and hence the result was considered of no toxicological importance. There were no other significant treatment-related changes observed in the functional performance tests.

*Sensory Reactivity Assessments* - There were no treatment-related changes in sensory reactivity.

*Bodyweight* – No significant changes in bodyweight were seen.

*Food Consumption* – There was a statistically significant increase in the food consumption for females in the high dose group in comparison to the controls. As this increase was not seen in the remainder of the study or for the high dose male group it was considered of no toxicological importance.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*

*Haematology* – There was a statistically significant increase in the prothrombin time (PT) and in the large unstained cell parameter of the differential leukocyte count for male animals in the high dose recovery group. As the same increases were not seen for male animals in the high dose group the results were considered of no toxicological importance. There were no other significant test substance-related alterations in haematology and coagulation parameters.

*Blood Chemistry* – A statistically significant higher mean chloride level in male animals in the mid dose group was not considered of no toxicological importance as no dose response relationship was seen. Slightly higher mean potassium levels and lower mean sodium levels in the male high dose recovery group and higher mean albumin and triglycerides levels in the female high dose recovery group were considered of no toxicological importance due to the slight magnitude of the changes and because corresponding changes were not seen in the high dose groups. There were no other test substance-related alterations in serum chemistry parameters.

*Urinalysis* - Females in the high dose recovery group had an increase in urine volume together with a reduction in the specific gravity. The differences were considered of no toxicological importance due to there being no dose response relationship present and corresponding changes were not seen in the high dose groups. There were no other test substance-related alterations in urinalysis parameters.

*Effects in Organs*

Review of the gross necropsy observations revealed no observations that were considered to be associated with administration of the test substance.

Lower mean final bodyweights were measured in male animals in the low, mid and high dose groups. Higher mean adrenal gland and brain weights relative to final body weights were also seen in the male low and mid dose groups. The differences were considered of no toxicological importance due to there being no dose response relationship present. There were no other test substance-related alterations in final body weights or organ weights.

There were no test substance-related microscopic findings at the scheduled necropsies. All histologic changes were incidental findings or related to experimental manipulation other than the administration of the test substance.

## Remarks – Results

Based on the results of this study, the notified chemical administered orally (gavage) to Crl:CD(SD) rats for 28 consecutive days did not result in toxicity in the evaluated parameters at dosage levels of 100, 300 or 1000 mg/kg/day.

## CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as > 1000 mg/kg bw/day based on the absence of any test substance related effects at the highest dose tested.

TEST FACILITY WIL (2008b)

**B.7. Genotoxicity – bacteria**

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.  
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.  
Plate incorporation procedure  
Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100  
*E. coli*: WP2uvrA<sup>-</sup>  
Metabolic Activation System Rat S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver  
Concentration Range in Main Test a) With metabolic activation: 50 – 5000 µg/plate  
b) Without metabolic activation: 50 – 5000 µg/plate  
Vehicle Tetrahydrofuran  
Remarks - Method No signs of toxicity were recorded in the preliminary test.  
Although a particulate precipitate was observed at and above 500 µg/plate this did not prevent the scoring of revertant colonies.  
No significant protocol deviations.  
GLP compliant.

## RESULTS

| Metabolic Activation | Test Substance Concentration (µg/plate) Resulting in: |                           |               |                  |
|----------------------|---|---------------------------|---------------|------------------|
|                      | Cytotoxicity in Preliminary Test                      | Cytotoxicity in Main Test | Precipitation | Genotoxic Effect |
| <i>Absent</i>        |   |                           |               |                  |
| Test 1               | > 5000  | > 5000                    | 500           | negative         |
| Test 2               |   | > 5000                    | 500           | negative         |
| <i>Present</i>       |   |                           |               |                  |
| Test 1               | > 5000  | > 5000                    | 500           | negative         |
| Test 2               |   | > 5000                    | 500           | negative         |

Remarks - Results The test material was tested up to the maximum recommended dose level of 5000 µg/plate. No toxicologically significant increases in the

frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

|               |   |
|---------------|---|
| CONCLUSION    | The notified chemical was not mutagenic to bacteria under the conditions of the test. |
| TEST FACILITY | Safepharm (2008e)   |

## B.8. Genotoxicity – in vitro

|                             |   |
|-----------------------------|---|
| TEST SUBSTANCE              | Notified chemical   |
| METHOD                      | OECD TG 473 In vitro Mammalian Chromosome Aberration Test.<br>EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.  |
| Species/Strain              | Human   |
| Cell Type/Cell Line         | Lymphocyte  |
| Metabolic Activation System | Rat S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver  |
| Vehicle                     | Tetrahydrofuran   |
| Remarks - Method            | Due to the marginal toxicity of tetrahydrofuran to human lymphocytes when dosed at 1% by volume the maximum dose volume was reduced to 0.5% by volume.<br>The selection of the maximum dose level for the main test was based on the pronounced precipitation seen in the preliminary test.<br>GLP compliant. |

| <i>Metabolic Activation</i> | <i>Test Substance Concentration (µg/mL)</i>      | <i>Exposure Period</i> | <i>Harvest Time</i> |
|-----------------------------|--|------------------------|---------------------|
| <i>Absent</i>               |  |                        |                     |
| Test 1                      | 0*, 9.77, 19.53, 39.06*, 79.13*, 156.25*, 312.5* | 4 hours                | 24 hours            |
| Test 2                      | 0*, 4.90, 9.77, 19.53*, 39.06*, 78.13*, 156.25*  | 24 hours               | 24 hours            |
| <i>Present</i>              |  |                        |                     |
| Test 1                      | 0*, 9.77, 19.53, 39.06*, 79.13*, 156.25*, 312.5* | 4 hours                | 24 hours            |
| Test 2                      | 0*, 9.77, 19.53, 39.06*, 78.13*, 156.25*, 312.5* | 4 hours                | 24 hours            |

\*Cultures selected for metaphase analysis.

## RESULTS

| <i>Metabolic Activation</i> | <i>Test Substance Concentration (µg/mL) Resulting in:</i> |                                  |                      |                         |
|-----------------------------|---|----------------------------------|----------------------|-------------------------|
|                             | <i>Cytotoxicity in Preliminary Test</i>                   | <i>Cytotoxicity in Main Test</i> | <i>Precipitation</i> | <i>Genotoxic Effect</i> |
| <i>Absent</i>               |   |                                  |                      |                         |
| Test 1                      | > 2500  | > 312.5                          | 79.13                | Negative                |
| Test 2                      |   | > 156.25                         | > 156.25             | Negative                |
| <i>Present</i>              |   |                                  |                      |                         |
| Test 1                      | > 2500  | > 312.5                          | 156.25               | Negative                |
| Test 2                      |   | > 312.5                          | 156.25               | Negative                |

|                   |  |
|-------------------|--|
| Remarks - Results | The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.<br><br>The test material did not induce any statistically significant increases in the frequency of cells with aberrations, or in the numbers of polyploid cells. |
|-------------------|--|

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

TEST FACILITY SafePharm (2008f)

### B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.  
EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Species/Strain Mouse

Cell Type/Cell Line L5178Y TK+/- 3.7.2c

Metabolic Activation System Rat S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver

Vehicle Tetrahydrofuran

Remarks - Method Due to the toxicity of tetrahydrofuran to L5178Y TK+/- 3.7.2c cells when dosed above 50 µL per 20 mL culture the maximum final concentration that could be tested was 1250 µg/mL.

The selective agent used was 5-trifluorothymidine, the selection time was not recorded.

GLP compliant.

| <i>Metabolic Activation</i> | <i>Test Substance Concentration (µg/mL)</i> | <i>Exposure Period</i> | <i>Expression Time</i> | <i>Selection Time</i> |
|-----------------------------|---|------------------------|------------------------|-----------------------|
| <i>Absent</i>               |   |                        |                        |                       |
| Test 1                      | 0, 78.13, 156.25, 312.5, 625, 937.5, 1250   | 4 hours                | 2 days                 | N/A                   |
| Test 2                      | 0, 78.13, 156.25, 312.5, 625, 937.5, 1250   | 24 hours               | 2 days                 | N/A                   |
| <i>Present</i>              |   |                        |                        |                       |
| Test 1                      | 0, 78.13, 156.25, 312.5, 625, 937.5, 1250   | 4 hours                | 2 days                 | N/A                   |
| Test 2                      | 0, 78.13, 156.25, 312.5, 625, 937.5, 1250   | 4 hours                | 2 days                 | N/A                   |

### RESULTS

| <i>Metabolic Activation</i> | <i>Test Substance Concentration (µg/mL) Resulting in:</i> |                                  |                      |                         |
|-----------------------------|---|----------------------------------|----------------------|-------------------------|
|                             | <i>Cytotoxicity in Preliminary Test</i>                   | <i>Cytotoxicity in Main Test</i> | <i>Precipitation</i> | <i>Genotoxic Effect</i> |
| <i>Absent</i>               |   |                                  |                      |                         |
| Test 1                      | > 1250  | > 1250                           | 78.13                | Negative                |
| Test 2                      | > 1250  | > 1250                           | 78.13                | Negative                |
| <i>Present</i>              |   |                                  |                      |                         |
| Test 1                      | > 1250  | > 1250                           | 78.13                | Negative                |
| Test 2                      |   | > 1250                           | 78.13                | Negative                |

Remarks - Results

The vehicle controls had acceptable mutant frequency values that were within the normal range for the L5178Y cell line at the TK +/- locus. The positive control materials induced marked increases in the mutant frequency indicating the satisfactory performance of the test and of the activity of the metabolising system.

The test material did not induce any toxicologically significant or dose-related increases in the mutant frequency at any dose level, either with or without metabolic activation, in either the first or the second experiment using a dose range where the maximum dose level was limited by difficulties in the test material formulation.

CONCLUSION The notified chemical was not clastogenic to mouse L5178Y TK+/- 3.7.2c cells treated in vitro under the conditions of the test.

TEST FACILITY                      Safepharm (2008g)

### B.10. Developmental toxicity

TEST SUBSTANCE                      Notified chemical

METHOD                      OECD 421 Reproduction/Developmental Toxicity Screening Test  
US EPA OPPTS Guidelines 870.3550

Species/Strain                      Rat/Crl:CD(SD)

Route of Administration                      Oral – gavage

Exposure Information                      Exposure period - female: 39 – 52 days (14 days prior to pairing through to the day prior to euthanasia).

Females with no evidence of mating or that failed to deliver were dosed through to the day prior to euthanasia for a total of 44-52 days.

Exposure period - male: 28 days (14 days prior to pairing through to 1 day prior to scheduled euthanasia).

Dose regimen: daily

Post-exposure observation period: 0

Vehicle                      Corn oil

Remarks - Method                      No significant protocol deviations.  
GLP compliant.

### RESULTS

| <i>Group</i> | <i>Number of Animals</i> | <i>Dose<br/>mg/kg bw/day</i> | <i>Mortality</i> |
|--------------|--------------------------|------------------------------|------------------|
| I            | 12 per sex               | 0                            | 0                |
| II           | 12 per sex               | 100                          | 0                |
| III          | 12 per sex               | 300                          | 0                |
| IV           | 12 per sex               | 1000                         | 0                |

#### *Mortality and Time to Death*

All animals survived to the scheduled necropsy.

#### *Effects on Dams*

There were no test substance-related effects on mean body weights, body weight gains or food consumption for females during the pre-mating treatment period at any dosage levels. The mean bodyweight gain in the high dose group during lactation days 1 – 4 was significantly greater than in the control group. The differences in the body weight gain were considered of no toxicological importance due to the control group having an uncharacteristically low mean body weight gain and the lack of a concomitant increase in the food consumption at this stage. A significant increase in the food consumption of female animals in the high dose group was seen during gestation days 0 – 4, however there was no corresponding increase in the food consumption during this period and hence considered of no toxicological importance.

No test substance-related effects on reproductive performance or gestation length were seen in any of the test groups.

There were no test substance-related histopathologic effects on reproductive organs. No test substance-related macroscopic findings were noted at the scheduled necropsies for males or females at any dosage level.

There were no test substance related alterations in mean organ weights observed at any dosage level. Statistically significant differences in organ weight were observed including the higher mean left epididymis weight relative to brain weight in high dose males. However as the mean left epididymis absolute weight, the mean left epididymis weight relative to body weight and the mean right epididymis absolute and relative weights showed no difference in comparison to control it was considered of no toxicological importance. The mean pituitary gland weights (relative to brain and body weights) in the mid dose female group was also lower

than in the control group. However as there was no dose response relationship present the finding was considered of no toxicological importance. There were no microscopic findings associated with either of the differences.

#### *Effects on Foetus*

The mean number of pups born, live litter size and the percentage of males at birth in all dose groups were similar to the control group values. Postnatal survival was unaffected by parental test substance administration.

Mean male and female pup body weights and body weight gains in all dose groups were unaffected by parental test substance administration.

Mandibular micrognathia was noted in one pup from the mid dose group, however as this condition was not seen in the high dose group it was considered of no toxicological importance.

#### Remarks - Results

In the absence of test substance-related effects on reproductive performance, gestation lengths and parturition, a dosage level of 1000 mg/kg/day (the highest dosage level tested) was considered to be the no-observed-adverse-effect level (NOAEL) for reproductive toxicity of the test substance when administered orally by gavage to Crl:CD(SD) rats. Based on the absence of test substance-related effects on parental survival, clinical condition, mean body weights, body weight changes, food consumption, organ weights or macroscopic changes at all dosage levels and microscopic changes at the 1000 mg/kg/day dosage level, the NOAEL for male and female systemic toxicity was considered to be 1000 mg/kg/day. The NOAEL for neonatal toxicity was also 1000 mg/kg/day based on the absence of effects on postnatal survival or pup body weights.

#### CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as > 1000 mg/kg bw/day based on the absence of any test substance related effects at the highest dose tested.

TEST FACILITY

WIL (2008c)

## **APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS**

### **C.1. Environmental Fate**

#### **C.1.1. Ready biodegradability**

|                       |  |
|-----------------------|--|
| TEST SUBSTANCE        | Notified Chemical  |
| METHOD                | OECD TG 301B Ready Biodegradability: CO <sub>2</sub> Evolution Test.<br>Commission Directive, Annex V. 67/548/EEC C.4-C, Carbon Dioxide Evolution.   |
| Inoculum              | ISO 10634: 1995 (E) Water Quality – Guideline for the preparation and Treatment of Poorly Water-soluble Organic Compounds for the subsequent Evaluation of their Biodegradability in An Aqueous Medium.<br>Activated sludge from Cambridge Wastewater Treatment Plant, Cambridge, Maryland   |
| Exposure Period       | 28 days  |
| Auxiliary Solvent     | Test substance was dissolved in THF and applied to silica gel. Solvent was then completely removed prior to study. Test material was studied as solvent-free coating on silica gel powder. Polysorbate 85 was used as solubilizer in some of the test groups.  |
| Analytical Monitoring | Measurement of CO <sub>2</sub> evolved throughout the study, dissolved organic carbon (DOC) of test chamber on Day 29.   |
| Remarks - Method      | The CO <sub>2</sub> produced from the degradation of organic carbon sources within the test chamber was trapped as K <sub>2</sub> CO <sub>3</sub> in the KOH solution and the amount of inorganic carbon in the trapping solution was measured at various intervals during the study, using a Shimadzu Model TOC-V <sub>CSH</sub> carbon analyzer.<br><br>Sodium benzonate was used as the reference substance. The test contained a blank control group, reference group, treatment group, treatment toxicity control group, control group containing solubilizer, treatment group containing solubilizer, treatment toxicity control group containing solubilizer and a solubilizer toxicity control group. All groups were conducted in duplicates. |

#### **RESULTS**

| <i>Test substance</i> |                       | <i>Sodium Benzonate</i> |                       |
|-----------------------|-----------------------|-------------------------|-----------------------|
| <i>Day</i>            | <i>% Degradation*</i> | <i>Day</i>              | <i>% Degradation*</i> |
| 15                    | 10                    | 7                       | 68                    |
| 18                    | 60                    | 18                      | 102.8                 |

\* Percentage of theoretical amount of carbon dioxide (ThCO<sub>2</sub>).

|                   |  |
|-------------------|--|
| Remarks - Results | The biodegradation of the reference reached 68% by day 7 of the test. The biodegradation of the notified chemical reached 102.5% of ThCO <sub>2</sub> at day 28, with an average of 10% by day 15 and 60% by day 18 of the study.<br><br>The results indicate that the existence of solubilizer inhibited the biodegradation process for both the reference and the notified chemical. This may be attributed to the emulsifying effect of the solubilizer to the test substances which blocked the access of microbials to the test substances. |
| CONCLUSION        | The notified chemical is considered ready biodegradable based on the test result.  |
| TEST FACILITY     | Wildlife International Limited (2008j)   |

#### **C.1.2. Bioaccumulation**

|                   |   |
|-------------------|---|
| TEST SUBSTANCE    | Notified Chemical   |
| Remarks - Results | Test not conducted. The bioaccumulation potential of the notified chemical was evaluated based on related study data and in silico modelling. It was concluded that the material is not expected to be bioaccumulative. The ready biodegradability of the notified chemical also indicates a low potential for bioaccumulation. |
| CONCLUSION        | The potential for bioaccumulation of the notified chemical is considered low.   |

## C.2. Ecotoxicological Investigations

### C.2.1. Acute toxicity to fish

|                       |   |
|-----------------------|---|
| TEST SUBSTANCE        | Notified Chemical   |
| METHOD                | OECD TG 203 Fish, Acute Toxicity Test - static test.<br>US EPA OPPTS 850.1075: Fish Acute Toxicity Test, Fresh Water and Marine.  |
| Species               | fathead Minnow ( <i>Pimephales promelas</i> )   |
| Exposure Period       | 96 hours  |
| Auxiliary Solvent     | None.   |
| Water Hardness        | 134 mg CaCO <sub>3</sub> /L   |
| Analytical Monitoring | HPLC with triple quadrupole mass spectrometry (LC/MS/MS) detection. The limit of quantitation (LOQ) was defined as 1.00 µg/L.   |
| Remarks – Method      | Three replicate test chambers were maintained at 22 ± 1 °C in the treatment group and in the control group, with 10 fish in each test chamber.<br><br>Due to the low solubility of the notified chemical, test solutions were prepared as water accommodated fractions (WAFs) by directly mixing the notified chemical and water at a nominal loading rate of 100 mg/L. The solutions were filtrated through a 0.22 µm filter prior to distribution into the test chambers. The test solutions appeared clear and colourless following mixing and filtration. |

#### RESULTS

| Concentration mg/L |        | Number of Fish | Mortality |      |      |      |      |
|--------------------|--------|----------------|-----------|------|------|------|------|
| Nominal            | Actual |                | 1 h       | 24 h | 48 h | 72 h | 96 h |
| 0                  |        | 30             | 0         | 0    | 0    | 0    | 0    |
| 100                |        | 30             | 0         | 0    | 0    | 0    | 0    |

|                   |   |
|-------------------|---|
| LL50              | > 100 mg/ L WAF nominal at 96 hours.  |
| NOEL              | 100 mg/L WAF nominal at 96 hours.   |
| Remarks – Results | No mortality or overt signs of toxicity was observed in all the groups throughout the 96-hour test. |
| CONCLUSION        | The notified chemical is not toxic to fathead minnow up to the limit of its water solubility.       |
| TEST FACILITY     | Wildlife International Limited (2009a).   |

### C.2.2. Acute toxicity to aquatic invertebrates

|                |                   |
|----------------|-------------------|
| TEST SUBSTANCE | Notified Chemical |
|----------------|-------------------|



|                       |   |
|-----------------------|---|
| METHOD                | OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Cladoceran ( <i>Daphnia magna</i> ). 48 hour static test<br>US EPA OPPTS 850.1010 Acute Toxicity for Daphnia – Cladoceran ( <i>Daphnia magna</i> ). 48 hour static test   |
| Species               | <i>Daphnia magna</i>  |
| Exposure Period       | 48 hours  |
| Auxiliary Solvent     | None  |
| Water Hardness        | 137 mg CaCO <sub>3</sub> /L   |
| Analytical Monitoring | HPLC with triple quadrupole mass spectrometry (LC/MS/MS) detection. The limit of quantitation (LOQ) was defined as 1.00 µg/L.   |
| Remarks - Method      | Daphnids were exposed to the notified chemical of five loading rates (6.3, 13, 25, 50 and 100 mg/L) and a negative control (dilution water) in duplicates with 10 animals used for each replicate.<br><br>Due to the low solubility of the notified chemical, test solutions were prepared as water accommodated fractions (WAFs) by directly mixing the notified chemical and water. The solutions were filtrated through a 0.22 µm filter prior to distribution into the test chambers. Test solutions appeared clear and colourless following mixing and filtration. |

## RESULTS

| Concentration mg/L |        | Number of <i>D. magna</i> | Number Immobilised |      |
|--------------------|--------|---------------------------|--------------------|------|
| Nominal            | Actual |                           | 24 h               | 48 h |
| Control            |        | 20                        | 0                  | 0    |
| 6.3                |        | 20                        | 0                  | 0    |
| 13                 |        | 20                        | 0                  | 0    |
| 25                 |        | 20                        | 0                  | 0    |
| 50                 |        | 20                        | 0                  | 0    |
| 100                |        | 20                        | 0                  | 0    |

|                   |  |
|-------------------|--|
| EL50              | >100 mg/L at 24 hours<br>> 100 mg/L at 48 hours  |
| NOEL              | 100 mg/L at 48 hours   |
| Remarks - Results | All the <i>Daphnia</i> in the negative control group and in all the treatment groups appeared normal through the test, with no mortality/immobility or overt signs of toxicity observed. One daphnia in the 13 mg/L treatment group was noted floating at the 24-hour observation, but was normal in appearance after gentle submersion. The no-mortality/immobility concentration and the NOEL were therefore determined to be 100mg/L. |

|            |   |
|------------|---|
| CONCLUSION | The notified chemical is not toxic to <i>Daphnia magna</i> up to the limit of its water solubility. |
|------------|---|

|               |   |
|---------------|---|
| TEST FACILITY | Wildlife International Limited (2009b). |
|---------------|---|

**C.2.3. Algal growth inhibition test**

|                       |  |
|-----------------------|--|
| TEST SUBSTANCE        | Notified Chemical  |
| METHOD                | OECD TG 201 Alga, Growth Inhibition Test.<br>EC Directive 92/69/EEC C.3 Algal Inhibition Test. |
| Species               | Freshwater alga ( <i>Pseudokirchneriella subcapitata</i> )                                     |
| Exposure Period       | 72 hours   |
| Concentration Range   | Nominal: 6.3, 13, 25, 50 and 100mg/l<br>Actual: < 0.001-0.00489 mg/L                           |
| Auxiliary Solvent     | None   |
| Water Hardness        | N/A  |
| Analytical Monitoring | HPLC with triple quadrupole mass spectrometry (LC/MS/MS) detection.                            |

Remarks - Method

The limit of quantitation (LOQ) was defined as 1.00 µg/L.

Algae were exposed to the notified chemical at five concentrations and a negative control (dilution water) in duplicates at  $23 \pm 2^\circ\text{C}$  and under continuous cool-white fluorescent lighting of  $6,000 \pm 20\%$  intensity.

Due to the low solubility of the notified chemical, test solutions were prepared as water accommodated fractions (WAFs) by directly mixing the notified chemical and algal medium. The mixtures were decanted followed by centrifuging 10 min at 9643 g to remove suspended material prior to distribution into the test chambers. Test solutions appeared clear and colourless following mixing and centrifugation.

## RESULTS

| <i>Biomass</i>                          |   | <i>Growth</i>                           |   |
|---|---|---|---|
| <i>E<sub>b</sub>L50</i><br>mg/L at 72 h | 95 % confidence interval<br>mg/L          | <i>E<sub>r</sub>L50</i><br>mg/L at 72 h | 95 % confidence interval<br>mg/L          |
| > 100 (WAF, Nominal)                    | Not applicable<br>Could not be calculated | > 100 (WAF, Nominal)                    | Not applicable<br>Could not be calculated |

Remarks - Results

There were no apparent treatment-related effects on any of the parameters measured for any of the concentration tested. Consequently, the 72-hour EL50 value based on cell density, area under the growth curve and growth rate was > 100mg/L and the 72-hour NOEL in this study was determined to be 100mg/L, the highest loading rate tested.

CONCLUSION

The notified chemical is not considered toxic to algae up to the limit of its water solubility.

TEST FACILITY

Wildlife International Limited (2009c).

**C.2.4. Inhibition of microbial activity**

TEST SUBSTANCE

Notified Chemical

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test.  
EC Directive 67/548/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.

Inoculum

Activated sludge collected from the Cambridge Wastewater Treatment Facility, Cambridge, Maryland

Exposure Period

3 hours

Concentration Range

Nominal: 10, 30, 100, 300 and 1000 mg/L

Remarks – Method

The respiration rates of the test solutions were measured using a YSI Model 50 B Dissolved Oxygen Meter.

RESULTS

Control, reference and treatment test mixtures were incubated at  $20 \pm 2^\circ\text{C}$  and aerated for three hours at a rate sufficient to provide aerobic conditions and maintain solids in suspension. 3,5-dichlorophenol was used for the reference control at levels of 3, 15 and 50 mg/L.

IC50

> 1000 mg/L

NOEC

24 mg/L

Remarks – Results

The respiration rates observed in the two controls were 36.0 and 32.7 mg O<sub>2</sub>/L/hr, with a difference of approximately 10%. The EC50 value for the reference substance was 20.5 mg/L, with 95 percent confidence limits of 3 and 50, and was within the 5 to 30 mg/L range considered acceptable for the test. The EC50 and 95% confidence limits were calculated using binomial probability with nonlinear interpolation.

Inhibitory effects upon respiration by the test substance at the concentrations evaluated in this study did not exhibit a concentration

dependent dose response pattern. The dose-response curve starting below zero at 10 mg/L, and rising to a maximum around 100 mg/L, before dropping below zero again around 1000 mg/L. The observed percent inhibitions for the notified chemical ranged from – 4.8 – 34.2%. The EC50 value for the test substance is therefore considered to be greater than 1000 mg/L, the highest concentration tested.

**CONCLUSION**

The notified chemical is not considered to be toxic to sludge micro-organisms based on the test results.

**TEST FACILITY**

Wildlife International, Ltd (2008k)

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