File No: STD/1512

August 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical A in BP Turbo Oil 2389

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

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
STD/1512	BP Australia Pty Ltd	Chemical A in BP Turbo Oil 2389	ND*	≤ 10 tonne/s per annum	Component of industrial turbine oils

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 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 assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

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:
  - Enclosed, automated systems, where possible

- 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:
  - Avoid eye and skin contact

- 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:
  - Impervious gloves
  - Eye protection
  - Protective coveralls

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

- 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 for the 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.

Disposal

- The notified chemical should be recycled, re-used by recovery of calorific content, or be disposed of to landfill.

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(2) of the Act; if
- the function or use of the chemical has changed from a component of industrial turbine oils or is likely to change significantly;
- the amount of chemical being introduced has increased, 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 a product containing 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)
BP Australia Pty Ltd (ABN: 53 004 085 616)
132 McCredie Road
GUILFORD, NSW 2161

NOTIFICATION CATEGORY
Standard (Reduced Fee Notification): Chemical other than polymer (more than 1 tonne per year) – Similar to a chemical that has been previously assessed by NICNAS.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, residual monomers, impurities, additives/adjuvants, use details, manufacture/import volume and identities of analogue chemicals.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant, particle size, flammability limits, acute inhalation toxicity, induction of germ cell damage, bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Chemical A in BP Turbo Oil 2389

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
No reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. COMMENTS REGARDING SIMILAR CHEMICAL

The notified chemical is considered to be similar to three other chemicals previously assessed by NICNAS (i.e., analogue chemicals). Therefore, the measured data referred to throughout this assessment is derived from studies conducted on suitable analogues.

5. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear liquid

Property	Value	Data Source/Justification
Freezing Point	< - 20.15 °C	Measured (analogue 1)
Boiling Point	> 399.85 °C at 99.7 kPa	Measured (analogue 1)
Density	946 kg/m^3 at 20.4 ± 0.5 °C	Measured (analogue 1)
Vapour Pressure	5.4 x 10^{-12} kPa at 25 °C	Measured (analogue 1)
Water Solubility	< 3.22 × 10^{-4} g/L at 20 ± 0.5 °C	Measured (analogue 1)

Hydrolysis as a Function of pH	$t_{½}$ > 1 year at pH 4-9 and 25 °C	Measured (analogue 1)
Partition Coefficient (n-octanol/water)	log P_{OW} ≥ 6.50 at 20°C	Measured (analogue 1)
Adsorption/Desorption	log K_{oc} > 5.63	Measured (analogue 1)
Dissociation Constant	Not determined	The notified chemical does not contain any dissociable functionality.
Flash Point	205 °C at 101.3 kPa	(M)SDS
Flammability	Not determined	Based on the low estimated vapour pressure and high flash point, the notified chemical is not expected to be highly flammable.
Autoignition Temperature	394 ± 5 °C	Measured (analogue)
Explosive Properties	Predicted negative	Contains no functional groups that would imply explosive properties
Oxidising Properties	Predicated negative	Contains no functional groups that would imply oxidative properties

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

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not 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.

6. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported as a component (≤ 35% concentration of notified chemical) of finished industrial turbine oil products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-5	1-5	1-5	3-8	5-10

PORT OF ENTRY
Port of Brisbane.

IDENTITY OF MANUFACTURER/RECIPIENTS
BP Australia Pty Ltd
AMLC Pty Ltd (Australasian Lubricants Manufacturing Company)

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia as a component of finished turbine oil products in 1 L cans. The notified chemical will be transported and stored in these containers prior to use. The turbine oils containing the notified chemical will be transported to end use sites on pallets by road or rail.

USE
The notified chemical is a component (at a concentration ≤ 35%) of industrial turbine oils (e.g. for use in the aviation industry).

OPERATION DESCRIPTION
The notified chemical will be imported in a finished product. There will be no manufacture, reformulation or repackaging of the turbine oils containing the notified chemical in Australia. The turbine oils will be warehoused prior to transport to commercial customers around Australia. In its aviation use, the turbine oil containing the

notified chemical will be used by licensed aircraft maintenance engineers to charge and top up aircraft machinery. The method of charging and topping up aircraft machinery is for the most part a manual process.

7. HUMAN HEALTH IMPLICATIONS

7.1. Exposure Assessment

7.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport workers	5	30
Storage workers	1	30
Licensed Aircraft Maintenance Engineers	2	50

EXPOSURE DETAILS
Transport and storage workers may come into contact with the turbine oils containing the notified chemical at concentrations ≤ 35% only in the event of accidental rupture of containers.

End users are unlikely to be exposed to the notified chemical except in cases of drips and spills during charging or top up activities or during turbine maintenance work. Exposure to the notified chemical at concentrations ≤ 35% will primarily be dermal although ocular exposure is also possible from drips and splashes. The notifier has stated that dermal and ocular exposure is expected to be minimised by the use of personal protective equipment (PPE; gloves, eye protection and coveralls). Inhalation exposure is not expected given the (estimated) low vapour pressure of the notified chemical..

7.1.2. Public Exposure
Public exposure to the notified chemical is not expected. The product containing the notified chemical will be imported, warehoused and then transported to commercial end users only. The turbine oils containing the notified chemical at ≤ 35% concentration are intended for use solely by trained personnel working in industrial settings.

7.2. Human Health Effects Assessment
No toxicological data were provided for the notified chemical.
The results from toxicological investigations conducted on a mixture of analogues (analogues 2 and 3) of the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 >5,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 >2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOAEL 150 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chromosome aberration in human lymphocytes	non genotoxic

Toxicokinetics, metabolism and distribution.
Dermal absorption of the notified chemical is possible due to the relatively low molecular weight (< 500 Da); however, this potential is expected to be limited by the high log Pow (> 6.5) and low water solubility, with the transfer from the stratum corneum into the epidermis expected to be slow.

Acute toxicity.
Based on the studies conducted in rats, the mixture of analogue chemicals was considered to be of low acute toxicity via the oral and dermal routes. The notified chemical is therefore expected to be of similarly low acute toxicity via these routes. The acute inhalation hazard of the notified chemical or of the analogues has not been

determined. However, given the low volatility of the notified chemical (vapour pressure) it is not expected to pose a significant inhalation hazard.

Irritation and sensitisation.
Based on studies conducted in rabbits and guinea pigs, the mixture of analogues was found to be slightly irritating to the skin and eyes, and there was no indication of skin sensitisation. The notified chemical is therefore expected to be only a slight skin and eye irritant and is not expected to be a skin sensitiser.

Repeated dose toxicity.
In a 28-day repeated-dose oral toxicity study using a mixture of the analogue chemicals, treatment-related increases in the liver weights were observed for animals of either sex treated at 1,000 mg/kg bw/day and for males treated at 500 mg/kg bw/day. There were no concomitant histopathological changes. While an increase in liver weights can be an adaptive response, in the absence of detectable hepatocyte enlargement or enzyme induction this is merely speculative, and so the increase in liver weights is considered a possible adverse effect. Treatment-related effects on the kidneys in all treated males were observed. These were considered to be characteristics of α2-microglobulin nephropathy, a male rat specific phenomenon, and were therefore considered to not be relevant for determining human hazard. The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on changes in the liver at higher doses.

Mutagenicity/Genotoxicity.
The mixture of analogues was found to not be mutagenic using the bacterial reverse mutation test method and not clastogenic to human lymphocytes in vitro. The notified chemical is therefore not expected to be a mutagen or clastogen.

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

7.3. Human Health Risk Characterisation

7.3.1. Occupational Health and Safety
Based on the toxicity data provided for the previously assessed analogue chemicals, the notified chemical is expected to be a slight eye and skin irritant, and is not expected to be a skin sensitiser. The analogues are not acutely toxic via the oral or dermal routes, but treatment-related effects were seen during sub-chronic exposure.

The potential for exposure is greatest during end use where turbine oils containing the notified chemical at ≤ 35% concentration, will primarily be manually poured from containers into the turbines. Exposure is most likely to occur via a dermal route although ocular exposure to the notified chemical during topping up, charging and maintenance activities is also possible. As the notified chemical is expected to be slightly irritating to eyes and skin, the workers should avoid skin and eye contact with products containing the notified chemical at a concentration of ≤ 35%, e.g. through the use of PPE (such as impervious gloves, safety eyewear and coveralls).

When used in the proposed manner, the risk to the health of workers is not considered to be unreasonable.

7.3.2. Public Health
The risk to the public from the notified chemical is not considered to be unreasonable, based on the very low potential for exposure, as the turbine oils (≤ 35% notified chemical) are intended solely for industrial use by trained personnel and will not be in any products available to the public.

8. ENVIRONMENTAL IMPLICATIONS

8.1. Environmental Exposure & Fate Assessment

8.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be manufactured, formulated and packaged into end-use containers overseas, and therefore, there will be no environmental release in Australia from this stage of the notified chemical's life-cycle.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be imported formulated in 1 L end-use containers. Due to the nature of the formulated end-use product and its proposed use, environmental release is expected to be limited to residues within the imported containers and from accidental spills during transport and use. It is estimated that these sources of release will account for less than 2% of the total import volume of the notified chemical.

RELEASE OF CHEMICAL FROM DISPOSAL
The used product containing the notified chemical is expected to be disposed of by accredited waste management companies. It will most likely be recycled, re-used by recovery of calorific content, or be disposed of to landfill in accordance with local government regulations.

In the event of disposal to landfill, the notified chemical is expected to be immobile and associate strongly with the organic compartment of soil based on its very low water solubility, and high P_{OW} and K_{OC}. Over time, the notified chemical is expected to degrade via biotic and abiotic processes to form water and oxides of carbon.

8.1.2. Environmental Fate
A ready biodegradability study for a mixture of analogues 2&3 of the notified chemical showed a 28 day biodegradation of 62% but the 10-day window criterion was not met. The notified chemical was considered not readily biodegradable based on the data for the analogue chemicals. For the details of the environmental fate studies please refer to Appendix C.

While the notified chemical has the potential to bioaccumulate based on its low water solubility and high P_{OW}, its potential to biodegrade, although not sufficiently to be classified as ready biodegradable, combined with negligible aquatic exposure suggest that this will not occur.

Most of the notified chemical is expected to be recycled, re-used by recovery of calorific content, or be disposed of to landfill. In either way, the notified chemical is expected to be decomposed to form water and oxides of carbon.

8.1.3. Predicted Environmental Concentration (PEC)
As significant aquatic exposure is not expected at any stage of the notified chemical's life-cycle within Australia, it is not necessary to calculate its predicted environmental concentration (PEC).

8.2. Environmental Effects Assessment
The results from ecotoxicological investigations conducted on a mixture of analogues 2&3 of the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LL50 > 100 mg/L	Not harmful
Daphnia Toxicity	48 h EL50 > 100 mg/L	Not harmful
Algal Toxicity	72 h EL50 > 100 mg/L	Not harmful
Inhibition of Bacterial Respiration	3 h EC50 > 100 mg/L	Not harmful

While ecotoxicity data were not provided for the notified chemical itself, studies were submitted for acceptable analogues. No significant adverse effects were observed in any of the provided tests. It is concluded that the notified chemical is not expected to be harmful to aquatic life up to the level of its solubility in water. Therefore, the notified chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic effects.

8.2.1. Predicted No-Effect Concentration
As no significant adverse effects were observed in any of the ecotoxicity tests submitted, it is not appropriate to attempt to predict a no-effect concentration (PNEC) as this concentration would be significantly greater than the notified chemical's solubility in water.

8.3. Environmental Risk Assessment
The Risk Quotient (RQ = PEC/PNEC) was not calculated since the PEC and PNEC were not calculated. The notified chemical is not expected to pose an unreasonable risk to the environment based on the assessed use pattern and the absence of any observed adverse ecotoxicological effects to aquatic organisms.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -20.15 °C (for analogue chemical)

Method	OECD TG 102 Melting Point/Melting Range EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	The test material became increasingly more viscous during cooling. No significant protocol deviations. GLP compliant.
Test Facility	Safepharm Laboratories (2007a)

Boiling Point > 399.85 °C at 99.7 kPa (for analogue chemical)

Method	OECD TG 103 Boiling Point EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	While no value for the boiling point temperature could be determined experimentally using the differential scanning calorimetry, the boiling temperature is expected to be > 399.85 °C. Using an adaptation of the Stein and Brown MPBP Win Version 1.41, the boiling point was calculated to be 504.85 °C.
Test Facility	Safepharm Laboratories (2007a)

Density 946 kg/m3 at 20.4 ± 0.5°C (for analogue chemical)

Method	OECD TG 109 Density of Liquids and Solids
Remarks	The density of the test substance was determined using a pycnometer. No significant protocol deviations. GLP compliant.
Test Facility	Safepharm Laboratories (2007a)

Vapour Pressure 5.4×10^{-12} kPa at 25 °C (for analogue chemical)

Method	OECD TG 104 Vapour Pressure
Remarks	The vapour pressure was measured using a vapour pressure balance method. No significant protocol deviations. GLP compliant. The test substance is considered an acceptable analogue for the notified chemical for this property.
Test Facility	Safepharm Laboratories (2007b)

Water Solubility $< 3.22 \times 10^{-4}$ g/L at 20 ± 0.5 °C (for analogue chemical)

Method	OECD TG 105 Water Solubility
Remarks	Flask Method. No significant protocol deviations. GLP compliant. The test substance is considered an acceptable analogue for the notified chemical for this property.
Test Facility	Safepharm Laboratories (2007a)

Hydrolysis as a Function of pH t½ > 1 year at pH 4-9 (for analogue chemical)

Method OECD TG 111 Hydrolysis as a Function of pH (for analogue chemical)

pH	*T (°C)*	*t½ <hours or days>*
4	25	>1
7	25	>1
9	25	>1

Remarks	No significant protocol deviations. GLP compliant. The test substance is considered an acceptable analogue for the notified chemical for this property.
Test Facility	Safepharm Laboratories (2007a)

Partition Coefficient (n-octanol/water) log Pow ≥ 6.5 at 20 °C (for analogue chemical)

Method	OECD TG 117 Partition Coefficient (n-octanol/water)
Remarks	HPLC Method. The test substance eluted after the reference chemical "DDT". No significant protocol deviations. GLP compliant. The test substance is considered an acceptable analogue for the notified chemical for this property.
Test Facility	Safepharm Laboratories (2007a)

Adsorption/Desorption – screening test log K_{oc} > 5.63 at 30 °C (for analogue chemical)

Method	OECD TG 121 Adsorption HPLC Screening Method
Remarks	HPLC Screening Method. The test substance eluted after the reference chemical "DDT". No significant protocol deviations. GLP compliant. The test substance is considered an acceptable analogue for the notified chemical for this property.
Test Facility	Safepharm Laboratories (2007a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Sprague-Dawley CD (Crl:CD BR)
Vehicle	Test substance administered as supplied
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	5,000	0/10

LD50	> 5,000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted during the study. All animals showed an expected gain in bodyweight during the study.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	There were no deaths and no overt signs of systemic toxicity.
CONCLUSION	The mixture of analogue chemicals is of low toxicity via the oral route
TEST FACILITY	Safepharm Laboratories (1998a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/ Sprague-Dawley CD (Crl:CD BR)
Vehicle	Test substance administered as supplied
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	There were no signs of skin irritation.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity. All animals showed an expected gain in bodyweight during the study.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	There were no deaths during the study.
CONCLUSION	The mixture of analogue chemicals is of low toxicity via the dermal route.
TEST FACILITY	Safepharm Laboratories (1998b)

B.3. Irritation – skin

TEST SUBSTANCE	Mixture of analogue chemicals

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied
Observation Period	7 Days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.33	1.3	0.33	2	< 7 days	0
Oedema	0	0.33	0	1	< 48 hours	0

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

Remarks - Results	Very slight erythema was noted at two treated skin sites at the 1 hour observation period. Very slight to well-defined erythema was noted at all treated skin sites at 24 hour observation. Very slight erythema was noted at one treated site at 48 and 72 hours. Very slight oedema was noted at one treated skin site at 1 and 24 hour observation. All treated skin sites appeared normal at 7 days.

CONCLUSION The mixture of analogue chemicals is slightly irritating to the skin.

TEST FACILITY Safepharm Laboratories (1998c)

B.4. Irritation – eye

TEST SUBSTANCE Mixture of analogue chemicals

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0	0	1	< 24 hours	0
Conjunctiva: chemosis	0	0	0	1	< 24 hours	0
Conjunctiva: discharge	0	0	0	2	< 24 hours	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	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 iridal effects were noted during the study. Moderate conjunctival irritation was noted in all treated eyes at 1 hour. All treated eyes appeared normal at the 24 hour observation.

CONCLUSION The mixture of analogue chemicals is slightly irritating to the eye.

TEST FACILITY Safepharm Laboratories (1998d)

B.5. Skin sensitisation

TEST SUBSTANCE Mixture of analogue chemicals

METHOD OECD TG 406 Skin Sensitisation - Magnusson and Kligman Maximisation Study in Guinea Pigs.
EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman Maximisation Study in Guinea Pigs.

Species/Strain Guinea pig/ Dunkin Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:
Intradermal: could not be determined, at 1% (lowest concentration tested) very slight to moderate/severe irritation was observed.
Topical: could not be determined, at 25% (lowest concentration tested) very slight irritation was observed.

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

INDUCTION PHASE Induction Concentration:
Intradermal injection 25% w/v in arachis oil BP
topical application 100%

Signs of Irritation *Intradermal induction*
Very slight or well defined erythema was noted at the intradermal induction site of all test group animals at 24 hours observation and 19 test animals at the 48 hour observation. Very slight erythema was noted at the intradermal induction sites of all control group animals at the 24 and 48 hour observation.

Topical induction
Very slight or well defined erythema and incidents of very slight oedema were noted at the induction sites of all test group animals at the 1 hour observation with very slight erythema and incidents of very slight oedema in ten test group animals at the 24 hour observation. Bleeding from the intradermal induction sites of four test group animals was noted at the 1 hour observation. Isolated incidents of small superficial scattered scabs or a hardened dark brown/black coloured scab were noted at 24 hour observation.

Bleeding from the intradermal induction sites were noted in one control animal at the 1 hour observation. No signs of erythema or oedema were noted at the treatment sites of control group animals at 1 and 24 hour observation.

CHALLENGE PHASE

1st challenge intradermal: 100 %
topical: 75 %

Remarks - Method No significant protocol deviations. GLP compliant.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100 %	0	0
	75 %	0	0
Control Group	75 %	0	0
	100 %	0	0

Remarks - Results No skin reactions were observed at the challenge sites of the control or test animals. Isolated incidents of small superficial scattered scabs or a hardened dark brown/black coloured scab were noted at the 24-hour

observation.

Bodyweight gains of guinea pigs in the test group, between Day 0 and Day 24 were comparable to those observed in the control group animals over the same period.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the mixture of analogue chemicals under the conditions of the test.

TEST FACILITY Safepharm Laboratories (1998e)

B.6. Repeat dose toxicity

TEST SUBSTANCE Mixture of analogue chemicals

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain	Rat/ Sprague-Dawley Crl:CD BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: None
Vehicle	Arachis oil BP
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5/sex	0	0/10
low dose	5/sex	150	0/10
mid dose	5/sex	500	0/10
high dose	5/sex	1000	0/10

Mortality and Time to Death
There were no deaths during the study.

Clinical Observations
No clinical signs of toxicity were observed during the study.
One male treated at the high dose showed red/brown staining around the eye on Day 18 and 19 whilst one female showed red/brown staining around the ano-genital area from Day 18 onward. A second female showed red/brown staining around the ano-genital area from Day 22 to Day 27. These isolated, incidental external changes considered of no toxicological importance.

Functional observations
All the inter and intra group differences in urination, defecation and transfer arousal scores were considered to be a result of normal variation of rats of the strain and age used in the study and therefore are of no toxicological significance.

There were no treatment related changes in the functional performance parameter measured. Statistical analysis of the data revealed no intergroup differences.

Sensory reactivity assessment did not reveal any treatment related changes. All inter and intra group differences in sensory scores were considered to be the result of normal variation for rats of the strain and age used in the study therefore they are considered of no toxicological significance. Statistical analysis of the startle reflex data revealed no intergroup differences.

No adverse effect on bodyweight development was detected during the study. A statistically significant ($p< 0.01$) reduction weight was detected for 150 mg/kg bw/day females during the first week. However, in the absence of a dose response relationship, the slight intergroup difference was regarded as incidental and of no

toxicological significance.

A slight reduction in food consumption was detected for females treated with 1000 mg/kg bw/day throughout the dosing period when compared with controls. Food efficiency (the ratio of bodyweight gain to dietary intake) however was similar to that of the controls for the same period. No adverse effect on dietary intake was observed for 1000 mg/kg bw/day males or animals of either sex treated at 500 or 150 mg/kg bw/day. Daily visual inspection of water bottles revealed no intergroup difference.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

A statistically significant ($p< 0.05$) increase in haemoglobin was detected for 1000 mg/kg bw/day males when compared to the control animals but in the absence of any other changes in haematological correlates, this was considered of no toxicological significance.

A statistically significant ($p< 0.05$) increase in plasma inorganic phosphorous was detected for 1000 mg/kg bw/day males when compared to the control, however in isolation this minimal intergroup difference was not considered to be toxicological significant.

Effects in Organs

Animals of either sex treated with 1000 mg/kg bw/day showed a statistically significant increase in liver weight both absolute ($p< 0.05$) and relative ($p< 0.05$) when compared with controls. This effect extended to the 500 mg/kg bw/day but statistical significance ($p< 0.05$) was only achieved for male relative liver weights.

Kidney weights in the males only were elevated at 1000 and 500 mg/kg bw/day. The difference achieved statistical significance ($p<0.05$) at 1000 mg/kg bw/day. The intergroup difference at 500 mg/kg bw/day failed to achieve statistically significance. A statistically significant ($p< 0.05$) increase in the relative kidney weight was observed at 500 and 1000 mg/kg bw/day. No effects were observed at 150 mg/kg bw/day.

All males treated with 1000 mg/kg bw/day showed speckled kidneys at terminal kill whilst two females from this treatment group showed pallor of the liver. One female treated with 500 mg/kg bw/day showed a pale liver at necropsy.

The remaining macroscopic findings including reddened or dark areas of the lungs, hydronephrosis and isolated gastric changes, while showing no dose-related response, were consistent with normally expected low incidence findings in laboratory maintained rats and therefore were considered to be of no toxicological significance.

Histopathology

Treatment related kidney changes were observed. Globular accumulations of the eosinophilic material were observed in the renal proximal tubular epithelium of males treated at 1000, 500 and 150 mg/kg bw/day. The presence of globular accumulations of eosinophilic material in the tubular epithelium is consistent with appearance of hydrocarbon nephropathy which results from the excessive accumulation of α_2 microglobulin in renal proximal tubular epithelial cells. This is a well-documented effect, peculiar to the male rat, which occurs in response to treatment with certain hydrocarbons. Female rats and other species do not develop "hydrocarbon nephropathy" and for this reason, the effect is not indicative of a hazard to human health.

All the remaining morphological changes were those commonly observed in laboratory maintained rats at the age and strain employed and there were no difference in incidence or severity between control and treatment group that were considered to be toxicological significance.

Remarks – Results

Terminal studies revealed an increased group mean liver weight at a dose of 1000 and 500 mg/kg bw/day and macroscopic examination of the tissues revealed two 1000 mg/kg bw/day and one 500 mg/kg bw/day female showing pallor of the liver. There was no evidence of histopathological change so the reason for the increased weight is unknown. Elevated liver weights can be associated with adaptive changes following treatment with xenobiotics but in the absence of detectable hepatocyte enlargement or enzyme induction this is only speculative.

Male animals exhibited characteristics of α2-microglobulin nephropathy, a phenomenon known to occur only in adult male rats; as such, this finding is without any interspecies toxicological significance.

Based on the increased liver weights the NOEL for females was established as 500 mg/kg bw/day. As treatment-related effects were observed for all males a NOEL cannot be established for males. However, as the kidney effects are considered to be male rat specific, the NOAEL for males was established as 150 mg/kg bw/day, based on the increases in liver weights at the two higher doses.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day for the mixture of analogue chemicals in this study, based on changes in the liver at higher doses.

TEST FACILITY	Safepharm Laboratories (1998f)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA$^-$.
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 50 – 5,000μg/plate. b) Without metabolic activation: 50 – 5,000μg/plate.
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Remarks - Results	The test material caused no visible reduction in the growth of the bacterial lawn at any dose level. The test material was therefore tested up to the maximum recommended dose of 5,000 μg/plate. An oily precipitate was observed at 5,000 μg/plate, this did not prevent the testing of revertant colonies. No significant increases in frequency of revertant colonies were recorded for any of the bacterial strain, with any dose of the test material, with or without metabolic activation. The positive controls showed 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 mixture of analogue chemicals was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Safepharm Laboratories (1998g)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Cultured human peripheral lymphocytes
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Vehicle	Acetone
Remarks - Method	In experiment 2, the final S9 concentration was increased from 1 to 2%. GLP compliant.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 39.06, 78.13, 156.25, 312.25, 625*, 1250*, 2500*, 5000*	4	20
Test 2	0*, 39, 78.1, 156.25, 312.5, 625*, 1250*, 2500*, 5000*	20	20
Present			
Test 1	0*, 39.06, 78.13, 156.25*, 312.5, 625*, 1250*, 2500*, 5000*	4	20
Test 2	0*, 156.25, 312.5, 625, 1250*, 2500*, 5000*	4	20

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	≥ 625	Negative
Test 2		> 5000	≥ 2500	Negative
Present				
Test 1	> 5000	> 5000	≥ 625	Negative
Test 2		> 5000	≥ 1250	Negative

Remarks - Results

Experiment 1
The test substance induced statistically significant ($p \leq 0.05$) increases in the frequency of the cells with gap-type aberrations at 2500 and 5000 µg/mL in the absence of S9 and at 5000 µg/mL in the presence of S9.
The test material did not induce a significant increase in the numbers of polypoid cells at any dose level in either of the treatment cases.

Experiment 2
The test material did not induce any statistically significant increases in the frequency of cells with chromosome aberrations, either including or excluding gaps, in the presence of metabolic activation (at 2% concentration) or with continuous 20 hour exposure in the absence of S9. Therefore the small increases observed in Experiment 1 were confirmed to be of no toxicological significance.
The test material did not induce a significant increase in the numbers of polypoid cells at any dose level in either of the treatment cases.

CONCLUSION

The test substance was not clastogenic to cultured human peripheral lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

Safepharm Laboratories (1998h)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge from the aerated stage of a local domestic wastewater treatment plant (Derbyshire, UK)
Exposure Period	28 d
Auxiliary Solvent	Nil
Analytical Monitoring	TOC
Remarks - Method	No significant deviation in protocol

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
1	5	1	24
2	17	2	53
3	23	3	59
6	25	6	62
8	39	8	66
16	46	16	79
24	59	24	86
28	62	28	91
29*	64	29*	92

*Day 29 values were corrected to include any carry over of CO_2 detected in Absorber 2.

Remarks - Results	The test substance attained 62% degradation after 28 days. However, despite attaining in excess of 50% the test substance failed to satisfy the 10 day window validation criterion by which 60% degradation must be attained within 10 days of the degradation exceeding 10% and therefore cannot be considered to be readily biodegradable under the strict terms of the test. All test validation criteria were satisfied. The test substances are considered an acceptable analogue for the notified chemical for this property.
CONCLUSION	The test substances, and hence the notified chemical, are not readily biodegradable.
TEST FACILITY	Safepharm Laboratories (1998i)

C.1.2. Bioaccumulation

REMARKS	Not determined. The notified chemical has the potential to bioaccumulate based on its physico-chemical properties. Although the analogous chemicals were not shown to be ready biodegradable, biodegradation between 14 – 62% occurred within the 28 day test period. Therefore, it is unlikely that the notified chemical will bioaccumulate. The potential for bioaccumulation is further minimised due to the expected negligible aquatic exposure of the notified chemical under its proposed use pattern within Australia.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi-static
Species	*Oncorhynchus mykiss*
Exposure Period	96 h
Auxiliary Solvent	Nil
Water Hardness	109 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. No significant protocol deviations.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	10	0	0	0	0	0
100	0.53	10	0	0	0	0	0

LL50	>100 mg/L (WAF) at 96 hours.
NOEL	100 mg/L (WAF) at 96 hours.
Remarks – Results	The results based on the TWA mean measured test concentration gave a 96 hour Lethal Loading Rate (LL) >0.53 mg/L. The test substances are considered an acceptable analogue for the notified chemical for the toxicity to fish.
CONCLUSION	The test substances, and hence the notified chemical, are not harmful to rainbow trout up to the limit of the water solubility.
TEST FACILITY	Safepharm Laboratories (1998j)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 202 *Daphnia sp.* Acute Immobilisation Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Water Hardness	116 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. No significant protocol deviations.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
100	0.40	40	0	0

EL50	>100 mg/L (WAF) at 48 hours
NOEL	100 mg/L (WAF) at 48 hours
Remarks - Results	No effects were observed. The 48-Hour EL50, based on the time-weighted mean measured concentrations, was greater than 0.40 mg/L and correspondingly the NOEL was equal to 0.40 mg/L.

	The test substances are considered an acceptable analogue for the notified chemical for the toxicity to *Daphnia*.
CONCLUSION	Under the study conditions the test substances, and hence the notified chemical, are not harmful to daphnids up to the limit of its water solubility.
TEST FACILITY	Safepharm Laboratories (1998k)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	Nominal: 100 mg/L Actual: < LOQ (= 0.73 mg/L)
Auxiliary Solvent	Nil
Water Hardness	GC
Analytical Monitoring	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. No significant protocol deviations.
Remarks - Method	OECD TG 201 Alga, Growth Inhibition Test.

RESULTS

Biomass		*Growth*	
E_bL50	*NOE_bL*	*E_rL50*	*NOE_rL*
mg/L at 96 h	*mg/L*	*mg/L at 0 – 96 h*	*mg/L*
>100 (WAF)	100 (WAF)	> 100 (WAF)	100 (WAF)

Remarks - Results	No effects were observed. Analysis of the 100 mg/L loading rate WAF showed the measured test concentration to be below the limit of quantification (0.73 mg/L) of the analytical method employed. The test substances are considered an acceptable analogue for the notified chemical for the toxicity to algae.
CONCLUSION	Under the study conditions the test substances, and hence the notified chemical, are not harmful to alga up to the limit of its water solubility.
TEST FACILITY	Safepharm Laboratories (1998l)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Mixture of analogue chemicals
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge from the aerated stage of a local domestic wastewater treatment plant (Derbyshire, UK).
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	No significant protocol deviations.
RESULTS	
EC50	> 1000 mg/L
NOEC	1000 mg/L
Remarks – Results	A relatively large increase in respiration rates observed in the test vessels after 30 minutes contact time is considered to be due to the possible

	horrmetric response of activated sewage sludge micro-organisms to the test material. The test substances are considered an acceptable analogue for the notified chemical for the toxicity to microbes.
CONCLUSION	The test substances, and hence the notified chemical, are not harmful to microbes up to the limit of its water solubility.
TEST FACILITY	Safepharm Laboratories (1998m)

BIBLIOGRAPHY

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

Safepharm Laboratories (1998a) Acute oral toxicity (limit test) in rats (SPL Project Number 334/117 April 1998), Derbyshire, UK (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998b) Acute dermal toxicity (limit test) in rats (SPL Project Number 334/118 April 1998), Derbyshire, UK (Unpublished report provided by BP Australia Pty Ltd).

Safepharm Laboratories (1998c) Acute dermal irritation test in the rabbit (SPL Project Number 334/119 April 1998), Derbyshire, UK (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998d) Acute eye irritation test in the rabbit (SPL Project Number 334/120 April 1998), Derbyshire, UK (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998e) Magnusson and Kligman maximisation study in the guinea pig (SPL Project Number 334/121 April 1998), Derbyshire, UK (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998f) Twenty-eight day repeated dose oral (gavage) toxicity study in the rats (SPL Project Number 334/122 October 1998), Derbyshire, UK (Unpublished report submitted by the BP Australia Pty Ltd).

Safepharm Laboratories (1998g) Reverse mutation assay "Ames Test" using *Salmonella typhimurium and Escherichia coli* (SPL Project Number 334/123 October 1998), Derbyshire, UK (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998h) Chromosome aberration test in human lymphocytes *in vitro* (SPL Project Number 334/124 October 1998), Derbyshire, UK (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998i) Assessment of Ready Biodegradability; CO_2 Evolution Test (Study No., 334/128, 28 July 1998), Derbyshire, England, Safepharm Laboratories Ltd (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998j) Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) (Study No., 334/125, 21 October 1998), Derbyshire, England, Safepharm Laboratories Ltd (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998k) Acute Toxicity to *Daphnia magna* (Study No., 334/126, 21 October 1998), Derbyshire, England, Safepharm Laboratories Ltd (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998l) Algal Inhibition Test (Study No., 334/127, 21 October 1998), Derbyshire, England, Safepharm Laboratories Ltd (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (1998m) Assessment of the Inhibitory Effect on the Respiration of Activated Sewage Sludge (Study No., 334/129, 23 July 1998), Derbyshire, England, Safepharm Laboratories Ltd (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (2007a) Determination of Hazardous Physico-Chemical Properties (Study No., 2430/0002, 25 June 2007), Derbyshire, England, Safepharm Laboratories Ltd (Unpublished report submitted by BP Australia Pty Ltd).

Safepharm Laboratories (2007b) Determination of General Physico-Chemical Properties (Study No., 2430/0001, 12 June 2007), Derbyshire, England, Safepharm Laboratories Ltd (Unpublished report submitted by BP Australia Pty Ltd).

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.