

File No: STD/1426 and STD/1427

September 2012

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

**PUBLIC REPORT**

**STD/1426: Chemical A in Mobil Jet Oil 387  
STD/1427: Chemical B in Mobil Jet Oil 387**

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

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

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

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:	<a href="http://www.nicnas.gov.au">www.nicnas.gov.au</a>

**Director  
NICNAS**

## **TABLE OF CONTENTS**

SUMMARY .....	3
CONCLUSIONS AND REGULATORY OBLIGATIONS .....	3
ASSESSMENT DETAILS .....	5
1. APPLICANT AND NOTIFICATION DETAILS .....	5
2. IDENTITY OF CHEMICAL.....	6
3. COMPOSITION.....	6
4. PHYSICAL AND CHEMICAL PROPERTIES .....	6
5. INTRODUCTION AND USE INFORMATION .....	7
6. HUMAN HEALTH IMPLICATIONS .....	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	8
6.2. Human Health Effects Assessment .....	8
6.3. Human Health Risk Characterisation .....	9
6.3.1. Occupational Health and Safety .....	9
6.3.2. Public Health .....	9
7. ENVIRONMENTAL IMPLICATIONS.....	9
7.1. Environmental Exposure & Fate Assessment .....	9
7.1.1. Environmental Exposure .....	9
7.1.2. Environmental Fate .....	10
7.1.3. Predicted Environmental Concentration (PEC).....	10
7.2. Environmental Effects Assessment.....	10
7.2.1. Predicted No-Effect Concentration .....	11
7.3. Environmental Risk Assessment .....	11
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES .....</u>	<u>12</u>
<u>APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS .....</u>	<u>13</u>
B.2.1. Chronic toxicity to aquatic invertebrates .....	13
B.2.2. Algal growth inhibition test.....	13
B.2.3. Inhibition of microbial activity .....	14
BIBLIOGRAPHY .....	15

## 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/1426 and STD/1427	Aviall Australia Pty Limited East Coast Lubes Pty Ltd Japan Airlines International Co., Ltd Lubes Direct Pty Ltd Mobil Oil Australia Pty Ltd Perkal Pty Ltd Southern Cross Oil Pty Ltd	Chemical A in Mobil Jet Oil 387 and Chemical B in Mobil Jet Oil 387	No	≤15 tonnes per annum	Components of aviation engine lubricants

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Hazard classification**

Based on the available information, the notified chemicals are 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 chemicals are not considered to pose an unreasonable risk to the health of workers.

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

### **Environmental risk assessment**

On the basis of the assessed use pattern, the notified chemicals are 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 safe work practices to minimise occupational exposure during handling of the notified chemicals:
  - Avoid contact with skin and eyes
- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemicals 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 chemicals should be disposed of in accordance with local regulations for recycling, re-use or recovery of calorific content.

#### Emergency procedures

- Spills or accidental release of the notified chemicals 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 chemicals 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 chemicals has changed from components of aviation engine lubricants, or is likely to change significantly;
  - the amount of chemicals being introduced has increased from 15 tonnes per annum, or is likely to increase, significantly;
  - the chemicals have begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemicals 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 (M)SDS of the product containing the notified chemicals 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**

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS. In addition, as the notified chemicals are considered to be similar to a chemical that was previously assessed by NICNAS, components of the health and environmental hazard assessment of the similar (analogue) chemical were used in this assessment report.

### **1. APPLICANT AND NOTIFICATION DETAILS**

#### APPLICANT(S)

Aviall Australia Pty Limited (ABN 38 006 224 764)  
20-22 Lindaway Place  
Tullamarine VIC 3043

East Coast Lubes Pty Ltd (ABN 37 117 203 611)  
Corner North and Mort Streets  
Toowoomba QLD 4350

Japan Airlines International Co., Ltd (ABN 99 000 564 358)  
Level 2, 22 Market Street  
Sydney NSW 2000

Lubes Direct Pty Ltd (ABN 75 117 841 308)  
174 Coreen Avenue  
Penrith NSW 2750

Mobil Oil Australia Pty Ltd (ABN 88 004 052 984)  
12 Riverside Quay  
Southbank VIC 3006

Perkal Pty Ltd (ABN 43 009 283 363)  
PO Box 14  
Welshpool WA 6106

Southern Cross Oil Pty Ltd (ABN 41 151 437 544)  
Level 2, 768 Lorimer Street  
Port Melbourne VIC 3207

#### NOTIFICATION CATEGORY

STD/1426: 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 (and assessed in Canada, as noted above).

STD/1427: Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Chemical is being notified at the same time as a similar chemical.

#### 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, degree of purity, impurities, additives/adjuvants, use details, import volume and identity of analogue chemical.

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

Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a function of pH, dissociation constant, flammability, acute inhalation toxicity and bioaccumulation.

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Commercial evaluation chemical permits.

## NOTIFICATION IN OTHER COUNTRIES

Canada

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Mobil Jet Oil 387 (containing  $\leq 90\%$  of a mixture of the notified chemicals)

## MOLECULAR WEIGHT

STD/1426: 400-800 Da

STD/1427: &gt;500 Da

## ANALYTICAL DATA

Reference NMR, UV/Vis and IR spectra were provided.

**3. COMPOSITION**

Inseparable mixture of notified chemicals A and B.

**4. PHYSICAL AND CHEMICAL PROPERTIES**

APPEARANCE AT 20 °C AND 101.3 kPa: Clear-slightly yellow\*

Property	Value	Data Source/Justification
Freezing Point*	<-25 °C	Measured
Boiling Point*	Decomposed at >325 °C	Measured
Density*	990 kg/m <sup>3</sup> at 20 °C	Measured
Vapour Pressure*	<1 × 10 <sup>-7</sup> kPa at 25 °C	Measured
Water Solubility*	<2 × 10 <sup>-5</sup> g/L at 20 °C	Measured. Neither an absolute value, nor a lower limit value, could be determined due to the presence of interfering species
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, no significant hydrolysis is expected due to its negligible solubility
Partition Coefficient* (n-octanol/water)	log Pow >6 at 25 °C	Measured
Adsorption/Desorption*	log K <sub>oc</sub> = 4.3 – 7.0 at 25 °C	Measured
Dissociation Constant	Not determined	No dissociable functionality
Fat solubility*	Miscible	Measured
Viscosity*	Kinematic: 49.1 mm <sup>2</sup> /s at 20 °C 22.0 mm <sup>2</sup> /s at 40 °C Dynamic: 48.7 mPa.s at 20 °C 21.8 mPa.s at 40 °C	Measured
Flash Point*	230 °C at 102.8 kPa	Measured
Flammability	Not determined	Not expected to be flammable based on flash point
Autoignition Temperature*	398 °C	Measured
Explosive Properties	Predicted negative	Contain no functional groups that would infer explosive properties
Oxidising Properties	Predicted negative	Contain no functional groups that would infer oxidising properties

\*Inseparable mixture of the notified chemicals.

## DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties that were not assessed in the Canadian report, refer to Appendix A.

*Reactivity*

The notified chemicals are 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 chemicals are 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.

## **5. INTRODUCTION AND USE INFORMATION**

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

The notified chemicals will be imported in formulated lubricant products (at up to 90% combined concentration).

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes*</i>	2-15	2-15	2-15	2-15	2-15

\*combined total of both notified chemicals

### PORT OF ENTRY

Sydney (potentially via other Australian ports in the future)

### IDENTITY OF RECIPIENTS

Aviall Australia Pty Limited  
East Coast Lubes Pty Ltd  
Japan Airlines International Co., Ltd  
Lubes Direct Pty Ltd  
Mobil Oil Australia Pty Ltd  
Perkal Pty Ltd  
Southern Cross Oil Pty Ltd

### TRANSPORTATION AND PACKAGING

The formulated product containing the notified chemicals (at up to 90% combined concentration) will be imported in 1.25 L stainless steel containers or in 200 L steel drums. The containers will be transported by road or rail.

### USE

The notified chemicals will be used as components (at up to 90% combined concentration) of aviation engine lubricants.

### OPERATION DESCRIPTION

Manufacturing and/or reformulation will not occur in Australia.

The imported product containing the notified chemicals (at up to 90% combined concentration) will be used at aircraft maintenance sites as an aviation engine lubricant. Workers will manually conduct oil changes and/or top ups during routine maintenance operations.

## **6. HUMAN HEALTH IMPLICATIONS**

### **6.1. Exposure Assessment**

#### **6.1.1. Occupational Exposure**

### CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Port and transport workers	1-3	6-12
Storage workers	1	70
Aircraft maintenance workers	2	50

## EXPOSURE DETAILS

Transport and storage workers will only be exposed to the notified chemicals in the unlikely event of an accident.

Dermal and potentially ocular exposure of workers to the notified chemicals may occur during oil change and top-up operations. Exposure is expected to be minimised through the use of personal protective equipment (PPE), such as protective clothing, safety glasses and impervious gloves. Inhalation exposure to the notified chemicals is not expected under the proposed usage scenario.

**6.1.2. Public Exposure**

The lubricant containing the notified chemicals will not be available to the general public and will only be used in the aviation industry. Therefore, exposure of the public to the notified chemicals is not expected.

**6.2. Human Health Effects Assessment**

The results from toxicological investigations conducted on an inseparable mixture of the notified chemicals and a suitable analogue of the notified chemicals (a similar chemical that was previously assessed by NICNAS) are summarised in the table below.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>	<i>Test Method</i>
<i>Inseparable mixture of the notified chemicals</i>		
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity	OECD 425
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity	OECD 402
<i>Analogue chemical</i>		
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity	OECD 401
Rabbit, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity	OECD 402
Rabbit, skin irritation	non-irritating	OECD 404
Rabbit, eye irritation	slightly irritating	OECD 405
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation	OECD 406
Rat, repeat dose oral toxicity – 28 days	NOAEL ≥1000 mg/kg bw/day	OECD 407
Mutagenicity – bacterial reverse mutation	non-mutagenic	OECD 471
Genotoxicity – <i>in vitro</i> chromosome aberration	non-genotoxic	OECD 473
Genotoxicity – <i>in vivo</i> micronucleus	non-genotoxic	OECD 474
Rat, developmental toxicity	NOAEL ≥1000 mg/kg bw/day	OECD 421

*Toxicokinetics, metabolism and distribution.*

While the mixture of notified chemicals may be absorbed across biological membranes (gastrointestinal tract and skin), the extent of absorption is expected to be limited by the relatively high molecular weight (only a small proportion with molecular weight <500 Da expected (namely, chemical A, STD/1426)), the low water solubility ( $<2 \times 10^{-5}$  g/L at 20 °C) and high partition coefficient (log Pow >6 at 25 °C) of the inseparable mixture of notified chemicals.

*Acute toxicity.*

The inseparable mixture of the notified chemicals was of low acute oral and dermal toxicity in rats (limit tests; LD50 >2000 mg/kg bw). In each study, there were no mortalities, clinical signs or visible lesions in the animals at necropsy.

The analogue chemical was of low acute oral toxicity in rats (limit test; LD50 >2000 mg/kg bw) and low acute dermal toxicity in rabbits (LD50 >2000 mg/kg bw). There were no mortalities in either study. In the oral toxicity study, the only observation was anogenital staining in 2/5 treated females 4-6 hours after administration of the test substance. In the dermal toxicity study, rabbits (5/sex/group) were administered the test substance at 2000 or 1900 mg/kg bw. The only treatment-related observations were skin irritation effects throughout the observation period and desquamation at the test site at necropsy.

No acute inhalation toxicity data were provided.

*Irritation and Sensitisation.*

The analogue chemical was non-irritating to rabbits (6 males; occlusive conditions) but was a slight eye irritant in rabbits (5 males, 1 female), with conjunctival effects noted from 1-hour after instillation of the test substance



and clearing by day-7 post-instillation. The effects do not warrant classification of the analogue chemical as an eye irritant.

The analogue chemical was non-sensitising to guinea pigs (20 test, 10 control) in a maximisation study (100% topical induction concentration; 50% challenge concentration; 10% rechallenge concentration). Following challenge, erythema was apparent in animals of both the treated and control groups, which was considered to be an irritation response. At rechallenge (one-week later), a reduced response was noted in test and control animals, with no response evident after 48 hours.

#### *Repeated Dose Toxicity.*

The NOAEL for the analogue chemical was established as the highest dose tested ( $\geq 1000$  mg/kg bw/day) in a 28 day gavage study in rats, with no significant treatment-related effects observed.

#### *Mutagenicity.*

Bacterial reverse mutation, *in vitro* chromosomal aberration (Chinese hamster ovary cells) and *in vivo* micronucleus (mice;  $\leq 2000$  mg/kg bw/day for 3 days) studies that were conducted on the analogue chemical were negative. It is not clear that the test substance was systemically absorbed (and reached the bone marrow) in the *in vivo* micronucleus study.

#### *Toxicity for reproduction.*

The NOAEL for the analogue chemical was established as the highest dose tested ( $\geq 1000$  mg/kg bw/day) in a developmental toxicity study in rats (females treated from days 6-15 of gestation), with no significant treatment-related effects observed.

Overall, the results of toxicity studies conducted on the inseparable mixture of the notified chemicals and the analogue chemical were indicative of low hazard. Therefore, the inseparable mixture of the notified chemicals is expected to be of low hazard.

#### **Health hazard classification**

Based on the available information, the notified chemicals are 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).

### **6.3. Human Health Risk Characterisation**

#### **6.3.1. Occupational Health and Safety**

Dermal and potentially ocular exposure of aviation workers to the notified chemicals may occur when manually refilling oil reservoirs or when performing oil changes. While the mixture of the notified chemicals is considered to be of low hazard, slight skin and eye irritancy effects were noted in studies conducted on the analogue chemical. As workers will be conducting operations with the notified chemicals at up to 90% combined concentration, skin and eye contact should be avoided (e.g. through the use of PPE such as coveralls, impervious gloves and goggles). Therefore, when used in the proposed manner, the risk to the health of workers is not expected to be unreasonable.

#### **6.3.2. Public Health**

As the lubricants containing the notified chemicals will only be used by professionals in the aviation industry, exposure of members of the public to the chemicals is not expected, except in the unlikely event of an accident. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

## **7. ENVIRONMENTAL IMPLICATIONS**

### **7.1. Environmental Exposure & Fate Assessment**

#### **7.1.1. Environmental Exposure**

##### **RELEASE OF CHEMICAL AT SITE**

The notified chemicals will be imported in end-use containers for use as aviation engine lubricant. No release of the notified chemicals is expected from manufacture, reformulation and repacking, as these activities will

not occur in Australia.

#### RELEASE OF CHEMICAL FROM USE

The product containing the notified chemicals is expected to be used in closed systems in aircraft that are anticipated to be fully contained; fugitive emissions are not expected. Minor spills may occur during addition and removal of the lubricant to aircraft. It is estimated that up to 1% of the total import volume of the notified chemicals may be released to the environment from the accident spillage and residues in the import containers. Any waste material is expected to be collected by waste management companies and be disposed of in accordance with local/state/territory regulations.

#### RELEASE OF CHEMICAL FROM DISPOSAL

Used product containing the notified chemicals is expected to be disposed of by accredited waste management companies. It will most likely be recycled or disposed of to landfill as residues in empty containers in accordance with local/state/territory regulations. If recycled, the notified chemicals are expected to be used as low grade burner fuel.

#### 7.1.2. Environmental Fate

Most of the notified chemicals will be thermally decomposed during use and recycling of waste products, and are expected to degrade into water and oxides of carbon.

A small amount of the notified chemicals is expected to be sent to landfill as residues in the empty containers or as a component of waste oil. Notified chemicals sent to landfill or spilt on the ground are expected to be immobile in soil based on the high soil adsorption coefficient ( $\log K_{oc} = 4.3-7.0$ ). They are expected to associate strongly with the organic compartment according to their potential to partition to organic phases ( $\log Pow > 6$ ). Based on the negligible vapour pressure ( $< 1 \times 10^{-7}$  kPa), low water solubility ( $< 2 \times 10^{-5}$  g/L) and high soil adsorption coefficient ( $\log K_{oc} = 4.3 - 7.0$ ), the notified chemicals are not expected to volatilize and will remain in moist and dry soil. The notified chemicals are anticipated to rapidly degrade given the result of the ready biodegradation test (84-86% over 28 days). In landfill and soil, the notified chemicals are expected to degrade into water and oxides of carbon.

The notified chemicals have a preference to partition to fatty substances, based on their high n-octanol/water partition coefficient ( $\log Pow > 6$ ). However, given the ready biodegradability of the notified chemicals, in addition to their anticipated lack of aquatic exposure, the notified chemicals have reduced potential for bioaccumulation in aquatic organisms.

#### 7.1.3. Predicted Environmental Concentration (PEC)

The calculation of predicted environmental concentration (PEC) was not considered necessary because significant aquatic exposure is not expected at any stage of the notified chemicals' life-cycle within Australia.

#### 7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on an inseparable mixture of the notified chemicals or analogue chemical are summarised in the table below. For full details of the studies that were not assessed in the Canadian report or the NICNAS, (i.e. the effects on the reproductive output of *Daphnia magna*, inhibition of algae growth and inhibition of activated sludge respiration), refer to Appendix B.

The fish test was conducted with an oil-in-water dispersion while the daphnia test was conducted with water-accommodated fractions. Analysis of the test substance was via total organic carbon. Given that toxicity cannot be attributed to a single component or a mixture of components but rather wholly to the test substance, the results are based on nominal loading rates only. In the acute fish study, two nominal loading rates of 100 mg/L and 150 mg/L were used. In the acute daphnia study, a range of loading rates were used from 62 mg/L to 1072 mg/L.

Study	Duration	Endpoint	Value	Test Method	Assessment Conclusion
Acute Fish Toxicity ( <i>Brachydanio rerio</i> )	96 h	LL50 NOEL	>150 mg/L = 150 mg/L	OECD 203	Not harmful
Acute Daphnia Toxicity ( <i>Daphnia magna</i> )	48 h	EL50 NOEL	>1072 mg/L = 1072 mg/L	OECD 202	Not harmful

Chronic Daphnia Toxicity ( <i>Daphnia magna</i> )	21d	NOEL	>135 mg/L	OECD211	Not harmful
Acute Algal Toxicity* ( <i>Scenedesmus subspicatus</i> )	72 h	E <sub>r</sub> L50 NOEL	>1000 mg/L* = 1000 mg/L*	OECD 201; EEC 92/69 C.3	Not harmful*
Activated Sludge Respiration Inhibition	3 h	EC50	>1000 mg/L	OECD 209; EEC 88/302 C.11	Not harmful

---

\* Results for the toxicity to algae were determined by read-across from analogue data.

No significant adverse effects were observed in any of the above tests, and it is concluded that the notified chemicals are not expected to be harmful to aquatic life up to the level of their solubilities in water. Therefore, the notified chemicals are not formally classified for acute or long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS, United Nations, 2009).

#### 7.2.1. Predicted No-Effect Concentration

As no significant adverse effects were observed in any of the ecotoxicity tests submitted, it was not appropriate to predict a no-effect concentration (PNEC), as this concentration would be significantly greater than the notified chemicals' solubility in water.

#### 7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not calculated because the calculation of PEC and PNEC were not considered meaningful. Based on the anticipated lack of aquatic exposure, the potential to biodegrade and the absence of any observed adverse ecotoxicological effects, the proposed use of the notified chemicals is not expected to pose an unreasonable risk to the environment.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**

<b>Fat (or n-octanol) Solubility</b>		Miscible in coconut oil at 37 °C
Method	OECD TG 116 Fat Solubility of Solid and Liquid Substances.	
Remarks	Analytical Method: Visual observation. The test substance (an inseparable mixture of the notified chemicals) was found to be miscible in all proportions in coconut oil.	
Test Facility	Huntingdon (2008a)	
<b>Viscosity</b>		49.1 mm <sup>2</sup> /s at 20 °C and 22.0 mm <sup>2</sup> /s at 40 °C (kinematic viscosity) 48.7 mPa.s at 20 °C and 21.8 mPa.s at 40 °C (dynamic viscosity)
Method	OECD TG 114 Viscosity of Liquids	
Remarks	Determined (on an inseparable mixture of the notified chemicals) at 20 °C and 40 °C using a pre-calibrated reverse flow capillary U-tube viscometer, in triplicate at each temperature.	
Test Facility	Huntingdon (2008b)	
<b>Flash Point</b>		230 °C at 102.8 kPa
Method	EC Council Regulation No 440/2008 A.9 Flash Point	
Remarks	Determined (on an inseparable mixture of the notified chemicals) in duplicate using a Pensky-Martens closed cup flash point apparatus.	
Test Facility	Huntingdon (2008b)	
<b>Auto-ignition temperature</b>		398 °C
Method	EC Council Regulation No 440/2008 A.15 Auto-ignition Temperature (Liquids and Gases) – BS 4056	
Remarks	Determined by injecting the test substance (an inseparable mixture of the notified chemicals) into heated flasks and observing any ignition. Flame observed at 398 °C and 400 °C.	
Test Facility	Huntingdon (2008b)	
<b>Explosive Properties</b>		Predicted negative
Method	EC Council Regulation No 440/2008 A.14 Explosive Properties	
Remarks	The chemicals contain no functional groups that would infer explosive properties.	
Test Facility	Huntingdon (2008b)	
<b>Oxidizing Properties</b>		Predicted negative
Method	EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids)	
Remarks	Contain no functional groups that would infer oxidising properties.	
Test Facility	Huntingdon (2008b)	

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

### **B.2.1. Chronic toxicity to aquatic invertebrates**

TEST SUBSTANCE	Inseparable mixture of the notified chemicals
METHOD	OECD TG 211 <i>Daphnia</i> sp. Reproduction Test, semi-static
Species	<i>Daphnia magna</i> Straus
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	>140 mg CaCO <sub>3</sub> /L
Analytical Monitoring	Total Organic Carbon (TOC) analysis
Remarks - Method	The study was performed by exposing 10 replicates (one daphnid per replicate) of daphnia to water accommodated fractions (WAFs) of the test substance at a loading rate of 135 mg/L for 21 days at 20.4-22.2 °C. A control treatment consisting of dilution water with no test chemical was run in parallel for 10 replicates (one daphnid per replicate). The WAFs were prepared by adding the approximate amount of test substance into dilution water in a glass aspirator bottle and stirring for approximately 24 hours. The mixtures were allowed to settle for 1 hour before removing WAFs from the mixing vessel through the outlet at the bottom of the vessel for the test. The WAFs and control treatments were prepared and renewed every other day. During the test, the test substance at 135 mg/L loading rate was observed to be a clear solution.

#### Results

Day 21				
Nominal Loading Rate (mg/L)	Mean Measured Loading Rate (mg/L)	Mean Percent Adult Survival (%)	Mean Number of Offspring Released per Female-Cumulative (SD)	Mean Body Length of Surviving Parental Daphnids (mm) (SD)
Solvent control	ND	100	112 (21)	4.9 (0.10)
135	≤1 (TOC)	80	107 (20)	5.0 (0.071)

EL50 (reproduction)	>135 mg/L at 21 days (based on loading rate)
NOEL (reproduction)	135 mg/L at 21 days (based on loading rate)
Remarks - Results	There were no significant deviations from the protocol and all validity criteria for the test were satisfied.

CONCLUSION	The notified chemicals are not considered to effect the reproduction and growth of aquatic invertebrates up to the limit of their water solubilities.
------------	---

TEST FACILITY	Exxon (2012)
---------------	--------------

### **B.2.2. Algal growth inhibition test**

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	<i>Selenastrum capricornutum</i>
Exposure Period	96 hours
Concentration Range	Nominal: 62.5, 125, 250, 500, 1000 mg/L
Auxiliary Solvent	None
Water Hardness	30 mg CaCO <sub>3</sub> /L
Analytical Monitoring	Total Organic Carbon (TOC) analysis
Remarks - Method	The test was conducted at a nominal loading rate (WAFs) of 62.5, 125, 250, 500, and 1000 mg/L of the test substance for 96 hours. The test was run in four replicates along with one algal nutrient medium control. Individual treatment solutions of WAFs of the test substance for each

loading level were prepared by adding the approximate amount of test substance into algal nutrient media in the glass aspirator bottles and stirring for approximately 24 hours. The mixtures were allowed to settle for 1 hour before removing WAFs from the mixing vessel through the outlet at the bottom of the vessel for the test. Except for the 1000 mg/L treatment level solution, all other treatment level solutions appeared clean with undissolved test substance floating on the surface. Four replicate chambers were prepared per treatment by removing WAFs for each test flask. Cell densities were determined for each replicate at 24, 48, 72 and 96 hours.

## RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>E<sub>b</sub>L50</i> <i>mg/L at 72 h</i>	<i>NOEL</i> <i>mg/L</i>	<i>E<sub>r</sub>L50</i> <i>mg/L at 72 h</i>	<i>NOEL</i> <i>mg/L</i>
>1000	1000	>1000	1000

## Remarks - Results

There were no significant deviations from the protocol, except that one control was run in the test. All validity criteria for the test were satisfied.

## CONCLUSION

The test substance and, by inference, the notified chemicals are not considered to be harmful to alga up to the limit of their water solubilities.

## TEST FACILITY

Exxon (1995)

**B.2.3. Inhibition of microbial activity**

## TEST SUBSTANCE

Inseparable mixture of the notified 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

## Exposure Period

3 hours

## Concentration Range

Nominal: 10, 100, 1000 mg/L

## Remarks – Method

The study followed the test guidelines of OECD TG 209. No deviations to the protocol were reported in the study summary submitted by the notifier.

## RESULTS

## EC50

>1000 mg/L

## NOEC

Not reported

## Remarks – Results

Raw test data for the dissolved oxygen concentrations, temperature, pH and measurement of respiration rate were not provided in the study report. The test was reported to meet the validity criteria for this method.

## CONCLUSION

The notified chemicals are not expected to inhibit the respiration of sludge microorganisms.

## TEST FACILITY

Huntingdon (2008c)

### **BIBLIOGRAPHY**

- Exxon (1995) Alga growth inhibition test (Study No. 121667, October, 1995). New Jersey, USA, Exxon Biomedical Sciences Inc. (Unpublished report submitted by the notifier).
- Exxon (2012) *Daphnia magna*, reproduction test (Study No. 0813546, February, 2012). New Jersey, USA, Exxon Biomedical Sciences Inc. (Unpublished report submitted by the notifier).
- Huntingdon (2008a) [Notified chemicals] Fat solubility and pH determination (Study No: EXN0098, October, 2008). Suffolk, UK, Huntingdon Life Sciences (Unpublished report submitted by the notifier).
- Huntingdon (2008b) [Notified chemical] Physicochemical Properties (Study No. EXN0111, December, 2008). Suffolk, UK, Huntingdon Life Sciences (Unpublished report submitted by the notifier).
- Huntingdon (2008c) [Notified chemicals] Activated sludge: Respiration inhibition test (Study No: EXN0114, November, 2008). Suffolk, UK, Huntingdon Life Sciences (Unpublished report submitted by the notifier).
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3<sup>rd</sup> edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3<sup>rd</sup> revised edition. United Nations Economic Commission for Europe (UN/ECE), <[http://www.unece.org/trans/danger/publi/ghs/ghs\\_rev03/03files\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html)>.