File No: EX/119 (STD/1251)

May 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in CP 8055

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 original assessment certificate for Chemical in CP 8055. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

Chemical in CP 8055

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Oronite Australia Pty Ltd (ABN: 16 101 548 716)
Level 10, 45 William Street
Melbourne VIC 3000

Applicant for an Extension of the Original Assessment Certificate:
Perkal Pty Ltd (Trading as Statewide Oil Distributors) (ABN 43 009 283 363)
14 Beete St
Welshpool WA 6106

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; CAS number; Molecular formula; Structural formula; Molecular weight; Spectral data; Purity; Identity of impurities and additives/adjuvants; Import volume; Identity of recipients.

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; Absorption/desorption; Dissociation constant; Acute inhalation toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2007)
Korea (2007)
USA (2007)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Salts of alkylhydroxybenzoic acids

MARKETING NAME(S)
XC 8055; SP 8055; CP 8055; OLOA 16305 (containing ≤ 70% notified chemical)

Extension Application:
Mobilgard M50 (finished product containing the notified chemical at a concentration of <15%)

ANALYTICAL DATA
Reference ^{1}H and ^{13}C NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
≤ 70%

4. PHYSICAL AND CHEMICAL PROPERTIES

Comments Tests were performed on the product CP 8055 containing the notified chemical at concentrations of ≤ 70%.

Appearance at 20ºC and 101.3 kPa Brown liquid

Property	Value	Data Source/Justification
Melting Point	13ºC	Measured
Boiling Point	324 - 735ºC	Measured
Density	990.5 kg/m^3 at 20ºC	Measured
Vapour Pressure	7.87 x 10^{-7} kPa at 20ºC	Calculated
Water Solubility	2.52 x 10^{-5} g/L at 30ºC	Measured
Hydrolysis as a Function of pH	Not determined	Expected to be stable except under very high or very low pH conditions.
Partition Coefficient (n-octanol/water)	log Kow > 7.4 at 20ºC	Estimated
Adsorption/Desorption	Not determined	Not expected to significantly absorb or desorb onto soil.
Dissociation Constant	Not determined	Not expected to dissociate.
Flash Point	180ºC	Product specification sheet and MSDS.
Flammability	Not flammable	Estimated based on flash point.
Autoignition Temperature	> 180 ºC.	Estimated based on flash point.
Explosive Properties	Not predicted to be explosive	Estimated

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

May react with strong oxidising agents, such as chlorates, nitrates and peroxides. Hazardous polymerisation will not occur.

Dangerous Goods classification

Based on the available physico-chemical properties the notified chemical is not classified as a Dangerous Good according to the Australian Dangerous Goods Code (FORS, 1998). However, the notified chemical is classified as a C2 combustible liquid according to *National Standard for the Storage and Handling of Workplace Dangerous Goods* (NOHSC 2001).

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported as a component of oil additive packages at concentrations of 7 – 70%.

Extension Application:

The notified chemical will be imported at a concentration of <15% in finished engine oils.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	10-100	10-100	10-100
Extension Application:					
Year	*1*	*2*	*3*	*4*	*5*
Tonnes	86	86	86	86	86

PORT OF ENTRY
Brisbane, Melbourne, Sydney, or Perth.

Extension Application:
Fremantle

IDENTITY OF MANUFACTURER/RECIPIENTS
Products containing the notified chemical will be sold to major lubricant oil companies. It may then be sold to commercial marine engine service shops.

TRANSPORTATION AND PACKAGING
The oil additive product containing the notified chemical will be transported by ship and offloaded to tank trucks or rail cars for distribution. Alternatively, the products may be shipped directly to customers in 250 L drums or isotanks.

Extension Application:
The finished oil products containing the notified chemical will be imported by ship in Isotanks, Intermediate Bulk Containers (IBC's) or 250 L drums and offloaded to tank trucks or rail cars for distribution to a storage facility or transported directly to the customers.

USE
The notified chemical will be used as a detergent additive in formulations for marine engine oils.

Extension Application:
The use of the notified chemical will be same as was for original assessment certificate.

OPERATION DESCRIPTION
At blending sites, products containing the notified chemical will be transferred, through hosing, into storage tanks.

Reformulation
Products containing the notified chemical (7 – 70%) will be transferred through hosing from storage tanks to blending tanks. It will then be blended with additives in an enclosed system to form the finished lubricants, containing the notified chemical at concentrations 1 – 5%. The finished product will then be transferred to a storage tank and later filled into drums, bulk tank trucks or rail cars. Quality control analysis is performed on the products containing the notified chemical both before and after reformulation.

End-use
Lubricant oils containing the notified chemical will be used to lubricate marine engines. When used in stationary engines, routine lubrication is likely to use dedicated lubricating oil reservoirs and piping to add fluids directly. When used in non-stationary marine applications, workers are likely to manually check the engine lubricant levels and additional fluid will be added using pneumatic delivery equipment.

Extension Application:
Only finished products containing the notified chemical will be imported and no reformulation would take place in Australia.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (min/day)*	*Exposure Frequency (days/yr)*
Reformulation			
Analysing additive package on arrival	1	10	30
Unloading tank trucks and drums	1-2	30	30
Sampling finished oil	1-2	10	220
Loading finished oil into tank trucks	1-2	30	220
End-use			
Adding finished oil to "top off" lubricant level (non-stationary marine applications – industrial lubricant users)	1-2	5	220
Pumping finished oil from drum (non-stationary marine applications – commercial lubricant users)	1-2	10	220
Adding finished oil to "top off" lubricant level (non-stationary marine applications – commercial lubricant users)	1-2	5	220
Stationary marine applications	1-2	5	220

Exposure Details

Reformulation

Dermal and ocular exposure of workers to the notified chemical may occur during transfer to and from vessels at different stages during the reformulation process. During the initial transfer to storage tanks (7 – 70% notified chemical), and when transferring the final lubricant (<5% notified chemical) to bulk containers (bulk tank trucks and rail cars) using hosing, exposure should be reduced by the use of an air back flush system, which minimises spillages. During transfer from the storage to the blending tank (7 – 70%), and transfer of the final lubricant product to storage tanks (<5%), exposure is likely to be minimised by automation of the process, involving the use of computer-controlled valves. During transfer of the final lubricant product to drums, worker exposure to the notified chemical (<5%) should be reduced by the use of automated weight scales to fill the drums, and by workers standing 3-6 feet away whilst ensuring that the drum filling mechanism operates correctly. In addition, the blending sites have good ventilation, and workers are likely to wear personal protective equipment, including gloves, eye protection, and protective clothing during all operations.

Worker exposure to the notified chemical is unlikely to occur during blending operations, as they take place in an enclosed and computer-controlled system.

End-use

Dermal and ocular exposure of workers to the notified chemical (<5%) may occur during end use of the final lubricant products. Worker exposure to the notified chemical may be minimal when the product is used in stationary marine engines, as human intervention is not required in order to top up fluids. When used in non-stationary marine engines, manual processes are more likely to be required, although fluids will be added using a pneumatic delivery system. Exposure may be minimised by the use of engineering controls and personal protective equipment that is expected to be available to workers, such as gloves, coveralls, eye protection and hard hats.

Extension application:

As only finished oils product containing the notified chemical will be imported under the extension application, exposure will be limited only during transportation, storage and end-use applications.

6.1.2. Public exposure

The notified chemical is intended for industrial use only and will not be available to the public. Public exposure to the notified chemical may occur in the unlikely event of a transport accident, or a spillage/loss of lubricant product from a marine engine.

6.2. Human health effects assessment

The results from toxicological investigations conducted on SP8055, containing the notified chemical, are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	low toxicity oral LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	low toxicity dermal LD50 >2000 mg/kg bw
Rabbit, skin irritation	irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL = 160 mg/kg bw/day NOAEL = 400 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic
Genotoxicity – in vivo mammalian erythrocyte micronucleus test	non genotoxic

SP8055 was of low acute oral and dermal toxicity in rats (LD50 > 2000 mg/kg bw). SP8055 was found to be irritating to the skin and slightly irritating to the eyes. In addition, there was evidence of sensitisation amongst a significant number of animals in a guinea pig Buehler test. The NOEL in a 28-day oral repeat dose study in rats was 160 mg/kg bw/day on the basis of clinical observations, serum chemistry effects at higher doses. The NOAEL was established as 400 mg/kg bw/day in this study. SP8055 was found to be non-mutagenic in a bacterial genotoxicity test, and in vitro and in vivo genotoxicity tests.

The major impurities present in the product are at levels below the cut off for irritation classification (<20%), based on the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). In addition, the impurities and additives/adjuvants have not been classified for sensitisation potential. Therefore, it is reasonable to assume that the irritation and sensitisation effects displayed by the product containing the notified chemical are due to the notified chemical itself, rather than other components of the product.

Based on the skin irritation and sensitisation, the notified chemical is 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

The notified chemical is a skin irritant and slight eye irritant, as well as a skin sensitiser.

The risk of irritation and skin sensitisation exists when handling the imported products that contain the notified chemical at concentrations up to 70%, particularly during transfer into different vessels when reformulating into final products. However, the risk should be minimised by the short exposure duration to the imported product, the use of engineering controls, automation of the processes, adequate general ventilation, and PPE, such as gloves, eye protection, and protective clothing.

The potential risk of skin sensitisation also exists during handling of the reformulated product containing <5% of the notified chemical, particularly during packaging operations. The risk also exists when the product is used for its intended purpose in marine engines, particularly when manually adding fluids to the engines. The risk may be reduced by the short exposure duration of workers to the lubricant products, the automation of some processes, the use of engineering

controls, and the personal protective equipment that is expected to be available to workers. However, the risk cannot be completely ruled out. Therefore, control measures should be in place.

6.3.2. Public health

The notified chemical is intended for industrial use only. Therefore, the risk to the public from exposure to the notified chemical will be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. It will be imported in an oil additive package for blending into oil products and will be supplied to 2-3 customers in Australia. The product will be transported either by ship and offloaded to tank trucks or rail cars for distribution to a blending facility or drums or isotank which will be shipped directly to the customers. At blending sites, the notified polymer will be transferred from drums, rail cars and tank truck into storage tanks.

Transfer from storage tank to blend tank will be automated, using computer controlled valves. The additive packages containing approximately 7-33 % of the notified chemical or the neat component containing 70 % of the notified chemical is blended into the finished lubricant, this translates to < 5% of the notified chemical in the finished oil. The blending process occurs in a closed system at 60°C and is computer controlled. The blended lubricant (<5 % notified chemical) is transferred automatically to a storage tank. The finished lubricants are packaged for shipment in drums.

In the unlikely event of an accident at the site, the spillage will be contained within concrete bunds and either reclaimed or sent to on-site wastewater treatment facilities where residual hydrocarbon based products will be separated from the aqueous stream by the Australian Petroleum Industry (API) process, with a claimed removal of greater than 90%. The aqueous waste undergoes further treatment involving pond aeration and biological treatment before being released to the sewage system. The remaining oily waste will be incinerated. As a result of these processes, the accidental release from blending process of the notified chemical and finished oils is unlikely to be significant.

RELEASE OF CHEMICAL FROM USE

Environmental exposure from use of the finished oil would be from drips while adding the finished oil to the engine or from the engine itself. It is not possible to estimate these losses, though they are expected to be small, since the notified chemical is present in the finished oil at a maximum of 5 %.

Used oil will be disposed of in a manner consistent with local and federal regulations. Most likely this will be burning fuel or by used oil recycling. In the case of used oil recycling, a recycling company such as Safety Kleen converts the used oil to fresh lubricant plus asphalt. The additives in the used oil ultimately end up in the asphalt portion.

A survey by the Australian Institute of Petroleum (AIP 1995) indicates that 60% of the annual sales of automotive engine oils in Australia, are potentially recoverable (ie not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases could be expected to be disposed of either to oil recycling or incineration. The remaining 14% are removed by “do it yourself” (DIY) enthusiasts, and in these cases some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. A recent report estimated that DIY activities account for between 7 to 10% of the unaccounted used oil (MEINHARDT, 2002).

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997), only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed to landfill, 5% is disposed of into stormwater drains and the remaining 50% unaccounted

for.

Consequently, assuming that oil removed by professional mechanics is disposed of appropriately (ie sent for recycling or possibly burning as workshop heating oil), negligible release of the notified chemical should result from these professional activities. During recycling it is expected that most of the chemical will decompose and any remainder will end up in the asphalt portion.

Assuming that 14% (14 tonnes) of the used oil is removed by the DIY enthusiasts it is possible to have 20% (2.8 tonnes) collected for recycling, 25% (3.5 tonnes) buried or disposed to landfill, 5% (700 kg) disposed into stormwater drains and 50% (7 tonnes) unaccounted for.

Since gear oil and hydraulic fluid changes are likely to be carried out by specialists, and will be disposed of more appropriately, an amount less than 1% of the total import volume of the notified substance could be expected to enter the aquatic environment via disposal into the storm water system. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified chemical in high concentrations is very unlikely except as a result of transport accidents.

Although use in water-cooled marine engines, including two stroke engines, is listed as a potential use, the notifier indicates that this is unlikely to occur. Therefore release to the aquatic environment via this route is unlikely to occur.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty drums that deliver the notified chemical to the lubricant blender containing residual notified chemical would be steam cleaned, with the residual waste sent to on-site waste water treatment facilities. Assuming 10 % of the volume is delivered by drum, and that 0.1 % of the finished product remains in the container after use, a worst-case estimate of 10 kg/yr of the notified substance will be sent to the waste water treater.

The waste water is sent to a pond where it is further treated by induced air floatation and biological treatment. The waste biological sludge from the biological treatment is sent off site for incineration. After biological treatment, the waste water is sent through a biodisk filter before the treated water is released to waterways. This additional process will remove another 80 % of the spilled additive package. Therefore, the amount of the notified chemical released to the environment from drums is expected to be 0.2 kg/yr.

7.1.2 Environmental fate

For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The low water solubility of the notified chemical and its limited release to the aquatic environment (mainly via stormwater drainage) reduce the possibility of sufficient amounts to remain in solution to cause acute toxicity. It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified chemical released into stormwater drains, which have the potential to directly enter the aquatic environment.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on SP8055 are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL_{50} > 1000 mg/L	Non-toxic up to the limit of its solubility
Daphnia Toxicity	EL_{50} > 1000 mg/L	Non-toxic up to the limit of its solubility
Algal Toxicity	EL_{50}> 1000 mg/L	Non-toxic
Inhibition of Bacterial Respiration	EC_{50}> 1000 mg/L	Non-inhibitory

7.2.1 Predicted No-Effect Concentration

Based on the ecotoxicity data provided, the notified chemical is not toxic up to the limit of water solubility where TOC = 1.23-9.87 mg/L. A PNEC could not be calculated based on the TOC value.

7.3. Environmental risk assessment

It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified chemical released into stormwater drains, which have the potential to directly enter the aquatic environment. However, a worst case estimated PEC can be calculated assuming that all of the 1% of the notified chemical expected to be released into stormwater drains (i.e. 1 tonne) is released into a single metropolitan area with a geographical footprint of 500 square kilometres and an average annual rainfall of 500 mm. With a maximum annual release into this localised stormwater system of 1000 kg and the annual volume of water drained from this region estimated to be approximately 250 x 10^6 m^3, the resultant PEC is approximately 4 µg/L. It should be stressed that this result is a worst case scenario, and that in reality releases of the chemical would be more diffuse than indicated here, and also at significantly reduced levels.

The notified chemical is not toxic to the aquatic organisms tested up to the limit of its water solubility where the TOC = 1.23-9.87 mg/L. This value allows for at least 3 orders of magnitude safety factor in comparing with the PEC of 4 µg/L. Further, the low water solubility of the notified chemical and its limited release to the aquatic environment (mainly via stormwater drainage) reduce the possibility of sufficient amounts to remain in solution to cause acute toxicity. The notified chemical released to water is expected to become associated with the sediments, and biodegradation will further reduce the risk to the aquatic life.

Overall, the environmental risk from the proposed blending and use of the notified chemical is expected to be low.

Extension Application:
Additional volume of the notified chemical will be used under this application and this was taken into account for the revised environmental risk assessment.

As stated above, the notified chemical is not toxic to the aquatic organisms tested up to the limit of its water solubility where the TOC = 1.23-9.87 mg/L. The calculated PEC, including the additional volume of the notified chemical for this application, was comparable with the original assessment, allowing for at least 3 orders of magnitude safety factor.

Overall, the environmental risk from the revised volume of the notified chemical is expected to be low.

8. Risk assessment relating to extension application

The use and the fate of the notified chemical will not change under the proposed extension. The increase in proposed introduction volume is not expected to significantly change the environment and health impacts. Therefore, there are no changes required in the risk assessment

9. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

9.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:
R38 Irritating to skin
R43 May cause sensitisation by skin contact

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Mild irritant	3	Causes mild skin irritation
Skin sensitiser	1	May cause allergic skin reaction

9.2. Human health risk assessment

9.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

9.2.2. Public health

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

9.3. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10. MATERIAL SAFETY DATA SHEET

The MSDS of the products containing the notified chemical provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS was found to be in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003).

Extension Application:
The applicant for extension application has provided MSDS of a product containing the notified chemical. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

11. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following hazard classification for the notified chemical:
  - R43 May cause sensitisation by skin contact
  - R38 Irritating to skin
- The following safety phrases for the notified chemical are recommended:
  - S24: Avoid contact with skin
  - S28: After contact with skin, wash immediately with plenty of water.

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - concentration ≥ 1%: R43
  - concentration ≥ 20%: R38, R43

Health Surveillance

- As the notified chemical is a sensitisation health hazard, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with eyes and skin.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Gloves
  - Safety glasses
  - Protective clothing

  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.

Environment

Disposal

- Recycle the material or dispose of according to local laws and regulations.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - Storage in accordance with the *National Standard for the Storage and Handling of Workplace Dangerous Goods* (NOHSC 2001) for C2 combustible liquids.

Emergency procedures

- Spills or accidental release of the notified chemical should be contained and placed in suitable containers for disposal.

12. REGULATORY OBLIGATIONS

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 Chemicals Notification and Assessment 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 marine engine oils, or is likely to change significantly;
- the amount of chemical being introduced has increased from 100 tonnes per annum, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available 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.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Melting Point 13ºC (pour point)

METHOD	ASTM D5950 (In-house method)
Remarks	The sample is heated, then cooled and examined at 1ºC intervals. The lowest temperature at which sample movement is detected is recorded as the pour point.
TEST FACILITY	Chevron (2007)

Boiling Point 324 - 735ºC (for 54.1% of recovered mass, the remaining 45.9% had boiling points > 735 ºC)

METHOD	ILT Test Code 59128 (In-house method); high temperature simulated distillation using gas chromatography.
Remarks	The sample is injected onto a column and the temperature increased. The hydrocarbon components are eluted in order of increasing boiling point.
TEST FACILITY	Chevron (2007)

Density 990.5 kg/m^3 at 20ºC

METHOD	ASTM D4052 (In-house method); oscillating densitimeter.
Remarks	The density of a sample is calculated based on the change in frequency of sample cell oscillation brought about by introduction of the notified substance.
TEST FACILITY	Chevron (2007)

Vapour Pressure 7.87 x 10^{-7} kPa at 20ºC

METHOD	Calculated using the Maxwell-Bonnell/ProVision method (In-house method)
Remarks	Calculations were performed using the density and boiling point.
TEST FACILITY	Chevron (2007)

Water Solubility 2.52 x 10^{-5} g/L at 30ºC

METHOD	OECD TG 105 Water Solubility.
Remarks	Flask Method
TEST FACILITY	Chevron (2007)

Partition Coefficient (n-octanol/water) log Kow >7.4 at 20ºC

METHOD	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method
TEST FACILITY	Chevron (2007)

Flash Point 180ºC (estimated)

METHOD	ASTM D93 (Pensky-Martens closed cup) (In-house method)
Remarks	Value given on product specification sheet and MSDS.
TEST FACILITY	In-house

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE SP8055

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague Dawley
Vehicle None
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	2000	1
2	4F	2000	0

LD50 >2000 mg/kg bw SP8055
Signs of Toxicity None
Effects in Organs None
Remarks - Results One animal from group 1 was found dead due to a dosing error.

CONCLUSION SP8055 is of low toxicity via the oral route.

TEST FACILITY Charles River (2006a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE SP8055

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain Rat/Sprague Dawley
Vehicle None
Type of dressing Occlusive.
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M	2000	0
2	5F	2000	0

LD50 >2000 mg/kg bw
Signs of Toxicity - Local Desquamation was noted in four male animals, starting on days 4 – 9, with the last disappearing by day 12.
Signs of Toxicity - Systemic None
Effects in Organs None
Remarks - Results Dark material around the eye and nose area was observed in all animals during the early stages of study observation, disappearing by day 3. Ocular lesions (no details given) were observed in one female animal on day 2 and disappeared by day 4. These lesions were considered to be either pre-existing or mechanical in nature and not related to test article exposure.

CONCLUSION SP8055 is of low toxicity via the dermal route.

TEST FACILITY Charles River (2006b)

B.3. Irritation – skin

TEST SUBSTANCE SP8055

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 males
Vehicle None
Observation Period Up to 14 days
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations. One animal was observed for 10 days, and the other for 14 days.

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	2	2	2	2	<14 days	0
Oedema	1	1	1	1	<10 days	0

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

Remarks - Results Very slight edema were observed in all animals at one hour. This persisted at the same level of severity until being completely resolved by 4 days in two of the animals, and 10 days in the remaining animal.
Moderate erythema were observed for several days in all animals, being completely recovered by 10 or 14 days.

CONCLUSION SP8055 is irritating to the skin.

TEST FACILITY Charles River (2006c)

B.4. Irritation – eye

TEST SUBSTANCE SP8055

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 males
Observation Period 96 hr
Remarks - Method No significant protocol deviations.

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	0.3	0.6	0.3	2	<72hr	0
Conjunctiva: chemosis	0	0.6	0.3	1	<72hr	0
Conjunctiva: discharge	0	0	0	2	<24hr	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results Redness, chemosis and discharge of conjunctiva were observed in all eyes at 1 hour. Redness had disappeared in two of the animals by the 48 hour

observation, and in the remaining animal by 72 hours. Chemosis disappeared in one animal by 24 hours, another by 48 hours, and the remaining animal by 72 hours. Discharge was no longer observed at 24 hour and beyond in all animals.

CONCLUSION SP8055 is slightly irritating to the eye.

TEST FACILITY Charles River (2006d)

B.5. Skin sensitisation

TEST SUBSTANCE SP8055

METHOD OECD TG 406 Skin Sensitisation - Buehler method.
Species/Strain Guinea pig/Hartley-derived albino
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 10% test substance in mineral oil, USP
MAIN STUDY
Number of Animals Test Group: 10 male, 10 female Control Group: 5 male, 5 female
INDUCTION PHASE Induction Concentration:
topical: 75% test substance in mineral oil, USP
Signs of Irritation Slight to moderate irritation was observed in most test animals at the 24 and 48 hour observations.
CHALLENGE PHASE
1st challenge topical: 10% test substance in mineral oil, USP
2nd challenge topical: 10% test substance in mineral oil, USP
Remarks - Method No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	10%	10/20	8/20	13/20	14/20
Control Group	10%	0/10	0/10	0/10	0/10

Remarks - Results The highest score observed following the challenges was 2, ie moderate irritation.
Skin irritation scores of 1 (slight irritation) and greater were considered for the purposes of the above table. Scores of 0.5 (slightly patchy erythema) were not considered.
A significant percentage of the tested animals showed evidence of sensitisation. This indicates that the test substance may be a strong sensitiser.

CONCLUSION There was evidence of reactions indicative of skin sensitisation to SP8055 under the conditions of the test.

TEST FACILITY Charles River (2006e)

B.6. Repeat dose toxicity

TEST SUBSTANCE SP8055

METHOD Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain	Rat/Crl:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Corn oil
Remarks - Method	No significant protocol deviations. Dosage levels were chosen based on a previous dose range-finding study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5M, 5F	0	0
II (low dose)	5M, 5F	160	0
III (mid dose)	5M, 5F	400	0
IV (high dose)	5M, 5F	1000	0
V (control recovery)	5M, 5F	0	0
VI (high dose recovery)	5M, 5F	1000	0

Mortality and Time to Death

No mortality was observed during the treatment or recovery phases.

Clinical Observations

Clinical findings related to the test substance were observed in animals treated with 1000 and 400 mg/kg, in particular, involving increased salivation with clear material around the mouth and some incidences of red material around the mouth, most often at 1 hour after dosing. The findings disappeared during the recovery period.

Males treated with 1000 mg/kg of the test substance were observed to have decreased weekly and cumulative body weight gains (13%), as well as slightly lower mean body weights (4.5%) compared to the controls. Whilst these changes were not statistically significant, these body weight parameters were consistently lower than in the control animals throughout the study.

No test article-related effects were observed on food consumption or functional observational battery evaluations.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

Statistically significant increases in the mean prothrombin time were observed in male and female animals treated with 1000 mg/kg of the test substance. In addition, increases in activated partial thromboplastin times (APTT) were also observed in males treated with 1000 mg/kg test substance. Following a 14-day recovery period, these values were similar to the control group. Increases in both prothrombin time and APTT suggest a deficiency in the common pathway of the coagulation cascade or multiple defects involving the intrinsic, extrinsic, and common pathways.

Other statistically significant differences in haematology parameters observed were not considered to be related to test substance administration.

Clinical chemistry

Alanine aminotransferase in the 400 and 1000 mg/kg males and females was significantly higher than the controls. Aspartate aminotransferase was significantly higher in 1000 mg/kg males and females compared to the controls. These findings were dose related and statistically significant. Globulin and total protein were significantly lower in the 1000 mg/kg males compared to the control group. In the females dosed at the same level, these parameters were numerically lower than the control group, however, these differences were not statistically significant. These serum chemistry changes were considered to be related to administration of the test substance, although they were not considered adverse because there was no corresponding macroscopic or microscopic liver changes observed.

Effects in Organs

Necropsy
No treatment related effects were detected.
Organ weights
No treatment related effects were detected.

Histopathology
No treatment related effects were detected.

Remarks – Results
Clinical findings and serum chemistry effects were observed at 400 and 1000 mg/kg, whilst body weight and coagulation parameter effects were observed at 1000 mg/kg. These changes were considered to be the result of direct contact with the test substance.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 160 mg/kg bw/day in this study, based on clinical observations and serum chemistry effects at higher doses. The No Observed Adverse Effect Level (NOAEL) was established as 400 mg/kg bw/day in this study, based on the fact that the clinical observations and serum chemistry level effects were not considered to be adverse due to the absence of related microscopic changes in the 400 and 1000 mg/kg/day groups.

TEST FACILITY WIL (2006)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE SP8055

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	Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 15 - 5000 µg/plate b) Without metabolic activation: 15 - 5000 µg/plate
Vehicle	Tetrahydrofuran
Remarks - Method	The volumes of tetrahydrofuran used were adjusted to allow for the toxicity of tetrahydrofuran to all of the bacterial tester strains. Accordingly, the test solution was dosed at 0.025mL rather than the recommended 0.05 or 0.1mL. The investigators stated that the test material is fully miscible in tetrahydrofuran, therefore it is an acceptable vehicle for use in this test system. The positive controls used for the assays performed without metabolic activation with TA98, TA100, and TA1535 were not those recommended by the test method. For TA100 and TA1535, N-ethyl-N'-nitro-N-nitrosoguanidine was used, and for TA98, 4-Nitroquinoline-1-oxide was used.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5,000	>5,000	≥500	Negative
Test 2		>5,000	≥500	Negative

Present				
Test 1	>5,000	>5,000*	≥500	Negative
Test 2		>5,000	≥500	Negative

* The number of revertants decreased by more than 50% at 50 and 150µg/plate for TA1535 only, however, this was not dose related.

Remarks - Results	No toxicity was observed. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	SP8055 was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (2006a)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	SP8055
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Human whole blood lymphocytes
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Vehicle	50% Pluronic F127 in ethanol (w/w)
Remarks - Method	No significant protocol deviations. The highest dose tested in the initial assay was 850µg/mL, which was above the solubility limit of the test substance after dosing in culture medium. The highest dose in the confirmatory assay was 200µg/mL.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	5.76, 8.24, 11.8, 16.8*, 24.0*, 34.3*, 49.0*†, 70.0, 100, 143, 204, 204, 292, 417, 595, 850	3hr	22hr
Test 2	1.56, 3.13, 6.25, 12.5, 25.0, 37.5*, 50.0*, 75.0, 100*, 150*, 200*	22hr	22hr
Present			
Test 1	5.76, 8.24, 11.8, 16.8, 24.0*, 34.3*, 49.0*, 70.0*, 100, 143, 204, 292, 417, 595, 850	3hr	22hr
Test 2	12.5, 25.0, 37.5*, 50.0*, 75.0, 100*, 150, 200*	3hr	22hr

†Cultures selected for metaphase analysis due to the mitotic index of this culture reaching the desired limit for this assay.
*Cultures selected for chromosomal aberrations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	N/A	>850	≥49.0	Negative
Test 2	N/A	>200	≥75.0	Negative
Present				

Test 1	N/A	>850	≥70.0	Negative
Test 2	N/A	>200	≥75.0	Negative

Remarks - Results

No statistically significant increases were observed in the frequency of cells with chromosomal aberrations, polyploidy, or endoreduplication.

In Test 1, absence and presence of metabolic activation, a 56% and 60% reduction, respectively, in the mitotic index of one culture from each test was observed. This was considered indicative of cytotoxicity; however, it was not a dose-related effect.

In addition, slight hemolysis was observed in Test 1 (presence of metabolic activation) at wash of cultures treated with ≥292µg/mL; and in Test 2 (absence of metabolic activation) at harvest of the cultures treated with 200µg/mL and in one of the cultures treated with 150µg/mL.

CONCLUSION

SP8055 was not clastogenic to human whole blood lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

Covance (2006)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE

SP8055

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mouse/Albino Crl:CD-1(ICR)BR
Route of Administration: Oral – gavage
Vehicle: Arachis oil
Remarks - Method: A range-finding toxicity test was performed to determine a suitable dose level for the micronucleus test. In addition, this study found that it was not necessary to perform the main test on both sexes, therefore, only male mice were used in the main study.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	7 males	0	48
II (vehicle control)	7 males	0	24
III (low dose)	7 males	300	24
IV (mid dose)	7 males	600	24
V (high dose)	7 males	1200	48
VI (high dose)	7 males	1200	24
VII (positive control, CP)	5 males	50	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity: Hunched posture and ptosis were observed in animals treated with the test substance at concentrations of 1200 mg/kg, indicating systemic absorption of the test substance.

Genotoxic Effects: The test substance did not induce a statistically significant increase in the frequency of micronucleated polychromatic erythrocytes over the levels observed in the vehicle control. The frequency of micronucleated polychromatic erythrocytes in the positive control was significantly higher than the vehicle control. There was no statistically significant decrease in the PCE/NCE ratio.

CONCLUSION

SP8055 was not clastogenic under the conditions of this in vivo mouse

	micronucleus assay.
TEST FACILITY	SafePharm (2005)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

ENVIRONMENTAL FATE

C.1.1. Ready biodegradability

TEST SUBSTANCE SP8055

METHOD OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
- Inoculum: Activated sewage sludge
- Exposure Period: 28 day
- Auxiliary Solvent: Not specified
- Analytical Monitoring: TOC
- Remarks - Method: The sample biodegradability is calculated from the released CO_2 compared to blank and the reference.

RESULTS

Sodium benzoate		Test material	
Day	*% Degradation*	*% Degradation*	*% Degradation Test Material plus Sodium Benzoate Toxicity Control*
0	0	0	0
1	35	0	0
2	61	0	1
3	84	0	3
6	75	2	2
8	80	0	22
12	81	3	23
14	80	3	29
16	87	4	33
20	74	0	35
22	76	2	41
27	82	7	44
28	79	6	44
29*	86	7	50

Day 29* values corrected to include any carry-over of CO_2

- Remarks - Results: Sample biodegradability = 6 % after 28 days. The reference indicated that the test criteria are met.

CONCLUSION SP8055 is biodegradable but is not considered readily biodegradable.

TEST FACILITY Safepharm (2006b)

C.1.2. Bioaccumulation

Based on a low partition coefficient and low aquatic exposure the notified substance is not expected to bioaccumulate.

ECOTOXICOLOGICAL INVESTIGATIONS

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	SP8055
METHOD	OECD TG 203 Fish, Acute Toxicity Test semi-static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish Test semi-static
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h LL_{50}
Auxiliary Solvent	None
Water Hardness	100 mg/L $CaCO_3$
Analytical Monitoring	TOC analysis
Remarks – Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its expected low water solubility. The test substance was tested for toxicity towards fish only up to the limit of its water solubility. An amount of test substance (21.0 g) was added via a syringe to the surface of 21 litres of dechlorinated water to give the 1000 mg/L loading rate. After addition of the test substance, the dechlorinated tap water was stirred by a magnetic stirrer using a stirring rate such that a vortex was formed to give a dimple at the water surface. This was stirred for 24 hours. The stirring was stopped after 24 hours and the mixture allowed to stand for 4 hours. A wide bore glass tube, covered at one end with Nescofilm was submerged into the vessel, sealed end down, to a depth of approximately 5 cm from the bottom of the vessel. A length of Tygon tubing was inserted into the glass tube and pushed through the Nescofilm seal. The aqueous phase or Water Accommodated Fraction (WAF) was removed by mid-depth siphoning (the first 75 mL discarded) to give the 1000 mg/L loading rate WAF. Microscopic inspection of the WAF showed no micro-dispersion or undissolved test substance to be present.

RESULTS

Nominal Loading Rate (mg/L)	*Number of Fish*	*Mortality*				
		3 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0
1000	10	0	0	0	0	0
1000	10	0	0	0	0	0
1000	11	0	0	0	0	0

LL_{50}	> 1000 mg/L WAF nominal at 96 hours.
NOEC	1000 mg/L WAF nominal at 96 hours.
Remarks – Results	All organisms of the control and the treatment at 1000 mg/L survived the 96 h WAF toxicity test.
CONCLUSION	SP8055 is considered to be non toxic to Rainbow trout (*Oncorhynchus mykiss*) up to the limit of its water solubility.
TEST FACILITY	Safepharm (2006c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	SP8055
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test –semi-static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia Test-semi-static.
Species	*Daphnia magna*
Exposure Period	48 hours EL_{50}
Auxiliary Solvent	Not specified
Water Hardness	250 mg/L $CaCO_3$
Analytical Monitoring	TOC analysis
Remarks - Method	Amounts of test substance (250 and 2500 g) were added separately, via a syringe to the surface of 2.5 litres of reconstituted water to give the 100 and 1000 mg/L loading rate respectively. After addition of the test substance, the dechlorinated tap water was stirred by a magnetic stirrer using a stirring rate such that a vortex was formed to give a dimple at the water surface. This was stirred for 24 hours. The stirring was stopped after 24 hours and the mixture allowed to stand for 4 hours. A wide bore glass tube, covered at one end with Nescofilm was submerged into the vessel, sealed end down, to a depth of approximately 5 cm from the bottom of the vessel. A length of Tygon tubing was inserted into the glass tube and pushed through the Nescofilm seal. The aqueous phase or Water Accommodated Fraction (WAF) was removed by mid-depth siphoning (the first 75 mL discarded) to give the 100 and 1000 mg/L loading rate WAF. Microscopic inspection of the WAF showed no micro-dispersion or undissolved test substance to be present.

RESULTS

Nominal Loading Rate (mg/L)	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	10	0	0
100	10	0	0
1000	10	0	0

EL_{50}	> 1000 mg/L WAF nominal at 48 hours.
NOEC	1000 mg/L WAF nominal at 48 hours
Remarks - Results	The 48-hour EL_{50} for the test substance to *Daphnia magna* based on nominal loading rates was greater than 1000 mg/L loading rate WAF and correspondingly the No Observed Effect Loading rate was 1000 mg/L loading rate WAF.
CONCLUSION	SP8055 is considered to be non-toxic to *Daphnia magna* up to the limit of its water solubility.
TEST FACILITY	Safepharm (2006d)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	SP8055
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours EL_{50}
Concentration Range	Nominal: 1000 mg/L
Auxiliary Solvent	Not specified

Water Hardness	Not given
Analytical Monitoring	TOC analysis
Remarks - Method	Amounts of test substance (2500 mg) was added separately, via a syringe to the surface of 2.5 litres of culture medium to give the 1000 mg/L loading rate respectively. After addition of the test substance, the dechlorinated tap water was stirred by a magnetic stirrer using a stirring rate such that a vortex was formed to give a dimple at the water surface. This was stirred for 24 hours. The stirring was stopped after 24 hours and the mixture allowed to stand for 4 hours. A wide bore glass tube, covered at one end with Nescofilm was submerged into the vessel, sealed end down, to a depth of approximately 5 cm from the bottom of the vessel. A length of Tygon tubing was inserted into the glass tube and pushed through the Nescofilm seal. The aqueous phase or Water Accommodated Fraction (WAF) was removed by mid-depth siphoning (the first 75 mL discarded) to give the 100 and 1000 mg/L loading rate WAF. Microscopic inspection of the WAF showed no micro-dispersion or undissolved test substance to be present.

RESULTS

Biomass		*Growth*	
Nominal (WAF) EL_{50} *mg/L at 96 h*	Nominal (WAF) NOEC *mg/L at 96 h*	*Nominal (WAF) EL_{50} mg/L at 96 h*	*Nominal (WAF) NOEC mg/L at 96 h*
> 1000	1000	> 1000	1000

Remarks - Results	The 48-hour EL_{50} for the test substance to *Pseudokirchneriella subcapitata* based on nominal loading rates was greater than 1000 mg/L loading rate WAF and correspondingly the No Observed Effect Loading rate was 1000 mg/L loading rate WAF.
CONCLUSION	The results for SP8055 showed no effect on *Pseudokirchneriella subcapitata* growth at a concentration of 1000 mg/L.
TEST FACILITY	Safepharm (2006e)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	SP8055
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sewage sludge
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	For the purpose of the definitive test, the test substance was dispersed directly in water. An amount of test substance (500 mg) was dispensed from a plastic disposable syringe into approximately 250 mL of water and subjected to ultrasonication for approximately 30 minutes. Synthetic sewage (16 mL), activated sewage sludge (200 mL) and water were added to a final volume of 500 mL to give the required concentration of 1000 mg/L. Analysis of the concentration, homogeneity and stability of the test material in the test preparation was not appropriate to the Test Guideline.
RESULTS	
EC_{50}	> 1000 mg/L (nominal)

NOEC	1000 mg/L (nominal)
Remarks – Results	The effect of the test substance on the respiration of activated sewage sludge gave a 3-Hour EC_{50} of greater than 1000 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 1000 mg/L
CONCLUSION	SP8055 is not inhibitory to the activated sludge micro-organisms.
TEST FACILITY	Safepharm (2006f)

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