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

PUBLIC REPORT

Chemical in PETROSTEP S-2/S-2 HA

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

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

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

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**Director
NICNAS**

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
STD/1401	Nalco Australia Pty Ltd	Chemical in PETROSTEP S-2/S-2 HA	Yes	≤ 1,500 tonnes per annum	A component in a surfactant blend for use in enhanced oil recovery operations

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the skin and eye irritation data on analogues 1 and 2, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

R38 Irritating to skin

R41 Risk of serious eye damage

and

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	<i>Hazard category</i>	<i>Hazard statement</i>
Skin Corrosion/Irritation	2	Causes skin irritation
Serious Eye Damage/Eye Irritation	1	Causes serious eye damage
Environment	Acute Category 1	Very toxic to aquatic life

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the assessed use pattern, the notified chemical is not considered to pose an unacceptable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classifications for the notified chemical:
 - R38 Irritating to skin
 - R41 Risk of serious eye damage
- Use the following risk phrases for products/mixtures containing the notified chemical:

- Conc \geq 20%: Xi; R41; R38
- \geq 10% Conc < 20%: Xi; R41
- \geq 5% Conc < 10%: Xi; R36

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
 - Avoid skin and eye contact
 - First aid procedures should be in place, in case of accidental contact
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
 - Safety goggles or face shield, gloves and 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

- The following control measures should be implemented by importers and users of the notified chemical to minimise environmental exposure during use of the notified chemical:
 - The notified chemical (including products or produced waters containing the notified chemical) should not be released to the aquatic environment.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification

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

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

- (1) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from a component in a surfactant blend for use in enhanced oil recovery operations, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1,500 tonnes per annum, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Nalco Australia Pty Ltd (ABN 41 000 424 788)
2 Anderson Street
BOTANY, NSW 2019

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 and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: vapour pressure, hydrolysis as a function of pH, partition co-efficient, absorption/desorption, dissociation constant, explosive properties, acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, skin irritation, eye irritation, skin sensitisation, repeated dose toxicity, induction of point mutations, induction of germ cell damage, ready biodegradation and bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (current)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

PETROSTEP S-2 (contains 20 – 30% notified chemical)

PETROSTEP S-2 HA (contains 35 – 45% notified chemical)

MOLECULAR WEIGHT

< 500 Da

ANALYTICAL DATA

Reference NMR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 77 – 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

<i>Chemical Name</i>	Sodium hydroxide		
<i>CAS No.</i>	1310-73-2	<i>Weight %</i>	PETROSTEP S-2: < 10 PETROSTEP S-2 HA: < 10
<i>Hazardous Properties</i>	Conc ≥ 5%: C; R35 ≥ 2% Conc < 5%: C; R34 ≥ 0.5% Conc < 2%: Xi; R36/38		

ADDITIVES/ADJUVANTS

<i>Chemical Name</i>	Ethanol, 2-butoxy-		
<i>CAS No.</i>	111-76-2	<i>Weight %</i>	PETROSTEP S-2 HA: < 10
<i>Hazardous Properties</i>	Conc ≥ 25%: Xn; R20/21/22; R36/38 ≥ 20% Conc < 25%: Xi; R36/38		

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow solid (the introduced product is a liquid)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Decomposes above 294°C	Measured
Boiling Point	Decomposes above 294°C	Measured
Density	1,050 kg/m ³ at 25°C (PETROSTEP S-2) 1,050 kg/m ³ at 25°C (PETROSTEP S-2 HA)	Measured
Vapour Pressure	1.07×10^{-19} to 1.52×10^{-14} kPa at 25°C	Calculated using the Modified Grain Method (MPBPVP v1.43, US EPA 2011)
Water Solubility	298 g/L at 30 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains functional groups that are generally resistant to hydrolysis.
Partition Coefficient (n-octanol/water)	log K _{ow} = 0.73 – 3.53	Calculated for representative species of the notified chemical (KOWWIN v1.68; US EPA 2011). However, the notified chemical is a surfactant and will tend to accumulate at the phase interface of octanol and water.
Adsorption/Desorption	log K _{oc} = 2.20 – 4.08	Calculated for representative species of the notified chemical (KOCWIN v2.0, MCI method; US EPA 2011). The notified chemical is a surfactant and is expected to adsorb to soil and sediment.
Dissociation Constant	Not determined	The notified chemical is a salt and is expected to be dissociated at environmental pH (4 - 9).
Particle Size	Not determined	Introduced in a liquid
Flash Point	> 94°C (PETROSTEP S-2)	Measured
Flammability Limits	Upper: 13% Lower: 4%	For the solvent ethanol, 2-butoxy- in the introduced products (Lide DR, 2000).
Autoignition Temperature	238°C	For the solvent ethanol, 2-butoxy- in the introduced products (Lide DR, 2000). The notified chemical is not expected to autoignite under normal

Explosive Properties	Not expected to be explosive	conditions of use. The structural formula contains no explosophores.
Oxidising Properties	Not oxidising	Estimated based on chemical structure.

DISCUSSION OF PROPERTIES

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

Reactivity

Stable under normal conditions of use.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured within Australia, but will be imported in 22,000 L International Maritime Organisation (IMO) freight containers at a concentration of 20 – 30% (PETROSTEP S-2) or 35 – 45% (PETROSTEP S-2 HA).

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>	< 500	< 1,500	< 1,500	< 1,500	< 1,000

PORT OF ENTRY

Fremantle

IDENTITY OF MANUFACTURER/RECIPIENTS

Oil field located in the Northern Perth Basin, Western Australia.

TRANSPORTATION AND PACKAGING

The notified chemical is expected to be imported in 22,000 L IMO containers by ship, before being transported by truck to the injection well site. The notified chemical will not be discharged or decanted from the original IMO container prior to arriving at the oilfield.

USE

The notified chemical will be used as a component in a surfactant blend for use in enhanced oil recovery operations. The notified chemical functions as a surfactant, aiding in the extraction of oil from a formation. The notified chemical will be imported in a liquid formulation as a component of PETROSTEP S-2 at 20 – 30% initially, and as a component of PETROSTEP S-2 HA at 35 – 45% in 22,000 L IMO containers, which will be transported to the injection well site for closed-system blending with PETROSTEP S-3B or PETROSTEP S-3B HA (STD/1402), respectively, and water prior to injection into 4 injection wells and 5 associated producing wells.

OPERATION DESCRIPTION

The notified chemical will not be manufactured within Australia. The imported 22,000 L IMO containers containing the notified chemical at concentrations up to 45% will be towed from the wharf by a prime mover into position on a bunded concrete pad (with suitable drain and sump). The prime mover will then be disconnected leaving the trailer and IMO container. There will be two tanks positioned on the bunded concrete pad as there are two main chemical parts to the surfactant blend (i.e., PETROSTEP S-2 or S-2 HA and PETROSTEP S-3B or S-3B HA). A transfer/metering pump suction line will be connected up to each IMO container with the two transfer/metering pumps discharges connected to the suction header of the existing triplex high pressure water injection pump. The transfer/metering pump will pump the imported product containing the notified chemical into the triplex suction line at the desired rate where it will mix with water and other chemicals in the suction line, the pump and the discharge line creating the final surfactant blend (< 1%

notified chemical) to be used in the injection well. The oil field and facilities are a closed system, where well fluids will be produced from the wellheads and separated into gas, oil and water. All water will remain within the vessels and pipe work, circulating through the plant, pumps and back into the reservoir through the injection wells and the notified chemical is expected to primarily remain in the water phase. At no time will water be discharged into the environment or water-table, or exposed to the atmosphere, such as in an evaporation pond. Emptied import containers will be cleaned, with the residue being used for injection into the wells.

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>
Transport workers	5-6	10
Process workers (hose connection/disconnection)	0.08	2.5
Process workers (pump monitoring)	0.5	15

EXPOSURE DETAILS

Transport workers are not likely to be exposed to the notified chemical except in the case of an accident involving damage to the import containers.

Dermal and ocular exposure to the notified chemical at up to 45% concentration is most likely to occur during connection and disconnection of the transfer/metering pump suction line. Exposure to the notified chemical during blending and injection into the oil well is expected to be limited by the low concentration (< 1%) of the notified chemical in the surfactant blend and the enclosed systems. Exposure to the surfactant blend containing the notified chemical at < 1% concentration may be possible during maintenance and monitoring of the transfer/metering pumps. Exposure will also be reduced by the use of PPE including protective clothing, gloves and eye/face protection.

Inhalation exposure to the notified chemical is also possible during its use as a component in a surfactant blend for use in enhanced oil recovery operations. However, due to its low vapour pressure (1.07×10^{-19} to 1.52×10^{-14} kPa at 25°C) and the enclosed systems the notified chemical is not expected to be available for inhalation in significant quantities unless aerosols are generated during the processes.

6.1.2. Public Exposure

The notified chemical is intended for industrial use on specific sites and therefore public exposure is not anticipated.

6.2. Human Health Effects Assessment

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

<i>Endpoint</i>	<i>Test Substance</i>	<i>Result and Assessment Conclusion</i>	<i>Source</i>
Rat, acute oral toxicity	Analogue 1 (37% active)	LD50 2,200 mg/kg bw; low toxicity	OECD (2007)
	Analogue 1 (25% active)	LD50 578 mg/kg bw; harmful	OECD (2007)
Mouse, acute oral toxicity	Analogue 2	LD50 2,430 mg/kg bw; low toxicity	OECD (2007)
Rat, acute dermal toxicity	Analogue 1 (37% active)	LD50 > 2,000 mg/kg bw; low toxicity	OECD (2007)
Rabbit, skin irritation	Analogue 1 (10% active)	moderately irritating	Hill Top Research (1982a)

	Analogue 1*	moderately irritating	Tox Monitor Laboratories (1993)
	Analogue 1 (5% active)	moderately irritating	Toxicity Research laboratories (1984)
	Analogue 1 (40% active)	moderately irritating	OECD (2007)
Rabbit, eye irritation	Analogue 1*	irritating	Hill Top Research (1982b)
	Analogue 1 (40% active)	irritating	OECD (2007)
	Analogue 1 (90% active)	severely irritating	OECD (2007)
	Analogue 1 (20-40% active)	severely irritating	OECD (2007)
Guinea pig, skin sensitisation – non-adjuvant test.	Analogue 1	no evidence of sensitisation	Raltech (1981)
Modified human repeat insult patch test	Analogue 1	irritating no evidence of sensitisation	Thomas J. Stephens & Associates (2008)
Rat, repeat dose oral toxicity – 104 weeks.	Analogue 1	NOAEL = 96 – 132 mg/kg bw/day	OECD (2007)
Rat, repeat dose oral toxicity – 26 weeks.	Analogue 2	NOAEL = 250 mg/kg bw/day	OECD (2007)
Mutagenicity – bacterial reverse mutation	Analogue 1	non mutagenic	OECD (2007)
	Analogue 2	non mutagenic	OECD (2007)
Genotoxicity – <i>in vitro</i> mammalian chromosomal aberration test (Chinese hamster V79 cells)	Analogue 1	non genotoxic	OECD (2007)
Genotoxicity – <i>in vitro</i> mammalian chromosomal aberration test (Chinese hamster CHL cells)	Analogue 2	non genotoxic	OECD (2007)

* Concentration unspecified in study

Toxicokinetics, metabolism and distribution.

Due to the low molecular weight (< 500 Da) of the notified chemical dermal absorption may occur. However toxicokinetic studies on ¹⁴C-labeled analogue 3 found the dermal absorption to be 0.6% (OECD, 2007). Absorption across the gastrointestinal tract was shown to be 73% for ¹⁴C-labeled analogue 3 (OECD, 2007).

Acute toxicity.

Analogue 1 was shown to have low acute oral toxicity (LD50 2,200 mg/kg bw) in one study conducted in rats but was harmful (LD50 578 mg/kg bw) in a second study. Analogue 2 was found to be of low oral toxicity in a study conducted in mice but no information on the concentration of the analogue in the test substance was provided.

Analogue 1 was also shown to have low acute dermal toxicity based on an occlusive test.

There is no data on the inhalation toxicity of the notified chemical or suitable analogues.

Based on the read across data the notified chemical is expected to be of low to moderate acute toxicity via the oral route and low toxicity via the dermal route.

Irritation and Sensitisation.

In four separate studies on analogue 1 at concentrations up to 40%, it was found to be moderately irritating to the skin of rabbits.

Analogue 1 was found to be irritating to the eyes in two studies in rabbits and severely irritating to the eyes in two further studies, also on rabbits. At the highest tested dose for analogue 1 (90%), severe cornea effects were still present at the end of the 21 day observation period and as it was only at the lower doses that the effects were not considered severely irritating. Therefore, it can be expected that at high concentrations the notified chemical would also be severely irritating to the eyes.

A primary irritation patch test conducted on 19 human volunteers using a 24 hour occluded application at concentrations of 0.3, 1.0 and 3.0% showed signs of irritation at all three dose levels (Hill Top Research, 1981).

There was no evidence of sensitisation noted in a guinea pig maximisation test with analogue 1. A modified human repeat insult patch test was also conducted using analogue 1 diluted to 1% under occlusive dressing (Thomas J. Stephens & Associates, 2008). Analogue 1 was irritating and non-sensitising under the conditions of this modified human repeat insult patch test.

Based on these results for analogue 1 the notified chemical should be considered to be irritating to the skin and severely irritating to the eyes but is not expected to be a sensitiser.

Repeated Dose Toxicity.

A 2 year feeding study in Sprague-Dawley CFY rats with analogue 1 at doses corresponding to 0, 39-57, 96-132 and 195-259 mg/kg bw/day gave a NOAEL of 96 – 132 mg/kg bw/day. There were no significant adverse treatment related effects apart from a slight reduction in food consumption (females) and a significant reduction in bodyweight gain (both sexes) in the high dose group between weeks 14 to 26.

In a 26 week oral (gavage) study in Wistar rats, analogue 2 was administered at doses up to 500 mg/kg bw/day. The NOAEL was determined to be 250 mg/kg bw/day, based on deaths in test animals at 500 mg/kg bw/day.

Based on the above studies on analogue 1 and 2 the notified chemical is not expected to be hazardous through repeated oral exposure up to 96 mg/kg bw/day.

Mutagenicity.

Three Ames tests on analogue 1 and two on analogue 2 were negative both in the presence and absence of metabolic activation. Analogue 1 and 2 also did not induce chromosome aberrations in Chinese hamster V79 cells or CHL cells respectively, both in the presence and absence of metabolic activation. The notified chemical is not expected to be mutagenic or genotoxic based on the results seen in the tests with analogues 1 and 2.

Health hazard classification

Based on the skin and eye irritation studies conducted on analogues 1 and 2, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

R38 Irritating to skin

R41 Risk of serious eye damage

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on studies conducted on analogues the notified chemical is expected to be irritating to the skin and cause serious damage to the eyes; however it is not expected to be acutely toxic via the oral or dermal routes. The notified chemical is also not expected to be mutagenic, genotoxic or a skin sensitiser. Given a NOAEL of > 96 mg/kg bw/day, the expected workplace controls used to reduce exposure and low dermal absorption (0.6 %) based on analogue studies, toxicity from repeated dermal exposure is not expected.

As the concentration of the notified chemical in the finished surfactant blend is low (< 1%) and the irritation potential is expected to be reduced at this concentration, the risk of skin irritation and eye damage will be greater for workers handling the notified chemical as introduced at concentrations up to 45%, particularly during connection and disconnection of the transfer/metering pump suction line. It is noted that the product containing the notified chemical is corrosive and workplace controls applied for this hazard will reduce exposure to the notified chemical. Given that the exposure is expected to be minimised due to the use of personal protective equipment during these operations, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health

The public are not likely to be exposed to the notified chemical as it will only be used at a limited number of industrial sites. Therefore the risk to public health is expected to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

As manufacturing and reformulation of the notified chemical will take place overseas, no release of the notified chemical will occur in Australia from these activities. The product containing the notified chemical will be stored in a bunded storage area at the end-use oil field where release to the environment is not expected.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be injected into < 10 on-shore oil wells to assist in the recovery of hydrocarbon materials. The notified chemical will be blended on-site with water and other chemicals prior to injection into the wells. The products containing the notified chemical are injected via a water injection well and will aid the release of trapped oil. Produced fluids that exit the well heads (oil, gas and water) will be processed in an on-site separation facility where oil is separated and stored. The notified chemical is extracted into the aqueous phase and produced water is re-injected into the oil wells. Notified chemical is not expected to be in oil after the separation process.

In the separation facility all water containing the notified chemical will remain within the vessels and pipe work, circulating through the plant and pumps, and back into a reservoir through the injection wells. Water containing the notified chemical will remain in a closed loop and is therefore not expected to be discharged into the environment or water table. Emptied imported containers are expected to be cleaned and the residues containing the notified chemical used for injection.

RELEASE OF CHEMICAL FROM DISPOSAL

Once field operations have ceased the notified chemical is expected to remain in produced waters that have been re-injected in the oil reservoir. The oil reservoir is ~30 m thick, with a top depth of 2,300 m below mean sea level and lying below shale. The shale provides a top seal preventing fluids from migrating to shallower formations. Therefore the notified chemical is not expected to be released to the surrounding environment once in the oil reservoir.

7.1.2. Environmental Fate

Fate studies were provided for an analogue (analogue 1) of the notified chemical. Analogue 1 was found to be readily biodegradable and has the potential to biodegrade in seawater. Analogue 1 is considered to be acceptable with respect to biodegradation as it has the same functional groups as the notified chemical and a very similar molecular weight range and structure. Therefore the notified chemical is likely to be readily biodegradable and is not expected to persist in the environment.

The notified chemical is not expected to be bioaccumulative based on data reported in a reliable, internationally peer reviewed report on the class of chemicals to which the notified chemical belongs (OECD, 2007). However, no release to surface water is expected as the notified chemical will be reinjected into the reservoir where it will remain until it degrades abiotically and biotically into water, oxides of carbon and sulfur, and inorganic salts.

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

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical is expected to be used in a closed loop system. Once field operations have ceased, the notified chemical is expected to remain in produced waters that have been reinjected back into oil reservoirs where it is expected to eventually degrade. Therefore, a Predicted Environmental Concentration (PEC) has not been calculated since no release of the notified chemical to the aquatic environment is anticipated.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on PETROSTEP S-2 (product containing the notified chemical) are summarised in the table below. The results were adjusted to 100% active ingredient (notified chemical). Details of these studies can be found in Appendix C. The results are comparable with data reported in a reliable, internationally peer reviewed report on the class of chemicals to which the notified

chemical belongs (OECD, 2007).

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity (96 h)	LC50 = 1.0 mg/L	Very Toxic
Daphnia Toxicity (48 h)	EC50 = 3.9 mg/L	Toxic
Algal Toxicity (72 h)	E _r C50 > 77 mg/L	Potentially harmful

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is classified as acutely very toxic to fish and acutely toxic to aquatic invertebrates. The notified chemical is considered potentially harmful to algae since the estimated 72 hr E_rC50 was found to be greater than the highest test substance concentration (77 mg/L) and therefore it was not known if the E_rC50 was above the 100 mg/L threshold for the harmful classification. Based on the toxicity to fish the notified chemical is formally classified under the GHS as “Acute category 1; Very toxic to aquatic life”. Based on the acute toxicity data, low potential for bioaccumulation and biodegradability studies, the notified chemical is not classified for long term hazard under the GHS.

7.2.1. Predicted No-Effect Concentration

The endpoint from the most sensitive species from the results of the ecotoxicological studies summarised above was used to calculate the Predicted No-Effect Concentration (PNEC). An assessment factor of 100 was used as acute toxicity endpoints are available for the effects of the notified chemical on aquatic species from three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
96 h LC50 (fish)	1.0	mg/L
Assessment Factor	100	
PNEC:	10	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient, Q (= PEC/PNEC), has not been calculated since a PEC is not available. The notified chemical exhibited acute toxicity to aquatic organisms, but has a low potential to bioaccumulate and is not expected to persist in the environment. The release of the notified chemical to aquatic ecosystems is not anticipated from the proposed use pattern. Therefore based on the assessed use pattern as a component of a surfactant blend for oil recovery operations, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point/Freezing Point** Decomposes above 294°C

Method	Thermogravimetric analysis was conducted according to an in-house method using a Perkin Elmer Pyris 1 thermogravimetric analyzer (TGA), from 30°C to 600°C at a heating rate of 10°C/minute. Pyris 8.0.0.0172 software was used to calculate the extrapolated onset temperature of decomposition.
Remarks	The notified chemical decomposed prior to boiling or melting.
Test Facility	Stepan Company (2011a)

Boiling Point Decomposes above 294°C

Method	Thermogravimetric analysis was conducted according to an in-house method using a Perkin Elmer Pyris 1 thermogravimetric analyzer (TGA), from 30°C to 600°C at a heating rate of 10°C/minute. Pyris 8.0.0.0172 software was used to calculate the extrapolated onset temperature of decomposition.
Remarks	The notified chemical decomposed prior to boiling or melting.
Test Facility	Stepan Company (2011a)

Density PETROSTEP S-2: 1,050 kg/m³ at 25°C
PETROSTEP S-2 HA: 1,050 kg/m³ at 25°C

Method	The sample density was determined by using a density meter to measure the period oscillation of a U-shaped tube. The natural frequency of the tube is influenced by the mass of the sample contained and the tube will only hold a certain volume of liquid, and therefore the density could be measured from the oscillations.
Remarks	Deionised water was used as the reference liquid.
Test Facility	Stepan Company (2003, 2011b)

Water Solubility 298 g/L at 30°C

Method	OECD TG 105 Water Solubility
Remarks	Based on the results of a preliminary test the Flask Method was used. Oven dried test substance (PETROSTEP S-2) was added to water and stirred at 30°C. Equilibration times of 24, 48 and 72 hrs were run in triplicate. The samples were centrifuged after equilibration time at 3000 rpm for 1 hr and the aqueous layer was removed. The anionic active (wt%) of the aqueous layers was determined by potentiometric titration. The reported solubility (29.8%) was the same for each equilibration time. All aqueous samples were found to have pH > 10.
Test Facility	Stepan Company (2011c)

Flash Point PETROSTEP S-2: > 94°C
PETROSTEP S-2 HA: > 94°C

Method	Similar to ASTM D93-90
Remarks	Pressure not specified Pensky-Martens Closed Cup Test
Test Facility	Stepan Company (2002, 2011b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE	Analogue 1 (10%)
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion. In accordance with the U.S. Regulation for the Enforcement of the Federal Hazardous Substances Act (16 CFR 1500)
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	Test substance administered as supplied
Observation Period	72 Hours
Type of Dressing	Occlusive
Remarks - Method	The concentration of analogue 1 in the test substance was not specified in the report. However, the notifier has stated that the concentration of the test substance was 10%. Both abraded and intact skin was exposed to the test substance. Observations were made 24 and 72 hours after application of the test substance but not at 48 hours. Observations were not continued beyond 72 hours despite effects still being present. The exposure period was 24 hours.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	2.3	3	> 72 Hours	2
<i>Oedema</i>	2.1	4	> 72 Hours	2

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals. Intact skin sites only.

Remarks - Results	Irritation effects included well-defined to moderate erythema and mild to severe oedema in all animals, as well as spreading of these effects beyond the immediate application sites. Changes in the colouration or texture of the skin included atonia, blanching, and coriaceousness in all six animals and fissured sites in three animals.
CONCLUSION	Analogue 1 at 10% concentration is moderately irritating to the skin.
TEST FACILITY	Hill Top Research (1982a)

B.2. Irritation – skin

TEST SUBSTANCE	Analogue 1 (test concentration not specified)
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion. A modification of U.S. Department of Transportation (D.O.T.) Regulations (corrosivity).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied
Observation Period	72 Hours
Type of Dressing	Occlusive
Remarks - Method	Effects were scored using the D.O.T. corrosivity scale, which is equivalent to the Draize scale. Observations were not continued beyond 72 hours despite effects still being present.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	2	2	2	2	> 72 hours	2
<i>Oedema</i>	1.7	1.7	2	2	> 72 hours	2

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

Remarks - Results Irritation effects included defined erythema and oedema in all animals. The Primary Irritation Index was calculated to be 3. The effects were still present in all animals at the end of the observation period.

CONCLUSION Analogue 1 is moderately irritating to the skin.

TEST FACILITY Tox Monitor Laboratories (1993)

B.3. Irritation – skin

TEST SUBSTANCE Analogue 1 (5%)

METHOD Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Vehicle Test substance administered as supplied
Observation Period 72 Hours
Type of Dressing Occlusive
Remarks - Method Observations were made 24 and 72 hours after application of the test substance but not at 48 hours. Observations were not continued beyond 72 hours despite effects still being present.
The exposure period was 24 hours.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	1.75	2	> 72 hours	2
<i>Oedema</i>	1.83	3	> 72 hours	2

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

Remarks - Results Irritation effects included moderate erythema and very slight to moderate oedema in all animals, as well as spreading of these effects beyond the immediate application sites.

CONCLUSION Analogue 1 at 5% concentration is moderately irritating to the skin.

TEST FACILITY Toxicity Research laboratories (1984)

B.4. Skin irritation – human volunteers

TEST SUBSTANCE Analogue 1 (test concentration not specified)

METHOD Primary irritation patch test
Three concentrations of test substance were applied to the backs of human test subjects for 24 hours under occlusive patch conditions. The test sites were scored for irritation 30 minutes, 24 and 48 hours after sample removal.
Study Design The test substance was applied at concentrations of 0.3%, 1.0% and 3.0%.
Study Group 19 subjects (18 male, 1 female)
Vehicle Not specified

Remarks - Method Prior to application to the test patches, the pH of test material was adjusted with citric acid to achieve a range of 6.0-7.0. Because of significant irritation visible on some subjects at the 48-hour scoring session, all subjects were requested to return for follow-up examination by the consultant dermatologists.
No scoring key was provided.

RESULTS

Remarks - Results Signs of irritation were noted at all three dose levels at all three observation times. As there was no scoring key provided and the scale does not appear to correspond to commonly used methods it is not possible to determine the level of irritation seen in the test subjects.

CONCLUSION

A primary irritation patch test was conducted using analogue 1 diluted to 0.3, 1.0 and 3.0% under occlusive dressing. Analogue 1 was irritating under the conditions of the test.

TEST FACILITY

Hill Top Research (1981)

B.5. Irritation – eye

TEST SUBSTANCE

Analogue 1 (test concentration not specified)

METHOD

Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
In accordance with the U.S. Regulation for the Enforcement of the Federal Hazardous Substances Act (16 CFR 1500)

Species/Strain

Rabbit/New Zealand White

Number of Animals

6

Observation Period

7 Days

Remarks - Method

The concentration of analogue 1 in the test substance was not specified.
The observation at 1 hour was not conducted.
Observations were not continued beyond 7 days despite effects still being present.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Conjunctiva: redness</i>	2.83	3	> 7 days	2
<i>Conjunctiva: chemosis</i>	1.17	4	> 7 days	1
<i>Conjunctiva: discharge</i>	1.94	3	> 7 days	1
<i>Corneal opacity</i>	0.67	1	< 4 days	0
<i>Iridial inflammation</i>	0.11	1	< 72 hours	0

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

Remarks - Results

A single application of the test material to the non-irrigated eye of six rabbits resulted in adverse effects including mild corneal opacity involving up to the entire area in all animals and mild iritis in two animals. Mild to extreme conjunctival irritation (erythema, chemosis, and discharge) were noted in all animals. Corneal effects were reversible by Day 4 in all animals, while mild or moderate conjunctival effects were still present on Day 7 in all animals.

CONCLUSION

Analogue 1 is irritating to the eye.

TEST FACILITY

Hill Top Research (1982b)

B.6. Skin sensitisation

TEST SUBSTANCE	Analogue 1
METHOD	Similar to OECD TG 406 Skin Sensitisation – Buehler method.
Species/Strain	Guinea pig/Hartley
PRELIMINARY STUDY	No preliminary study was conducted.
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 4
INDUCTION PHASE	Induction Concentration: topical: 50%
Signs of Irritation	Signs of irritation were seen in all of the test and control group animals during the induction phase.
CHALLENGE PHASE	
1 st challenge	topical: 50%
Remarks - Method	1-Chloro-2,4-dinitrobenzene was used as the positive control. A negative control was not used. The induction phase consisted of three applications per week for three weeks. The same concentration was used for both the induction and challenge phases of the test. The challenge concentration used was at a level where the test substance was irritating rather than being at the maximum non-irritating concentration. The reported results for each animal averaged the effects seen in the 24 and 48 hour observations.

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after: 1st challenge</i>
<i>Test Group</i>	50%	10/10
<i>Positive Control Group</i>	0.05%	4/4

Remarks - Results	<p>There were no deaths or substance-related signs of toxicity during the study. All of the animals in the test group showed signs of irritation at the challenge phase. This is expected to be due to the concentration of the test substance used being irritating as was shown during the induction phase where the same concentration was used. In the test group, 9 of the animals exhibited weaker average reactions to the challenge application than those produced during the induction phase. The remaining animal exhibited a slightly greater average oedema reaction to the challenge application (2.0) than that produced from the induction applications (1.8). This animal still had a lower average erythema value (2.0) after the challenge applications than produced after the induction applications (2.2). All four of the animals receiving positive control exhibited greater average erythema and oedema reactions after the challenge application than during the induction applications.</p> <p>As all but one of the test group animals exhibited weaker average reactions to the challenge application than those produced during the induction phase the 15% cut-off for evidence of positive responses to meet the classification criteria was not met.</p> <p>Normal body weight gains were recorded for all animals during the course of the study.</p>
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CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to analogue 1 under the conditions of the test.
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TEST FACILITY	Raltech (1981)
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B.7. Skin sensitisation – human volunteers

TEST SUBSTANCE	Analogue 1
METHOD	Modified Human Repeat Insult Patch Test
Study Design	Induction Procedure: subjects were occlusively patched with 50 µL of the test material nine times at approximately 48 to 72-hour intervals. An occlusive patch dosed with 100 µL of 1% Sodium Lauryl Sulphate (SLS) served as the positive control, and an un-dosed occlusive patch served as the negative control. Rest Period: 12 – 24 days Challenge Procedure: patches were applied to original and alternate (naive) sites. Subjects removed the patches approximately 48 hours after application (approximately two hours prior to grading), and sites were graded approximately 48 and 96 hours post application.
Study Group	52 (47 female, 5 male)
Vehicle	Water
Remarks - Method	The challenge phase was not conducted on the controls. Analogue 1 was tested as part of a larger study where 12 other chemicals were tested. The positive control used was sodium lauryl sulfate (SLS).
RESULTS	
Remarks - Results	Two subjects were removed from the study after showing redness at all patch sites except the negative control. The study authors stated that the effects seen could have possibly been related to the test substances. Analogue 1 was classified (Berger and Bowman, 1982) by the study authors as “probably mild in normal use” (evidence of slight potential for very mild cumulative irritation under the conditions of test). The positive control was classified by the study authors as “possibly mild in normal use” (evidence of moderate potential for mild cumulative irritation under the conditions of test). Under the exposure conditions of this test, analogue 1 did not induce delayed contact sensitisation (allergic contact dermatitis) in any subject completing the study.
CONCLUSION	A Modified Human Repeat Insult Patch Test was conducted using analogue 1 diluted to 1% under occlusive dressing. Analogue 1 was irritating and non-sensitising under the conditions of the test.
TEST FACILITY	Thomas J. Stephens & Associates (2008)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Inoculum	Activated sludge from urban sewage water treatment plant
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	CO ₂ analysis
Remarks - Method	No significant protocol deviations were reported. The test substance was tested in duplicate at 10 mg/L and 20 mg/L organic carbon at 22 ± 2°C. A reference substance (aniline, 20 mg C/L) was run in parallel.

RESULTS

<i>Test substance</i>		<i>Aniline</i>	
<i>Day</i>	<i>% Degradation*</i>	<i>Day</i>	<i>% Degradation</i>
4	23.0	4	19.0
8	59.5	8	64.4
15	74.2	15	80.2
28	79.9	28	89.5

*Mean of 10 mg/L and 20 mg/L organic carbon samples

Remarks - Results	No significant deviations from test guidelines were reported. The reference substance reached the pass level by day 14 and thus confirmed the suitability of the inoculum and test conditions. The test substance reached the pass level for biodegradation within the 10 day window at both concentrations tested.
CONCLUSION	The test substance, and by inference the notified chemical, is readily biodegradable
TEST FACILITY	INERIS (1993)

C.1.2. Biodegradability in seawater

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 306 Biodegradability in Seawater – closed bottle test
Inoculum	Microorganisms in aged seawater
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	WTW 320 oxygen meter
Remarks - Method	No significant protocol deviations were reported. The study was performed with the test substance in duplicate at a concentration of 3.0 mg/L (COD = 0.85 × 10 ⁶ mg O ₂ /L) at 20.0 ± 1.4°C. Seawater salinity was 34.6‰. A positive control and toxicity control were run in parallel with sodium benzoate (1.5 mg/L) as the reference substance.

RESULTS

<i>Test substance</i>		<i>Sodium Benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
0	0	0	0
7	28	7	66
14	58	14	66
21	88	21	68
28	92	28	72

Remarks - Results

All validity criteria for the test were satisfied and no significant deviations from test guidelines were reported.

The BOD of the mixture of test and reference substance was not equal to the sum of the BOD of the separate solutions of the two substances. This indicates that the test substance can be considered to be inhibitory to bacteria at the concentration used.

CONCLUSION

The test substance, and by inference the notified chemical, has the potential to biodegrade in the marine environment

TEST FACILITY

AnalyCen Ecotox AS (2003)

C.2. Ecotoxicological Investigations**C.2.1. Acute toxicity to fish**

TEST SUBSTANCE

PETROSTEP S-2 (product containing notified chemical; purity < 25%)

METHOD

Species

OECD TG 203 Fish, Acute Toxicity Test – Flow through

Exposure Period

Oncorhynchus mykiss (rainbow trout)

Auxiliary Solvent

96 hours

Water Hardness

None reported

Analytical Monitoring

144 mg CaCO₃/L

Remarks – Method

HPLC

All test solutions were adjusted to 100% active ingredient (a.i; notified chemical) during preparation, based on test substance purity. Based on a preliminary range finding test, fish were exposed to concentrations from 0.39 to 2.5 mg/L of active ingredient under flow through conditions (200 mL/min, 10 volume changes/day). A primary stock solution of test substance was prepared by mixing an amount of test substance in reverse osmosis water to give a nominal concentration of 50 mg a.i/L. The stock solution was mixed for approximately 5 min and appeared clear and yellow with a foam on the surface of the solution. Four secondary stock solutions were prepared by dilution of the primary stock.

The median lethal concentration (LC50) at 96 hours was calculated by probit analysis, the moving average method and binomial probability with non-linear interpolation. The NOEC was determined by visual inspection of the mortality and observation data.

RESULTS

<i>Concentration mg a.i./L</i>		<i>Number of Fish</i>	<i>Mortality</i>				
<i>Nominal</i>	<i>Actual</i>		<i>3 h</i>	<i>24 h</i>	<i>48 h</i>	<i>72 h</i>	<i>96 h</i>
Control	< LOQ	20	0	0	0	0	0
0.39	0.26	20	0	0	0	0	0
0.65	0.43	20	0	0	0	0	0
1.1	0.73	20	0	0	0	0	0
1.8	1.4	20	0	4	20	20	20

	3.0	2.5	20	0	20	20	20	20
a.i. = active ingredient; LOQ = 0.104 mg a.i./L								
LC50	1.0 mg a.i./L at 96 hours (based on measured test concentrations; 95% CI – 0.73 – 1.4 mg a.i./L)							
NOEC	0.73 mg a.i./L at 96 hours (based on measured test concentrations)							
Remarks – Results	All validity criteria for the test were satisfied and no significant deviations from test guidelines were reported. Test solutions in mixing chambers appeared clear and colourless with white foam on the surface of the solutions. Test solutions in test chambers appeared clear and colourless with no precipitation observed in any control or treatment solution. Signs of toxicity in the 1.4 mg a.i./L treatment group included lethargy and loss of equilibrium. All fish in the < 1.4 mg a.i./L treatment groups and the negative control appeared normal with no overt signs of toxicity.							
CONCLUSION	The notified chemical is very toxic to fish							
TEST FACILITY	Wildlife International Ltd (2010a)							

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	PETROSTEP S-2 (product containing notified chemical; purity < 25%)
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test - Flow through
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	140 mg CaCO ₃ /L
Analytical Monitoring	HPLC
Remarks - Method	All test solutions were adjusted to 100% active ingredient (a.i; notified chemical) during preparation, based on test substance purity. Based on a preliminary range finding test daphnia were exposed to concentrations from 1.1 to 2.5 mg/L of active ingredient under flow through conditions (2.0 mL/min, 5 volume changes/day). A primary stock solution of test substance was prepared by mixing an amount of test substance in UV sterilised well water to give a nominal concentration of 100 mg a.i./L with pH adjusted to 7.1. Five secondary stock solutions were prepared by dilution of the primary stock in UV sterilised well water. The secondary stock solutions appeared clear and yellow with a foam on the surface of the solution. The EC50 at 48 hours was calculated by probit analysis, the moving average method and binomial probability with non-linear interpolation. The NOEC was determined by visual inspection of the mortality and observation data.

RESULTS

Concentration mg a.i./L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	< LOQ	20	0	0
1.1	0.76	20	0	0
1.9	1.2	20	0	0
3.2	2.3	20	0	5
5.3	3.9	20	0	6
8.8	6.8	20	4	19

a.i. = active ingredient; LOQ = 0.104 mg a.i./L

EC50	3.9 mg a.i./L at 48 hours
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NOEC (based on measured test concentrations; 95% CI 3.2 – 4.7 mg a.i./L)
 1.2 mg a.i./L at 48 hours (based on measured test concentrations)
 Remarks - Results All validity criteria for the test were satisfied and no significant deviations from test guidelines were reported. Test solutions in mixing chambers appeared clear and colourless with white foam on the surface of the solutions. Test solutions in test chambers appeared clear and colourless with no foam on the surface and no precipitation observed in any control or treatment solution.

CONCLUSION The notified chemical is toxic to aquatic invertebrates

TEST FACILITY Wildlife International Ltd (2010b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE PETROSTEP S-2 (product containing notified chemical; purity < 25%)

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species *Pseudokirchneriella subcapitata*

Exposure Period 96 hours

Concentration Range Nominal: 3.1, 6.3, 13, 25, 50, 100 mg a.i./L

Actual: 0.39, 0.54, 0.82, 15, 34, 77 mg a.i./L

Auxiliary Solvent None reported

Water Hardness 0.15 mmol/L (Ca²⁺ and Mg²⁺)

Analytical Monitoring HPLC

Remarks - Method All test solutions were adjusted to 100% active ingredient (a.i.; notified chemical) during preparation, based on test substance purity. Based on a preliminary range finding test algae cells were exposed to the notified chemical with nominal concentrations from 3.1 to 100 mg a.i./L. A primary stock solution of test substance was prepared by mixing an amount of test substance in algal media to give a nominal concentration of 100 mg a.i./L. The stock solution inverted to mix and after mixing appeared clear and colourless with a foam on surface of the solution. Five secondary stock solutions were prepared by dilution of the primary stock.

The E_bC50 at 72 and 96 hours and the E_rC50 at 96 hours were calculated using non-linear regression with treatment response and geometric mean measured test concentrations. The E_rC50 at 72 hours was estimated by visual observation of the data. The NOECs at 72 and 96 hours were determined from comparison of the treatment groups to negative controls using Dunnett's test (p=0.05).

RESULTS

Biomass		Growth	
NOEC	E _b C50	NOEC	E _r C50
0.54 mg a.i./L at 72 h	4.2 mg a.i./L at 72 h (95% CI 2.3 – 7.5 mg a.i./L)	0.54 mg a.i./L at 72 h	> 77 mg a.i./L at 72 h (95% CI – not calculable)
0.39 mg a.i./L at 96 h	5.2 mg a.i./L at 96 h (95% CI 3.3 – 8.0 mg a.i./L)	0.54 mg a.i./L at 96 h	71 mg a.i./L at 96 h (95% CI 60 – 84 mg a.i./L)

a.i. = active ingredient

Remarks - Results All validity criteria for the test were satisfied and no significant deviations from test guidelines were reported. There were no noticeable changes in cell morphology in algal cells except in the 34 and 77 mg a.i./L test concentrations, where the cells appeared enlarged compared to control replicates.

The notified chemical is considered *potentially* harmful to algae since the estimated 72 hr E_rC₅₀ was found to be greater than the highest test substance concentration (77 mg/L) and therefore it was not known if the E_rC₅₀ was above the 100 mg/L threshold for the harmful classification.

CONCLUSION

The notified chemical is potentially harmful to algae

TEST FACILITY

Wildlife International Ltd (2010c)

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