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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Gyptron T-454 and Gyptron KT-252

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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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NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Champion Technologies Pty Ltd (ABN: 22 008 079 614)
Suite 1, 5 Brodie-Hall Drive
Technology Park
Bentley, WA 6102

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, purity and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting point, Boiling point, Vapour pressure, Water solubility, Hydrolysis, Partition coefficient, Adsorption constant, Dissociation constant, Flash point, Flammability limits, 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, Chromosome Damage, Acute Toxicity to Fish, Acute Immobilisation/Reproduction Daphnia sp., Algal growth inhibition, Bioaccumulation and Biodegradation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PS-2117 (imported product containing < 30% notified chemical)
Gyptron KT-252 and Gyptron T-454 (reformulated products containing < 12% notified chemical)

MOLECULAR WEIGHT
< 700 Da

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Dark amber liquid (imported aqueous solution, < 30% notified chemical)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	76-167°C	Calculated (Episuite v4.0)
Boiling Point	480°C	Calculated (Episuite v4.0)
Density	1280-1380 kg/m^3 at 20°C (imported aqueous solution, < 30% notified chemical)	MSDS
Vapour Pressure	2.74×10^{-12} kPa at 25°C	Calculated (Episuite v4.0). An acceptable analogue chemical (analogue 2) is reported to have a vapour pressure of 1.67×10^{-13} – 1.33×10^{-8} kPa. The notified chemical is expected to be very slightly volatile.
Water Solubility	Not determined	A solubility of 1000 g/L at 25˚C has been calculated using EPIsuite 4.0. The acceptable analogue (analogue 2) which is slightly more hydrophilic than the notified chemical is reported to have a water solubility of 500 g/L at 25°C. The notified chemical is expected to be readily soluble in water.
Hydrolysis as a Function of pH	Not determined	Hydrolysis half-life rates for acceptable analogues were found to be 50 – 200 days at 15 – 25˚C (pH not stated).
Partition Coefficient (n-octanol/water)	Not determined	The partition coefficient is expected to be low. A log K_{OW} = -4.29 was calculated using EPIsuite 4.0. The acceptable analogue (analogue 2) is reported to have a log K_{OW} of -3.40. The notified chemical is expected to partition equally in water/oil mixture at 60˚C based on the tested data for an acceptable analogue.
Adsorption/Desorption	Not determined	Strong adsorption of the notified chemical from water to soil sediment is expected due to the presence of potential anionic and cationic functional groups and the strong adsorption displayed by the notified chemical.
Dissociation Constant	Not determined	The notified chemical is expected to be ionised in the aquatic environment due to the presence of dissociable functional groups.
Particle Size	Not determined	Imported as an aqueous solution
Flash Point	Not determined	Imported as an aqueous solution
Flammability	Not determined	Imported as an aqueous solution
Autoignition Temperature	Not determined	Imported as an aqueous solution
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

DISCUSSION OF PROPERTIES

Reactivity

Stable under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a < 30% aqueous solution.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 15	< 15	< 15	< 15	< 15

PORT OF ENTRY
Freemantle WA

TRANSPORTATION AND PACKAGING
The notified chemical will be introduced in 200 L drums and 1,250 kg IBCs and after reformulation will be in 1000 L stainless steel or polypropylene containers or 200 L drums. The products containing the notified chemical will be transported throughout Australia by road and to off shore oil platforms by boat.

USE
Scale inhibitor used in oil and gas production.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. It will be imported as a < 30% aqueous solution in 200 L drums or 1,250 kg IBCs and will be reformulated in Australia to produce the finished scale inhibitor product containing < 12% notified chemical.

Reformulation
During reformulation, the notified chemical (< 30% aqueous solution) will be transferred from the imported containers into a blend tank using automated pumping/dosing equipment. The containers will be connected to the blend vessels by pipes/hoses using quick connect fittings. During reformulation, water and other chemicals are added and the resultant concentration of the notified chemical in the finished scale inhibitor product will be < 12%. The blend vessels will not be sealed, but will be fitted with a fume extraction device. Following blending, a filling spear is inserted into the blend tank through the top man-hole cover for drumming off into 1000 L bulk containers (either stainless steel or polypropylene) or 200 L drums.

End-use
After filling, the bulk containers or drums will be transported to oil wells on land or offshore. In either case, the containers or drums of the notified chemical formulation are hooked up to a chemical injection pump facility via a flexible connection hose connected to the bottom outlet camlocked valve of the tank which has ball valve isolation. Continuous injection by small dosage chemical pumps is used to maintain levels of 3.6 ppm (of the notified chemical) through stainless steel tubing directly into the pipeline flow downhole.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	2-3	2-3	5-10
Shipping to the platform	2-3	2-3	5-10
Reformulation workers	3	2	12
End use	5-6	1	300

EXPOSURE DETAILS
Storage and transportation
It is anticipated that transport and storage workers would only be exposed to the material in the event of an

accident

Reformulation
Dermal and ocular exposure to the notified chemical (< 30%) is possible when plant operators are connecting and disconnecting pump lines to storage tanks or blending vessels. The opportunity also exists for dermal exposure when cleaning up spills or leaks and during maintenance of the blend vessel. Workers involved in the blending process are expected to wear impermeable gloves, goggles and protective clothing to minimise exposure.

Inhalation exposure is expected to be negligible given the very low calculated vapour pressure of the notified chemical (2.74×10^{-12} kPa at 25°C). In addition, potential for inhalation exposure will be minimised by the fume extraction equipment that will be used and the respiratory protection that is expected to be available to workers when ventilation is not adequate.

End use
There is potential for dermal and ocular exposure to the notified chemical (< 12%) during the connection and disconnection of the chemical injection pump facility to the tank containing the reformulated scale inhibitor. Exposure is expected to be minimised by the use of gloves, goggles and protective clothing.

6.1.2. Public exposure
The products containing the notified chemical will not be sold to the public. Therefore the public will only be exposed to the notified chemical in the event of accidental spill during transportation.

6.2. Human health effects assessment

The results from toxicological investigations conducted on a suitable analogous chemical are summarised in the table below. Details of the analogue chemical and references are included in the exempt information section of the report.

Endpoint	*Test Substance*	*Result and Assessment Conclusion*	*Source*
Rat, acute oral toxicity	Analogue 1 (25% aqueous solution)	LD50 = 2910 mg/kg bw; low toxicity	IUCLID (2000)
	Analogue 1 (50%)	LD50 > 5000 mg/kg bw; low toxicity	IUCLID (2000)
Mouse, acute oral toxicity	Analogue 1 (50%)	LD50 = 2790 mg/kg bw; low toxicity	IUCLID (2000)
Rabbit, acute dermal toxicity	Analogue 1 (25% aqueous solution)	LD50 > 6310 mg/kg bw; low toxicity	IUCLID (2000)
Rabbit, skin irritation	Analogue 1 (50% aqueous solution)	slightly irritating	IUCLID (2000)
Rabbit, eye irritation	Analogue 1 (powder)	irritating	IUCLID (2000)
	Analogue 1 (powder)	irritating	IUCLID (2000)
	Analogue 1 (50% aqueous solution)	irritating	IUCLID (2000)
Guinea pig, skin sensitisation – adjuvant test.	Analogue 1 (concentration unspecified)	no evidence of sensitisation	IUCLID (2000)
Rat, repeat dose oral toxicity – 24 months.	Analogue 1	NOEL = 150 mg/kg bw/day	IUCLID (2000)
Rat, repeat dose oral toxicity – 34 days.	Analogue 1	NOAEL > 1000 mg/kg bw/day	IUCLID (2000)
Mutagenicity – bacterial reverse mutation	Analogue 1	non mutagenic	IUCLID (2000)
Genotoxicity – in vitro Mammalian Mouse micronucleus Test	Analogue 1	non genotoxic (without metabolic activation) genotoxic (with metabolic activation low pH) non genotoxic (with metabolic activation pH neutral)	IUCLID (2000)

Developmental and reproductive effects	Analogue 1	NOAEL Parental > 3000 ppm NOAEL F1 offspring > 3000 ppm NOAEL F2 offspring > 3000 ppm	IUCLID (2000)
	Analogue 1	NOAEL Parental > 3000 mg/kg bw/day NOAEL F1 offspring > 3000 mg/kg bw/day NOAEL F2 offspring > 3000 mg/kg bw/day	IUCLID (2000)
Carcinogenicity	Analogue 1	non carcinogenic	IUCLID (2000)

Toxicokinetics, metabolism and distribution.
Due to the low molecular weight (< 700 Da) of the notified chemical dermal absorption may occur, however based on the toxicokinetic studies on analogue 1 transfer through the skin or gastrointestinal tract is expected to be slow.

Toxicokinetic studies on analogue 1 showed absorption across the gastrointestinal tract of 1.85-2.01% in one study and 2.15% in another (IUCLID 2000). Dermal absorption was found to be between 0.6 and 0.94% for analogue 1 (IUCLID 2000).

Acute toxicity.
Analogue 1 was shown to have low oral toxicity in a range of tests conducted in rats and mice where the lowest LD50 value was 2790 mg/kg bw. Analogue 1 was also shown to have low acute dermal toxicity based on tests in rats and rabbits. Based on the read across data the notified chemical is expected to be of low toxicity via the oral and dermal routes. There is not data on the inhalation toxicity of the notified chemical or suitable analogues.

Irritation and Sensitisation.
A 50% aqueous solution of analogue 1 was found to be slightly irritating to the skin in a study conducted to OECD test guideline 404. A maximum score of 1 after 1 hour was reported for erythema and eschar formation. No oedema formation was reported in any animal.

Analogue 1 was found to be irritating to the eyes based on three studies in rabbits. However, based on the limited data it is not possible to determine if the analogue can be classified as an eye irritant under the Approved Criteria (NOHSC, 2004).

There was no evidence of sensitisation noted in a guinea pig maximisation test with analogue 1.

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

Repeated Dose Toxicity (sub acute, sub chronic, chronic).
A 24 month oral study in rats with analogue 1 gave a NOEL of 150 mg/kg bw/day. At the only higher dose tested, 500 mg/kg bw/day, reduced body weights and changes in the liver, spleen and kidney weights or weight ratios were observed.

In a 34 day study in Long-Evans rats where analogue 1 was administrated in the food at doses up to 1000 mg/kg bw/day no adverse treatment related effects were noted. No clinical chemistry or haematology parameters were measured in this study.

Based on the above studies on analogue 1 the notified chemical is not expected to be hazardous through repeated oral exposure up to 150 mg/kg bw/day.

Mutagenicity.
Analogue 1 was negative in an Ames test and an *in vitro* micronucleus test. Genotoxicity was seen in the micronucleus test with metabolic activation where the pH was low, as low pH can trigger genotoxic effects in L5178Y mouse lymphoma cells, but once the pH had been neutralised the result was negative. The notified chemical is not expected to be mutagenic or genotoxic based on the results seen in the tests with analogue 1.

Carcinogenicity.
A 24 month study with analogue 1 in Long-Evans rats showed a similar incidence of neoplastic and non neoplastic lesions in all groups including the control. The notified chemical is not expected to be clastogenic based on the test conducted using analogue 1.

Toxicity for reproduction.
In an oral study over three generations in Long-Evans rats at concentrations up to 3000 ppm no adverse treatment related effects were observed.

Another three generation study with analogue 1 administered orally to rats showed no adverse treatment related effects in any of the test groups with the highest concentration tested being 3000 mg/kg bw/day.

The notified chemical is not expected to cause teratogenic or developmental effects based on the results of the tests conducted using analogue 1.

Health hazard classification
Based on the available data on the analogue chemical, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Eye irritation scores are not available for the studies conducted with the analogue chemical. Therefore the notified chemical can not be classified as an eye irritant using the Approved Criteria.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Based on studies conducted on an analogue the notified chemical is expected to be slightly irritating to the skin and irritating to the eyes; however it is not expected to be acutely toxic via the oral or dermal routes. The notified chemical is not expected to be mutagenic, genotoxic, clastogenic, a skin sensitiser, teratogenic or a developmental toxicant.

Occupational dermal and ocular exposure to the notified chemical may occur at concentrations up to 30% during reformulation or at concentrations up to 12% during end use of the scale inhibitor product.

Local effects
There is potential for the risk of skin and eye irritation particularly when handling the notified chemical as introduced at up to 30%. However, given the exposure is expected to be minimised due to the use of personal protective equipment and the engineering controls in place, the risk of irritation is not considered to be unacceptable.

Systemic effects
There is no systemic toxicity data available on the notified chemical. However, the NOEL for a suitable analogue (analogue 1) was found to be of 150 mg/kg bw/day.

Dermal exposure to the notified chemical at up to 30% during reformulation activities can be estimated using the EASE (1997) model assuming reasonable worst case defaults and based on non-dispersive use with intermittent direct handling. This gives an estimated daily exposure of 0.37 mg/kg bw/day for a 70 kg worker, assuming a 10% dermal absorption factor (based on toxicokinetics for analogue 1) and an average surface area of 860 cm^2 for the hands (RVIM, 2006). Using the 150 mg/kg bw/day NOEL from analogue 1 as an estimate for the notified chemical the margin of exposure (MOE) for the proposed use is 405. A MOE greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects is acceptable for workers involved in reformulation of products containing the notified chemical. For end-users the risk of repeated exposure to the notified chemical is reduced due to the lower concentrations (< 12%).

The risk of repeated exposure is not considered unacceptable, considering the estimated MOE and the expected toxicological profile of the notified chemical.

6.3.2. Public health

The notified polymer or products containing it will not be sold to the public. Therefore the risk to the public from the notified polymer is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of an aqueous solution product for use as a scale inhibitor in oil and gas industry in Australia. Further blending of the imported product is required to produce the final scale inhibitor product. The reformulation of the imported product containing the notified chemical will be done in a bunded area. The mixing vessel and import containers will be cleaned with water and the rinsings will be charged to the next batch of blended product. Any liquid spills will flow to a collection pit and will be collected by a waste disposal company. It is estimated that a maximum of 1% of product may be released from reformulation processes as a result of accidental spills and leaks, which may be either released to a sewer or be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

When scale inhibitors are used in wells, the production of oil and gas is suspended or reduced during the treatment. Scale inhibitors are usually used in older wells as the oil reserves decrease and water increases. Usually the technique downhole squeezing is used whereby inhibitor chemicals in solution are injected into the well. Adsorption squeezes involve five steps:

1. Preflushing with a small volume of an emulsifier and surfactant solution.
2. Injecting a scale inhibitor solution (5 to 10 vol% concentration in filtered water).
3. Injecting a water overflush to move the inhibitor some distance from the wellbore.
4. Shutting in for 24 hours to allow complete adsorption.
5. Resuming production.

The notified chemical is expected to be injected by batch treatment at 3.6 ppm. Typically for squeezes using these types of chemicals a third is effective which can last up to 18 months. Therefore, 2/3 could be flushed out initially in the overflush. Over the next several months the notified chemical will be slowly desorbed from the rock matrix and released with the oil and produced water with ~50% in each phase.

For off shore application, some of the wells pipe the oil and produced water back on shore for treatment and disposal. However, the majority of wells discharge the treated produced formation water directly to the ocean (Cobby, 2002). Therefore, up to 50% of the notified chemical will be discharged to the ocean with the produced water and the remainder will share the fate of the oil.

For on shore applications, the notifier indicates that the water phase containing the notified chemical will be separated from the crude oil and fed into biodegradation ponds followed by release to STPs for further treatment. The notified chemical adsorbs strongly on to sediments and suspended particles, which further reduces the exposure of the notified chemical to the aquatic compartment to an extent of > 85%.

Environmental release of the notified chemical in oil pipelines is expected to be minimal. The notified chemical within the oil phase (from both off shore and on shore applications) will either share the same end-use fate as the oil or be removed during oil refining, in which case it will remain in the distillation residues/tar fraction.

RELEASE OF CHEMICAL FROM DISPOSAL

The residues in "empty" drums are estimated to be up to 2% of the amount that will be used. These drums will be sent to reconditioners where the residues will be incinerated producing oxides of carbon, nitrogen, phosphorus and hydrogen. Releases during normal product transfer operations (discounting accidental spillage) have been estimated to be 1% and will be collected and disposed of to landfill.

7.1.2 Environmental fate

Off shore fate

For the produced water disposed of off shore, the worst case scenario is that ~50% of the total import of the notified chemical will be discharged to the ocean over a short period of time as a result of overflushing. However, more typically, it's expected a lower percentage of notified chemical will be released from overflushing followed by a continuous, very low concentration release over the next several months as it desorbs from the rock matrix in the well. In the marine environment the notified chemical will be chelated with metal ions and/or will adsorb to sediment and any suspended particulate matter. It is expected to slowly degrade by biotic and abiotic processes to water & oxides of carbon, phosphorus and nitrogen. Based on its high water solubility and the presence of potential anionic and cationic functional groups, the notified chemical is not considered to have potential for bioaccumulation in aquatic organisms.

On shore fate

For the produced water disposed of on shore, it will be fed into biodegradation ponds followed by release to STPs. More than 85% of the notified chemical in STP influence will adsorb to the sludge. And therefore, for the worst case, ~43% (50% × 85%) of the notified chemical in the STP influence will share the fate of the sludge being disposed to landfill or used for soil remediation. About 7% of the total import amount of notified chemical is expected to be released to the water environment in a worst case scenario.

It is indicated that the notified chemical is not expected to readily biodegrade in waste water treatment plants but will adsorb strongly to the sludge. It is indicated the notified chemical and analogous chemicals bind strongly to soil sediment soon after entering a water/sediment system, and the analogue chemical is subject to quicker biodegradation (DT50 = 74 days) than in the water column. The notified chemical disposed of to landfill will be bound to soil due to its expected strong adsorption to soils, and undergo degradation processes via abiotic or biotic pathways forming water and oxides of carbon, phosphorus and nitrogen.

A maximum of 50% of the total import amount of the notified chemical is expected to be sent to oil refineries in the oil phase. It may either be removed during oil refining and remain in the distillation residues/tar fraction that will be most likely used as road base, or share the fate of the oil product. The oil will mainly be disposed of to landfill (e.g. car engine oils) or when used as burner fuels (e.g. recycles engine oils), thermally decomposed to water and oxides of carbon, nitrogen and phosphorus.

7.1.3 Predicted Environmental Concentration (PEC)

Off shore release

Assuming for the worst case scenario that all the produced water will be directly discharged into the ocean, and the concentration of the notified chemical in the pumped out oil/water mixture remains undiluted, the expected maximum concentration of notified chemical in the produced water is 3.6 mg/L. The PEC of the notified chemical in sea water is expected to be 3.6 µg/L for the worst case scenario assumption of 1000 fold dilution by the sea water after the discharge of the water based on the CHARM model (Payne & Thatcher, undated).

However, a significant amount (~1/3) of the notified chemical will be typically adsorbed to the rock matrix and will not be flushed out initially but will be desorbed and released in the oil phase and the produced water at much lower concentrations over several months. Sea water contains a very high concentration of metal ions that are expected to chelate with the notified chemical. Therefore, the vast majority of the notified chemical in the water compartment is expected to bind with metal ions and/or adsorb to the sediment over time.

On shore release

The PEC of the notified chemical for the aquatic compartment has been calculated assuming that the total import volume of the notified chemical is for land wells only, there is an immediate release of 50% of the used chemical to the sewer after overflushing and there is 85% removal of the notified chemical from waste water to sludge in STPs. This is considered to be the worst case scenario since any use of the notified chemical for off shore wells, the binding of the notified chemical (about 1/3 of the applied amount) to the rock matrix in the wells, and any removal of the notified chemical in the biodegradation ponds have not been considered.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	15,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	7500	kg/year

Days per year where release occurs	260	days/year
Daily chemical release:	28.85	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	85%	**Mitigation**
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.02	µg/L
PEC - Ocean:	0.10	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 57.935 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.386 mg/kg in applied soil. This assumes that degradation of the notified chemical does not occur in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 1.93 mg/kg and 3.86 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 1.022 µg/L may potentially result in a soil concentration of approximately 6.816 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 34.08 µg/kg and 68.16 µg/kg, respectively.

7.2. Environmental effects assessment

No reports on ecotoxicity studies were available for the notified chemical. It is expected that the notified chemical will be toxic to algae due to its polyanionic functional groups which chelate with nutrient elements needed for algal growth. The ecotoxicological properties of an acceptable analogue (analogue 2) of the notified chemical, demonstrate the toxicity of these types of chemicals to fresh water algae (reference in exempt section). Fresh water species' endpoints are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h EC50 > 180 mg/L	Not harmful to fish
Daphnia Toxicity	48 h EC50 = 242 mg/L	Not harmful to Daphnids
Algal Toxicity	96 h EC50 = 0.45 mg/L NOEC = 0.63 mg/L	Very toxic to alga
Sediment invertebrate dweller (*Chironomus tentans)*	48 h NOEC = 7589 mg/kg soil	Not harmful to sediment dwellers
Inhibition of Bacterial Respiration	IC50 > 2500 mg/L	Not harmful to sewage bacteria

The endpoints indicate that alga is the most sensitive freshwater aquatic species to the notified chemical based on its similarity to the analogue chemical.

Marine ecotoxicity data for fish, aquatic and sediment invertebrates and algae for similar types of chemicals which have the same toxicity mode of action also indicate that the most sensitive species is algae, *Skeletonema costatum*. The lowest endpoint found is 12 mg/L for analogue 3. This is higher than the lowest endpoint for freshwater algae, *Selenastrum capricornutum* (EC50 = 0.45 mg/L) for analogue 2. It is expected that the notified chemical will be more toxic in freshwater than in seawater since seawater contains an over-abundance of metal ions.

Under the Globally Harmonised System of Classification and Labeling of Chemicals (United Nations, 2009) the notified chemical, based on its similarity to the analogue chemical, is not harmful to fish or aquatic invertebrates, but is very toxic to algae. The notified chemical, based on its similarity to the analogue chemical, was predicted to be not readily biodegradable, and based on its high acute toxicity to algae it was classified as very toxic to aquatic life with long lasting effects.

7.2.1 Predicted No-Effect Concentration

Sediment compartment
The vast majority of notified chemical in STPs is expected to adsorb strongly to sludge and will be removed for disposal to landfills or as soil remediation. However, the PNEC for sediment was not calculated since the endpoint for the sediment dweller is too high for any toxicity concerns from the notified chemical.

Aquatic compartment
The most sensitive aquatic species to the notified chemical, based on its similarity to the analogue chemical, in freshwater & seawater is algae. In freshwater, the analogous chemical had the lowest endpoint of 0.45 mg/L for alga (*Selenastrum capricornutum*). In seawater, a similar chemical had an endpoint of 12 mg/L for *Skeletonema costatum*, marine alga. The lowest endpoint, 0.45 mg/L, will be used for determination of both the freshwater and seawater PNECs; a conservative consideration.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
EC50 (Alga)	0.45 mg/L
Assessment Factor	100
PNEC:	4.5 µg/L

The PNEC has been calculated based on an EC50 of 0.45 mg/L for the most sensitive freshwater and seawater species, alga. An assessment factor of 100 has been used since the endpoint is from an analogue chemical, there is a wide variety of species' endpoints available, and the lowest endpoint in freshwater or seawater is used.

7.3. Environmental risk assessment

Off shore oil or gas/oil application
The Risk Quotient (Q = PEC/PNEC) for the worst case scenario around the discharge point of the produced water is calculated to be 0.8 (3.6/4.5 = 0.8) for off shore application, indicating a relatively narrow safety margin as a result of the expected high toxicity for this chemical to algae. However, the risk is mitigated by the high content of metal ions in sea water which will chelate with the notified chemical and an expected lower concentration of the notified chemical due to its adsorption to the rock matrix (about 1/3) in the well and dilution in the ocean water by currents and diffusion.

On shore oil or oil/gas application

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	1.02	4.5	**0.227**
Q - Ocean	0.10	4.5	**0.023**

The Risk Quotients (Q = PEC/PNEC) have been calculated to be < 1 for the aquatic compartment, indicating no unacceptable risk potential to the aquatic lives from the use of the notified chemical used in land wells. The risk will be lowered since smaller concentrations of notified chemical are expected due to a significant amount of notified chemical will be initially adsorbed to the rock matrix in the well, all of the total import volume of notified chemical is used in land wells and/or off shore wells which pipe the produced water and oil on shore and biodegradation ponds and biodegradation of the notified chemical in the biodegradation ponds will be occurring.

Gas only well application

The notified chemical may be also applied to gas wells. However, this fraction is expected to be very minor. For the worst case scenario assuming 100% of the notified chemical is released to the produced water, the Q values are expected to be double the above worst case scenario values. Since the proportion of notified chemical being used for gas wells is expected to be low and due to the mitigation factors listed above for off shore and on shore oil or oil/gas wells (e.g. adsorption to the rock matrix in wells, biodegradation in ponds), the notified chemical is expected not to pose an unacceptable risk.

The calculated results and mitigation considerations for both off shore and on shore oil and gas applications indicate that the notified chemical is not expected to pose an unacceptable risk to the aquatic environment based on the reported use pattern and the maximum annual importation volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Eye irritation scores are not available for the studies conducted with the analogue chemical. Therefore the notified chemical can not be classified as an eye irritant using the Approved Criteria.

The classification of the 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***
Aquatic environment	Acute Category 1	Very toxic to aquatic life
Aquatic environment	Chronic Category 1	Very toxic to aquatic life with long lasting effects

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern and the total import volume, the notified chemical is not expected to pose a risk to the environment.

Recommendations

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 skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - 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.

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 scale inhibitor used at < 12% in oil and gas production, or is likely to change significantly;
- the amount of chemical being introduced has increased from 15 tonnes, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of 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.

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