

File No: STD/1370

August 2010

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

FULL PUBLIC REPORT

Chemical in P-332

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

TABLE OF CONTENTS

<u>FULL PUBLIC REPORT</u>	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. COMPOSITION	3
4. PHYSICAL AND CHEMICAL PROPERTIES.....	3
5. INTRODUCTION AND USE INFORMATION.....	5
6. HUMAN HEALTH IMPLICATIONS.....	6
7. ENVIRONMENTAL IMPLICATIONS	10
8. CONCLUSIONS AND REGULATORY OBLIGATIONS.....	12
<u>BIBLIOGRAPHY</u>	14

FULL PUBLIC REPORT**Chemical in P-332****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, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all the data required under the schedule of data requirements.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

P-332 (product containing the notified chemical at up to 20% concentration)
Cortron R2553

MOLECULAR WEIGHT

Mn >1000 Da.

ANALYTICAL DATA

Reference IR spectra was 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

No data on the physical and chemical properties of the notified chemical was provided. The figures below are for analogue chemicals or estimates unless otherwise specified.

APPEARANCE AT 20°C AND 101.3 kPa: Brown liquid (notified chemical)

Property	Value	Data Source/Justification
Freezing Point	-4 to -10°C	Measured (Analogues 1 and 4)
	173°C	Calculated (US EPA, 2009)
Boiling Point	Not determined	Decomposed before boiling (Analogues 1 and 4)
	429 °C	Calculated (US EPA, 2009)
Density	947 kg/m ³ at 16°C	Measured (Product containing the notified chemical at < 20%)
Vapour Pressure	Not determined	Expected to be low given the notified chemical is a salt.
Water Solubility	Not determined	The notifier indicates the notified chemical is highly hydrophobic (even though it is a salt) and will not partition to the water fraction. A solubility of 1.54×10^{-4} g/L at 20°C has been estimated (EPI Suite) for the neutral form of Analogue 5, and 3.7×10^{-4} g/L measured at 20°C using OECD TG 105 for the neutral form of the lower molecular weight Analogue 1. Therefore, it appears the large hydrophobic portions will outweigh the charges on the two moieties of the notified chemical and the water solubility is low or at least the rate of dissolving in water is slow.
Hydrolysis as a Function of pH	Not determined	Due to a lack of hydrolysable functionality, the notified chemical is not expected to hydrolyse in the environmental pH range (4-9).
Partition Coefficient (n-octanol/water)	Not determined	The partition coefficient of the neutral form of the anionic moiety (Analogue 4) of the notified chemical, at pH 2, has been measured as $P_{OW} = 2.2 - 8.9$ ($\log_{10} P_{OW} = 0.342 - 0.949$). This is surprisingly low, particularly given its neutral form. By contrast, the estimated (EPI Suite) value for Analogue 5 (the cationic moiety of the notified chemical) is $\log_{10} P_{OW} = 7.2$ (noting this value is also probably for the neutral form). However, based on the expected hydrophobicity of the notified chemical, it is expected to largely partition to the n-octanol phase.
Adsorption/Desorption	Not determined	Varying estimates (EPI Suite) have been made for Analogue 4, but the model warns that they may be sensitive to pH. Similar estimates for presumably the neutral form of Analogue 5 are $K_{OC} = 5.1$ to 6.2. However, based on the expected hydrophobicity of the notified chemical, it is expected to adsorb to organic carbon.

Dissociation Constant	Not determined	Varying estimates (EPI Suite) have been made on proposed analogues (Analogue 4 pK_a = 4.74 – 4.75; Analogue 2 pK_a = 7.4). However due to the complexity of the notified chemical, the dissociation constants are difficult to predict without an actual test. Further, the extent of the various charged and neutral species forming throughout the environmental pH range of 4-9 is unclear.
Flash Point	71°C	Measured (Product containing the notified chemical at up to 20%)
Flammability	Not expected to be flammable	Estimated based on chemical structure
Autoignition Temperature	Not expected to readily autoignite	Estimated based on chemical structure
Explosive Properties	Not expected to be explosive	Estimated based on chemical structure

DISCUSSION OF PROPERTIES

Reactivity

The notified chemical is expected to be stable under normal environmental conditions.

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 does 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 be imported by sea as a component of a formulation at up to 20% concentration.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	<7	<7	<7	<7	<7

PORT OF ENTRY

Sydney, Melbourne

IDENTITY OF RECIPIENTS

Champion Technologies Pty Ltd

TRANSPORTATION AND PACKAGING

The notified chemical will be imported in a formulation at up to 20% in 200 L polydrums or 1250 intermediate bulk containers (IBCs). It will be transported by road from the wharf to the notifier's site for reformulation.

USE

The notified chemical will be used as a corrosion inhibitor in oil and gas pipelines at less than 10% concentration.

OPERATION DESCRIPTION

The notified chemical will be imported in a formulation at up to 20% concentration.

Reformulation

Drums or IBCs containing a formulation with the notified chemical at up to 20% will be placed onto scales and a hose and pump will be attached to transfer a specified amount into a mixing vessel. The notified chemical in the mixing vessel will be blended with water and other chemicals to produce a formulated corrosion inhibitor product containing the notified chemical at less than 10%. The blending will take place without the use of heat in a closed vessel in an area fitted with local and general ventilation.

At the end of the blending process, a sample of the product will be manually taken from the mixing vessel for quality control testing. Once formulated, the product containing the notified chemical will be transferred via pipeline into bulk holding tanks.

The mixing vessel and fill lines will be cleaned after the formulation of each batch by flushing the system.

End-use

The formulated product containing the notified chemical at less than 10% will be injected into oil and gas pipelines. The product will be injected using an automated process between two pigs (used to inspect the inside of the pipeline) using a skid mounted injection system equipped with a positive displacement pump and a 1000 L feedstock tank. Once injected in between the pigs, it will be driven through the pipeline by the pressure of the hydrocarbon liquid to a receiving pump station. The pipeline will be pigged annually with corrosion inhibitor product at the rate of approximately 3 L per inch pipe diameter, per mile of pipeline. An average volume of 200 L product (~15 L of notified chemical) will be used per pigging operation. The intention will be to provide a coating, approximately 3 mm thick on the inside pipe surface to prevent internal corrosion and failure of the pipeline.

The product containing the notified chemical at less than 10% will be distributed throughout the length of the pipeline during this process. Product remaining in the hydrocarbon fluid will enter the refining process. Occasionally, a drain connection will be installed at the pig receiver, to take remaining product through a closed pipe system to a liquids hydrocarbon collection tank (15,000 L capacity) at the receiving pump station for disposal.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	2-3	3	5-10
Reformulation	3	2	12
End-use injection into pipelines	5-6	3	1-2

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.

Workers may experience dermal and ocular exposure to spills, drips and splashes of the notified chemical at up to 20% during connecting and disconnecting hoses to the import containers, transfer of the formulated product into containers, testing for quality control and cleaning equipment. However, the system is expected to be closed and automated and exposure after addition to the mixing vessel, during the blending process itself is not anticipated. Exposure is also expected to be minimised by the use of personal protective equipment (PPE) such as chemical resistant gloves, protective clothing and safety goggles. Inhalation exposure is not anticipated during reformulation as exhaust ventilation is expected to be in use.

Dermal and ocular exposure may occur during filling of the injection system with the formulated corrosion inhibitor product containing the notified chemical at less than 10% as well as cleaning and maintenance.

Dermal and ocular exposure during injection into the pipelines is expected to be minimal due to the use of an automated injection system. The use of PPE such as safety glasses, gloves and coveralls would be expected to further minimise dermal and ocular exposure for these workers.

Inhalation exposure to airborne aerosols of the notified chemical at less than 10% may be possible while the injection system is pumping the corrosion inhibitor formulation into the pipelines. However, the system will be operated outdoors and any exposure to aerosols is not expected to be significant.

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

No toxicity data were submitted on the notified chemical. However, toxicological data on several analogues is presented below.

<i>Endpoint</i>	<i>Analogue Chemicals</i>			
	<i>1</i>	<i>2</i>	<i>3</i>	<i>5</i>
Summary of Acute Toxicity Studies				
Rat, acute oral toxicity LD50 (mg/kg bw)	>2000	1932	>5000	>5000
Rat, acute dermal toxicity LD50 (mg/kg bw)	>2000	>2000	-	-
Summary of Repeated Dose Toxicity Studies				
Rat, repeat dose oral toxicity – 90 days (mg/kg bw/day)	NOAEL = 100	-	NOAEL > 2200	-
Dog, repeat dose oral toxicity – 90 days (mg/kg bw/day)	-	-	NOAEL = 1322 (males) NOAEL = 1948 (females)	-

The likely oral LD50 for the notified chemical is expected to be 1932-5000 mg/kg bw, based on the oral LD50 values obtained for analogues as shown above. Given the number of test results on analogues with the oral LD50 > 2000 mg/kg bw and the one oral LD50 result of 1932 mg/kg bw, the notified chemical is not considered to be harmful following acute oral exposure.

The notified chemical is likely to be of low toxicity following acute dermal exposure. The likely dermal LD50 for the notified chemical is >2000 mg/kg bw/day, based on the dermal LD50 values obtained for analogues as shown above.

In a 90-day repeat dose oral toxicity study in rats on Analogue 1, a no observed adverse effect level (NOAEL) was established at approximately 100 mg/kg bw/day, based on the changes in clinical chemistry parameters and histopathological effects reported in animals treated with doses of 100, 1000 and 5000 mg/kg bw/day. The histopathological findings in the mid- and high-dose groups considered to be treatment-related included: macrophages with brown pigment in the spleen of both sexes in the mid- and high-dose groups, bile duct proliferation and bile duct sclerosis of males in the high-dose group, cortical vacuolation of the adrenals in females in the mid- and high-dose groups and follicular epithelial hypertrophy in the thyroids of females in the high-dose group. Aggregation of macrophages in the mesenteric lymph nodes of both sexes and macrophages with brown pigment in the spleen of females were also observed in the groups treated with 100 mg/kg bw/day. However, in the absence of other adverse effects at this dose level, these effects were not considered to be adverse and the NOAEL was determined to be 100 mg/kg bw/day.

In a 90-day repeat dose oral toxicity study in rats on Analogue 3, a NOAEL was established at > 2200 mg/kg bw/day, based on the lack of treatment-related adverse effects reported in animals treated with doses of 22, 220, 730 and 2200 mg/kg bw/day.

In a 90-day repeat dose oral toxicity study in beagle dogs on Analogue 3, animals were treated with 142, 366 and 1322 mg/kg bw/day (for males) and 144, 632 and 1948 mg/kg bw/day (for females). Slight variations in the various parameters were noted in all treated groups. However, these findings were not considered to be of toxicological significance and therefore, the NOAEL was established at 1322 mg/kg bw/day (males) and 1948 mg/kg bw/day (females).

The relevance of these findings to the notified chemical is unknown, given the anticipated difference in oral absorption potential between these analogues and the notified chemical.

<i>Endpoint</i>	<i>Analogue Chemicals</i>			
	<i>1</i>	<i>2</i>	<i>3</i>	<i>5</i>
Summary of Irritation Effects				
Rabbit, skin irritation	-	severely irritating	-	-
Rabbit, eye irritation	-	severely irritating	-	-
CONCLUSION	The notified chemical is likely to be a severe skin and eye irritant, based on the effects observed on Analogue 2.			

<i>Endpoint</i>	<i>Analogue Chemicals</i>			
	<i>1</i>	<i>2</i>	<i>3</i>	<i>5</i>
Summary of Mutagenicity and Genotoxicity studies				
Mutagenicity – bacterial reverse mutation	non mutagenic	non mutagenic	non mutagenic	-
Genotoxicity – in vitro Mammalian Cell Gene Mutation Test	non genotoxic	-	-	-
Genotoxicity – in vitro Mammalian Chromosomal Aberration Test	non genotoxic	non genotoxic	non genotoxic	-
Genotoxicity – Unscheduled DNA synthesis	-	non mutagenic	non mutagenic	-
CONCLUSION	The notified chemical is unlikely to be mutagenic or clastogenic, based on the negative findings for Analogues 1, 2 and 3.			

<i>Endpoint</i>	<i>Analogue Chemicals</i>			
	<i>1</i>	<i>2</i>	<i>3</i>	<i>5</i>
Summary of Reproductive and Developmental Toxicity studies				
Rat, Reproductive and Developmental Toxicity (mg/kg bw/day)	Reproductive and Developmental NOAEL = 1858	Maternal NOAEL = 65 Developmental NOAEL = 100	Maternal and Developmental NOAEL = 1000 (1 st study) and 1875 (2 nd study)	

A reproductive and developmental study was conducted in rats using Analogue 1 at approximately 18, 180 and 1858 mg/kg bw/day. No significant adverse effects were observed in the parents or their offspring throughout the study. Therefore, the NOAEL was determined to be approximately 1858 mg/kg bw/day for reproductive and developmental toxicity.

A reproductive and developmental toxicity study was conducted in rats using Analogue 2 at doses of 15, 65 and 100 mg/kg bw/day. Mortalities were reported in 2 dams from the high dose group. However, the cause for the mortalities was not reported. No significant adverse effects were observed in any of the surviving dams from any of the treatment groups and no developmental abnormalities were reported in any of their offspring. Therefore, the maternal NOAEL was established at 65 mg/kg bw/day due to the mortalities reported in the high dose group and the developmental NOAEL was established at 100 mg/kg bw/day based on the lack of adverse effects in offspring at any dose level.

Evaluation of potential reproductive effects for Analogue 3 was undertaken during a 13-week repeat dose toxicity study in rats. Histological evaluation reported no adverse effects on reproductive organs at dose levels up to 1322 mg/kg bw/day.

Two reproductive and developmental toxicity studies were conducted in rats using Analogue 3: one using doses of approximately 100, 300 and 1000 mg/kg bw/day and another using doses of approximately 200, 350, 610 and 1875 mg/kg bw/day. A dam treated with 300 mg/kg bw/day was found moribund and was sacrificed on day 10 of gestation in the 1st study. In the 2nd study, 1 female from the group treated with 1875 mg/kg bw/day was found to be nonpregnant and another from the same group contained only non-viable fetuses. No other mortalities or adverse effects of toxicological significance were reported during the studies. Therefore, the maternal and developmental NOAEL were determined to be 1000 mg/kg bw/day (1st study) and 1875 mg/kg bw/day (2nd study), respectively.

Summary of human health effects

The notified chemical is a high molecular weight (>1000 Da.) salt with low water solubility and relatively high log Pow (>4). Based on these characteristics, it is not expected to be absorbed following oral, dermal or inhalation exposure.

Analogues 4 and 5 represent the anionic and cationic moieties of the notified chemical respectively. However, no

toxicity data was provided on Analogue 4 and only an acute oral toxicity study was provided on Analogue 5. Analogue 1 also resembles a component of the notified chemical. Analogue 2 is not predicted to provide a reliable indication of the properties of the notified chemical, with respect to the environment, as it lacks a reactive functional group. Analogue 3 is not predicted to provide a reliable indication of the properties of the notified chemical given the additional component which is not part of the notified chemical.

The Analogues showed low acute oral and dermal toxicity, indicating similar results for the notified chemical.

The notified chemical is expected to be severely irritating to the eye and skin, based on studies on Analogue 2.

The notified chemical does not contain any structural alerts for skin sensitisation (Barratt et al. 1994) and is therefore not expected to be a skin sensitiser.

The notified chemical is not expected to be mutagenic or clastogenic based on negative results obtained in studies on Analogue chemicals 1 and 2.

Health hazard classification

Based on the data provided for Analogue chemicals, the notified chemical should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (2004)] with the following risk phrases:

R38 Irritating to skin

R41 Risk of serious damage to eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The main concerns relating to the use of the notified chemical are severe eye irritation and skin irritation.

Workers are of greatest risk while handling the imported formulation containing the notified chemical at up to 20% concentration during reformulation. The use of PPE such as gloves, safety glasses and coveralls, as well as automated processes, is expected to minimise dermal and ocular exposure and therefore the risk of irritation.

Workers handling the reformulated corrosion inhibitor product containing the notified chemical at less than 10% are not expected to experience exposure during filling of product packaging or filling the automated injection system prior to injecting into the pipelines. However, if exposure were to occur from spills or splashes, the risk of irritation (especially to the eye) cannot be ruled out entirely and this risk would be minimised with the use of safety glasses, gloves, and coveralls.

Overall, the risk of eye and skin irritation is not expected to be unacceptable provided that appropriate PPE is used by workers handling the reformulated products.

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 and once injected into pipelines is not expected to be released. Therefore, the risk to public health is expected to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical is manufactured overseas and is imported by sea into Australia as a component of a product in 200 L poly drums or 1250 kg IBC (ISO tank) containers. From the wharf, it will be transported by road to the notifier's site for reformulation with other ingredients to produce the end-use product. Once reformulated, the notified chemical containing end-use product will be transported by road to the end-users in 1000 L bulk tanks for use in terrestrial pipes.

Other than from accidental spills during transport and handling, which are expected to be handled in accordance

with the emergency procedures, environmental release at this stage is expected to be limited to residual quantities of notified chemical in:

- import and transport containers (<0.5% of the annual introduction volume); and
- the reformulation mixing vessel, pipe work and on-site storage tanks (<0.5% of the annual introduction volume).

Residual notified chemical within import and transport containers is expected to be removed during drum reconditioning, and will be disposed to landfill as extracted solids. Residual notified chemical in the mixing vessel used in reformulation, pipe work and on-site storage tanks is expected to be recovered and re-used in subsequent batches, but may also be recovered using solvent during cleaning operation, and will be disposed of to landfill as extracted solids.

RELEASE OF CHEMICAL FROM USE

The notified chemical is a component of a corrosion-inhibition product used annually or biannually to treat the inside walls of terrestrial pipelines fitted with pigging (pipe-line inspection) facilities. The product is pumped from the 1000 L bulk tanks via a positive displacement pump and is introduced to the pipelines at pig-launching stations, a funnel shaped Y section in the pipeline. The product is then pushed through the pipelines, coating the walls of the pipes as it passes. Excess product is removed at a downstream pig-receiving station and captured for re-use or if excessively contaminated, for disposal. It is expected that all but the small quantity of excess notified chemical contained in the recovered product that is sent for disposal, will ultimately share the fate of the fluid(s) transported in the pipelines, as the coating wears due to friction. It is expected that notified chemical will be chemically transformed/destroyed during the subsequent processing of the pipeline fluids.

Excess notified chemical contained in the recovered product that is sent for disposal is expected to be disposed of to landfill after solidification treatment.

RELEASE OF CHEMICAL FROM DISPOSAL

Notified chemical disposed of to landfill is expected to have undergone solidification treatment. Based on the expected hydrophobicity of the notified chemical, it is not expected to leach, but rather, overtime, degrade *in situ* via biotic and abiotic processes to form water and simple organic and nitrogenous compounds. Release to the aquatic environment is not expected at any stage in the notified chemical's life-cycle, based on both its expected physico-chemical properties, and its proposed terrestrial use.

7.1.2 Environmental fate

Environmental fate data were not submitted for the notified chemical itself. However, environmental fate data, in the form of US EPA Robust Summaries of OECD TG301B "Ready Biodegradability: Modified Sturm Test", were submitted for Analogue 4 showing only 11% degradation after 28 days. A similar test for the less suitable Analogue 3 showed only 5% degradation after 20 days. In addition, the results of EPI Suite (BCFBAF Program v3.00) estimation of BCF were provided for Analogue 1, 4 and 5 (3.2-10 and 1491, respectively). The analogue chemicals and results are sufficiently representative of and consistent with the structure and properties of the notified chemical, with respect to environmental fate, to conclude that the notified chemical is not expected to be classed as readily biodegradable and is expected to have a low-moderate potential for bioconcentration. Limited release to water will further reduce the potential for the latter.

7.2. Environmental effects assessment

Ecotoxicity data were not submitted for the notified chemical itself. However, environmental effects data, in the form of US EPA Robust Summaries were submitted for Analogues 1, 2 and 3. These show the following results:

Fish (Analogues 1, 2 and 3, in 3 species) 96 h LC50 >1000, 1.17 and 59 mg/L respectively.

Daphnia (Analogues 1 and 2, in 2 tests) 48 h EC50 >1000 and 1.5-1.7 mg/L, respectively.

Algae (Analogue 1) 72 h EC50 >1000 mg/L.

As can be seen, there is quite a variation in the toxicity within species, depending on the analogue tested. Further, no data are available for Analogues 4 and 5, which are the anionic and cationic moieties of the notified chemical. More importantly, data for the individual components may not reflect the aquatic toxicity of the combined components in water. Therefore, no conclusion can be made concerning the ecotoxicity of the notified chemical. However, test results are not required given the low potential for release to water from the proposed use.

7.3. Environmental risk assessment

While the notified chemical is indicated to be toxic to aquatic organisms (fish/invertebrates) based on data provided for analogues, deliberate release to the aquatic environment is not expected at any stage in the life-cycle of the notified chemical within Australia. Further, based on the proposed terrestrial use pattern, nature of the formulated product containing the notified chemical, and the industry in which it will be used, it is expected that adequate physical engineering controls (e.g. bunding) will be in place to further mitigate the risk of the notified chemical entering the aquatic environment. Any notified chemical that is disposed of to landfill is expected to have undergone solidification treatment, and in combination with the notified chemical's expected hydrophobicity, should remain within the landfill environment and not migrate to groundwater. Thus, the notified chemical is not considered to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided for analogue chemicals, the notified chemical should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (2004)] with the following risk phrases:

R38 Irritating to skin

R41 Risk of serious damage to eyes

As a comparison only, 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.

	<i>Hazard category</i>	<i>Hazard statement</i>
Skin irritation	2	Causes skin irritation
Eye irritation	1	Causes serious eye damage

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 reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Use the following risk phrases for products/mixtures containing the notified chemical:
 - conc. \geq 20%: R41 Risk of serious damage to eyes; R38 Irritating to skin
 - \geq 10% conc. < 20%: R41 Risk of serious damage to eyes
 - \geq 5% conc. < 10%: R36 Irritating to eyes

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 at up to 20% in P-332:
 - Avoid contact with skin and eyes
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as used in formulations at < 10%:

- Avoid contact with skin and eyes
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced at up to 20% in the product P-332 and as used in formulations at < 10%:
 - Safety glasses
 - Coveralls
 - Gloves

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. Do not allow the notified chemical to enter waterways.

Regulatory Obligations

Secondary Notification

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

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

- (1) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of a corrosion inhibitor product at less than 10% concentration, or is likely to change significantly;
 - the notified chemical is proposed for use which has the potential to result in aquatic exposure;
 - the amount of chemical being introduced has increased from < 7 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.

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.

BIBLIOGRAPHY

- Barratt et al. (1994) An Expert System Rulebase for Identifying Contact Allergens, *Toxicology In Vitro*: 8(5), pp.1053-1060.
- NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.