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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Bio-Reporter

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Director
NICNAS

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Bio-Reporter

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nalco Australia Pty Ltd (ABN 41 000 424 788) of 2 Anderson St, Botany NSW 2019

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS number, Molecular formulae, Structural formulae, Molecular weight, Spectral data, Non-hazardous impurities, Identity of manufacturing site(s), Processes at manufacturing site(s).

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a Function of pH, Particle Size, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Low Volume Chemical Permit in May 2003 (LVC/543) and May 2006 (LVCR/8)

NOTIFICATION IN OTHER COUNTRIES
Philippines (Full notification, 1996)
Korea (Low Volume Exemption, 2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Bio-Reporter, 3DTBR20, 3DTBR06, TX12539, and TX1257

METHODS OF DETECTION AND DETERMINATION

METHOD UV-Visible Spectroscopy

METHOD ^{1}H-NMR Spectroscopy

3. COMPOSITION

DEGREE OF PURITY
>85%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia by sea, as a component of finished products in pellet or liquid form. The pellet form (<50% notified chemical) will be contained in 1.8 L plastic bottles containing approximately 1,200 pellets, and the liquid form (<1% notified chemical) will be contained in 20 L plastic pails.

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

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

USE
The notified chemical is used as an indicator in industrial cooling tower systems, where it circulates in cooling water at ppb levels. Microbiological growth in the cooling water leads to a change in the properties of the notified chemical. This change in the notified chemical is detected and fed to a computer, which determines the bacterial population in the cooling tower, and controls the dosage of biocide and further notified chemical.

The notified chemical will be imported in both a liquid form (containing <1% notified chemical, for use in smaller cooling systems) and a solid pellet form (<50% notified chemical, for use in larger cooling systems). Both forms are added to the water of cooling towers in an automated fashion.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Botany, NSW

IDENTITY OF MANUFACTURER/RECIPIENTS
Nalco Australia Pty Ltd., Botany, NSW

TRANSPORTATION AND PACKAGING
The notified chemical will be transported from the port of entry (Botany Bay) to Nalco by road. The notified chemical will be in pellet form (in 1.8 L plastic bottles) or dilute liquid form (20 L capacity plastic pails). The products will be distributed to customer sites by road from Nalco. There are 123 potential customer sites Australia-wide.

Neither the notified chemical, nor the formulations containing it, are Dangerous Goods for transportation considerations.

5.2. Operation description

No reformulation or repacking will be performed in Australia.

At customer sites, the products containing the notified chemical will only be handled by Nalco sales staff, approximately once a month at each site. Pellets will be emptied from bottles into the hopper of an auto-feeder system, which will add the notified chemical to the cooling water on an as-needed basis, controlled by a computer. Liquid formulations will be transferred into cooling water from the 20 L pail in a similar computer-regulated fashion.

Maintenance of the pellet auto-feeder system will be required occasionally, where the pellet tube and strainers of the unit may have to be cleaned of pellet residues.

Periodically, cooling water will be cleared to wastewater ("sent to blowdown") to control scaling and precipitation within the system. The notified chemical will be present in blowdown wastewater. The frequency and volume of blowdown will be dependent on a number of factors, including the quality of feed water. Wastewater will be either recycled or discharged to sewer through an industrial wastewater agreement.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Nalco Salesperson	60	<5 minutes	36 days/year
Nalco Service Engineers	Unknown	As needed	Occasional
Cooling tower maintenance workers	60	8 hours	1-2 days/year

Exposure Details
Only trained Nalco sales people will handle the imported products containing the notified chemical. The MSDS recommends personal protective equipment (PPE) such as safety glasses, gloves and overalls be worn while handling products containing the notified chemical.

- Pellets: A Nalco salesperson will empty the contents of a 1.8 L plastic bottle of pellets (containing <50% notified chemical) into an auto-feeder. The plastic bottle has a self-sealing lid and the auto-feeder is an enclosed system. Under rare circumstances, dermal exposure is possible.
- Liquid formulation: A Nalco salesperson will open the lid of the pail containing the liquid formulation, and insert a calibrated pre-set dosing pump. Dermal exposure to the notified chemical at <1% may result from splashes and/or contact with liquid residues on the pump or on the pails.

Nalco Service Engineers carrying out maintenance on the auto-feeder apparatus will likely be exposed to dust and/or liquid residues of the notified chemical. Residues are expected to be minimal, but any residual material may be brushed, wiped or rinsed from the device. Therefore, dermal, ocular and/or inhalation exposure to the notified chemical may be experienced. These workers will wear rubber gloves and a dust respirator while performing maintenance.

Cooling tower maintenance workers may be exposed to the notified chemical in cooling water (ppb levels), and thus dermal or ocular exposure may occur. General PPE (hard hat, safety goggles, P4 cartridge respirator, gloves, disposable overalls, and safety boots) is worn by these workers.

Recycling of wastewater at some sites will involve the use of settling ponds, where flocculants and coagulants are used to remove suspended particles. These ponds will require periodical cleaning, and during this process, workers may experience dermal or ocular exposure to the notified chemical. Extensive PPE is generally worn during this procedure, due to the chemical and biological hazards present in these ponds.

5.4. Release

RELEASE OF CHEMICAL AT SITE
No notified chemical release is expected from Nalco sites, as reformulation and repacking will not be performed in Australia.

RELEASE OF CHEMICAL FROM USE
Notified chemical release will only occur with controlled blowdown. This is dictated by factors such as the level of solid particles and impurity levels of the cooling water. The frequency of blowdown is increased when used with hard water. At some sites, the blowdown water is recycled, where a proportion of the released notified chemical is expected to be bound to the solids, which are removed either in the settling ponds or by using flocculants and coagulants. Captured solids are expected to be disposed of to landfill. The balance of the notified chemical will be released to sewer.

Up to 1% of the total annual import volume of notified chemical will remain as residual within import containers, and is expected to be disposed of to landfill.

5.5. Disposal

Disposal of the notified chemical is unlikely, other than via blowdown and from container residues (as described above). It is expected that disposal will occur primarily to sewer, as a result of blowdown. A proportion will be disposed of to landfill from container residues or from notified chemical that is associated with precipitated solids arising from the recycling of blowdown water.

Notified chemical that is disposed of to landfill is expected to degrade via biotic and abiotic process over time to form simple organic compounds. Notified chemical that is disposed of to sewer may partition to soil and sediments. Over time, it is expected to degrade via biotic and abiotic process over

time to form simple organic compounds.

5.6. Public exposure

As the notified chemical is intended only for use in industrial cooling water systems, public exposure is unlikely. Exposure during a transportation accident is possible but improbable.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Dark green to black powder

Melting Point/Freezing Point 321.3ºC (estimated using MPBPWIN v1.41)
>360ºC (non-standard test)

Remarks In a non-standard test, no visible signs of melting or decomposition were observed following heating to ≥360ºC. Subsequent ^{1}H-NMR investigation of the heated sample indicated that decomposition had occurred under these conditions.

Boiling Point 732.7ºC at 101.3 kPa

Remarks Test not conducted. Value estimated using MPBPWIN v1.41.

Density 566 kg/m^3

Remarks Tapped bulk density of solid notified chemical.

Vapour Pressure 1.35×10^{-18} kPa at 25ºC

Remarks Test not conducted due to the notified chemical's high melting point. The notified chemical did not melt, but decomposed into a mixture of compounds that were also solid. Value estimated using MPBPWIN v1.41.

6.5 **Water Solubility** 12.01 ± 0.05 g/L at 23ºC

METHOD OECD TG 105 Water Solubility
Remarks Shake Flask Method. Solutions were prepared by adding 0, 104, 617, and 1,005 mg of notified chemical to 50 mL aliquots. The latter two solutions were filtered immediately prior to analysis by HPLC.
TEST FACILITY BC Research Inc. (2003a)

Hydrolysis as a Function of pH Test not conducted.

Remarks Based on the chemical structure, the notified chemical is unlikely to undergo hydrolysis at environmental pH (4 – 9).

Partition Coefficient (n-octanol/water) log Pow = -2.29 ± 0.03 at 23ºC

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks FI and HPLC Method. No significant deviations from the test protocol were reported.
TEST FACILITY BC Research Inc. (2003b)

Adsorption/Desorption log K_{oc} = 3.065

Remarks Test not conducted. Value estimated using PCKOCWIN v1.66. The estimated K_{oc} may vary significantly with pH.

Dissociation Constant pKa = 6.93

Remarks Value obtained from literature (P.G.T., 2001).

Particle Size Test not conducted.

Remarks The notified chemical is formulated as a liquid or as solid pellets only.

Flash Point Test not conducted.

Remarks The notified chemical is a solid with very low vapour pressure.

Flammability Limits Test not conducted.

Remarks The notified chemical decomposes upon heating to >360ºC, and is unlikely to be pyrophoric.

Autoignition Temperature Test not conducted.

Remarks The notified chemical decomposes upon heating to >360ºC.

Explosive Properties Test not conducted.

Remarks Based on the chemical structure of the notified chemical, it is not likely to exhibit explosive characteristics.

Reactivity

Remarks Stable under normal conditions. No hazardous reactions with air or water have been observed.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Genotoxicity – *in vivo* mouse micronucleus assay	Non-genotoxic
in vitro oocyte fertilisation and embryo development	Inhibition of embryo development

7.1. Genotoxicity – *in vivo*

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	*Mus musculus*/CD-1
Route of Administration	Intraperitoneal injection
Vehicle	Sterile water
Remarks - Method	The maximum tolerated dose chosen was based on the acute toxicity symptoms exhibited by the test animals.

Dose range finding study

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I	3F, 3M	632.9	24
II	3M	200.3	24
III	3M	63.4	24
IV	3M	20.1	24
V	3M	6.4	24
VI (negative control)	3F, 3M	0	24

Definitive study

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
VII	5F, 5M + 5F, 5M	632.9	24 and 48
VIII	5F, 5M + 5F, 5M	200.3	24 and 48
IX	5F, 5M + 5F, 5M	63.4	24 and 48
X (negative control)	5F, 5M + 5F, 5M	0	24 and 48
XI (positive control, cyclophosphamide)	5F, 5M	15	24
XII (positive control, cyclophosphamide)	5F, 5M	75	24

RESULTS

Doses Producing Toxicity	At the highest dose (632.9 mg/kg bw), the test animals exhibited overt signs of toxicity. Dyspnea, unresponsiveness to stimuli, and lethargy were observed, lasting up to 5 hours after dosing. In addition, the extremities of the mice had turned a purple hue 10 minutes after dosing.
Genotoxic Effects	Furthermore, there were no significant increases in the production of micronucleated polychromatic erythrocytes (mPCE) in the notified chemical-treated groups as compared to the concurrent negative controls.
Remarks - Results	The positive controls used elicited the appropriate response, indicating the ability of the system to accurately detect clastogenic mutagens. Gross manifestations of toxicity were noted with the top dose of the notified chemical, indicating that this dosage was sufficient to elicit a biological response.

CONCLUSION — The notified chemical was not clastogenic in this *in vivo* Mammalian Erythrocyte Micronucleus Test under the conditions of the test.

TEST FACILITY — AppTec Laboratory Services (2006).

7.2. *in vitro* oocyte fertilisation and embryo development

TEST SUBSTANCE — Notified chemical

METHOD — Non-standard test method.

Bovine oocytes were isolated from the follicles of ovaries and subjected to *in vitro* maturation (IVM) in culture. Motile spermatocytes were purified from cryopreserved bovine semen, and these were used for *in vitro* fertilisation (IVF) studies with mature oocytes. The cleavage rate was determined 48 hours after exposure of oocytes to spermatozoa by microscopy.

Following IVF, embryos were *in vitro* cultured (IVC) with increasing content of foetal bovine serum over the duration of the study. Cultured embryos were examined by microscopy for development on days 6, 8 and 10 (IVF = Day 0).

Species/Strain — *Bos taurus*

RESULTS

Fertilisation of oocytes with notified chemical-treated spermatozoa:

Duration of treatment with the notified chemical, prior to IVF	*Oocyte cleavage rate at 48 hrs*	*Percentage (%) of cleaved ova developed to:*		
		Morulae (Day 6)	*Blastocysts (Day 8)*	*Expanded and hatching (Day 10)*
0 min	84.9%	43.6	20.1	13.1
15 min	87.0%	40.7	20.3	12.6
30 min	86.0%	40.7	20.4	13.3
60 min	86.8%	43.2	20.9	13.6

Development of embryos treated with the notified chemical during *in vitro* maturation, fertilisation and culture:

Group	*Treatment with 1.8 µg/mL notified chemical during:*			*Oocyte cleavage rate (48 hrs)*	*Percentage (%) of cleaved ova developed to:*		
	IVM	*IVF*	*IVC*		*Morulae (Day 6)*	*Blastocysts (Day 8)*	*Expanded and hatching (Day 10)*
Control	-	-	-	81.7%	38.4	17.3	10.2
1	+	-	-	74.0%	33.9	12.5	6.9
2	-	+	-	82.0%	43.9	15.1	6.1
3	-	-	+	76.2%	35.5	6.4	1.1
4	+	+	+	81.7%	31.2	3.5	0.4

Remarks - Results: The treatment of spermatocytes for up to 60 minutes with the notified chemical showed no significant subsequent effects on oocyte cleavage rate or embryo development.

The treatment of oocytes and embryos with the notified chemical during IVC or IVM/IVF/IVC (Groups 3 and 4) showed significant decreases in post-cleavage embryo development when compared to control or to where treatment occurred only during IVF or IVM alone (Groups 1 and 2). Treatment with the notified chemical during only IVM or IVF (Groups 1 and 2) did not significantly affect embryo development.

CONCLUSION: Treatment of bovine embryos with the notified chemical during the *in vitro* culture of embryos resulted in their reduced development and survival.

TEST FACILITY: Wang *et al* 1998

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test – test conditions not reported.
Species: *Oncorhynchus mykiss*
Analytical Monitoring: Temperature, pH, HPLC.
Remarks – Method: While the submitted test report indicated extensive analysis on test substance concentrations before and after the test, no information was provided regarding the actual test procedure.

RESULTS
Remarks – Results: Apart from the title of the test report, the only reference indicating that a test occurred is the sentence: “Therefore, the LC50 is >100 mg test substance/L”. Apart from this, there is no evidence that fish were actually exposed to the notified chemical.

CONCLUSION: The test report was deemed inadequate, and no conclusions could be drawn regarding the toxicity of the notified chemical to fish.

TEST FACILITY: BC Research Inc. (2003c)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia *sp*. Acute Immobilisation Test and Reproduction Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	80-100 mg $CaCO_3$/L
Analytical Monitoring	pH, Temperature, HPLC
Remarks - Method	The 48 h EC_{50} and its 95% confidence limits were calculated using the log-logit interpolation method and Toxcalc. Calculation of the EC_{50} estimates were based on mean measured concentrations, because the measured concentrations were not with 80 to 120% of the nominal purity adjusted concentrations.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*
Nominal	*Actual (mean)*		*48 h*
0	0	20	0
56	57	20	0
113	99	20	17
225	163	20	20
451	249	20	20
902	561	20	20

EC50	90.7 mg/L at 48 hours (95: CI = 65.8-95.0)
NOEC	57 mg/L at 48 hours
Remarks - Results	Chemical analysis of the notified chemical in the test solutions at test initiation and termination indicated that the notified chemical was stable of the exposure period. The measured concentrations were 53% to 101% of nominal purity adjusted concentrations, which indicates that some of the measured concentrations were lower than the expected concentrations at both test initiation and termination. At test termination a small amount of black residue or precipitate was observed at the bottom of the test vessels at concentrations of 163, 249 and 561 mg/L, which may explain the lower than expected measured concentration.
CONCLUSION	The notified chemical was found to be harmful to *Daphnia magna*.
TEST FACILITY	BC Research Inc. (2003d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 0, 0.46, 1.18, 2.91, 7.28, 18.2, 45.5 mg/L Actual: 0, 0.25, 0.74, 2.01, 5.46, 13.8, 37.6 mg/L
Auxiliary Solvent	None reported
Analytical Monitoring	Temperature, HPLC
Remarks - Method	Non-linear regression was used to estimate the EC50 and 95% confidence limits.

RESULTS

Growth	
EC50	*NOEC*
mg/L at 72 h	*mg/L*
4.01	0.25
(95% CI: 3.47 – 4.65)	

Remarks - Results: Recalculation of the test endpoint was performed, as the measured concentrations at test termination were not within 80 to 120% of the nominal concentrations. The LOEC was 0.74 mg notified chemical /L.

CONCLUSION: The notified chemical is toxic to algae.

TEST FACILITY: BC Research Inc. (2003e)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
- Inoculum: Activated sludge
- Concentration Range: Nominal: 0, 156, 278, 500, 887, 1553, 2774 mg/L
  Actual: 0, 29, 145, 350, 726, 1377, 2633 mg/L
- Remarks – Method: The EC20, EC50 and EC80 of the notified chemical were determined by linear regression of the percent inhibition of aerobic respiration vs. the concentration of notified chemical, using a simple linear regression model.

RESULTS
- IC50: 1,009 mg/L (95% CI: 743 – 1,663 mg/L)
- Remarks – Results: Measured notified chemical concentrations were 19 – 95% of purity corrected nominal concentrations at test initiation. These results suggested that an adsorption effect may have occurred in the samples, as the lower concentration samples had lower measured/nominal ratios than the higher concentration samples.

  As recommended by the OECD 209 Test Guideline, due to the variability of the activated sludge respiration inhibition test, the ECXX values should be reported in orders of magnitude. Therefore the EC50 for the notified chemical is in the range of 1,000 to 10,000 mg/L.

CONCLUSION: The notified chemical is not harmful to microbial organisms.

TEST FACILITY: BC Research Inc. (2003f)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Environmental exposure is difficult estimate for the proposed use. As a worst case scenario, it is assumed that the entire annual import volume is released to sewer throughout Australia, without mitigation and with blowdown events only occurring on week days. The resultant Predicted Environmental Concentration has been calculated using these assumptions.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release	3.85	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.94	µg/L
PEC - Ocean	0.09	µg/L

9.1.2. Environment – effects assessment

The following Predicted No-Effect Concentration for the Aquatic Compartment has been calculated using a conservative assessment of 100 given the deficiencies of the fish ecotoxicity test.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga)	4.01	mg/L
Assessment Factor	100	
PNEC	40.10	µg/L

9.1.3. Environment – risk characterisation

The following risk quotient has been derived by dividing the PEC by the PNEC for both River and Ocean release scenarios.

Risk Assessment	PEC (µg/L)	PNEC (µg/L)	Q
Q - River:	0.94	40.1	0.023
Q - Ocean:	0.09	40.1	0.002

This indicates that the risk to the aquatic environment from the proposed use manner and level is expected to be acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Overall, a low likelihood of significant exposure is presented, as the notified chemical is formulated as either a solid pellet or as a very dilute liquid, and because of the use of automated dispensing technology.

Nalco sales people will experience the most frequent exposure to the notified chemical, in the greatest concentrations. However, during the addition of pellets to the auto-feeder system, there is a low probability of any exposure to the pellets occurring under normal conditions. Dermal exposure to low concentrations of the notified chemical in liquid formulations (<1%) may occur while replacing the pail, from splashes and/or contact with liquid residues on the pump or on the

pails. Low-level dermal exposure is also possible from either liquid or pellet formulations in the event of an accident (e.g. spillage).

Nalco service engineers performing maintenance on the auto-feeding apparatus will likely be exposed to dust and liquid residues of the notified chemical. The potential level of exposure will likely be low, due to the limited amount of residues that will be present within each machine, and the infrequency of required maintenance.

Cooling tower maintenance workers may experience very low-level dermal or ocular exposure to the notified chemical in cooling water (i.e., to parts per billion of the notified chemical). The extensive PPE worn by these workers (eg gloves, respirator, overalls, boots) for protection against chemical and biological hazards would further limit any potential exposure. For assessment purposes, the exposure of these workers is considered negligible.

Workers carrying out the cleaning of settling ponds of wastewater recycling processes at some sites may experience dermal and ocular exposure to the notified chemical. The probable concentration of the notified chemical in these ponds is likely to be highly variable between sites, but generally low. The PPE worn by workers during this procedure are intended to protect against agents of greater hazard, and so these workers are unlikely to experience significant levels of exposure to the notified chemical.

9.2.2. Public health – exposure assessment

The public are unlikely to be exposed to the notified chemical, as it will only be used in industrial cooling towers.

9.2.3. Human health – effects assessment

Toxicokinetics:

Absorption of the notified chemical is likely to occur from the gastrointestinal tract (GIT), and this may occur with water transport or through aqueous pores in the gastrointestinal mucosa. While the notified sodium salt is hydrophilic ($logP_{ow}$ = -2.29), in the pH range of the stomach and small intestine (pH 1-6) the notified chemical will be largely unionised and would thus have a more hydrophobic character. An estimated $logP_{ow}$ of 0.94 for the unionised form was determined using KOWWIN v1.67 (EPIWIN software package). Thus, it may also be absorbed directly through the GIT mucosae. Experimental evidence supporting the absorption of the notified chemical from the GIT is seen in the oral dosing of the rat acute lethality study (below).

Only limited transdermal absorption of the notified chemical is likely to occur, due the hydrophilic nature of the notified chemical preventing its absorption across the stratum corneum. However, at the normal pH of human skin (average pH range 5.4-5.9 (Braun-Falco and Korting, 1986), a greater potential for absorption exists, as the notified chemical will be largely unionised. Within the viable epidermis, the notified chemical is likely to be ionised, as the pH is closer to physiological (pH 7.4), and it may be able to distribute away from the dermis. Therefore, due to the amphiphilic nature of the notified chemical, some absorption is predicted to occur following dermal exposure. However, no data are available to verify this prediction.

Absorption of the notified chemical is likely to occur from the lung, should respirable dusts be generated and inhalation exposure occurs. Given its water solubility and the $logP_{ow}$ values of its ionised and unionised forms, it is likely to either be absorbed through aqueous pores or directly across the respiratory mucosa.

Following absorption, the notified chemical is likely to distribute throughout the body. At the physiological pH of 7.4, the notified chemical is expected to be partially ionised. As the notified chemical displays amphiphilic characteristics (depending on its ionisation state), and as it has a low molecular weight, it is likely to distribute to most if not all tissues. In the *in vivo* mouse micronucleus assay, the notified chemical was administered by intraperitoneal injection, yet systemic effects such as dyspnoea and lethargy were observed. These results demonstrate that the notified chemical is able to distribute from its administration site.

Given the probable wide distribution of the notified chemical throughout body tissues, it is likely to undergo some kind(s) of biotransformation. It is water soluble, and may be excreted directly into urine; however, given its amphiphilicity, this route of excretion is likely to be limited without metabolic conjugation.

Toxicity:
Little toxicological data were submitted under the Limited notification category. Therefore, it is not possible to fully assess the possible human health effects of the notified chemical. The following acute lethality data for the acid form of the notified chemical were found on ChemIDplus (http://chem.sis.nlm.nih.gov/chemidplus):

Species	*End-point (route of administration)*	*Reference*
mouse	LD_{Lo} = 179mg/kg bw (intravenous)	Lutty GA (1978)
rat	LD_{Lo} = 500mg/kg bw (oral)	National Academy of Sciences (1953)

The two lethal dose low (LD_{Lo}) values indicate that the notified chemical has the potential to cause significant toxicity, such that death occurred in animals of two species (neither study was reviewed by NICNAS). The cause of death of these animals is unknown.

Toxic effects of the notified chemical were observed in mice during the *in vivo* mouse micronucleus test (AppTec Laboratory Services, 2006). At the highest dose (632.9 mg/kg bw intrperitoneal), the test animals exhibited dyspnea, unresponsiveness to stimuli and lethargy, as well as purple-stained extremities. No mortality was observed over the duration of the test (animals were sacrificed at 24 or 48 hours). This dosage exceeded the LD_{Lo} value above; it is unknown if mortality would have occurred after a longer observation period.

Two *in vitro* studies have also been identified that investigated the effects of the notified chemical on bovine oocyte fertilisation and embryo development. No significant toxic effects on cultured embryo development (morula and blastocyst formation) *in vitro* were observed following treatment with the notified chemical concentration of 5 µg/mL in the media in one study (Wang *et al* 1996). In the second study, pre-treatment of spermatozoa with the notified chemical at 17.6 µg/mL did not affect their ability to fertilise oocytes (Section 7.2; Wang *et al* 1998). However, treatment of *in vitro* cultured embryos with the notified chemical at 1.8 µg/mL was found to result in a significant reduction in their survival and ability to develop into blastocysts. No data was found describing the effect of the notified chemical on embryonic survival and development *in vivo*.

The notified chemical was found to be not clastogenic in an *in vivo* mouse micronucleus test (AppTec Laboratory Services, 2006). Some similar chemicals are mutagenic through reaction with DNA and/or intercalation within the DNA strand, and others are able to induce DNA strand breakage through a photolytic mechanism. One study of the notified chemical showed that it possess photosensitive properties that enable it to generate free radical species in the presence of cellular H-atom donors such as NADH or GSH (W.A.P., 1996). However, its photosensitivity was not enhanced by DNA or a protein model, suggesting that it may not possess DNA-reactive properties. Based on the available evidence, any carcinogenic properties of the notified chemical cannot be properly evaluated. However, there is no evidence to suggest that it is likely to be carcinogenic to humans.

Due to the lack of relevant toxicological data, the notified chemical cannot be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Nalco Salespeople will handle the most concentrated forms of the notified chemical the most regularly, and therefore have the highest potential exposure. However, the frequency of any exposure is low and of short duration, and the worker's tasks should not involve direct contact with products containing the notified chemical (except perhaps in the event of an accident of spill). The recommended PPE would reduce any foreseeable risk to these workers.

- Pellet forms of the notified chemical are not likely to present a significant risk to workers as long as the generation of significant levels of dusts containing the notified chemical does not occur. Given the description of the tasks undertaken, the generation of such dust levels is not probable.
- Liquid formulations of the notified chemical would present a more significant risk to these workers' health than the solid pellet formulations, because of difficulties in handling (eg

splashes and drips) and from the facilitation of absorption provided by the already-dissolved state. However, the low concentration of the notified chemical (<1%) in the liquid formulation means that any risk is reduced.

Therefore, any risk posed by the notified chemical to Nalco salespeople is likely to be low, based on the exposure scenarios presented.

Nalco service engineers will only be exposed during the occasional servicing of pellet and/or liquid auto-feeding systems. The risk to these workers, arising from dermal, inhalation or ocular exposure to residues or dusts containing the notified chemical will be low, based on the limited amount of notified chemical in these residues. When the PPE worn is taken into account, any risk presented by the notified chemical to these workers is negligible.

Cooling tower maintenance workers and workers involved in the cleaning of settling ponds will be exposed to very low concentrations of the notified chemical in cooling water (approximately ppb levels). The already low levels of exposure resulting from the low concentration of the notified chemical in the cooling water are expected to be further reduced by the use of PPE required to protect against other hazards.

The notified chemical has an unknown toxicity profile, but workers are likely to only experience low to very low levels of exposure to the notified chemical in the indicated use scenarios. Therefore, the notified chemical is unlikely to present a significant risk to occupational health and safety.

9.2.5. Public health – risk characterisation

The introduction of the notified chemical for the indicated use will not result in any public exposure, except in the unlikely event of a transportation spill or an uncontained spill during use. Therefore, the notified chemical presents a negligible risk to public health.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Due to the lack of available data the notified chemical cannot be classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

The notified chemical is not considered to pose a significant risk to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is negligible risk to public health when used as an indicator in industrial water cooling systems.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. 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 contact with products containing the notified chemical.*
  - *Avoid generating airborne dusts where powders containing the notified chemical might occur.*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical and products containing the notified chemical:
  - *safety glasses, gloves and overalls should be worn while handling products containing the notified chemical; and*
  - *where dusts of the notified chemical may be present, a dust respirator should be worn.*

- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical.

or

(2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required. In this event, a full version of the fish ecotoxicity report and results should be provided.

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