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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Nalco 73199

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Nalco 73199

1. APPLICANT

Nalco Australia Pty Ltd (ACN 000 424 788) of 2 Anderson St Botany NSW 2019 has submitted a standard notification statement in support of their application for an assessment certificate for Nalco 73199.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of exact import volume, use and application of the notified chemical have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: Nalco 73199

3. PHYSICAL AND CHEMICAL PROPERTIES

The notifier applied variation of schedule requirements for the physico-chemical properties of Nalco 73199. The following data are generated from a structurally related compound which is accepted as an analogue for Nalco 73199. These properties relate variously to the analogue and the imported aqueous solution as specified.

Appearance at 20°C & 101.3 kPa:	Yellow odourless liquid
Boiling Point (analogue):	204°C at 15 mmHg, 159°C at 2 mmHg
Melting Point (analogue):	98.5°C
Specific Gravity (aq. solution):	1160 kg/m^3 at 25°C
Vapour Pressure (analogue):	5.33 x 10^{-3} kPa at 20°C
Water Solubility (analogue):	1.98 x 10^4 mg/L at 25°C
Partition Co-efficient (n-octanol/water):	log K_{ow} = 1.44
Hydrolysis as a Function of pH:	No hydrolysis (predicted)
Adsorption/Desorption:	K_{oc} = 145 (estimated)
Particle size:	Not applicable – manufactured as a liquid.
Dissociation Constant (analogue):	pK_a = 8.37 at 20°C
Flash Point:	No data available
Flammability Limits:	No data available
Autoignition Temperature:	No data available
Explosive Properties:	May explode during vacuum distillation
Reactivity/Stability:	Very stable toward acids, alkalies and toward oxidation

and reduction. Forming stable metallic salts.

4. PURITY OF THE CHEMICAL

Degree of Purity: 40 %

Hazardous Impurities:

Chemical name:	Sodium hydroxide
CAS No.:	1310-73-2
Weight percentage:	< 0.1%
Toxic properties:	At concentrations between 0.5% and 2%: Irritating to eyes and skin (R36/38) (NOHSC, 1999a) NOHSC exposure standard 2 mg/m^3 (TWA) (NOHSC, 1995)

Chemical name:	1,2-Benzenediamine
CAS No.:	95-54-5
Weight percentage:	< 0.04 %
Toxic properties:	At concentrations ≥5%: Toxic (T) - Toxic by inhalation, in contact with skin and if swallowed (R23/24/25), May cause sensitisation by skin contact (R43). At concentrations between 1% and 5%: Harmful (Xn) – R20/21/22 and R43 (NOHSC, 1999a). NOHSC exposure standard 0.1 mg/m^3 (TWA) sensitiser, carcinogen category 3 (NOHSC, 1995)

Non-hazardous Impurities (> 1% by weight): None

Additives/Adjuvants:

Chemical name:	Water
CAS No.:	7732-18-5
Weight percentage:	Up to 60 %

5. USE, VOLUME AND FORMULATION

The notified chemical will be imported into Australia as part of the corrosion inhibitor product for cooling water systems in 200 L steel drums, senior Portafeed tanks (~1500 L) or bulk containers (>1500 L). Its imported volume will be less than 50 tonnes per year. The imported product contains <50% notified chemical in aqueous solution.

The imported product containing the notified chemical will be transported from the dockside to the notifier's site for storage, repackaging and reformulation. Automatic pumping equipment will be used to decant the product directly into alternate containers or via an enclosed decanting/blending vessel and this will take place in a well-ventilated area. A QC chemist will collect samples of the product to ensure it meets specifications. The notifier has indicated that the product may also be blended with other chemicals to form other product mixtures for sale in Australia. In this situation other raw materials are added to the decanting/blending vessel by top charging through hard piping. The concentration of notified chemical in the reformulated products will range between 2 and 4%. Gravity filling of containers via the bottom of the decanting/blending vessel will occur using a flexible hose and spear arrangement. Alternatively, automatic decanting equipment, typically for filling carboys, will be available. Containers used for repackaging include 15 L plastic carboys, 200 L plastic mauser drums, and 1000 L plastic tote boxes.

At the customer sites the product is added to water systems at a concentration of approximately 0.5-2 ppm to prevent corrosion. The product will typically be fed continuously, using a small dosing pump.

6. OCCUPATIONAL EXPOSURE

Transport and storage workers (2-3 hours/day, 10-15 days/year)
Waterside (2 workers), warehouse (5 workers), truck drivers (5 workers), receiving clerks (2 workers), and forklift drivers (2 workers) will handle sealed containers and thus are unlikely to be exposed to the notified chemical unless the packaging is breached.
Product packaging/reformulation and vessel cleanout (4 workers, 2-5 hours/day, 30 days/year)
Repackaging/reformulation workers may experience dermal exposure to drips, spills and splashes containing < 50% notified chemical when handling and cleaning the decanting vessel. Automatic pumping equipment will be used to decant the product directly into alternate containers or via an enclosed decanting/blending vessel and will occur in a well-ventilated area. Such decanting/blending vessel allows venting to a wet scrubber to remove any fumes/vapours/mists generated. Repackaging/reformulation workers will wear overalls, chemical resistant gloves and chemical splash goggles.

QC chemists (2 workers, 2 hours/day, 8 days/year)
QC chemists may receive dermal exposure to drips, spills and splashes when analysing samples of the imported product or of the reformulated product. QC chemists will wear laboratory coats, gloves and safety glasses.

Customer service and assurance representatives (15 workers, 1-4 hours/day, 60 days/year)
Sales representatives may receive dermal exposure to drips, spills and splashes when demonstrating the setting up of the dosing/feeding equipment and verification of the dosage levels. Sales representatives will wear overalls, chemical resistant gloves and chemical splash goggles.

Customer site operators (30 workers, 1-2 hours/day, 340 days/year)
Customer site operators may receive dermal exposure to drips, spills and splashes containing the notified chemical at approximately 50% when setting up, dosing, testing and calibration of the dosing/feeding equipment. It is estimated that such operations will take 5-10 minutes at a time. Customer site operators will wear overalls, chemical resistant gloves and chemical splash goggles.

7. PUBLIC EXPOSURE

Public exposure to the notified chemical via dermal contact is possible following transport accidents. The importation, preparation and use involve industrial processes which are unlikely to result in public exposure except in the event of accidental release to the environment. The notified chemical is not available to the public. Therefore, in the ordinary course of events, the potential for public exposure to the notified chemical is minimal.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

It is anticipated that approximately 0.5% of the total import volume will be released through spills prior to reformulation. This equates to a loss of up to 250 kg per annum of the notified chemical. A further 1% of the notified chemical may be lost during formulation which would be equal to a maximum of 500 kg/annum. Approximately 1% or up to 500 kg/annum of the notified chemical will remain as residues in the importation drums. Presumably, the import and reformulation drums containing residues will either be reused or disposed of in landfill.
The notified chemical will be used as a corrosive inhibitor in enclosed water cooling systems at up to 50 end user sites. It is estimated that 20-50% of the notified chemical is consumed during the process. During treatment of the cooling water, the efficacy of the chemical diminishes and new chemical solution is continually added to the system. A continuous bleeding and discharge of the treated water compensates replenishment of the chemical in the system.

Majority of the notified chemical will be released to the environment by this way and when cooling systems undergo either short-term manual system blowdown (BD) or total shut-down and are cleaned.

For example, the volume of purge or blowdown from a small site with a BD of 0.5 tonnes per hour per one cooling tower would be approximately 4.5 ML/year. The quantity of the notified chemical released would be 9 kg/year. A large cooling plant system would have a BD of 21 tonnes per hour, which is equivalent to 170 ML/year. This equates to a release of approximately 340 kg/year of the notified chemical after on-site treatment.

Most cooling towers operate with a maximum drift of 0.002% of the recirculation rate. The recirculation rate in a small site cooling tower may be 900 tonnes/hour. Assuming a 2 ppm concentration of notified chemical in the cooling tower, 36 mg/hour or 316 g/year would be lost due to drift. In a larger system the recirculation rate is in the order of 9000 tonnes/hour and this would result in 3.16 kg/year of notified chemical being released due to drift.

8.2 Fate

While not specifically indicated by the notifier, empty drums and their residues are expected to be sent to either licensed drum reconditioners or the drums disposed of directly to a licensed landfill site. Presumably, drum reconditioners will also dispose of solid residue from drums to licensed waste landfill sites. Washings from pipes and mixing equipment will be used in the formulation of the next batch of water treatment solution or will be treated at the Malabar Sewerage Treatment Plant. Here wastewater is adjusted to a pH of 7-8, which is expected to precipitate the notified chemical. The resulting sludge is then passed through anaerobic digesters prior to the its repackaging as fertiliser.

The notifier has provided the results of a biodegradation study for the notified chemical using a Warburg Apparatus (Agatha Corp., 1971). An attempt was made to link its biodegradation to oxygen uptake after the medium was inoculated with a mixed population of aquatic microorganisms. The results showed that the results obtained do not contribute to the determination of biodegradability as they show no oxygen uptake. The authors indicated that the results were inconclusive and that the test needed to be conducted over a longer period of time (24 h). The notifier did provide a result of a modified Zahn-Wellens test for the parent compounde of the notified chemical. After 28 days, the 80-90% degradation was observed based on the MSDS. Boyer and Selvarajan (1969) have also shown that, when irradiated with light at a wavelength of 300 nm, the notified chemical slowly photolyse to give aniline and anisidine.

During use the notifier indicates that the feed rate of the notified chemical will be adjusted to maintain a concentration of up to 2 ppm of the active chemical in the cooling water system. The cooling tower concentrations of the notified chemical are, therefore, expected to be less that 2 ppm.

Typically cooling water represents about 60% of the total effluent volume discharged from a facility. The remaining water comes from boiler and process streams. The concentration of the notified chemical in the plant effluent would, therefore, be about 1.2 ppm. If a secondary effluent plant is used prior to discharge, generally a ten-fold dilution occurs and 50% of the notified chemical is expected to be removed through the waste treatment facilities as sludge and disposed to landfill. Discharge from the plant would, therefore, contain less than 0.06 ppm of the notified chemical. Subsequent treatment at local sewage treatment plants would further dilute and remove the notified chemical to very low concentration levels (less than 0.006 ppm).

Based on these assumptions, it is expected that some of the notified chemical will find its way to landfill. Here it will be moderately mobile. It should not bioaccumulate as the chemical has a high water solubility. (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

The notifier applied variation of schedule requirements for toxicological data. The following data were summarised from the database HSDB (2000) reporting on a structurally related compound.

The full test reports were not provided for assessment. Therefore results and details on test guidelines were unable to be verified.

9.1 Acute Toxicity

Table 9.1 Acute oral, dermal and inhalation toxicity of the analogue (HSDB, 2000).

Species	Route	LC50/LD50
Mouse	Oral	615 mg/kg bw
Rat	Oral	600 mg/kg bw
Rat, male	Oral	673 mg/kg bw
Rat, female	Oral	566 mg/kg bw
Rat, male	Oral	909 mg/kg bw
Rat, male	Inhalation (3 hr)	1900 mg/m^3
Rabbit	Dermal	>10 g/kg bw

In an acute oral toxicity study, mortalities were not reported at any dose level of the 10% suspension of the test substance. With 50% suspension, mortality was observed in 4 rats within 14 days post dosing at 1000 and 2150 mg/kg. Clinical observations at these high doses included depressed righting and placement reflexes, absence of pain, shallow respiration, followed by death. Gross necropsy revealed paled extremities, slight to moderate congestion of lungs, kidneys and adrenals, and slight irritation of the small intestines. In another study, although no mortality was observed, test animals were reported with moderate weakness, prostration, cyanosis, rapid breathing and slight twitching (gross necropsy not reported) (HSDB, 2000).

The acute inhalation toxicity (3 hours) was evaluated in 5 groups of 10 male Sprague-Dawley rats. Mortalities were observed at all concentration levels ranging from 0.78 - 2.71 mg/L with LC50 being 1900 mg/m^3. Clinical observations included deep abdominal breathing with open mouth gasping. Gross necropsy revealed a severe accumulation of white frothy fluid in the trachea and a moderate to severe incidence of dark red haemorrhagic areas in the lungs (HSDB, 2000).

The acute dermal toxicity was evaluated in 4 groups of 4 albino rabbits (sex and strain not specified) receiving a single application of the test substance onto intact and abraded abdominal skin areas for 24 hours. No mortalities were observed. Clinical observations included mild to spotted erythema and desquamation in all animals. A purulent nasal discharge appeared randomly. Gross necropsy revealed congested kidneys in 4 animals, cystic kidneys in 1 animal, and depleted body fat stores in 2 rabbits (HSDB, 2000).

9.2 Skin Irritation

A 50% solution of test substance in ethanol was found to be mildly irritating to the skin of guinea pigs (HSDB, 2000).

Four male and female New Zealand albino rabbits were administered occlusively with 1 g of powered test substance moistened with distilled water to a 4" x 4" shaved dermal area. Signs of irritation were evaluated using a modified Draize method after removal of the patches 3 days later, and again at 11 and 26 days post-treatment. No sign of skin irritation was noted at any time on any of the four animals (HSDB, 2000).

9.3 Eye Irritation

The analogue as a dry powder (0.1 mL) is severely irritating to the unwashed rabbit eye while prompt water washing after treatment reduces irritation considerably (HSDB, 2000).

One eye of six adult rabbit (New Zealand albino) was treated with a single corneal surface application of test substance moistened with 0.2 mL distilled water. The test material was removed 5 minutes later with a copious wash of sterile physiological saline. Combined injury to cornea, iris and conjunctivae was assessed according to the method of Draize. A maximal mean irritation score (81.0) in 4 rabbits was recorded at 24 hours post treatment. Signs of irritation resolved somewhat by day 26, with a mean irritation score of 31.0 being observed. Corneal injury had worsen at the final 26th day observation with a mean corneal irritation score of 3.5, the maximal score recorded during the study. These scores were increased over those for controls (salt, sand and sucrose) due to mechanical instillation. Instillation of control substances resulted in transient conjunctivitis with no signs of corneal irritation in any treated animal (HSDB, 2000).

9.4 Skin Sensitisation

The analogue was not a sensitiser in guinea pigs when tested (details not stated) at concentrations up to 50% in ethanol (HSDB, 2000).

The test substance was evaluated for dermal sensitisation using the optimisation test. Pirbright white guinea pigs (10/sex/group) were administered 10 consecutive 0.1 mL intracutaneous injections of 0.1% test substance in saline or vehicle alone (negative control group). Induction was initiated on Day 1 with an intracutaneous injection both into the shaved flank and into the back, followed by a single injection into the back every other day, excluding weekends. After a 14-day resting period, challenge with 0.1 mL intracutaneous injections of 0.1% in saline failed to cause sensitisation. Injection sites were inspected 24 hours after induction and challenge. No significant (exact Fisher's test, $p>0.01$) increase in the number of positive reactions was noted among inducted guinea pigs (3/20 positive reactions) relative to controls (2/20 positive reactions). A second challenge, consisting of a subirritant epicutaneous application (30% in vaseline) under occlusive wrap for 24 hours, followed the first challenge by 10 days. Reactions (based on the Draize irritation index) to epicutaneous challenge, evaluated 24 hours later, also failed to demonstrate sensitisation in inducted animals (0/20 positive reactions) (HSDB, 2000)

9.5 Repeat Dose Toxicity

The subchronic toxicity of test substance was evaluated in Sprague-Dawley albino rats (5/sex/group) after intraperitoneal injections of 0 and 150 mg/kg bw in solution (75% propylene glycol and 25% distilled water) for 5 days. After the final treatment all animals were sacrificed for determination of iron and copper levels in whole blood (3 mL/animal) and the liver (1 g/animal). No mortality was reported. While a slight depression in bodyweight gain was treatment-related, gross appearance and behaviour, haematological values and iron and copper levels in blood and liver were comparable to controls. A slight increase in relative liver weight in males was due to slight reductions in bodyweight gains relative to controls. Relative liver weights in females were within historical limits (HSDB, 2000).

Mortality rates were also not reported in groups of 5 male rats (strain not stated) fed test substance in the diet at doses of 0, 103 and 978 mg/kg bw/day for 13 days. Feed consumption and body weight gain were normal in low-dose rats, but decreased in high-dose animals. The only clinical effect of treatment was a small amount of hair loss observed in two high-dose rats. Haematological and chemistry parameters were comparable in treated and control rats. Relative kidney and liver weights were not affected by the treatment. Levels of aspartate aminotransferase and lactate dehydrogenase were elevated in one high-dose rat, but were normal in all other rats. There were no abnormal gross or histological changes observed in treated rats (HSDB, 2000).

9.6 Genotoxicity - Bacteria

The mutagenic potential of test substance was investigated in histidine-auxotrophic mutants of *Salmonella typhimurium* (TA 100, TA 1535, TA 1537 and TA 1538), both with and without metabolic activation by Chinese hamster S9 fraction liver microsomes and co-factors (Ames Test). The bacteria strains (0.1 mL), with or without microsomal activation, were cultured with test substance at concentrations of 444, 667, 1000, 1500 and 2250 µg and acetone/0.1 mL and in a repeat study with 500, 1000, 2000, 4000 and 8000 µg and acetone/0.1 mL per plate. Control cultures were exposed to 0.1 mL acetone both in the presence and absence of metabolic activation. Slight increases in back-mutant colonies of strain TA 1535 were found associated with concentrations of 1000 and 1500 µg (without metabolic activation). Cytotoxicity was indicated by the reduction of histidine-prototrophic mutants of strains TA 100, TA 1535 and TA 1537 at concentrations of 4000 and 8000 µg due to an inhibitory effect on bacterial growth. These deviations from controls suggest a minor mutagenic potential of the test substance (HSDB, 2000).

9.7 Carcinogenicity

In a controlled bioassay study, groups of 50 animals of each sex were administered in feed the analogue at one of two time weighted average doses: Fischer 344 rats with either 6700 or 12100 ppm for 78 weeks, and B6C3F1 mice with either 11700 or 23500 ppm for 104 weeks. Rats were observed for 104-106 weeks, mice for 106-109 weeks and all surviving animals were then sacrificed. It was recorded that there was an increased incidence of brain tumours in Fischer 344 rats and an increased incidence of alveolar/bronchiolar carcinomas in female B6C3F1 mice, suggesting a possible carcinogenic effect of test substance. However, it was concluded that there

was no convincing evidence that under the conditions of this bioassay that the test substance was carcinogenic. A NOAEL/NOEL was not reported (HSDB, 2000).

9.8 Summary of Toxicological Investigations

Endpoint & Result	*Assessment Conclusion*
Rat/mouse, acute oral LD50 = 566-909 mg/kg bw	Harmful
Rabbit, acute dermal LD50 >10 g/kg bw	Low toxicity
Rat, acute inhalation LC50 = 1.91 mg/L/3 hr	Toxic
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Irritating
Guinea pig, skin sensitisation - Adjuvant test	No evidence of sensitisation
Repeat Dose Toxicity	NOEL not established
Genotoxicity - bacterial reverse mutation	Potential of mutagenic
Carcinogenicity – in vitro	Non Carcinogenic
Carcinogenicity – in vivo	Non Carcinogenic

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Full test reports on the ecotoxicity studies of the related compound were provided by the notifier.

Test	*Species*	*Results*
96 h Acute Toxicity	Bluegill sunfish	LC_{50} = 191.2 mg/L
	Lepomis macrochirus	NOEC = 56.0 mg/L
96 h Acute Toxicity	Rainbow trout	LC_{50} = 23.7 mg/L
	Oncorhynchus mykiss	NOEC = 10.0 mg/L
21 d Chronic Toxicity	Daphnia magna	LC_{50} = 5.8 mg/L
		RI_{50} = 2.1 mg/L

NOEC - no observable effect concentration; RI_{50} – Concentration needed to reduce cumulative reproduction by 50%.

The test on Bluegill sunfish (UCES, 1979a) was performed using a static methodology. Observations were performed at 24, 48, 72 and 96 hours. The test was performed using ten specimen fish per test concentration at a temperature of 21°C. The tests were conducted using nominal concentrations of 32, 56, 100, 180 and 320 mg/L. The results of the definitive study showed that no mortalities or sublethal effects were observed in the test vessels containing less than 56 mg/L of the notified chemical. After 96 h, 50 and 80% mortality was observed at 100 and 320 mg/L, while sublethal effects such as irritation, and slowed respiration were exhibited at 100, 180 and 320 mg/L of the notified chemical. The 96-hour LC_{50} for the structural analogue of the notified chemical to *Brachydanio rerio* is 191.2 mg/L, while the no observed effect concentration is 56 mg/L.

The test on Rainbow Trout (UCES, 1979b) was performed using a static methodology. Observations were performed at 24, 48, 72 and 96 hours. The test was performed using ten specimen fish per test concentration at a temperature of 12°C. The tests were conducted using nominal concentrations of 5.6, 10, 18, 32 and 56 mg/L. The results of the definitive study showed that no mortalities or sublethal effects were observed in the test vessels containing less than 10 mg/L of the notified chemical. After 96 h, 100% mortality was observed at both 32 and 56 mg/L, while sublethal effects such as irritation, surfacing, varidiscolouration and laboured respiration were exhibited at 18 and 32 mg/L of the notified chemical. The 96-hour LC_{50} for the structural analogue of the notified chemical to *Oncorhynchus mykiss* is 23.7 mg/L, while the no observed effect concentration is 10 mg/L.

The immobilisation and reproduction tests with *Daphnia* (UCES, 1979c) were performed under flow through conditions with observations performed at 1, 2, 3, 4, 7, 9, 11, 14, 16, 18 and 21 days. The test was performed using 15 daphnids per flask at a temperature of 20°C. The tests were conducted using measured concentrations of 1.8, 4.4, 10.9, 19.7 and 42.5 mg/L. After 21 days, 13, 35, 35, 80, 86 and 93% immobilisation was exhibited at 0, 1.8, 4.4, 10.9, 19.7 and 42.5 mg/L, respectively. The 21 day EC_{50} for the structural analogue of the notified chemical to *Daphnia magna* is 5.8 mg/L (CI = 1.8-12.0 mg/L). The effect of the chemical on Daphnid reproduction was also examined over a 21-day period using measured concentrations of test substance of 1.8, 4.4, 10.9, 19.7 and 42.5 mg/L. After 21 days, mean brood size exhibited at 0, 1.8, 4.4, 10.9, 19.7 and 42.5 mg/L was 16, 3, 3, 0, 0 and 0, respectively. The 21 day RI_{50} for the structural analogue of the notified chemical to *Daphnia magna* is 2.1 mg/L (CI = 1.2-3.6 mg/L).

The ecotoxicity data indicates the notified chemical is likely to be practically non-toxic to slightly toxic to fish and daphnia. Furthermore, exposure of Daphnia to the structural analogue of the notified chemical also resulted in significant reductions in their capacity to reproduce.

The notifier has provided a result for the ecotoxicity of the notified chemical to green algae but has not submitted the test report. The 72 h EC_{50} for *Selenastrum capricornutum* is 231 mg/L as found on the MSDS. As no test report has been provided for algae, a PNEC has been calculated by applying a safety factor of 10 to the lower confidence limit for the LC_{50} for Daphnia (1.2 mg/L). Therefore, the predicted no effect concentration (PNEC) for the aquatic compartment is 0.12 mg/L.

As indicated in the MSDS for the parent compound of the notified chemical, a respiration inhibition test with activated sludge conducted in accordance with OECD TG 209 gave an EC_{50} of 1060 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The intended use pattern of the notified chemical is expected to result in the majority of the chemical being eventually released to the environment. However, this will be in dilute manner as the notified chemical contained within the water treatment solution released from cooling towers will be at a low concentration. The company expects further dilution as well as adsorption will occur at treatment plants. Discharge from the on-site treatment sites is expected to contain the notified chemical at a concentration of <0.06 ppm. Subsequent treatment at local sewage treatment plants would further dilute and remove the notified chemical to very low concentration levels. If the notified chemical is used at other sites that do not have on-site treatment plants then environmental exposure is still expected to be low since the chemical is only expected to be used at a maximum concentration of 2 ppm.

Furthermore, the ecotoxicity data provided indicates the notified chemical is likely to be practically non-toxic to slightly toxic to fish and slightly toxic to daphnia and low toxicity to algae is likely. As a worst case, daphnia are expected to be the most sensitive species with a PNEC of 0.12 mg/L.

In a worst case based on maximum annual imports of 40 tonnes/annum, all of which is released to sewer and assuming that none is removed during sewage treatment processes, assuming a national population of 19,000,000 and that each person contributes an average 150 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 38 µg/L.

Amount of entering sewer annually	40000 kg
Population of Australia	19 million
Amount of water used per person per day	150 L
Number of days in a year	365
Estimated PEC	38 µg/L (38 ppb)

When released to receiving waters the concentration is generally understood to be reduced by a further factor of at least 10, and so the Predicted Environmental Concentration (PEC) is around 3.8 µg/L. If the notified chemical were to be used in one major capital city, such as Sydney (pop. 3500000), the PEC in the receiving waters would be 20.8 µg/L.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 0.03 and use in one major capital city, is 0.17. These values are significantly less than 1, indicating no immediate concern to the aquatic compartment.

No ecotoxicological data was provided for terrestrial organisms.

Wastes containing the notified chemical including residues from imported drums, from formulation and sludge will be disposed of in landfill and are expected to be immobile. Even though the notified chemical is soluble in water, it will be slowly adsorbed to soil and sediment.

Therefore, the environmental exposure and overall environmental hazard from the notified chemical is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

12.1. Hazard Assessment

The toxicological data for the notified chemical Nalco 73199 are not available. The toxicological data of a chemical analogue are presented and is based on a summary of peer reviewed articles. It is apparent from these sources that the analogue is harmful on ingestion (LD50 = 566-909mg/kg bw) and inhalation (LC50, 3 hr = 1.91 mg/L). It has a low dermal toxicity in rabbits. It is an eye irritant but not a skin irritant in the rabbit. There is no evidence of sensitisation in guinea pig (adjuvant test). The analogue was shown to have mutagenic potential in bacteria.

On the basis of the available data, the analogue, and by analogy the notified chemical, is determined to be hazardous according to the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 1999b). It is classified as Harmful (Xn) and Irritant (Xi):

- Risk phrases: R20/22 – Harmful by inhalation and if swallowed, R36 – Irritating to eyes
- Safety phrases: S25 – Avoid contact with eyes, S26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice, S39 – Wear eye/face protection.

12.2. Occupational Health and Safety

Transport and storage workers will only be exposed to the notified chemical in the event of an accident or damage to packaging. Therefore, the occupational health risk posed by the chemical to this group of workers is considered negligible.

Repackaging/reformulation workers are expected to wear overalls, chemical resistant gloves and splash goggles when handling the chemical solution (containing <50% notified chemical) and cleaning equipment. Decanting of the solution into the blending vessel or alternate containers will take place in a well-ventilated area and via an automatic pumping system. In addition, the vessel is designed so that any fumes and vapours generated will be removed through ventilation. Workers may experience dermal exposure through drips, spills and splashes. Considering the engineering controls and personal protective equipment (PPE), direct exposure (via any routes) is unlikely. The risk of adverse health effects is determined to be low.

QC chemists may come into contact with the notified chemical through drips, spills and splashes when sampling and analysing the chemical. They will wear laboratory coats, gloves and safety glasses. Given the training they receive, the anticipated low exposure to the notified chemical and PPE worn, the risk of adverse health effects is determined to be low.

At the user sites, sales representatives and site operators will be potentially more frequently exposed to the notified chemical than other worker categories, predominantly via the dermal route. It is recommended they wear adequate PPE including overalls, chemical resistant gloves and chemical splash goggles. Based on the expected low dermal toxicity and irritation of the chemical, the implementation of safe work practice and appropriate PPE, a significant health risk is not anticipated.

12.3. Public Health

The importation, preparation and use of the notified chemical are not activities in which the public will be involved. Contact is likely to be limited to transport or industrial accidents. The most likely contact will be dermal. On the basis of the above information and the low toxicity of the notified chemical, it is considered that the notified chemical will not pose a significant risk to public health when used as proposed.

13. RECOMMENDATIONS

REGULATORY CONTROLS

- The NOHSC Chemicals Standards Sub-committee should consider the following hazard classification and labelling for the notified chemical:

  The notified chemical is determined to be hazardous and classified as Harmful (Xn) and Irritant (Xi) with the labelling details as follows:
  - Risk phrases: R20/22 – Harmful by inhalation and if swallowed, R36 – Irritating to eyes
  - Safety phrases: S25 – Avoid contact with eyes, S26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice, S39 – Wear eye/face protection.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Automatic pumping equipment
  - Well ventilated areas for product packaging/reformulation

- Employers should implement the following safe work practices to minimise occupational exposure to the notified chemical:
  - Adequate induction and training programs for workers handling the notified chemical

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Overalls/laboratory coats,
  - Chemical splash goggles; and
  - Chemical resistant gloves (where appropriate).

  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/release of the notified chemical should be should be contained as described in the MSDS (ie soak up with absorbent material and transfer to a sealable, properly labelled waste container) and the resulting waste is disposed of in landfill.

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product containing <50% notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REFERENCES

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NOHSC (1999a) List of Designated Hazardous Substances [NOHSC:10005(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (1999b) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

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UCES (1979b) Acute toxicity of Cobratec TT 50S to the rainbow trout *Salmo gairdneri* (Project No 11507-17-01). Union Carbide Environmental Services, Tarrytown, New York. (Unpublished report submitted by Nalco).

UCES (1979c) *Daphnia magna* Chronic study testing for Cobratec TT 50S (Project No 11507-16. Union Carbide Environmental Services, Tarrytown, New York. (Unpublished report submitted by Nalco).