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19 April 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

PROSOFT TQ 1003 and REZOSOL 1095

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Director
Chemicals Notification and Assessment

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PROSOFT TQ 1003 and REZOSOL 1095

1. APPLICANTS AND DETAILS OF SECONDARY NOTIFICATION

Assessment of Prosoft TQ 1003 was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the IC(NA) Act), as NA/956, with the Summary Report of the assessment published in the *Chemical Gazette* of 5 February 2002.

In March 2003, the Director of NICNAS was informed of changes to the certificate holder, product name and formulation, import volume, and use pattern. Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical known as Prosoft TQ 1003.

In accordance with Section 65 of the IC(NA) Act, a notice requiring the secondary notification of Prosoft TQ 1003 was published in the *Chemical Gazette.* The notice of 6 May 2003 stipulated the following data were required to undertake further assessment of Prosoft TQ 1003:

Part A Summary of Notification
- 2. Summary of Health and Environmental Effects

Part B Identity, Properties and Uses
- 3. Use
- 5. Manufacture/Import Volume
- 6. Occupational Health and safety
- 7. Environmental Impact
- 8. Public Health
- 9. Physical and Chemical Data
- 11. Label
- 12. MSDS
- 13. Emergency procedures

Part C Toxicity
- Acute Toxicity
- Ecotoxicity
- Biodegradation

Hercules Chemical Solutions Pte Ltd of 1612-1638 Centre Road SPRINGVALE VIC 3207 has complied with this requirement.

This report, SN/11, represents the revised assessment for Prosoft TQ 1003 and Rezosol 1095. New information submitted by the applicants and considered in this secondary notification assessment are located in this report at Sections:

2. Identity of the chemical
3. Physical and chemical properties
4. Purity of the chemical
5. Use, volume and formulation
6. Occupational exposure
8. Environmental exposure
10. Assessment of environmental effects
11. Assessment of environmental hazard
12. Assessment of public and occupational health and safety effects
13. Recommendations
15. References

2. IDENTITY OF THE CHEMICAL

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

Marketing Name:	Prosoft TQ 1003 Rezosol 1095
Method of Detection and Determination:	A copy of a ^{13}C NMR spectrum which serves to characterise the new chemical was included in the original notification dossier for this chemical.

3. PHYSICAL AND CHEMICAL PROPERTIES

The data listed below pertain to the commercial products Prosoft TQ 1003 and Rezosol 1095.

Appearance at 20°C & 101.3 kPa:	Yellow viscous liquid
Boiling Point:	> 90°C (with some decomposition)
Specific Gravity:	1.00 (from MSDS)
Vapour Pressure:	Not determined. See comments below.
Water Solubility:	Not determined. See comments below.
Partition Co-efficient (n-octanol/water):	Not determined due to likely surfactant properties.
Hydrolysis as a Function of pH:	Not determined. Chemical is expected to be stable to hydrolytic degradation in the environmental pH region where 4<pH<9. See further comments below.
Adsorption/Desorption:	Not determined due to likely surfactant properties.

Dissociation Constant:	Not determined. See comments below.
Flash Point:	Not applicable as the chemical is a non-flammable solid. >93°C (close cup method, from MSDS)
Flammability Limits:	Not flammable
Autoignition Temperature:	Not determined
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable
Viscosity:	1120 cps at 21°C (from MSDS)
pH:	4.7 (1% emulsion, from MSDS)

3.1 Comments on Physico-Chemical Properties

The notified chemical is a high molecular weight organic salt, and is therefore expected to have very low vapour pressure.

The company stated that the chemical is completely miscible with water. The compound contains large hydrocarbon moieties linked to a polar head group. Accordingly, the chemical nature is such that it would very likely have powerful surfactant properties, and while such compounds have low true water solubility, their effective assimilation into the aqueous phase can be very high due to formation of colloidal aggregates called micelles (Tanford, 1991).

No partition coefficient data were provided due to the expected surfactant properties of the chemical. However, the cationic charge indicates that the chemical would have little affinity for the oil phase.

No data on hydrolytic degradation of the chemical were provided, but the amide linkages are expected to be stable under ambient environmental pH conditions (4<pH<9).

No data on adsorption/desorption from soils were provided. However, the positive charge indicates that it would have affinity through electrostatic interactions for humic material in soils that contains a high content of (anionic) carboxylic acid residues. Once the compound has become associated with the organic component of soils and sediments, it would be unlikely to be re-mobilised.

No dissociation data were provided, but the functional groups are not expected to be basic.

4. PURITY OF THE CHEMICAL

Degree of Purity: 71-80.3%

Additives for Prosoft TQ 1003:

Chemical name: Hydrogen peroxide
CAS No.: 7722-84-1
Weight percentage: < 1%

Chemical name: Polyethyleneglycol
CAS No.: 25322-68-3
Weight percentage: 17%

Additives for Rezosol 1095:

Chemical name: Poly(oxy-1,2-ethanediyl), a-hydro-w-hydroxy-
CAS No.: 25322-68-3
Weight percentage: 15.4

Chemical name: Alcohols, C12-C14-secondary, ethoxylated
CAS No.: 84133-50-6
Weight percentage: 4.3

5. USE, VOLUME AND FORMULATION

Both Prosoft TQ 1003 and Rezosol 1095 containing the notified chemical will be imported in 1000 L ISO tanks and will be sold to Kimberley Clark in Mount Gambier, SA and to other potential customers, where it will be used as a production aid in the manufacture of soft tissue paper (at 0.2%). Specifically, the chemical is used to promote softness in the paper tissue.

Up to 200 tonnes of the chemical will be imported each year (100 tonnes as Prosoft TQ1003 and 100 tonnes as Rezosol 1095). The percentages of active in the products Prosoft TQ 1003 and Rezosol 1095 are 75% and 80.3%, respectively. The notified chemical is mainly used at a single paper manufacturing facility, and a volume of 40 tonnes would be sold to other potential users.

Information from a flow sheet of the paper making process provided in the original notification indicates that, at the Kimberley Clark paper manufacturing plant, the chemical is transferred as required from the ISO tanks to a 1000 L mixing tank where it is further diluted with water prior to being pumped into the process stream and mixed with the dispersion of cellulose fibres in water. The flow sheet and other information provided in the dossier indicated that each day the production process at Kimberley Clark facility uses 114 tonnes of fibre (dispersed in water) and around 228 kg of the notified chemical.

The new submission provides more specific details on the addition rates. The planned addition rate is 5.1 kg notified chemical to one tonne of the Eucalypt fibre portion of the tissue sheet. A further 0.29 kg of the chemical per tonne of total tissue will be used for fabric lubrication. The Eucalypt fibre portion is only 65% of the final tissue sheet. The aqueous fibre dispersion is then fed into the paper making machine where the pulp is subjected to a series of drying and pressing processes (Kent, 1992) to produce the finished paper.

The application of the chemical will depend on the product used. Rezosol 1095 is applied to the tissue sheet via a spray after the tissue sheet has formed. Rezosol 1095 is:

- added with other chemicals;
- diluted (at least to 100:1) with water; and
- sprayed through a spray bar onto a large drying cylinder called a yankee cylinder, with a shroud surrounding the spray system.

Most of the water in the original pulp is removed during the processing and sent to a comprehensive waste water treatment facility before being discharged to Lake Bonney or to the sewer.

6. OCCUPATIONAL EXPOSURE

Import and Transport

Import containers will not be opened prior to end-use and so the likelihood of occupational exposure of import and transport workers via accidental puncture of import containers is expected to be very low.

Paper Manufacturing

Fifteen plant operators working approximately 1-2 hours/week for 350 days/year will handle import containers of notified chemical. These operators will transfer the chemical from import containers into storage tanks via a spear/hose connected to a pump.

From storage containers, Prosoft TQ 1003 containing the notified chemical will be metered automatically into a closed 1000 L mixing tank where the chemical is mixed with paper fibres and other chemicals. Wet paper pulp containing the notified chemical will be dried and pressed automatically in enclosed plant without manual handling.

Rezosol 1095 will be mixed with other chemicals in the paper manufacturing facilities. The mixture will then be diluted and sprayed through a spraybar onto a large drying cylinder. At the workshop, a shroud surrounds the spray system.

Exposure, mainly dermal but also possibly ocular may occur from slops and spills during the removal of bungs and manipulation of spear/hoses when decanting the notified chemical from import containers. Inhalation exposure may also occur during the spray process. Worker exposure will be controlled by ventilation and by personal protective equipment consisting of impervious clothing, gloves, safety glasses and respirator.

Following processing, the notified chemical will become adsorbed to cellulose fibres. Therefore, exposure of workers to the chemical during the paper manufacturing process and whilst handling dried paper is not expected.

Plant Maintenance

For 2-4 maintenance workers, exposure to the notified chemical as residual on plant may occur during routine and unscheduled maintenance. In this case, exposure is expected to occur mainly via the dermal route. Exposure will be controlled by the use of impervious clothing and gloves.

7. PUBLIC EXPOSURE

It is possible but unlikely for public exposure to the concentrated form of the notified chemical to occur following a transport accident. Contact with the highly diluted notified chemical in the environment following effluent disposal is also unlikely. The notified chemical will not be available to the public. Any contact that does occur is likely to be dermal. The use of tissue paper containing the notified chemical represents the greatest opportunity for contact with the notified chemical. It is however strongly bound to the tissue fibres and is expected to be non-transferable to the skin of the user. Therefore, the potential for public exposure to the notified chemical is assessed as minimal.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Since the notifier did not provide the exact distribution of the imported Prosoft TQ 1003 and Rezosol 1095 between the Kimberley Clark Millicent plant and other users, the average of the percentages of active present in the two products (78%) is used in all the calculations. No figures for losses of the chemical through spills or tank cleaning operations were provided, but if this is assumed to be 0.5%, then annually approximately 780 kg would be lost, and it is expected that this would be sent to the on site effluent treatment plant.

The notifier provided the results of two studies on the retention rates of the chemical on paper. A retention rate of 84% was observed in the first test when Prosoft TQ1003 was added as a debonder at an addition level of 5.1 kg/MT with bypassing the screw press step (which removes excess debonder rich water from the stock). The retention rate was higher when the screw press was not bypassed. However, the differences were not significant at 95% level. In a second study, the effects of debonder mixing time, addition rate and dilution on the retention were studied using another product with an identical imidazoline based debonder as active. The results showed that retention of 81.6% and 88% were achieved after 12 and 60 seconds of mixing, respectively, and reached a maximum of 90.1% during the following 4 minutes. The notifier indicated that the debonder will be mixed with the fibre and left for around 1.5 hours, which is adequate to maximise retention.

Therefore, if a fixation rate (of the chemical to fibre) of 84% is assumed, approximately 20 tonnes of the chemical will be lost annually from the Millicent plant and sent to a wastewater treatment plant prior to discharge to Lake Bonney. Similarly, a further 5 tonnes of the chemical is expected to be released with waste water resulting from other user activities. In the Millicent plant the released chemical remaining in the process water would be mixed with other effluent streams and treated at an on site waste water treatment facility before being discharged to Lake Bonney. The wastewater from other sites can be expected mostly to be treated onsite prior to release to the sewer system.

Most of the chemical would become associated with tissue paper (in which it is present at 0.2% w/w) and most of this would be discharged to the domestic sewer (toilet paper) or, in the case of facial tissues, placed into landfill. The flow sheet provided in the original notification dossier indicated that approximately 2/3 of the paper production is for toilet tissue and 1/3 for facial tissue, and consequently around 87 tonnes of the chemical will be disposed of to sewer each year and 44 tonnes into landfill.

8.2 Fate

No test data on biodegradation under either aerobic or anaerobic conditions were supplied, and such data would have been useful in assessing the likely persistence of the chemical once released to the environment. However, the chemical structure of the compound indicates that it does not contain groups known to be highly refractory to biodegradation, although biodegradation is likely to be a slow process. It is expected that under aerobic conditions the compound will be ultimately mineralised to water, oxides of carbon (carbonates) and oxides of nitrogen, while in anaerobic environments the primary degradation products would be methane, oxides of carbon and ammonia. The chemical has a cationic residue, and consequently is expected to interact strongly with negatively charged colloidal material in the environment. Most natural waters contain colloidal humic material which is negatively charged as a consequence of its high content of carboxylate groups, and so any notified chemical released to the water compartment will become associated with colloidal material and would eventually become assimilated into bottom sediments and would be slowly degraded in sludge and bottom sediments.

No data on bioaccumulation was included in the notification, but the high water compatibility and relatively high molecular weight indicate low potential for bioaccumulation (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data for the notified chemical were available only for skin and eye irritation and genotoxicity endpoints. Conclusions about other toxicological endpoints were drawn from data in reviews for similar quaternary ammonium compounds. No new data were provided in the secondary notification.

Summary of the toxicity of the notified chemical

Endpoint and Result	*Assessment Conclusion*
Rabbit, skin irritation	Corrosive
Rabbit, eye irritation	Corrosive
Genotoxicity – bacterial reverse mutation	Non-mutagenic
Genotoxicity – in vitro human lymphocytes	Non-clastogenic
Genotoxicity – in vitro mouse lymphocytes	Mutagenic

9.1 Acute Toxicity

9.1.1 Oral Toxicity

Oral toxicity data were not submitted for the notified chemical. However, analogue oral toxicity data were provided. No deaths were observed in a rat acute oral toxicity study of alkyl imidazoline at 20g/kg (Muller, Innis and Hakkinen, 1989). A USEPA Reregistration Eligibility Decision (RED) document (USEPA, 1995) notes alkyl imidazoline LD_{50} values for rat acute oral toxicity of 1880 - 1948mg/kg.

In a review of quaternary ammonium compounds (IPCS, 1999), a rat oral LD_{50} of 240mg/kg for benzalkonium chloride is noted (Wade and Weller, 1994). The review also notes human fatalities following oral doses of quaternary ammonium compounds of 1 – 3 g (Arena, 1964) or 100 – 400mg/kg (Ellenhorn et al, 1997).

Overall, these analogue data suggest a moderate acute oral toxicity for the notified chemical with an LD_{50} of approximately 200 - 2000mg/kg.

9.1.2 Dermal Toxicity

Dermal toxicity data were not submitted for the notified chemical. A USEPA RED document (USEPA, 1995) presents the rabbit acute dermal toxicity of alkyl imidazoline at LD_{50} > 2000mg/kg. An IPCS review lists rat dermal LD_{50} values for benzalkonium chloride of 1560mg/kg (skin) and 400mg/kg (subcutaneous).

These analogue data suggest that the notified chemical should possess a moderate acute dermal toxicity with an LD_{50} in the range 400 – 2000mg/kg.

9.1.3 Inhalation Toxicity

Inhalation toxicity data were not submitted. On the basis of observed corrosivity in skin and eye irritation studies, the notified chemical is likely to be corrosive also to lung.

9.1.4 Skin Irritation (Hoff, 2000)

Species/strain:	Rabbit, New Zealand White
Number/sex of animals:	1 male
Observation period:	72 hours
Method of administration:	0.5mL of test substance applied to shaved intact skin via a surgical gauze patch secured with semi-occlusive dressing. Exposure was conducted for 3 minutes, 1 hour and 4 hours.
Test method:	OECD TG 404

Draize scores:

Time after treatment

Exposure time	*1 hour*	*24 hours*	*48 hours*	*72 hours*
Erythema				
3 minutes	1[a]	nd	nd	nd
1 hour	2	nd	nd	nd
4 hours	2	3[p]	4[pg]	4[g]
Oedema				
3 minutes	1	nd	nd	nd
1 hour	2	nd	nd	nd
4 hours	2	3	3	3

[a] see Attachment 1 for Draize scales [p] pale areas [g] gray areas [nd] not determined

Comment: Body weight changes were normal and no abnormal systemic signs were noted during the observation period.

Result: The notified chemical was corrosive to the skin of rabbits.

9.1.5 Eye Irritation (Cerven, 2000)

Species/strain: Rabbit, New Zealand White

Number/sex of animals: 1 male

Observation period: 48 hours

Method of administration: 0.1 mL of test substance instilled into the conjunctival sac of one eye; the contralateral eye served as an untreated control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation								
Animal	***1 hour***			***24 hours***			***48 hours***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***
	2[1]		1	3		1	nd		nd
Iris									
		0			1			nd	
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
	2	3	3	2	4	3	nd	4	3[cw, dw]

[1] see Attachment 1 for Draize scales

o = opacity a = area r = redness c = chemosis d = discharge

[cw] conjunctiva white and discharge [dw] white discharge [nd] unable to be determined due to chemosis

Comment: No abnormal systemic signs were observed during the observation period. The study was terminated following the 48 hour observation due to the severity of the responses.

Result: The notified chemical was corrosive to the eyes of rabbits.

9.1.6 Skin Sensitisation

Skin sensitisation data for the notified chemical were not submitted. In the IPCS review (IPCS, 1999), dermal sensitisation (Fisher and Stillman, 1972) and respiratory sensitisation (Bernstein et al, 1994) are reported after prolonged occupational contact with the quaternary ammonium compound benzalkonium chloride. In this review, cases of bronchoconstriction also are reported from nebulised benzalkonium chloride as a preservative in corticosteroid preparations (Beasley et al, 1986, 1987, 1998). On the basis of this analogue data, the notified chemical is likely to be both a skin and respiratory sensitiser.

9.2 Repeated Dose Toxicity

No repeat dose toxicity data for the notified chemical were submitted. A 91-day oral toxicity study of ditallow imidazoline in rats established a No Observed Effect Level (NOEL) of 120mg/kg/day, based on decreased body weight gain (Muller, Innis and Hakkinen, 1989). In a corresponding dermal study in rabbits by the same authors, the NOEL was 200mg/kg/day, also based on decreased body weight gain.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Callander, 2000)

Strains: *Salmonella typhimurium* TA1535, 1537, 98, 100; *Escherichia coli* WP2P uvrA

Metabolic activation: Phenobarbital- and β-naphthoflavone-induced rat liver homogenate, S9 fraction

Concentration range: 100, 200, 500, 1000, 2500, 5000 μg/plate for phase 1;
20, 50, 100, 200, 500, 1000 μg/plate for phase 2 and phase 3 (+S9)
10, 20, 50, 100, 200, 500 μg/plate for phase 3 (-S9)

Test method: OECD TG 471, 472

Comment: Positive controls behaved accordingly. No significant increases

in the number of revertant colonies were observed for any strain.

Result: The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in Human Lymphocytes (Fox, 2000)

Cells: Human peripheral blood lymphocytes

Metabolic activation system: Phenobarbital- and β-naphthoflavone-induced rat liver homogenate, S9 fraction

Dosing schedule:

Metabolic Activation	Experiment Number	Test concentration (μg/mL)	Controls
-S9	1	treatment time = 3 hours harvest time = 20 hours 1 - 100μg/mL	Positive: Mitomycin C
	2	treatment time = 3 hours harvest time = 20 hours 0.5 - 50μg/mL	Negative: Polyethylene glycol 400
+S9	1	treatment time = 3 hours harvest time = 20 hours 1 - 100μg/mL	Positive: Cyclophosphamide
	2	treatment time = 20 hours harvest time = 20 hours 0.5 - 50μg/mL	Negative: Polyethylene glycol 400

EMS - ethyl methanesulphonate
CP - cyclophosphamide
DMSO – dimethylsulphoxide

Test method: OECD TG 473

Comment: Positive controls behaved accordingly. Mitotic activity was decreased markedly at test substance concentrations > 25μg/mL. No statistically significant increases in percentages of aberrant cells above solvent control values were recorded for the test substance either in the presence or absence of metabolic activation.

Result: The notified chemical was non clastogenic under the conditions of the test.

9.3.3 L5178Y $TK^{+/-}$ Mouse Lymphoma Mutation Assay (Clay, 2000)

Cells: L5178Y $TK^{+/-}$ mouse lymphoma cells

Metabolic activation system: Phenobarbital- and β-naphthoflavone-induced rat liver homogenate, S9 fraction

Dosing schedule:

Metabolic Activation	***Experiment Number***	***Test concentration (μg/mL)***	***Controls***
-S9	1	test concentrations = 3.1, 6.3, 12.5, 25, 50, 100μg/mL treatment time = 4 hours expression time = 2 days selection time = 10-13 days	Positive: EMS
	2	test concentrations = 0.8, 1.6, 3.1, 6.3, 12.5μg/mL treatment time = 4 hours expression time = 2 days selection time = 10-13 days	Negative: Polyethylene glycol 400
	3	test concentrations = 0.1, 0.2, 0.5, 1, 2, 4, 6, 8, 10, 20, 30μg/mL treatment time = 4 hours expression time = 2 days selection time = 10-13 days	
+S9	1	test concentrations = 3.1, 6.3, 12.5, 25, 50, 100μg/mL treatment time = 4 hours expression time = 2 days selection time = 10-13 days	Positive: Benzo[a]pyrene
	2	test concentrations = 1.6, 3.1, 6.3, 12.5, 25μg/mL treatment time = 4 hours expression time = 2 days selection time = 10-13 days	Negative: Polyethylene glycol 400
	3	test concentrations = 1, 2, 4, 6, 8, 10, 15, 20, 25, 30, 40μg/mL treatment time = 4 hours expression time = 2 days selection time = 10-13 days	

EMS - ethyl methanesulphonate
CP - cyclophosphamide
DMSO – dimethylsulphoxide

Test method: OECD TG 476

Comment: In the first experiment, toxicity was observed at 50 and 6.3 μg/mL, with and without metabolic activation and so lower

	concentrations were used in the other two experiments. Similarly, toxicity was observed at the higher concentrations in these tests. Statistically significant increases in mutant frequency, compared to control cultures were observed in cultures treated with the test substance in all experiments in both the presence and absence of metabolic activation. Positive controls behaved accordingly.
Result:	The notified chemical was mutagenic under the conditions of the test.

9.4 Developmental Toxicity (USEPA, 1995)

No developmental toxicity data for the notified chemical were submitted. However, analogue developmental toxicity data were provided for alkyl imidazoline in a USEPA RED document (USEPA, 1995). Pregnant Sprague-Dawley derived CD rats were administered alkyl imidazoline in corn oil by gavage during gestation days 6 – 15 at doses of 0, 15, 65 or 100mg/kg/day. Based on excessive salivation and/or staining of the skin/fur in the anogenital area, a maternal toxicity LOEL of 15mg/kg/day and NOEL of < 15mg/kg/day were assigned.

Alkyl imidazoline has no effect on any developmental toxicity parameters examined and no developmental effects attributable to treatment were observed. On this basis, a developmental toxicity NOEL of ≥ 100mg/kg/day and LOEL of > 100mg/kg/day were assigned.

9.5 Overall Assessment of Toxicological Data

No data for oral and dermal toxicity were provided for the notified chemical. On the basis of analogue data for quaternary ammonium compounds, the notified chemical should possess moderate acute oral and dermal toxicity.

Skin and eye irritation studies in rabbits revealed that the notified chemical was corrosive in both tests. Although inhalation toxicity data were not provided for the notified chemical, a similar corrosive effect would be expected with lung tissue.

Skin sensitisation data for the notified chemical were not provided. However, several cases of skin and respiratory sensitisation in humans are reported for similar quaternary ammonium compounds.

No repeat dose toxicity data were provided for the notified chemical. A 91-day oral study of an analogue established a NOEL of 120mg/kg/day, based on decreased body weight gain. In a corresponding dermal study in rabbits by the same authors, the NOEL was 200mg/kg/day, also based on decreased body weight gain.

No developmental toxicity data were provided for the notified chemical. However, in an analogue study of alkyl imidazoline, no developmental effects attributable to treatment were observed. On this basis, a developmental toxicity NOEL of ≥ 100mg/kg/day and LOEL of >

100mg/kg/day were assigned.

Three in vitro genotoxicity assays were submitted for the notified chemical. In a bacterial reverse mutation assay, the notified chemical was non-mutagenic. In contrast, mutagenicity was observed in a mouse lymphoma mutation assay. In a human lymphocyte chromosome aberration assay the notified chemical was shown to be non-clastogenic. Data are insufficient for the notified chemical to attract a genotoxic classification.

On the basis of the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999), the notified chemical should be classified Harmful (Xn) and Corrosive (C) with the risk phrases R20/21/22 – Harmful by Inhalation, in Contact with Skin and if Swallowed, R34 – Causes Burns and R42/43 – May Cause Sensitisation by Inhalation and Skin Contact.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

In the original notification, test reports on the toxicity of the notified chemical to two species of fish, and *Daphnia* were available. The notifier provided a test report on algal toxicity with the secondary notification. The tests were conducted in accordance with accepted US EPA or OECD test protocols. No data were supplied for the toxicity of the chemical against sewage bacteria.

Test	Species	Results
Acute toxicity to fish EPA/600/4-90/027F	Rainbow trout ONCORHYNCHUS MYKISS	96 h LC_{50} = 2.2 mg/L NOEC* = 1.3 mg/L
Acute toxicity to fish EPA/600/4-90/027F	Fathead minnow PIMEPHALES PROMELAS	96 h LC_{50} = 0.93 mg/L NOEC <0.63 mg/L
Acute toxicity to *Daphnia* EPA/600/4-90/027F	DAPHNIA MAGNA	48 h LC_{50} = 0.22 mg/L NOEC = 0.15 mg/L
Acute toxicity to algae	RAPHIDOCELIS SUBCAPITATA (*Selenestrum capricornutum* ATC22662)	48 h EC_{50} (Growth)= 1.9 mg/L (CI** 0.5 to 3.4 mg/L) 72 h EC_{50} (Growth)= 2.5 mg/L (CI** 0.5 to 3.3 mg/L)

* NOEC - no observable effect concentration
** CI – 95% Confidence interval

Fish

The test against rainbow trout (Hercules Inc., 2000a) was conducted over a 96 hour test period at 12±1ºC using a static renewal methodology. Nominal concentrations of the test substance used were 0 (control), 0.63, 1.3, 2.5, 5 and 10 mg/L, and the test was performed in duplicate using 10 juvenile fish in each test chamber, with the number of dead fish and their general condition monitored every 24 hours. After 72 hours six fish (ie 30%) in the nominally 2.5 mg/L solutions had died and as exposure increased (i.e. exposure time and concentration) mortality progressively increased till all fish had died after 24 hours exposure to the nominally 5 mg/L solution. Sublethal effects (stress) noted during the course of the test, although further details were not provided. The data were analysed using standard statistical

techniques (Spearman-Karber) to provide a (nominal) LC_{50} of 2.2 mg/L and a (nominal) No Observed Effect Concentration (NOEC) of 1.3 mg/L.

These results indicate that the chemical is toxic to this fish species (Mensink *et al*, 1995).

The test against fathead minnow (Hercules Inc., 2000b) was conducted over a 96 hour test period at 20±1ºC using a static renewal methodology. Nominal concentrations of the test substance used were the same as for the rainbow trout test ie.0 (control), 0.63, 1.3, 2.5, 5 and 10 mg/L. The test was performed in duplicate at each test concentration using 10 fish in each test chamber, with the number of dead fish and their general condition monitored every 24 hours. After 96 hours two fish (ie 10%) in the nominally 0.63 mg/L solutions had died and as exposure increased (i.e. exposure time and concentration) mortality progressively increased till all fish had died after 72 hours exposure to the nominally 2.5 mg/L solution. Sublethal effects (stress) noted during the course of the test, although further details were not provided.

The data were analysed using standard statistical techniques (Spearman-Karber) to provide a (nominal) LC_{50} of 0.93 mg/L and a (nominal) No Observed Effect Concentration (NOEC) of less than 1.3 mg/L.

These results indicate that the chemical is highly toxic to this fish species (Mensink *et al*, 1995).

Daphnia

The *Daphnia* test (Hercules, 2000c) was conducted against daphnia instars using a static method. The tests were conducted over a 48 hour test period at 20±1ºC using nominal concentrations of the test substance of 0 (control), 0.15, 0.23, 0.36, 0.55, 0.85, 1.3 and 2 mg/L. Each test was performed in duplicate using 10 *daphnia* in each test chamber with the number of dead (immobilised) animals and their general condition monitored every 24 hours. After 24 hours 5 daphnids (25%) in the nominally 0.23 mg/L solutions were immobile and as exposure increased (i.e. exposure time and concentration) immobilisation progressively increased till all were immobile (dead) after 48 hours exposure to the nominally 0.55 mg/L solution. Sublethal effects (stress) noted during the course of the test, although further details were not provided.

The data were analysed using standard statistical techniques (Spearman-Karber) to provide a (nominal) LC50 of 0.22 mg/L and a (nominal) No Observed Effect Concentration (NOEC) of 0.15 mg/L.
These results indicate that the chemical is highly toxic to this species (Mensink *et al*, 1995).

Green Algae

It is well known in the literature that as a general class, quaternary ammonium surfactants (such as the notified chemical) are usually toxic to highly toxic against these species (Nabholz *et al*, 1993). Consequently, it was expected that Prosoft TQ 1003 would exhibit high toxicity against green algae.

The algal test (Hercules, 2003) was conducted on Prosoft TQ1003 following OECD TG 201 over a 72 hour period at 24 ± 2ºC using nominal concentrations of 0, 0.08, 0.16, 0.31, 0.63, 1.3, 2.5 and 5.0 mg/L. The test was conducted in a 96-well microplate (three plates per treatment and six replicates per plate). The pH and temperature were satisfactorily

maintained. Optical density measurements taken at test initiation and at 24, 48 and 72 hours were converted to cell densities using a conversion factor.

The inoculum from an exponentially growing culture was introduced to make the initial cell density of test solutions about 10,660 cells. The concentrations that inhibited growth by 50 % relative to the controls and the 95% confidence limits were derived using the ICPIN Program and the NOEC values were calculated using the Toxstat version 3.4. The EC50 values at 48 and 72 hours were 1.9 and 2.5 mg/L, respectively. The NOEC at both 48 and 72 hours was 0.63 mg/L.

These results indicate that the chemical is moderately toxic to this species (Mensink *et al*, 1995).

Field Studies

Information originally supplied by Kimberley Clark (the major end user of the chemical) indicated that the Millicent paper making facility discharges its effluent to Lake Bonney after biological treatment in aeration ponds. Because this facility uses a variety of polymers and chemical additives in processing, some of which are known to be toxic to aquatic organisms, toxicity monitoring of the effluent discharged to Lake Bonney is undertaken each quarter. Rainbow trout and daphnia toxicity tests and a Microtox bacterial fluorescence test are included in this test regime. With the secondary notification the company submitted a summary of the effluent toxicity data and reports for samples taken between Februrary 2000 and March 2003, indicating that the effluent is not toxic[1].

The notified chemical has been used by the company from November 2000, therefore, the tests were performed using effluent containing the chemical except for 3 out of the 19 occasions. The timing of past tests, however, have not correspond well with the usage times of the chemical or the peak concentration of the chemical in the effluent treatment outflow (about 3 weeks later).

Based on several toxicity and biodegradability tests performed using a different debonder product containing the same active ingredient as in the notified product, the notifier claims that a well designed and operated biological treatment system will remove significant amounts of the chemical that may otherwise be present at toxic levels. The secondary notification provided the results of a study conducted in a lagoon system (with 2 aerated lagoons followed by 2 facultative polishing lagoons) in one of their facilities in the USA with a total retention time of 10 days and BOD inflow of about 20 to 50 mg/L. The results showed that about 69% of the cationic surfactants and about 66.7% of the non-ionic surfactants were removed after about 5 days of retention time. The removal rates in the Millicent system are expected to be better due to its higher BOD loading (about 500 mg/L) and longer residence time (about 20 days). Based on these characteristics of the Millicent lagoon system, the notifier estimates an 80% reduction of the chemical through biological removal in the combined aerobic and anaerobic processes. Therefore, a biological removal rate of 80% was used below in determining the concentration of the chemical in the effluent exiting the Millicent lagoon system.

[1] However, it should be noted that prior to 1993 the plant effluent exhibited significant toxicity, and in this year the effluent treatment plant was installed. After 1993 the effluent quality progressively improved till in 1997 the effluent exhibited no toxicity, and this situation has apparently continued.

11. ASSESSMENT OF ENVIRONMENTAL RISK

Approximately 87 tonnes of the chemical will be released to the sewer in association with used toilet paper, and assuming that the tissue is released into sewers throughout Australia and that the annual volume of sewage[2] is of the order of 1.46 x 10^{12} L, the global Predicted Environmental Concentration (PEC) of the chemical in sewage is estimated as 0.0598 mg/L. However, it is important to note that the chemical would initially be associated with the solid cellulose material in paper and is not in aqueous solution. As the cellulose fibres get broken down through biological action the chemical may be released but would then become associated with negatively charged humic material and be assimilated into sewage sludges. Periodically sludges are removed from the sewage systems by the water authorities and are usually placed into landfill.

A further 44 tonnes of chemical will be placed into landfill with used facial tissue. Based on an annual quantity of municipal solid waste of 13 million tonnes, the average concentration of the notified chemical entering landfill from the disposal of facial tissues would be approximately 3.38 ppm (44 tonnes/year × 1/13,000,000 tonnes/year).

No biodegradation data were provided in the notification, but since the chemical does not contain any functional groups which are known to be refractory to degradation, it is expected to be ultimately biodegradable. Under aerobic conditions it would be mineralised to water and oxides of carbon and nitrogen, while in anaerobic environments it would decompose to water, methane and ammonia.

The release of the notified chemcial with the greatest potential for environmental impact is the discharge of the wastewater from the pulp and paper mills including Kimberley Clark Millicent and other users of the chemical.

Kimberley Clark Millicent Plant

Assuming 84% fixation of the notified chemical to fibre, a maximum of approximately 20 tonnes will be lost annually from the paper making process and sent to a water treatment plant prior to discharge to Lake Bonney. The waste treatment plant consists of a primary clarifier and a series of three aerobic degradation ponds including a stage of extended aeration in treatment ponds. The expected low rate of biodegradation indicates that it is unlikely that much of the chemical would degrade in this plant.

The notifier expects 80% (claimed to be a conservative estimate) of the notified chemical in the wastewater to be removed by the Millicent plant's clarifiers with suspended solids and fibre. The water exiting clarifiers and fed in to the aerated lagoons will contain 4 tonnes of the chemical annually. The Millicent aerated lagoon system has a BOD inflow of about 500 mg/L and a residence time of abut 20 days. Being a cationic surfactant the notified chemical is expected to be adsorbed to the negatively charged solids in the ponds and carried to the sludge at the bottom. The sludge and its components are expected to be digested by the anaerobic processes. The exact residence time for the sludge layer is not known but estimated to be in the order of several months. The company previously indicated that waste

[2] Assuming each person in Australia produces an average of 200 L of sewage each day for 365 days per year and that the Australian population is 20,000,000, the total annual sewage volume is estimated as 1.46 x 10^{12} L.

sludge from the clarifiers is composted with bark and other materials and this would eventually be applied to land – probably forests.

The notifier estimated an 80% reduction of the chemical through biological removal due to the combined aerobic and anaerobic processes. The effluent exiting the lagoons will therefore, contain 0.8 tonnes of the chemical per annum. Assuming a daily mill effluent of 40 ML the concentration of the chemical in final treated effluent will be 0.0554 mg/L.

After treatment the effluent then passes into an 11 km drain before discharging into Lake Bonney. The flow in the drain is significant and contains little sediment. Hence, adsorption in the drain is unlikely to reach equilibrium and the adsorption rate in the drain is likely to be lower than the 50-90% assumed by the US EPA (Boethling and Nabholz 1997). Additionally it is possible that with continual discharge of the notified chemical that the adsorption sites within the drain will be exhausted, further diminishing the adsorption rate. Therefore a conservative estimate of the US EPA adsorption rates range (50%) was used. Based on this, the concentration of the notified chemical in the effluent entering Lake Bonney will be 0.0277 mg/L.

Lake Bonney is dune bound and the water level is managed in such a way as to minimise the need for marine discharge – release to the marine environment has occurred only twice in the last decade (LBMC 1996), and so it appears that the total volume of water flowing into the lake is roughly in balance with the evaporation rate. Mixing in the lake is not efficient as evidenced by the measurement of faecal coliform levels around the drain (faecal coliforms are also discharged in paper mill effluent). The concentration of bacteria decreases rapidly with distance from the drain (LBMC 1996). Consequently, for the purpose of making some estimate of the residual chemical concentration in the lake water, a dilution factor of 1:5 will be assumed, which gives a Predicted Environmental Concentrations (PEC) of approximately 0.0055 mg/L in the effluent stream and in Lake Bonney near to the drain discharge.

The notified chemical is toxic to highly toxic to fish (96 h LC50 = 2.2 mg/L for rainbow trout and 0.93 mg/L for fathead minnow), highly toxic to *Daphnia* (48 h LC50 = 0.22 mg/L) and is also moderately toxic to green algae (48 h ECr50 = 1.9 mg/L and 72 h ECr50 = 2.5 mg/L). A predicted no effect concentration (PNEC - aquatic ecosystems) of 0.0022 mg/L (2.2 µg/L) has been derived by dividing the lowest end point value of 0.22 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

The resulting risk quotient (PEC/PNEC) value of 2.5 is greater than 1 indicating a potential concern for the aquatic environment. The actual PEC and the risk quotient (RQ) values could be expected to be lower, given that the level of exposure of the notified chemical will further reduce due to adsorption to sediments in the lake. If mitigation due to removal by dissolved organic carbon (DOC) in the lake was assumed to be 50% (a worst-case) and 90% (a best-case), the RQ would be reduced to 1.25 and 0.25, respectively.

Conclusion

The calculations above indicate that the notified chemical could potentially present a risk to the aquatic environment when it is used at the Millicent plant. Further, the PECs resulting from the proposed use rates represent the concentrations entering the lake on a daily basis. The continual discharge of the notified chemical into the lake will result in a build up in the concentration of the chemical, especially as the chemical is not easily biodegradable.

Other users of the notified chemical

A worst-case scenario is considered to determine the PEC resulting from the activities of other users of the chemical. It is assumed that all of the 40 tonnes are used by one customer in a geographical location with a population equivalent to 10% of Australian population, each person contributing an average 200 L/day to overall sewage flows. A maximum of 5 tonnes will be lost (assuming a 84% retention on paper) annually during the paper making process.

If it is assumed that this paper processing plant does not have an in-house wastewater treatment facility, all of the chemical (5 tonnes) is sent to the sewer system. The daily release to receiving waters is estimated to be 14 kg/day. The predicted concentration in sewage effluent, PEC values in marine and fresh water and the respective RQ values for 3 different scenarios (based on the percentage of chemical removed at sewage treatment plants - STP) were derived and are given in the table below (Environment Australia 2003).

	Concentration in Effluent (µg/L)	***PEC in Marine Water (µg/L)***	***PEC in Fresh Water (µg/L)***	***PNEC (µg/L)***	***RQ****
All of the chemical (5 tonnes) released to the sewer with no in-house treatment					
• No removal in STP	34.1781	3.4178	34.1781	2.2	15.5
• 50% removal in STP	17.0891	1.7089	17.0891	2.2	7.8
• 80% removal in STP	6.8356	0.6836	6.8356	2.2	3.1

- RQ determined based on PEC in fresh water. PEC values for fresh and marine water are based on dilution factors of 1 and 10 respectively.

The resulting RQ values for fresh water are greater than 1 indicating a potential concern for the aquatic environment, especially when there is no removal of the chemical by in-house treatment.

However, the actual PEC and the risk quotient values in the aquatic environment could be expected to be lower, given that the level of exposure of the notified chemical would be further reduced due to:

- dispersed usage (i.e. multiple users in different locations);
- removal and degradation due to in-house wastewater treatment facilities;
- removal and degradation during sewage treatment; and
- chemical adsorbing to the colloidal humic material and sediments in receiving waters.

Therefore, the following RQ values were derived assuming that 50% of the chemical was removed during in-house wastewater treatment at the user facility and consequently 2.5 tonnes were released to the sewage system. The daily release to receiving waters is estimated to be 6.84 kg/day.

	Concentration In Effluent (µg/L)	*PEC in Marine Water (µg/L)*	*PEC in Fresh Water (µg/L)*	*PNEC (µg/L)*	*RQ**
2.5 tonnes released to the sewer following in-house treatment					
• No removal in STP	17.0891	1.7089	17.0891	2.2	7.8
• 50% removal in STP	8.5445	0.8545	8.5445	2.2	3.9
• 80% remoal in STP	3.4178	0.3418	3.4178	2.2	1.5

- RQ determined based on PEC in fresh water. PEC values for fresh and marine water are based on dilution factors of 1 and 10 respectively.

Conclusion

The assessment of risks imposed by the other customers (using 40 tonnes) shows that using the notified chemical at paper mills that do not have in-house wastewater treatment plants could pose a threat to the aquatic environment. The above worst-case predictions of PEC for fresh water are all above one indicating a potential impact on the aquatic compartment, especially if all 40 tonnes of the notified chemical are used in a single paper mill located in a regional centre and released to the sewer with no in-house treatment.

However, most natural waters contain colloidal humic material, which is negatively charged as a consequence of its high content of carboxylate groups. The notified chemical released to the water compartment would become associated with colloidal material and eventually assimilated into bottom sediments and would be unlikely to be re-mobilised. Therefore, when the sewer water containing the chemical is discharged into aquatic environment including Lake Bonney, the resulting risk quotients can be expected to be further reduced. Although only slow biodegradation is expected, some degradation through direct and indirect photolysis may also be possible. The chemical is not expected to bioaccumulate.

Based on the above risk assessment, the use of the notified chemical for the manufacture of tissue paper has the potential to pose an unacceptable risk to the aquatic life, possibly through localised impacts at Lake Bonney and other user site(s). The build up of the chemical in Lake Bonney will be mitigated to some extent by the breakdown of the chemical and the effect of natural waters. However, considering that the chemical is not easily biodegradable, the treatment plant effluent discharged into Lake Bonney should be continually monitored. Any increase in the toxicity of the effluent noticed after increasing the usage rate of the chemical should be immediately conveyed to NICNAS. The notified chemical should not be used at paper mills that do not treat the wastewater prior to releasing to the sewer. An adequate dilution of sewer effluent in the receiving waters is also essential.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY RISK

Hazard Assessment

Based on analogue data, the notified chemical should possess moderate acute oral and dermal toxicity. Irritation studies in rabbits show that the notified chemical is corrosive to skin and

eyes. Although inhalation toxicity data were not provided for the notified chemical, a similar corrosive effect would be expected in lungs.

Cases of skin and respiratory sensitisation in humans are reported for quaternary ammonium compounds analogous to the notified chemical.

No repeat dose toxicity data were provided for the notified chemical. A 91-day oral study of an analogue established a NOEL of 120 mg/kg/day, based on decreased body weight gain. In a corresponding dermal study in rabbits by the same authors, the NOEL was 200 mg/kg/day, also based on decreased body weight gain. No developmental toxicity data were provided for the notified chemical. In an analogue study of alkyl imidazoline, no developmental effects attributable to treatment were observed. On this basis, a developmental toxicity NOEL of ≥100 mg/kg/day and LOEL of > 100 mg/kg/day were assigned.

In a bacterial reverse mutation assay, the notified chemical was non-mutagenic. In contrast, mutagenicity was observed in a mouse lymphoma mutation assay. In a human lymphocyte chromosome aberration assay the notified chemical was shown to be non-clastogenic. Data are insufficient for the notified chemical to attract a genotoxic classification.

On the basis of the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999), the notified chemical should be classified Harmful (Xn) and Corrosive (C) with the risk phrases R20/21/22 – Harmful by Inhalation, in Contact with Skin and if Swallowed, R34 – Causes Burns and R42/43 – May Cause Sensitisation by Inhalation and Skin Contact.

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Acute toxicity	4 (oral)	Harmful if swallowed.
	4 (dermal)	Harmful if in contact with skin.
	4 (inhalation)	Harmful if inhalated.
Skin corrosion/ irritation	1	Causes severe skin burn and eye damage.
Serious eye damage/ eye irritation	1	Causes serious eye damage.
Respiratory sensitizer	1	May cause allergic or asthmatic symptoms or breathing difficulties in inhaled.
Skin sensitizer	1	May cause an allergic skin reaction.
Chronic hazards to the aquatic environment	1	Very toxic to aquatic life with long lasting effects

Occupational Health and Safety

The main activities during which exposure to the notified chemical may occur are decanting from import containers and routine maintenance of plant during the paper manufacturing process. Given the enclosed nature of the process, exposure downstream of the initial mixing

process is unlikely. The main routes of exposure are likely to be dermal and ocular from slops and spills. Inhalation exposure may also occur during the spray process.

The toxicity profile of the notified chemical indicates that if dermal and/or ocular exposure occurs, especially at the decanting stage where concentrated chemical is handled, severe and possibly permanent damage is likely to skin and eyes. Although the low vapour pressure indicates that vapour formation is unlikely, the notifier indicated in the secondary notification that spray technique will be used. If inhalation exposure does occur, for example from aerosols produced during manufacturing processes, the severity of effects to skin and eyes suggests that severe permanent respiratory damage would also result. Moreover, on the basis of analogue data, the notified chemical is a skin and respiratory sensitiser and so exposure via these routes may be associated with occupational sensitisation.

Although the potential for worker exposure to the notified chemical during paper tissue manufacture is restricted, the notified chemical is of concern to occupational health and safety, given the severity of its health effects.

Given the identified exposure routes and these potentially serious health impacts, personal protective equipment must be used. It is important that during handling of the notified chemical especially in imported form that skin and eye exposure be prevented by the use of impervious clothing and footwear, gloves and chemical safety goggles. In addition, given the unpredictable nature of allergic sensitisation, it is prudent that personnel such as maintenance workers also be protected from exposure to even small amounts of chemical residue such as on plant. As a minimum, these workers should also use impervious clothing/footwear and gloves.

Public Health

Public exposure to the notified chemical arising from use, waste disposal or during transport is expected to be minimal. The public will be exposed by dermal contact with tissue paper containing the notified chemical. However, the chemical is likely to be strongly bound to the fibres of the tissue paper and transfer to skin of the user is expected to be negligible. It is considered that the notified chemical will not be a significant risk to public health.

13. RECOMMENDATIONS

REGULATORY CONTROLS

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

  - R20/21/22 – Harmful by Inhalation, in Contact with Skin and if Swallowed;
  - R34 – Causes Burns;
  - R42/43 – May Cause Sensitisation by Inhalation and Skin Contact;
  - S24/25 – Avoid Contact with Skin and Eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:

  - ≥ 25%: R20/21/22, R34, R42/43
  - ≥ 10% - < 25%: R34, R42/43

– ≥ 5% - < 10%: R36/38, R42/43
– ≥ 1% - < 5%: R42/43

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:

  – Enclosure of manufacturing process as much as possible.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:

  – Avoid spillage and generation of aerosols.

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

  – Impervious clothing and footwear
  – Impervious gloves
  – Chemical goggles or faceshield
  – Respirator

  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.

Health Surveillance

- As the notified chemical is a skin and respiratory sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of occupational asthma or contact (allergic) dermatitis.

Environment

- The following monitoring should be conducted to measure environmental release during use of the notified chemical:

  – It is recommended that the quarterly sampling and biological assaying of the treated effluent in the main drain at the EPA recognised sampling plant continue

in order to monitor any potential for biological harm. If there is an increase in the toxicity of the effluent after increasing the usage rate of the chemical, this information is to be immediately conveyed to NICNAS. The timing of such monitoring should coincide with the expected peak concentration of the notified chemical in effluent.

– It is also recommended that the notified chemical should only be used at paper mills that have in-house wastewater treatment plants and which release to sewers that have adequate receiving water flows to dilute effluent by 1:10.

13.1 Secondary notification

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required.

As stated in the original assessment of this chemical, under Subsection 64(1) of the Act; if

- additional information becomes available on adverse environmental effects of this chemical;
- the method of use changes in such a way as to further increase the environmental exposure, particularly to natural waters; or
- any increase in the toxicity of effluent released to Lake Bonney after increasing the usage rates; then

a further secondary notification may be required. Given the high toxicity of this chemical to aquatic invertebrates, it would also be highly desirable for a chronic test on *Daphnia magna* to be undertaken in support of any further secondary notification.

The Director will then decide whether secondary notification is required.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 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.

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Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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