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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Prosoft TQ 1003

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Director
Chemicals Notification and Assessment

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Prosoft TQ 1003

1. APPLICANT

Betzdearborn Australia Pty Ltd of 69-77 Williamson Road, Ingleburn NSW 2565 (ABN 84 001 221 941) has submitted a standard notification statement in support of their application for an assessment certificate for Prosoft TQ 1003.

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

3. PHYSICAL AND CHEMICAL PROPERTIES

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.
Flammability Limits:	Not flammable
Autoignition Temperature:	Not determined
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable

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: 71-79%

Additives/Adjuvants:

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

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

5. USE, VOLUME AND FORMULATION

Prosoft TQ 1003 is used as a pulp additive for paper making. It will be imported in 1000L bulk containers at a rate of 72 tonnes per annum for the first 5 years and used at a single paper manufacturing facility. No reformulation will occur prior to end-use. The manufactured paper containing Prosoft will be used in the production of toilet and facial tissues (at 0.2%) with the notified chemical acting as a tissue softener.

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, the notified chemical will be metered automatically into a closed 1000L mixing tank where the chemical is mixed with paper fibres and other chemicals.

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. Due to the low vapour pressure of the notified chemical and good natural ventilation, inhalation exposure is not expected. Worker exposure will be controlled by personal protective equipment consisting of impervious clothing, gloves and safety glasses.

Wet paper pulp containing the notified chemical will be dried and pressed automatically in enclosed plant without manual handling. 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

No figures for losses of the notified chemical through spills or tank cleaning operations were provided, but if this is assumed to be 0.5%, then annually approximately 400 kg would be lost (1.1 kg/day), and it is expected that this would be sent to the on site effluent treatment plant.

However, it was also estimated that around 10% of the chemical (23 kg/day, or annually a maximum of 8.4 tonnes) would remain in the process water from the paper manufacturing stages and this would be mixed with other effluent streams and treated at an on site waste water treatment facility before being discharged to Lake Bonney.

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 would be placed into landfill. The flow sheet provided by the company indicated that approximately 2/3 of the paper production is for toilet tissue and 1/3 for facial tissue, and consequently around 50 tonnes of the chemical will be disposed of to sewer each year and 25 tonnes placed into landfill.

8.2 Fate

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 a high content of carboxylate groups. Therefore, any Prosoft TQ 1003 released to the water compartment will become associated with colloidal material and eventually become assimilated into bottom sediments.

No biodegradation test data were provided in the submission, but it is expected that the compound would slowly degrade in sludge and bottom sediments.

No 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

chemical 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.

Annually assuming 90% fixation of the chemical to fibre, approximately 8.4 tonnes of the chemical will be lost from the paper making process and sent to a water treatment plant prior to discharge to Lake Bonney. Although the waste treatment plant incorporates a stage of extended aeration in treatment ponds, the expected low rate of biodegradation indicates that it is unlikely that much of the Prosoft TQ 1003 would be degraded in this plant. However, it is probable that the chemical would become associated with humic material in solid sludge at the bottom of the aeration lagoons. The company indicated that waste sludge from this plant is composted with bark and other materials and this would eventually be applied to land – probably forests.

Most of the chemical will be released to the sewer or to landfill in association with used toilet paper and facial tissues respectively, and this would amount to approximately 75 tonnes each year, with approximately 50 tonnes going to sewer and 25 tonnes to landfill.

No data on bioaccumulation were included in the notification, but the high water compatibility and relatively high molecular weight indicates 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.

9.1 Acute Toxicity

Summary of the acute toxicity of Prosoft TQ 1003

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} 1880-1948 mg/kg	USEPA (1995)
	rat	LD_{50} 240 mg/kg	IPCS (1999)
acute dermal toxicity	rabbit	LD_{50} > 2000 mg/kg	USEPA (1995)
	rat	LD_{50} 400 mg/kg	IPCS (1999)
skin irritation	rabbit	corrosive	Hoff (2000)
eye irritation	rabbit	corrosive	Cerven (2000)
skin sensitisation	human	sensitising	IPCS (1999)

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

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

The notifier provided test reports on the toxicity of the new chemical to two species of fish, and daphnia. The tests were conducted in accordance with accepted US EPA test protocols. No data was supplied for the toxicity of the chemical against green algae or 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

* NOEC - no observable effect concentration

Fish

The test against rainbow trout (Hercules Inc., 2000a) was conducted over a 96 hour test period at 12±1°C 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 nominal 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 nominal 5 mg/L solution. Sublethal effects (stress) were noted during 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±1°C 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 nominal 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 nominal 2.5 mg/L solution. Sublethal effects (stress) were noted during 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±1°C 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 nominal 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 nominal 0.55 mg/L solution. Sublethal effects (stress) were noted during 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 0.22 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

No studies of the toxicity against green algae were provided, but it is known from the literature that quaternary ammonium surfactants such as the notified chemical are usually toxic to highly toxic against these species (Nabholz *et al*, 1993).

Consequently, it is expected that Prosoft TQ 1003 will exhibit high toxicity against green algae.

Field Studies

Information supplied by Kimberley Clark (the end user of the new 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. The tests are apparently conducted against rainbow trout and daphnia, and a Microtox bacterial fluorescence test is also a component of this test regime. The company submitted a summary of the effluent toxicity data (four samples) taken between January and December 2000, and this indicated that the effluent is not toxic. However, 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. However, since the new chemical would not have been used during the period of these studies, these data provide no information on potential toxic effects of the chemical following its introduction.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Approximately 50 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 is approximately 10^{12} L (assuming each person in

Australia produces an average of 150 L of sewage each day for 365 days per year and that the Australian population is 19,000,000) the global Predicted Environmental Concentration (PEC) of the chemical in sewage is estimated as 0.05 mg/L. However, the chemical would initially be associated with the solid cellulose material in paper and is not in aqueous solution. As the cellulose fibres break down through biological action, the chemical may be released but would then associate with negatively charged humic material and assimilate into sewage sludges. Periodically sludges are removed from the sewage systems by the water authorities and are usually placed into landfill.

A further 25 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 2 ppm (25 tonnes/year × 1/13,000,000 tonnes/year).

No biodegradation data was provided in the notification, but since the chemical does not contain any functional groups that 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 chemical with the greatest potential for environmental impact is the discharge of the waste water from the pulp and paper mill.

Annually, assuming 90% fixation of the new chemical to fibre, a maximum of approximately 8.4 tonnes will be lost from the paper making process and sent to a water treatment plant prior to discharge to Lake Bonney. Although the waste treatment plant incorporates 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. However, it is probable that the chemical would become associated with humic material in solid sludge at the bottom of the aeration lagoons. The company indicated that waste sludge from this plant is composted with bark and other materials and this would eventually be applied to land – probably forests.

The volume of waste water discharged from the paper plant is approximately 40 megalitres each day, so the maximum concentration of the chemical in the paper plant effluent is expected to be $8.4 \times 10^6/365$ grams/40×10^6 litres = 0.57 mg/L.

The waste treatment plant consists of a primary clarifier and a series of three aerobic degradation ponds, and the residence time in the plant is approximately 10 days. After treatment the effluent then passes into an 11 km drain before discharging into Lake Bonney. Although biodegradation during the aeration stages is unlikely, it is probable that much of the chemical would adsorb to humic material in the lagoons and would eventually be assimilated into bottom sediments. If it is assumed that (as with the paper fibres) around 90% of this discharged Prosoft TQ 1003 is removed into sediments, the worst case Predicted Environmental Concentration (PEC) of the chemical in the effluent discharged to Lake Bonney is estimated as 0.06 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 the PECs in the effluent stream and in Lake Bonney near to the drain discharge of approximately 0.01 mg/L.

The new 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 very likely highly toxic to green algae. The PECs above indicate that even for the worst case PEC of 0.01 mg/L, the safety factor for environmental effects to *Daphnia* is around 20. The safety factor Q is estimated from the ratio of the LC50 for the most sensitive species for which data is available (in this case Daphnia with LC50 = 0.22 mg/L) against the PEC. In the present case, Q = 0.22/0.01 =22. This safety factor would be further increased due to association of the chemical with colloidal organic matter (humic material) in the lake water.

Once the chemical has entered the Lake Bonney water, although only slow biodegradation is expected, some degradation through direct and indirect photolysis may be possible. However, it is expected that association with humic material would effectively remove the chemical through its incorporation into sediments. The chemical is not expected to bioaccumulate.

Provided the new chemical is used for the manufacture of tissue paper as described, it is not expected to be a hazard to the environment, although the calculations outlined above indicate that some localised impacts could be possible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

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 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. 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.

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.

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.

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, 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

  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 monitoring of the treatment plant effluent discharged into Lake Bonney be continued and NICNAS should be informed of any increase in toxicity.

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 Subsection 64(1) of the Act:

  – If quarterly monitoring of the treatment plant effluent discharged into Lake Bonney indicates any increase in the toxicity of the effluent after introduction of the new chemical, this information be immediately conveyed to the Director, NICNAS;

or

(2) Under Subsection 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 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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