File No: NA/495

August 1997

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PPT

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PPT

1. APPLICANT

Novo Nordisk Bioindustrial Pty Ltd of Unit 3, 22 Loyalty Road NORTH ROCKS NSW 2151 has submitted a limited notification statement in support of their application for an assessment certificate for 10H-phenothiazine-10-propionic acid; hereafter referred to as PPT. No claims for exempt information were made by the notifier, and the assessment report is published here in its entirety.

2. IDENTITY OF THE CHEMICAL

Chemical Name: 10H-phenothiazine-10-propionic acid

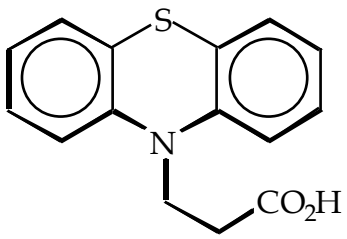
Chemical Abstracts Service (CAS) Registry No.: 362-03-8

Other Names:
10-phenothiazine propionic acid
3-(10-phenothiazinyl) propionic acid
β-(10-phenothiazinyl) propionic acid
3-phenothiazine-10-yl-propionic acid
10-(propionic acid) phenothiazine
PPA
PPT

Trade Name:
DeniLite™ (3% notified chemical)
DeniLite™ Plus (9% notified chemical)

Molecular Formula: $C_{15}H_{13}NO_2S$

Structural Formula:



Molecular Weight: 271.3

Method of Detection and Determination:	high performance liquid chromatography (HPLC)
Spectral Data:	ultraviolet/visible (UV/Vis), infrared (IR) and nuclear magnetic resonance spectra were provided by the notifier; major characteristic peaks were found in the IR spectrum at: 2 500-3 300, 1 710, 1 590, 1 450, 1 000-1 400 and 400-1 000 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	the notified chemical in pure form is an off white crystalline powder
Melting Point:	160 - 164.5°C
Boiling Point:	> 180°C (decomposes before boiling)
Specific Gravity:	1.351
Vapour Pressure:	1.0 x 10^{-4} kPa at 25°C
Water Solubility:	51.2 ± 0.9 mg/L (pH approximately 6.7)
Partition Co-efficient (n-octanol/water):	log P_{ow} = 1.87 at 22 ± 0.5°C
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0, 7.0, 9.0 > 1 year (estimated)
Adsorption/Desorption:	not provided
Dissociation Constant:	pK_a is approximately 5-6 (in 50% ethanol)(see comments below)
Surface Activity:	62.4 mN/m
Particle Size:	> 105 μm 28.2% (% mass) 60.0 - 105 μm 3.3% 30.0 - 60.0 μm 30.7% 10.4 - 30.0 μm 29.5% 0.5 - 10.4 μm 8.3% (particle size determined by image analysis)
Flash Point:	non-flammable
Flammability Limits:	non-flammable

Autoignition Temperature:	no relative self-ignition temperature below its melting range
Explosive Properties:	not explosive
Reactivity/Stability:	not oxidising

Comments on Physico-Chemical Properties

Tests were performed according to OECD test guidelines (1) at facilities complying with OECD Principles of Good Laboratory Practice.

The notified chemical is hydrolytically stable over the environmental pH range.

No data has been provided for the adsorption/desorption behaviour of the chemical. The moderate water solubility and relatively low partition coefficient would indicate that the chemical is not likely to adsorb strongly to soils and sediments.

The dissociation constant was determined in a 50% ethanolic solution because of the relatively low water solubility of the chemical. The value is typical for a carboxylic acid.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (2).

4. PURITY OF THE CHEMICAL

Degree of Purity:	97-100%
Toxic or Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	10-H-phenothiazine (0-1%) polyacrylate (0-2%)
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured or reformulated in Australia. It will be used in the textile industry as a enzyme mediator in oxido-reductase catalysed reactions and will be imported as a component of two end use products; DeniLite™ and DeniLite™ Plus (containing 3.0% and 9.0% of PPT, respectively). These products will be used for the bleaching of textile dyes without the use of chlorine based chemicals.

Up to one tonne of the notified chemical will be imported per annum for each of the

first five years.

6. OCCUPATIONAL EXPOSURE

End use products containing the notified chemical will be imported in 25 kg jerry cans. Waterside, warehouse and transport workers are unlikely to come into contact with the notified chemical except in the event of an accident or leaking packaging.

Dermal exposure to the notified chemical is possible when workers pour end use products into closed systems such as dosing tanks, prior to addition to industrial washing machines. Inhalation exposure is unlikely at this stage, although accidental ocular contact may occur. The notifier states that workers are expected to be handling the end use products for only several minutes per day.

Mixing of DeniLite™ with water in an industrial washing machine will form low concentrations of free radicals as an intermediate in the bleaching process. The notifier indicates that it is not known if the free radical form of the notified chemical will form in the event of a spillage or skin/eye contact. Presumably, however, free radical formation would occur if the spilt product contacted water. The toxicological significance of this intermediate is also not known.

Dermal exposure to an oxidised derivative, 10H-phenothiazine-10-propionic acid 5-oxide (PPTO) is likely when workers are unloading textiles from industrial washing machines. Concentrations of both the notified chemical and the oxidised derivative are both expected to be very low, however, as there are several rinsing steps which follow immediately after treatment of the fabric.

Worker exposure to other potentially hazardous components of the end use products may also occur.

7. PUBLIC EXPOSURE

Products containing the notified chemical will be used for bleaching of dyes such as indigo (used for dyeing denim) to produce a highly abraded textile appearance. At the completion of the bleaching process, the notified chemical, PPT, will be totally oxidised to PPTO. After bleaching, the textiles will be washed, and the notified claims that all PPTO will be removed.

The notifier has indicated that the chemical will not be present in textiles used for clothing manufacture. However, minimal quantities of the oxidised form of the notified chemical may not wash out. If small amounts of the oxidised form is retained in the textiles, dermal exposure could occur following contact. However, exposure should be minimal.

Minimal public exposure may result from disposal of the unused products which contain the notified chemical, or accidental spillage of the products during transport and storage. However, adequate measures are described by the notifier to minimise the risk of public exposure during disposal, or in the event of accidental spillage.

8. ENVIRONMENTAL EXPOSURE

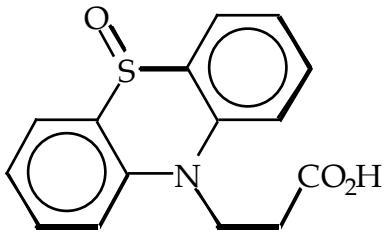
Release

No release or exposure to the environment is expected from this chemical during transportation, with the exception of accidental spillage. There are adequate instructions on the Material Safety Data Sheets (MSDS) for the products containing the notified chemical to cope with accidental spillage.

After emptying, the jerry cans which contain the notified chemical will be rinsed into industrial washing machines leaving trace amounts in cans. Empty cans will be disposed of to landfill.

The notified chemical undergoes rapid conversion to the oxidised derivative PPTO during treatment of the fabric (the structure of PPTO is shown below). Because of this oxidation, the notified chemical will not be released with the effluent from the fabric treatment process. Almost all the imported notified chemical will be discharged to the sewer as PPTO after dilution in on-site sewerage treatment plants.

PPTO



Fate

PPTO will be discharged into the sewer at low levels. The partition coefficient and water solubility of PPTO have not been determined. Calculation of the log K_{ow} for PPT and PPTO, using atom/fragment contribution method developed by Syracuse Research Corporation (3), shows a drop of greater than 2 orders of magnitude in log K_{ow} between PPT and PPTO. Hence, PPTO is not expected to adsorb strongly. Additionally, due to its high polarity the water solubility of PPTO would be significantly greater than that of PPT.

Although no biodegradation data needs to be provided for chemicals imported at rates less than 1 000 kg per annum according to the Act, the notifier has provided biodegradation data for both PPT and PPTO. Both PPT and PPTO were examined for biodegradation potential using EEC Directive 92/69, Part C.4-C (Modified Sturm

Test), and OECD Test Guideline 301B (1, 2). At levels of 10 and 15 mgC/L (mg carbon/litre), PPT showed cumulative CO_2 production values of 3 and 7% of theoretical values, respectively. PPTO was no more than 1% degraded at 10 and 15 mgC/L and no degradation was observed at 15 mgC/L. These results indicate that neither PPT or PPTO are readily biodegradable under the conditions of the test. Bacterial inhibition tests using a modified closed bottle test (OECD Method 301D (1)) were conducted for both PPT and PPTO. The biodegradation of the

reference material, sodium benzoate, was examined over five days at concentrations of 10 and 15 mgC/L. Both PPT and PPTO were found to have no inhibitory effect on the biodegradation of the reference material under these conditions.

Given the expected low partition coefficient, moderately high water solubility and lack of biodegradability it is anticipated that PPTO will remain dissolved in waste water and will not be removed during sewerage treatment, according to the SimpleTreat model (4).

PPT is not expected to bioaccumulate due to its moderately high water solubility and low partition coefficient (5). As it is anticipated that PPTO would have higher water solubility and a lower partition coefficient it would also not be expected to bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required for chemicals with import volumes less than 1 tonne per annum, according to the Act. However, the following toxicological data were provided by the notifier for PPT.

9.1 Acute Toxicity

Summary of the acute toxicity of PPT

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(6)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(7)
inhalation toxicity	rat	LC_{50} > 5.32 mg/L	(8)
skin irritation	rabbit	non-irritant	(9)
eye irritation	rabbit	slight irritant	(10)
skin sensitisation	guinea pig	non-sensitiser	(11)

9.1.1 Oral Toxicity (6)

Species/strain:	rat/CD strain
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	single dose of 2 000 mg/kg given by gavage; vehicle was 0.5% (w/v) methyl cellulose in purified water
Clinical observations:	none

Mortality:	none
Morphological findings:	none
Test method:	similar to EEC Directive 92/69/EEC (2)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical is of low oral toxicity in rats

9.1.2 Dermal Toxicity (7)

Species/strain:	rat/CD strain
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	single dose of 2 000 mg/kg applied to an intact skin site and moistened with purified water; occlusive dressing applied for 24 hours; the dressing was removed and excess test material wiped away
Clinical observations:	there were no local signs of reaction to treatment; one male showed pigmented orbital secretion on day 2
Mortality:	none
Morphological findings:	none
Test method:	similar to EEC Directive 92/69/EEC (2)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity (8)

Species/strain:	rat/CD strain
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	the test material was passed through an ultracentrifugal mill fitted with a 0.2 mm screen; material was packed into a Wright Dust Feed Mechanism; atmosphere generated by suspending material scraped from the surface of the compressed powder in a stream of dry air; the exposure period was 4 hours; the nominal atmospheric concentration was 8.12 mg/L; the achieved chamber concentration was 5.32 mg/L; the mass median equivalent aerodynamic diameter was 6.73 μm
Clinical observations:	during the exposure period a number of animals exhibited soiled and wet fur, reduced respiratory rate, exaggerated respiration, struggling in the restraint tube and excessive salivation; hunched posture and wet fur was noted in all animals during the 2 hours following exposure; all animals appeared normal from the day following exposure to the end of the study
Mortality:	none
Morphological findings:	none
Test method:	similar to EEC Directive 92/69/EEC (2)
LC_{50}:	> 5.32 mg/L
Result:	the notified chemical was of low inhalation toxicity in rats

9.1.4 Skin Irritation (9)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/male
Observation period:	72 hours

Method of administration:	0.5 g of the test substance was moistened with purified water and applied to a 6 cm^2 intact dorsal skin site; skin covered by gauze and semi-occlusive dressing for 4 hours; excess material removed from test site after dressing removed; observations made at 1 hour, 1, 2 and 3 days after removal of dressing and scored according to the method of Draize (12)
Draize scores (12):	all Draize scores were zero
Test method:	similar to EEC Directive 92/69/EEC (2)
Result:	the notified chemical was not a skin irritant in rabbits

9.1.5 Eye Irritation (10)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 male/1 female
Observation period:	72 hours
Method of administration:	0.1 g of the test material was placed in the conjunctival sac of the left eye of each animal; right eye served as control

Draize scores (12) of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Cornea	no corneal effects were noted											
Iris												
1	1			0			0			0		
2	1			0			0			0		
3	0			0			0			0		
Conjunctiva	r^a	c^b	d^c	r^a	c^b	d^c	r^a	c^b	d^c	r^a	c^b	d^c
1	2	0	0	2	0	0	2	0	0	0	0	0
2	2	0	2	2	0	0	1	0	0	0	0	0
3	1	0	1	2	0	1	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
[a] redness [b] chemosis [c] discharge

Test method: similar to EEC Directive 92/69/EEC (2)

Result: the notified chemical was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (11)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 15/sex

Induction procedure:

Day 1: 3 pairs of intradermal injections:
- 0.1 mL Freund's complete adjuvant (FCA): purified water (1:1(v/v))
- 0.1 mL of 3% concentration of test material in propylene glycol
- 0.1 mL of 3% concentration of test material in FCA: propylene glycol (1:1 (v/v))

Day 7: test area treated with 0.5 mL 10% (w/v) sodium lauryl sulfate in petrolatum

Day 8: occluded application of 0.6 mL test material (50% in propylene glycol) for 48 hours

Challenge procedure: Day 22: occluded application of 0.03 mL test material (50% and 10% in propylene glycol) for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
10%	0/20**	0/20	0/10	0/10
50%	0/20	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method: similar to EEC Directive 92/69/EEC (2)

Result:	the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (13, 14)

The results of two repeat dose oral toxicity studies were submitted by the notifier. One of these is summarised below (13). The second study dosed rats for a 28 day period at 25, 150 and 1 000 mg/kg/day (14). A brief comment on the outcome of the second study is provided in under the 'results' heading of this section.

Species/strain:	rat/CD strain
Number/sex of animals:	40/sex
Method of administration:	gavage; vehicle was 0.5% (w/v) methyl cellulose
Dose/Study duration::	test material administered daily for a total of 28 days: control: 0 mg/kg/day low dose: 50 mg/kg/day mid dose: 150 mg/kg/day high dose: 750 mg/kg/day all animals were sacrificed at the end of the treatment period
Clinical observations:	the following symptoms were observed in animals which died or were killed *in extremis* during the study: post-dose salivation and piloerection, underactiveness, prostration, poor reflexes; survivors in the high dose group also exhibited underactiveness and excess salivation; pink stained, ungroomed fur were noted in these animals from week 3 food consumption, body weight gain and food utilisation of animals in the high dose group were lower than controls
Mortality:	2 males and 3 females from the high dose group died or were killed *in extremis* during the study; these deaths occurred by day 6
Clinical chemistry/Haematology:	packed cell volumes, haemoglobin concentration and erythrocyte numbers were lower in animals from the high dose group when compared with controls; total leucocyte and platelet numbers of animals in this group were higher than controls

	plasma alanine and aspartate amino-transferase activities and total bilirubin, urea and creatinine concentrations were higher in animals from the high dose group than controls
Histopathology:	adrenal, kidney, liver and testes weights of animals of the high dose group were higher than controls
	at necropsy of the animals which survived the test period, 2 animals in the high dose group were found to have areas of change on the kidneys; cystic and non-cystic tubular dilation with or without proteinaceous casts; interstitial inflammation and basophilic tubules and less frequent pyelonephritis and capsular fibrosis were observed in animals from the high dose group
	enlargement and congestion of the spleen was observed in a number of the high dose animals
Test method:	similar to OECD guidelines (1)
Result:	treatment of rats with the notified chemical at the high dose (750 mg/kg/day) induced a number of changes in the kidneys and red blood cells indicative of organ toxicity; results of the second repeat dose study (14) also found evidence of kidney toxicity at high (1 000 mg/kg/day) doses

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (15)

Strains:	*Salmonella typhimurium* TA 98, TA 100, TA 1535 TA 1537
Concentration range:	25 - 2500 μg/plate; vehicle was DMSO; assays were carried out in the presence or absence of rat liver S9 fraction
Test method:	similar to OECD guidelines (1)
Result:	the notified chemical was not mutagenic in the bacterial strains tested in the presence or

	absence of metabolic activation; concurrent positive controls demonstrated the sensitivity of the assay

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (16)

Species/strain:	mouse/CD1 strain
Number and sex of animals:	90/sex
Doses:	250, 500 or 1 000 mg/kg/day for 2 consecutive days; vehicle was 1% methyl cellulose; animals were sacrificed 24 or 48 hours after final treatment
Method of administration:	gavage
Test method:	similar to OECD guidelines (1)
Comments:	signs of systemic toxicity were noted in several animals from the high dose group and 2 animals died following the second administration; one treated male from the 48 hour high dose group showed increased levels of polychromatic erythrocytes which influenced statistical analysis; treated males and females at the 24 hour sample and females at the 48 hour sample did not exhibit increased frequencies of polychromatic erythrocytes when compared with concurrent controls
Result:	the notified chemical did not produce a statistically significant increase in polychromatic erythrocytes (following non-parametric testing) when compared with controls

9.3.3 Chromosomal Aberrations in Cultured Human Lymphocytes (17)

Doses:	*without S9 mix:* 21 hour harvest: 25-200 μg/mL 45 hour harvest: 12.5-200 μg/mL (cells exposed continuously for the test period) *with S9 mix:* 21 hour harvest: 50-1 000 μg/mL 45 hour harvest: 50-800 μg/mL (cells exposed for 3 hours and harvested 18 or

42 hours later)

Test method: similar to OECD Guidelines for Testing of Chemicals (1)

Result: the notified chemical showed clear evidence of clastogenic activity in the presence of metabolic activation (S9 mix), although only at cytotoxic concentrations (800 μg/mL in the first test and 600 μg/mL in the second test)

9.3.4 Unscheduled DNA synthesis in Rat Liver (18)

Species/strain: rat/Wistar

Number and sex of animals: 15/male

Doses: 632.5 or 2 000 mg/kg; animals were sacrificed 2-4 hours or 12-14 hours after treatment; hepatocytes were isolated and examined for unscheduled DNA synthesis

Method of administration: gavage; vehicle was 1% (w/v) methyl cellulose

Test method: UKEMS Test Guidelines (19)

Result: the notified chemical did not induce unscheduled DNA synthesis under the conditions employed

9.4 Preliminary Teratology Study (20)

Species/strain: rat/CD strain

Number/sex of animals: 24/female

Method of administration: gavage; vehicle was 0.5% (w/v) methylcellulose

Dose/Study duration: test material administered daily to pregnant rats from day 6 to day 15 inclusive; scheduled doses were as follows:

control:	0 mg/kg/day
low dose:	100 mg/kg/day
mid dose:	300 mg/kg/day
high dose:	1 000 mg/kg/day

all animals were sacrificed on day 20 of gestation and uterine contents examined

Clinical observations:	3 females receiving 1 000 mg/kg/day were killed *in extremis* on day 7 of gestation as a result of treatment; the remainder of the animals in this group were removed from the study
Comments:	macroscopic examination of females from groups dosed with 100 or 300 mg/kg/day at necropsy showed no treatment-related signs; litter responses were similar in all groups (as assessed by the numbers of corpora lutea, implantations and viable young, extent of pre- and post- implantation losses and foetal and placental weights); macroscopic examination of the foetuses did not reveal any findings considered to be treatment related
Test method:	similar to EEC Directive 92/69/EEC (2)
Result:	doses of up to 300 mg/kg/day for a 10 day period during gestation did not induce teratogenic effects in a preliminary teratology study

9.5 Overall Assessment of Toxicological Data

The notified chemical was of low acute oral and dermal toxicity to rats (LD_{50} > 2 000 mg/kg in both studies). The LC_{50} was found to be greater than 5.32 mg/L in an inhalation toxicity study in the same species, indicating that the notified chemical is also of low toxicity when administered via this route. It was not a skin irritant when tested in rabbits but caused slight eye irritation in the same species. The notified chemical was not a skin sensitiser in guinea pigs.

A 28-day repeat dose oral toxicity study in rats indicated that treatment with high doses of the notified chemical (750 mg/kg/day) resulted in some kidney and erythrocyte effects. A second study confirmed kidney toxicity at high doses (1 000 mg/kg/day)

Genotoxicity studies indicated that the notified chemical was not mutagenic in a bacterial reverse mutation study and did not induce unscheduled DNA synthesis in rat hepatocytes in an *in vivo/in vitro* study. Clastogenic activity was noted in an *in vitro* human lymphocyte study, however, this was only observed at cytotoxic concentrations. Some evidence of chromosome damage was noted in an *in vivo* mouse micronucleus assay at high doses. The results of these tests indicate that the notified chemical may be weakly genotoxic.

A preliminary teratology study indicated that maternal doses of up to 300 mg/kg/day did not induce abnormalities, as assessed by foetal numbers and development.

Based on the results of toxicological studies summarised above, PPT would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (21).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although no ecotoxicological data needs to be provided for chemicals imported at rates less than 1 tonne per annum according to the Act, the following ecotoxicity studies have been supplied by the notifier for PPT and PPTO. The tests were carried out according to OECD Test Methods (1).

Species	*Test*	*Results*
	PPT	
fathead minnow *Pimephales Promelas*	Acute Toxicity (OECD Method 203)	LC_{50} = 88.1 mg/L NOEC = 11.2 mg/L
Daphnia magna	Acute Immobilisation (OECD Method 202, Part 1)	NOEC = 3.12 mg/L EC_{50} = 8.42 (7.13-10.3) mg/L
algae *Selenastrum capricornutum*	Growth Inhibition (OECD Method 201)	NOE_bC = 0.067 mg/L (72 hour) NOE_rC = 0.89 mg/L (72 hour) E_bC_{50} = 2.03 mg/L (72 hour) E_rC_{50} = 6.58 mg/L (0-72 hour)
	PPTO	
fathead minnow *Pimephales Promelas*	Acute Toxicity (OECD Method 203)	NOEC = 95.1 mg/L
Daphnia magna	Acute Immobilisation (OECD Method 202, Part 1)	NOEC = 81.8 mg/L
algae *Selenastrum capricornutum*	Growth Inhibition (OECD Method 201)	NOEC = 37.7 mg/L (72 hour) E_bC_{50} = 88.7 mg/L (72 hour) E_rC_{50} > 101 mg/L (0-72 hour)

In the acute toxicity test for fish of PPT only two measured concentrations showed lethal effects. The LC_{50} was estimated to be 88.1 mg/L, based on 50% mortality at this concentration. No unusual observations were made during the acute toxicity to fish for PPTO. The effects were only examined at one measured concentration in a limit test.

For PPT the highest measured concentration at which *Daphnia* immobilisation was 5% or less (also the NOEC) after 48 hours was 3.12 mg/L; at the highest measured concentration 95% immobilisation was observed. The effect of PPTO on daphnia

was only examined at one measured concentration in a limit test. No immobility or adverse effects were observed at this concentration.

The algal E_bC_{50} and E_rC_{50} for PPT were determined by non-linear interpolation between two concentrations that bracket the 50% effect level. For PPTO, the 50% inhibition of the growth rate was not observed and therefore the E_rC_{50} must be greater than 101 mg/L.

The ecotoxicity data for the notified chemical, PPT, is moderately toxic daphnia and algae and slightly toxic to fish, while PPTO is likely to be practically non-toxic to fish, daphnia and algae. As noted above, neither PPT or PPTO is likely to inhibit sewerage micro-organisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notifier has estimated a predicted environmental concentration (PEC) of 6.25 ppb of PPTO as a result of discharge from a large textile plant to the sewer (based on the use of 5 kg of PPT, with a waste water flow of 4 000 m^3 per day and a surface dilution factor of 200). The major user of the notified chemical will be in Adelaide and the discharge from the textile plants waste water treatment system is expected to be treated at the Bolivar sewerage treatment works (average flow rate of between 130 and 160 ML per day). The discharge of 5 kg of PPT as PPTO into this sewerage system would result in a concentration of 40 ppb in discharge from the Bolivar sewerage treatment works. This would undergo a further 10 fold dilution in receiving waters to give a PEC of 4.0 ppb. This concentration is four orders of magnitude lower than the lowest NOEC observed for algae (the most sensitive species). Thus, the discharge of PPTO from textile plants is not expected to be hazardous to aquatic organisms. Assuming that the PPT was discharged (*ie* no oxidation occurred) the PEC would be approximately 3.8 ppb. This level is around three orders of magnitude lower than the lowest OEC observed for algae. Thus, it would not be hazardous to aquatic organisms. Dilution rates in other capital cities are likely to be similar or greater.

The environmental hazard from the proposed use the notified chemical and its resulting oxidised form is rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The occupational health risk posed to transport workers is negligible under normal circumstances, as they will only be handling unopened jerry cans of products containing the notified chemical.

Workers in textile processing factories will be exposed to products containing relatively low concentrations of the notified chemical for several minutes per day. Results of toxicological studies in animals indicate that PPT is unlikely to be acutely

toxic, and will not cause skin irritation or sensitisation if repeated skin contact occurs. Based on the outcome of rabbit studies, some eye irritation may result if accidental ocular exposure occurs in the workplace. Based on the results of genotoxicity studies, which showed PPT to have weak genotoxic activity, personal protective equipment should be worn when handling end use products containing the notified chemicals. Given that end-use products contain relatively low concentrations of PPT, however, and that effects in genotoxicity studies and a repeat-dose study were seen only at high doses, adverse health effects following long-term use of PPT are unlikely. Based on the expected low worker exposures and the results of toxicity studies, the risk posed to workers in textile processing is low.

The notifier states that normal handling precautions should be taken to prevent exposure to other components of the end use products, which include ethoxylated fatty alcohol (skin and eye irritation potential) and enzyme products (potential for sensitisation by inhalation).

Textiles treated with the notified chemical will be used for clothing. In the unlikely event that the oxidised derivative, PPTO is retained in the textiles, the amount would be minimal and should therefore pose a negligible hazard to the public. The potential for minor public exposure exists during transport and disposal of products containing the notified chemical, This is minimised by the recommended practices during storage and transportation.

13. RECOMMENDATIONS

To minimise occupational exposure to PPT, the following guidelines and precautions should be observed:

- It is good work practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (AS) 2919 (22) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (23) to minimise exposure when handling any industrial chemical;

- Impermeable gloves or mittens should conform to AS 2161 (24);

- Spillage of products containing the notified polymer should be avoided, spillages should be cleaned up promptly and put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

Workers should be aware that DeniLite™ and DeniLite™ Plus contain other potentially hazardous ingredients, and appropriate precautions should be taken in the workplace to avoid exposure to these components.

14. MATERIAL SAFETY DATA SHEET

The MSDS for a product containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (25).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

If conditions of use are varied, greater exposure to the public to the notified chemicals may occur. In such circumstances, further information may be required to assess the hazards to public health. The additional information should include toxicology data on PPTO and data on PPTO retention in bleached and washed textiles.

16. REFERENCES

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Attachment 1

The Draize Scale 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 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