File No: NA/320

August 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PRIAZUL 2118

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PRIAZUL 2118

1. APPLICANT

Unichema Australia Pty Ltd of 14 Woodruff Street PORT MELBOURNE VIC 3207 has submitted a standard notification statement in support of their application for an assessment certificate for Priazul 2118.

2. IDENTITY OF THE CHEMICAL

Priazul 2118 is considered not to be a hazardous substance based on the nature of the chemical and the data provided. The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name:	Priazul 2118; BioSurf 18:1 (trade name in Europe)
Method of Detection and Determination:	electronic spectrophotometry, ultraviolet/visible (UV/vis), infrared (IR), and proton and carbon-13 nuclear magnetic resonance (NMR) spectroscopy

Comments on Chemical Identity

Characteristic functional groups have been identified in the IR and proton NMR spectra. An example of the carbon-13 NMR spectrum for a sample of the chemical was also included in the submission. Molar extinction coefficients have been determined for wavelength maxima in the electronic spectra. Detection of Priazul 2118 should be carried out by extraction with a lipophilic solvent and spectrometric analysis by IR, NMR or HPLC techniques.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	pale yellow to brown, viscous to very viscous or paste at ambient conditions with odourless to faint fatty acid odour
Boiling Point:	>165ºC at 1.333 Pa (theoretical - reduced pressure distillation, see comments below)
Specific Gravity:	1.016 at 60ºC

Vapour Pressure:	< 2 x 10^{-7} Pa at 20°C (calculated - modified Watson correlation)
Water Solubility:	0.6 - 2.2 g.L^{-1} at 20°C (see comments below)
Partition Co-efficient (n-octanol/water):	log K_{ow} > 3 (estimated, see comments below)
Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined (see comments below)
Flash Point:	not determined (see comments below)
Flammability Limits:	not determined (see comments below)
Autoignition Temperature:	not determined (see comments below)
Explosive Properties:	no explosion under the effect of a flame
Reactivity/Stability:	stable
Surface Activity:	30.2 mN.m^{-1} at 0.6 g.L^{-1} at 20°C ("saturated" solution); 30.2 mN.m^{-1} at 0.3 g.L^{-1} at 20°C (half saturated)
Fat Solubility:	mixable in all ratios with fat simulant HB 307 at 37°C

Comments on Physico-Chemical Properties

The notified chemical generally decomposes before the boiling point is reached.

Due to a high Tyndall effect and the formation of micelles (CMC = 0.4 g.L^{-1}), solubility behaviour deviates from that of simple organics. The chemical is dispersible in water (Priazul 2118 is a nonionic surfactant).

No hydrolysis data was available for the notified chemical. Hydrolysis of the chemical is expected to be slow at neutral pH but may be accelerated under either acid or alkaline conditions. The notified chemical is unlikely to hydrolyse under the normal environmental pH range (4-9).

The partition coefficient was derived from the Material Safety Data Sheet (MSDS). No indication on how this value was estimated has been given. Surface active substances are impossible to measure using the shake-flask method and must be calculated from the individual solubilities in water and n-octanol (1). Any results are expected to be unreliable.

Therefore, due to the surface activity of the notified chemical, a partition coefficient is not required, under the data requirements of the Schedule to the Act.

No measurement of adsorption/desorption was made. The notifier has indicated very low mobility in soil is expected, but that Priazul 2118 should biodegrade and not persist in the environment under normal conditions. It may decompose at elevated temperatures or with strong oxidants. Given the chemical structure of Priazul 2118, it is not expected to dissociate.

The notified chemical is expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 $mN.m^{-1}$ (2).

Considering its molecular structure and low vapour pressure, Priazul 2118 is not expected to be flammable. Priazul 2118 was too viscous to determine the autoignition temperature.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported in pallets of 4 x 180 L drums. The chemical will be supplied in this form; however, the notified chemical may be transported to larger customers in tank cars, where customer has adequate facilities to handle such deliveries.

The notifier has not specified the end use products for Priazul 2118. The notifier has indicated general use in "specialty" hair care and body wash products. These types of products are usually applied to the skin or hair for short periods of time and removed with water shortly thereafter. The products will be primarily for domestic use, but may use by workers in hairdressing and beauty salons. The proportion to be used in each end use situation has not been established and will depend on customer interest.

The notifier indicates that Priazul 2118 can also be used in formulations for metal cleaning, primarily in industrial or commercial applications. The notifier did not provide any details for this use.

6. OCCUPATIONAL EXPOSURE

Categories of workers potentially exposed to the notified chemical include transport workers, warehouse workers, manufacturing plant workers, drum cleaning workers, retail workers and end users of retail products.

Priazul 2118 will be transported by road from Australian wharves to customer warehouses and manufacturing plants for formulation. Transport workers and warehouse workers could only be exposed in the event of accidental spillage.

The notifier has not provided specific information on the number of customers that will be involved with the notified chemical or the types of equipment used in the formulation of the final retail product. The notifier expects 1 to 3 customers in the first year of import, rising to 4 or 5 customers by 1999.

At formulation sites, manufacturing workers are required to open drums of Priazul 2118 and connect them to formulation equipment. The formulation process is typically automated and within a fully enclosed system. Workers may experience direct skin contact if a spill occurs in the formulation or filling lines.

Drum cleaning workers clean drums that have contained Priazul 2118. A drum cleaning worker would be required to wash approximately 5 drums for every tonne of Priazul 2118 imported.

Retail workers unpack sealed containers containing Priazul 2118 formulations and pack containers on to shelves. Retail workers will only be exposed to the notified chemical through damaged and leaking containers.

A typical formulation will contain Priazul 2118 at 5% (w/v). End users will usually be exposed to formulations containing the notified chemical for short periods of time. The duration and frequency of exposure for end users will vary between hairdressing and beauty salons. Typically, a hair care worker may shampoo up to 20 customers per day resulting in 20 separate exposure incidents should the shampoo contain the notified chemical.

No occupational exposure data was provided concerning use of the notified chemical as a metal cleaning substance.

7. PUBLIC EXPOSURE

Public exposure to the notified chemical is expected to be high. The primary use of Priazul 2118 will be in domestic hair care and bodywash formulations. The public may also be exposed to Priazul 2118 in hair and beauty salons. Exposure of this nature may occur once a day on external body surfaces. The formulation may also come into contact with the eyes.

The secondary use of Priazul 2118 is in metal cleaning formulations for industrial and commercial applications. Public exposure to the notified chemical via the metal cleaning formulations is unlikely.

8. ENVIRONMENTAL EXPOSURE

Release

During the formulation process, the notified chemical is lost to waste from the cleaning of equipment and lines, transport equipment and drums. The amount of Priazul 2118 lost to waste is expected to be minimal and overall waste generation is expected to be less than 2%. All waste containing Priazul 2118 generated during normal formulation, packaging and cleaning activities is expected to be disposed of to sewer in a diluted form, with or without pretreatment.

Any spillages of the notified chemical that may occur will be contained by either sand, earth or other absorbent material. The high viscosity of the chemical at ambient conditions should facilitate cleaning and recovery. Used absorbent is to be sealed in drums or containers and disposed of to landfill at approved sites or incinerated. Quantities of such material are thought to be limited.

Use of Priazul 2118 formulations as hair and beauty products will result in the ultimate release of all chemical to the sewer or septic tanks, from either domestic or commercial sites around Australia. A typical formulation will contain Priazul 2118 at a concentration of 5% (w/v). Under normal conditions of use Priazul 2118 is expected to be further diluted.

Fate

The highest environmental exposure of the notified chemical will be to the sewer or septic tanks through the normal use of formulations containing Priazul 2118. Small amounts resulting from spillage may be placed into landfill in accordance with local, state and federal regulations or be incinerated. Amounts consigned to landfill should be negligible.

Biodegradability of Priazul 2118 was not determined. Biodegradability of a similar compound Priazul 2102 (see below), of which Priazul 2118 is a minor component, was assessed using COD methods (1). Priazul 2102 was found to be 83 - 84% biodegraded over 28 days under the test conditions and could be classed as readily biodegraded. However, while unsaturated fatty acids are more susceptible to oxidation than saturated fatty acids and are expected to undergo addition reactions at their double bonds, biodegradation would be expected to proceed more slowly for an unsaturated fatty acid due to the additional metabolic steps required. These additional steps are necessary for the catalytic conversion of the Δ^3 - *cis* form of the fatty acid to the Δ^2-*trans* form.

While it is reasonable to assume that the fatty acid ester present in Priazul 2118 will biodegrade, given the additional metabolic requirement and that longer chain fatty acids are degraded more slowly, the rate of biodegradation of Priazul 2118 could be slower than that of Priazul 2102.

There is a strong potential for bioaccumulation of the chemical because of its low to moderate water solubility (3) and its high fat solubility. It is, however, expected to be biodegradable and unlikely to persist in the environment.

9. EVALUATION OF TOXICOLOGICAL DATA

No data on the toxicity of Priazul 2118 was presented. Toxicological data on Priazul 2102 was presented. The monoesters in Priazul 2102 and Priazul 2118 have similar functional groups. Priazul 2102 mixture comprises of 11.6% Priazul 2118.

9.1 Acute Toxicity

Summary of the acute toxicity of Priazul 2102 (containing 12 % of the notified chemical)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg.kg^{-1}	(4)
acute dermal toxicity	guinea pig	LD_{50} > 2 000 mg.kg^{-1}	(5)
inhalational toxicity	rat	LC_{50} > 1 980 mg.m^{-3},	(6)
skin irritation	rabbit	slight irritant	(7)
eye irritation	rabbit	slight irritant	(8)
skin sensitisation	guinea pig	non-sensitiser	(9)

9.1.1 Oral Toxicity (4)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	single dose of Priazul 2102 in corn oil by oral gavage
Clinical observations:	no clinical signs of toxicity or effects on bodyweight gain were noted
Mortality:	nil
Morphological findings:	no organ abnormalities were noted
Test method:	according to OECD guidelines (1)
LD_{50}:	> 2 000 mg.kg^{-1}
Result:	Priazul 2102 was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (5)

Species/strain:	guinea pigs
Number/sex of animals:	5/sex

Observation period:	14 days
Method of administration:	a single dose of Priazul 2102 was applied to the clipped and shaved dorsum, and covered with a permeable dressing for 24 hours
Clinical observations:	no oedema was observed in any of the animals; 9 guinea pigs showed very slight to well defined erythema within 24 hours after application
Mortality:	nil
Morphological findings:	no abnormalities related to the treatment were observed
Test method:	according to OECD guidelines (1)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	Priazul 2102 was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity (6)

Species/strain:	rat/Spraque-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	animals were exposed (snout only) for four hours to an aerosol of 1.98 $mg.L^{-1}$ Priazul 2102 in corn oil; approximately 70% of the aerosol mass had a particle size less than 0.9 μm
Clinical observations:	an unkempt appearance was noted for all animals; bodyweight profiles did not differ significantly for control or test animals
Mortality:	nil
Morphological findings:	two treated males and one control male had slightly mottled lungs
Test method:	according to OECD guidelines (1)
LC_{50}:	> 1 980 $mg.m^{-3}$.

Result: Priazul 2102 was of low acute inhalational toxicity in rats

9.1.4 Skin Irritation (7)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 4 female

Observation period: 72 hours

Method of administration: Priazul 2102 (0.5 mL) was applied to intact skin and covered with a gauze patch for 4 hours

Draize scores (10):

Time after treatment (days)	***Animal #***			
	1	***2***	***3***	***4***
Erythema				
1	[a]2	1	2	1
2	1	0	1	1
3	1	0	1	0
Oedema				
1	1	0	2	0
2	0	0	1	0
3	0	0	1	0

[a] see Attachment 1 for Draize scales

Test method: according to OECD guidelines (1)

Result: Priazul 2102 was a slight irritant to the skin of rabbits

9.1.5 Eye Irritation (8)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 4 females

Observation period: 72 hours

Method of administration: Priazul 2102 (0.1 mL) was given into the conjunctival sac of one eye

Clinical observation: the Draize scores for redness, chemosis, cornea or iris lesions were all zero from day 1 to day 3, except for two rabbits had Draize score of 1 for redness at day 1

Test method: according to OECD guidelines (1)

Result: Priazul 2102 was a slight irritant to the eyes of rabbits

9.1.6 Skin Sensitisation (9)

Species/strain: guinea pig/Dunkin-Hartley albino

Number of animals: 20 in test group, 20 in control group

Induction procedure: a 6 hour closed topical application of Priazul 2102 (100%) on one day each week for 3 consecutive weeks

Challenge procedure: a closed patch topical application of Priazul 2102 (25% or 50% in paraffin oil) on week 5

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	**0/18***	0/18	0/20	0/20
50%	0/18	0/18	0/20	0/20

* time after patch removal
** number of animals exhibiting positive response
*** two animals died of unknown causes during the test

Test method:	according to OECD guidelines (1)
Result:	Priazul 2102 was not sensitising to the skin of guinea pigs

9.2 Repeated Dose Toxicity (11)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex/group
Method of administration:	gavage
Dose/Study duration:	Priazul 2120 (300, 700 and 1 000 $mg.kg^{-1}.day^{-1}$ in corn oil) was given by gavage for 28 days; an additional 5 animals/sex were treated with Priazul 2102 (1 000 $mg.kg^{-1}.day^{-1}$) or corn oil for 28 days and observed for a further 14 days
Clinical observations:	no deaths or signs of clinical toxicity were observed in the study; reductions in bodyweight gains and food intake were noted for low dose males and low and mid dose females
Clinical chemistry/Haematology	the level of sodium in the blood of high dose males was slightly decreased at week four and increased at week six compared to control values; slight increases in blood urea nitrogen (BUN), alkaline phosphatase and albumin-globulin ratio were noted for high dose males at week six but not at week four; as these results were not noted in females and were not consistent, they are believed not to be treatment-related; no apparent treatment-related haematological alterations were noted
Histopathology:	there was a small, significant, decrease in pituitary weight in high-dose females at week six; no pathological changes were noted
Test method:	EEC Part B.7, Sub-acute Toxicity (oral) (20) which is similar to OECD guidelines (1)
Result:	Priazul 2102 exhibited no organ toxicity in the oral repeat-dose study

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (12)

Strains:	TA 98, TA 1537, TA 100 and TA 1535
Concentration range:	6.25 - 5 000 μg/plate either in the absence or presence of rat liver S9
Test method:	according to OECD guidelines (1)
Result:	Priazul 2102 was toxic at doses at or above 200 μg/plate depending on the strain of *S. typhimurium*; there were no dose-related or significant increases in the number of revertant colonies in any of the test strains used, either in the presence or absence of metabolic activation; under the test conditions, Priazul 2102 was not mutagenic in *S. typhimurium*.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (13)

Species/strain:	mouse/CD-1
Number and sex of animals:	5/sex/dose
Doses:	1 250, 2 500 or 5 000 $mg.kg^{-1}$ of Priazul 2102 in corn oil
Method of administration:	oral
Test method:	according to OECD guidelines (1)
Result:	there was no increase in the frequency of micronucleated polychromatic erythrocytes for treated groups; Priazul 2102 did not induce micronuclei formation in bone marrow cells of mice

9.4 Overall Assessment of Toxicological Data

The acute oral, inhalation and dermal toxicy of Priazul 2102 is low. Limit tests for these routes of exposure resulted in no deaths of the test species. Priazul 2102 caused slight ocular and dermal irritation in rabbits. Dermal exposure to Priazul 2102 did not result in skin sensitisation in guinea pigs. No treatment-related effects were found when rats were repeatedly exposed to Priazul 2102 at up to 1 000 $mg.kg^{-1}.day^{-1}$ via the oral route.
Priazul 2102 did not induce gene mutation in bacteria, nor micronuclei in polychromatic erythrocytes in the bone marrow of mice. An *in vitro* study on chromosomal aberrations was not performed. Given the results of the *in vivo* and the gene mutation assay results

Priazul 2102 is thought to be non-genotoxic.

Priazul 2102 would not be classified as a hazardous substance under the National Occupational Health and Safety Commission (NOHSC) Approved Criteria (14), in relation to acute lethal effects (oral, inhalational and dermal), irritant effects (ocular and dermal), sensitisation effects (dermal) and repeat dose toxicity effects (oral), found for the surrogate data provided for assessment.

No toxicological data were provided for Priazul 2118. The notifier indicated that Priazul 2118 is not expected to show a significant difference in toxicological behaviour, because it has similar chemical properties to Priazul 2102.

Priazul 2102 is a mixture of esters and contains approximately 12% Priazul 2102. Under the worst case scenario if all the toxic effects of Priazul 2102 were due solely to Priazul 2118 present at 12 %, Priazul 2118 at 100 % would be approximately 8 times more toxic than Priazul 2102. Priazul 2118 would be expected to be at least a skin and eye irritant and may well have higher systemic toxicity.

The applicant states that some drying or irritation of skin may occur after prolonged contact with Priazul 2118. No additional (human) data was provided; however, the statement is consistent with the finding of slight irritation in experimental animals.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity testing for Priazul 2118 has not been undertaken. Priazul 2118 is a minor component (approximately 12%) of Priazul 2102 (assessed as NA/318). The notifier has indicated that, based on the similar chemical properties of the components of Priazul 2102 and Priazul 2118, Priazul 2118 is not expected to show a significant difference in toxicological behaviour.

However, the toxicity profile of Priazul 2118 will not necessarily be similar to Priazul 2102. The toxic effects observed for surfactants are generally associated with the chemical and physical properties of the specific material; however, the actual mechanism responsible for the toxic effects in this case is unclear. Saturated and unsaturated fatty acids have quite different conformations and consequently have different physical and chemical properties. The introduction of a *cis* - bond in the fatty acid chain reduces the flexibility of the chain by the introduction of a rigid kink as a result of the non - rotating double bond.

While a *trans*-bond will most closely resemble the extended form of a saturated chain, the *cis* configuration produces a rigid bend of about 30^{o} in the aliphatic chain. Such changes could have a very marked effect on the properties of the two classes of fatty acids. Priazul 2118 has a much higher water solubility than Priazul 2101 and a significantly higher critical micelle concentration. The fact that properties of the two fatty acids are different and that the mechanism of the toxic effect is uncertain, means that no clear conclusions can be made concerning the possible toxicity of Priazul 2118, which does not represent a high proportion of the chemical composition of Priazul 2102.

Nonetheless, in the absence of further data, when comparing the toxicity of Priazul 2118 to Priazul 2102 (see Table 1), the worst case has been assumed where all of the toxic effects of Priazul 2102 are due to the single component Priazul 2118.

One of the impurities present in Priazul 2118 is a degradation product in biological systems. Ecotoxicity test results for the impurity are presented below in Table 2.

Table 1: Ecotoxicity Test Results for Priazul 2102

Test	Species	Results
Acute Toxicity 96 hours Semi-static	Rainbow Trout (*Oncorhynchus mykiss*)	LC_{100} = 21 mg.L^{-1} NOEL = 11 mg.L^{-1}
Acute Immobilisation 48 hours	Water Flea (*Daphnia magna*)	EC_{50} = 260 mg.L^{-1} NOEL = 100 mg.L^{-1}
Heterotrophic Activity	Secondary Sewage Bacteria	<u>Assimilation</u> EC_{50} = 13.6 mg.L^{-1} EC_{20} = 2.5 mg.L^{-1} <u>Respiration</u> EC_{50} = 18.0 mg.L^{-1} EC_{20} = 2.7 mg.L^{-1}

Table 2: Ecotoxicity Test Results for the Impurity

Test	Species	Results
Acute Toxicity 96 hours Semi-static	Rainbow Trout (*Oncorhynchus mykiss*)	LC_{50} > 1 000 mg.L^{-1} NOEL > 1 000 mg.L^{-1}
Acute Immobilisation 48 hours	Water Flea (*Daphnia magna*)	EC_{50} > 1 000 mg.L^{-1} NOEL > 1 000 mg.L^{-1}
Heterotrophic Activity	Secondary Sewage Bacteria	<u>Assimilation</u> EC_{50} = 2.7 mg.L^{-1} EC_{20} < 2.7 mg.L^{-1} <u>Respiration</u> EC_{50} = 56.0 mg.L^{-1} EC_{20} = 5.0 mg.L^{-1}

In determining the environmental effects of Priazul 2118, by comparing it to the ecotoxicity of Priazul 2102, it has been assumed that all of the toxic effects of Priazul 2102 are due to the

single component Priazul 2118. This implies that the notified chemical is potentially 8.3 times [1] more toxic than Priazul 2102.

Considering the above, and assuming all of the toxic effects of Priazul 2102 are due to the Priazul 2118 component, the notified chemical is expected to be moderately toxic to fish and slightly toxic to the water flea.

No information regarding algae growth inhibition was supplied. Based on the chemical structure of the chemical it is unclear whether it could act on algae to produce a toxic effect.

Priazul 2102 displayed slight toxicity to heterotrophic activity in secondary sewerage, while ethyl glucoside exhibits moderate toxicity. Therefore, the notified chemical could be expected to be highly toxic to heterotrophic microorganisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is expected that the vast majority of imported chemical will be discharged to sewer following use as either hair care or body wash products. Although the chemical will ultimately find its way to sewers from normal usage, it will be in diluted form. Concentrations resulting from spillages are likely to be at levels that may cause toxic effects and spillage should be avoided.

Overall, the notified chemical is assessed as presenting a slight hazard to the environment. Risk assessment for the notified chemical appears to give a satisfactory safety margin. However, when it is used in conjunction with the two other similar products (Priazul 2102 and Priazul 2112) at levels up to their maximum amounts, the toxicity of the common degradation product returns a narrower margin of safety. Therefore, the notifier has agreed to limit the total import quantity of the notified chemical to an agreed quantity per annum.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

There were no toxicological studies presented for Priazul 2118. Priazul 2102 contains approximately 12% Priazul 2118. The toxicology studies provided for Priazul 2102 have been used as a surrogate to assess the hazard potential of Priazul 2118. Priazul 2102 is likely to be of low oral and dermal toxicity in humans and to be slightly irritating to the eyes and skin. It is likely to be a non-sensitiser to the skin. No treatment-related effects were found when rats were repeatedly exposed to Priazul 2102 via the oral route. Given the *in vivo* and the gene mutation assay results, Priazul 2102 was found to be non-genotoxic. Priazul 2102 would not be classified as a hazardous substance according to NOHSC Approved Criteria. Inhalation exposure is not likely due to the low vapour pressure of the notified chemical.

Extrapolating the toxicity of Priazul 2102 to Priazul 2118 as a worst case scenario, Priazul 2118 is unlikely to be a skin sensitiser but could be an eye and skin irritant. It may well have higher systemic toxicity.

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[1] Priazul 2101 contains Priazul 2118 at ~12%.

The notified chemical will be imported and then formulated into a variety of products, only loosely defined by the notifier. Exposure to the notified chemical is possible via skin or eye contact during formulation or end use. Exposure of manufacturing plant workers to Priazul 2118 during formulation is controlled by the use of an automated and enclosed formulation process. Packaging of products containing Priazul 2118 also occurs via a closed system. Formulated products will be placed directly into containers which are sealed immediately. A low health risk exists for manufacturing plant workers and drum cleaning operators. Eye and skin protection should be used to minimise exposure to the notified chemical.

Retail workers, transport workers and warehouse workers are only likely to handle Priazul 2118 or the formulated products when in sealed containers or packages.

Hair and beauty industry workers will normally be handling dilute solutions of the notified chemical. They may wear skin and eye protection to protect against other additives in these and related formulations. Skin and eye protection is not necessary for workers exposed to dilute solutions of Priazul 2118 for short periods of time. However, gloves could be worn to protect the skin from dryness resulting from repeated exposure to water and surfactants.

Given the low intrinsic health hazard of the notified chemical and its high exposure scenario, the occupational health risk arising from use is expected to be low, despite of the fact that frequent contact with dilute solutions of the substance may occur.

The public may also use hair care and body wash products containing the notified chemical. Public exposure to the notified chemical is expected to be high as the products will be available for domestic and salon use, and are applied to external surfaces of the body. Priazul 2102 is of low acute oral, inhalation and dermal toxicity, but a slight skin and eye irritant. However, it is unclear which component of the formulation is responsible for the observed irritancy. Since shampoo and bodywash application is for a short duration and the product is usually rinsed-off with copious amounts of water, the likelihood of irritation in these situations is minimised. The proposed use of the notified chemical is not expected to pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Priazul 2118 the following guidelines and precautions should be observed by workers up to the stage of end use:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (15) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (16);
- Industrial clothing should conform to the specifications detailed in AS 2919 (17);
- Impermeable gloves or mittens should conform to AS 2161 (18);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be 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.

- Should the notifier wish to import quantities of the notified chemical greater than the agreed quantity, the notifier will need to submit acute toxicity test reports for fish, algae and sewage microorganisms (OECD Test Guideline 209).

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (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* (19).

The 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.

The notifier has indicated that the notified chemical can also find a use in metal cleaning products. As no data was provided for this potential application, secondary notification for this use is required under Section 64(2a) of the Act.

If the import quantities of the notified chemical exceed the agreed quantity, a secondary notification is also required under Section 64 (2b) of the Act.

16. REFERENCES

1. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.

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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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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