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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PRIAZUL 2102

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For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PRIAZUL 2102

1. APPLICANT

Unichema Australia of 164 Ingles Street PORT MELBOURNE VIC 3207 has submitted for a standard notification statement with their application for the assessment certificate of PRIAZUL 2102.

2. IDENTITY OF THE CHEMICAL

PRIAZUL 2102 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the composition of the chemical, some information of use and exact estimated import have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: PRIAZUL 2102

Structural formula: notified chemical is a complex product of a chemical reaction

Method of detection and determination:

The notified substance can be isolated by high pressure liquid chromatography (HPLC) and identified by ultraviolet/visual (UV/Vis) , infrared (IR) and nuclear magnetic resonance (NMR) spectral analysis.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: viscous liquid or paste, pale yellow to brown

Odour: none or slightly fatty acid odour

Boiling Point: > 191°C at 0.01 mm Hg (theoretical - reduced pressure distillation. Test guideline A.2 EC Directive 84/449/EEC). The compounds are generally decomposed before boiling point is reached.

Pour Point: 26°C

Density: 1065 kg/m^3 at 40°C

Vapour Pressure: < 6 x 10^{-12} kPa at 20°C (calculated - modified Watson correlation)

Surface Tension at 20°C: 28.9 mN/m (“saturated” solution at 20°C). OECD harmonised ring method. Test guideline A.5 EC Directive 84/449/EEC

Water Solubility:	not available. Dispersible in water. PRIAZUL 2102 is a nonionic surfactant
Fat Solubility:	mixable in all ratios with fat simulant HB 307 at 37°C
Partition Co-efficient (n-octanol/water) log P_{OW}:	>3 (estimated)
Hydrolysis as a function of pH:	not determined
Viscosity:	18000 mPa at 40°C
Adsorption/Desorption:	not determined. Given the chemical structures of monoesters in PRIAZUL 2102 they may not expect to dissociate
Flash Point:	237°C

not determined

Dissociation Constant pKa**:**	not determined. Given the chemical structures of monoesters in PRIAZUL 2102 they may not expect to dissociate
Flammability Limits:	not determined
Combustion Products:	not provided
Pyrolysis Products:	not provided
Decomposition Temperature:	not provided
Decomposition Products:	not provided
Autoignition Temperature:	not provided
Explosive Properties:	not explosive
Reactivity/Stability:	not determined. Stable and unreactive under normal conditions. May decompose at elevated temperatures or with strong oxidants
Particle size distribution:	not applicable

Comments on Physico-Chemical Properties

Water solubility data was not available. PRIAZUL 2102 is a surfactant (by EEC definition, a chemical has surface activity when the surface tension is < 60 mN/m) (1) soluble in ethanol and propylene glycol. A similar compound Prizul 2112 (NA/319) has a solubility of 0.18 g/L max at 20°C for a visually clear solution. Due to a high Tyndall effect and the formation of micelles (CMC = 0.092 g/L) solubility behaviour deviates from that of simple organics.

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

The partition coefficient has taken from the Material Safety Data Sheet (MSDS). No indication of how this value was estimated has been given. Strictly speaking this parameter is only meaningful for substances that do not dissociate in water and are not surface active as these properties could render this value unreliable.

No measurement of adsorption/desorption were made. The notifier has indicated that they expect very low mobility in soil, but that PRIAZUL 2102 should biodegrade and not persist in the environment.

4. INDUSTRIAL USE

The notified substance will be imported into Australia and then formulated into a variety of products. Expected import rates of the notified chemical are > 1 tonne per annum for the next five years.

PRIAZUL 2102 is intended for use in haircare and bodywash formulations in Australia. The proportion of PRIAZUL 2102 that will be employed for each use has not been established and will depend on customer interest in the product and customer assessment of the marketing potential for each type of formulation in Australia.

5. OCCUPATIONAL EXPOSURE

Categories of workers potentially exposed to the notified substance include transport workers, warehouse workers, manufacturing plant workers, drum cleaning workers and retail workers.

Transport workers and warehouse workers will only be exposed in the event of accidental spillage.

Manufacturing plant workers (10-25) are required to open drums of PRIAZUL 2102 and connect them to formulation equipment. Formulation is automated and is usually fully enclosed. Direct skin contact may occur if a spill occurs in the formulation or filling lines. Drum cleaning workers are involved in cleaning drums that have contained PRIAZUL 2102. A drum cleaning worker would be required to clean roughly 5 drums for every tonne of PRIAZUL 2102 imported to Australia. Retail workers are required to unpack sealed containers containing PRIAZUL 2102 formulations and pack containers on shelfs. Retail workers will only be exposed to the notified chemical through damaged and leaking containers. End users will generally be exposed to formulations containing the notified substance for short periods of time. The exposure time will vary greatly between workplaces, hair care industries. Typically, a hair care worker may be expected to shampoo up to 20 customers per day.

6. PUBLIC EXPOSURE

Public exposure to the notified substance is expected to be high. The primary use of PRIAZUL 2102 (est. 80%) will be in domestic hair care and bodywash formulations. The public may also be exposed to PRIAZUL 2102 in hair / beauty salons. The typical proportion of PRIAZUL 2102 in shampoos is 5%. Exposure of this nature may occur once a day on external body surfaces, although the formulation may contact the eyes. The secondary use of PRIAZUL 2102 is in metal cleaning formulations for industrial and commercial applications. Public exposure to the notified substance via the metal cleaning formulations is unlikely

7. ENVIRONMENTAL EXPOSURE

Release

During the formulation process material is lost to waste from cleaning of equipment and lines. The amounts of PRIAZUL 2102 lost to waste is expected to be minimal and overall waste generation is expected to be <1%. All waste containing PRIAZUL 2102 generated during normal formulation, packaging and cleaning activities is expected to be disposed of to sewer in a diluted form, with or without pretreatment.

Waste will also be generated from the cleaning of transport equipment and drums. Overall waste generation from this source is expected to be <1%. Waste is expected to be disposed of to sewer in a diluted form, with or without pretreatment. Spillage and small volumes of off-specification material are to be disposed of to either landfill or incineration.

Any spillage of the notified material that may occur is to be contained by either sand, earth or other absorbent. The high viscosity of the material 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 2102 formulations as hair and beauty products will result in the ultimate release of all material to the sewer or septic tanks from either domestic or commercial sites around Australia. A typical formulation contains PRIAZUL 2102 at a concentration of 5% w/v. Under normal conditions of use PRIAZUL 2102 is expected to be further diluted.

Fate

The highest environmental exposure of the notified material will be to the sewer or septic tanks through the normal use of formulations containing PRIAZUL 2102. Small amounts resulting from spillage may be placed into landfill in accordance with local, state and federal regulations or be incinerated. Amounts to landfill should be negligible.

Biodegradability of PRIAZUL 2102 was assessed using COD methods specified in OECD Test Guideline 301D and EEC Directive 67/548 Annex V C.6 (as published in 84/449/EEC). The "pass" level of 60% was reached within 10 days of exceeding the 10% level and the material was found to be 83 - 84% biodegraded over 28 days under the test conditions. PRIAZUL 2102 can be classified as readily biodegradable. It is expected that it will be largely biologically degraded in the sewer or sewage treatment plants.

There is a strong potential for bioaccumulation of the material because of its high P_{OW}, low to moderate water solubility (2) and its high fat solubility. It is however readily biodegradable and unlikely to persist in the environment.

8. EVALUATION OF TOXICOLOGICAL DATA

8.1 Acute Toxicity

Table 1 Summary of the acute toxicity of PRIAZUL 2102

Test	Species	Outcome	Reference
Acute oral toxicity (Gavage)	Rat (Wistar)	LD_{50} > 2000 mg/kg, no deaths	(3)
Dermal toxicity	Guinea pig	LD_{50} > 2000 mg/kg, no deaths	(4)
Inhalation toxicity	Rat (SpragueDawley)	LC_{50} > 1980 mg/m3, no deaths	(5)
Skin Irritation	Rabbit (New Zealand White)	Slight irritation	(6)
Eye irritation	Rabbit (New Zealand White)	Slight irritation	(7)
Skin sensitisation	Guinea pig (Dunkin-Hartley)	Non-sensitiser	(8)

8.1.1 Oral Toxicity (3)

Ten young adult Wistar rats (five/sex/group) were administered a single dose of corn oil (carrier) or 2000 mg/kg bw of PRIAZUL 2102 by gavage. The rats were observed for 14 days. Animals had free access to domestic water adjusted to pH 3 with citric acid. No deaths, clinical signs of toxicity, effects on bodyweight gain or organ abnormalities were noted. The oral LD_{50} of PRIAZUL 2102 in rats was greater than 2000 mg/kg bw.

8.1.2 Dermal Toxicity (4)

Ten guinea pigs (five/sex) were dermally treated with 2000 mg/kg bw of PRIAZUL 2118 under non-occlusive dressing for 24 hours. The observation period was 14 days. No deaths or systemic effects were noted. Two animals removed the bandage during the evening and consequently the exposure time is unknown. Nine animals (one with unknown exposure time) displayed signs of erythema up to 30 hours after application of the test material. Two animals were incorrectly sexed and housed in cages with the opposite sex. Sexual activity may have affected the bodyweight gains that were variable. One female was pregnant at the completion of the study. The dermal LD_{50} in guinea pigs was greater than 2000 mg/kg bw.

8.1.3 Inhalation Toxicity (5)

Sprague-Dawley rats (five/sex/group) were exposed (snout only) for four hours to either an aerosol of 1.98 mg/L PRIAZUL 2102 in corn oil or corn oil. Approximately 70% of the aerosol mass had a particle size less than 0.9 mm. Animals were observed for 14 days. No animals died during the study. An unkempt appearance was noted for all animals. Bodyweight profiles did not differ significantly for control or test animals. Two treated and one control males had slightly mottled lungs. The LC_{50} of PRIAZUL 2102 in rats was greater than 1980 mg/m^3.

8.1.4 Skin Irritation (6)

Four female New Zealand White rabbits received 0.5 mL of PRIAZUL 2102 on the intact skin under semi-occlusive dressing for four hours. All rabbits displayed grade 2 erythema and grade 1 edema 30-60 minutes after application. All rabbits displayed signs of erythema (grades 1 or 2) 24 hours after application. Two rabbits displayed slight erythema after seven and nine days. Edema was observed in one rabbit 72 hours after application. The primary irritation index was 0.75. PRIAZUL 2102 was considered a slight skin irritant in rabbits.

8.1.5 Eye Irritation (7)

Four female New Zealand White rabbits received 0.1 mL of PRIAZUL 2102 into the conjunctival sac of one eye. Conjunctival redness and chemosis were observed at one and 24 hours in three rabbits. The total scores were 1.13, 0.25 and 0.00 at 1, 24 and 48 hours, respectively. No effects on the cornea or iris were observed. PRIAZUL 2102 was a slight eye irritant in rabbits.

8.1.6 Skin Sensitisation (8)

The skin sensitisation potential of PRIAZUL 2102 was studied in female Dunkin-Hartley albino guinea pigs using the Buehler Test. PRIAZUL 2102 was dissolved in paraffin oil. Twenty guinea pigs were subjected to a six hour topical application of PRIAZUL 2102 under occlusive dressing once a week for three weeks. As controls, twenty guinea pigs were subjected to paraffin oil in the same manner. Two weeks after the completion of the induction procedure all animals were challenged with a topical application of PRIAZUL 2102 at either 50 or 25% v/v in paraffin oil.

After each induction application of PRIAZUL 2102 all animals displayed slight erythema. No animals displayed signs of erythema after being topically challenged with PRIAZUL 2102. One test animal died before the second induction application. Another test animal died before the challenge. In both cases the cause of death was not known. PRIAZUL 2102 when applied dermally was found to be a non-sensitiser in guinea pigs.

8.2 Repeated Dose Toxicity (9)

Sprague-Dawley rats (five/sex/group) were given repeated doses by gavage of 0, 300, 700 or 1000 mg/kg bw/day of PRIAZUL 2102 in corn oil for 28 days. An additional five rats per sex were treated with corn oil or 1000 mg/kg bw/day PRIAZUL 2102 for 28 days and observed for a further 14 days.

No deaths occurred in the study. No signs of clinical toxicity were observed. Reductions in bodyweight gains and food intake were noted for low dose males and low and mid dose females. No apparent treatment-related haematological alterations were noted.

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.

Non-significant increases in relative kidney weights were observed at weeks four and six for high dose males. The relative liver weights of high dose females were non-significantly lower than control and other group values. There was a small, significant, decrease in pituitary weight in high-dose females at week six. No pathological changes were noted.

8.3 Genotoxicity

Table 2: Summary of genotoxicity studies

Test System	Species and Strain	Test Conditions	Results
Salmonella typhimurium, Plate incorporation assay	*S. typhimurium* (TA1535, TA1537, TA100, TA98)	6.25-5000 μg/plate, with and without metabolic activation	negative
Micronucleus test	CD-1 mouse	1250-5000 mg/kg bw	Negative

8.3.1 Salmonella typhimurium Reverse Mutation Assay (10)

Strains of *Salmonella typhimurium* (TA98, TA1537, TA100 and TA1535) were cultured with 6.25 - 5000 μg/plate of PRIAZUL 2102. The assays were performed either in the absence or presence of rat liver S9. The rat liver microsomal fraction (S9) was prepared from Sprague-Dawley rats that had been treated with Aroclor 1254. PRIAZUL 2102 and positive controls were dissolved in dimethyl sulphoxide. Solvent controls were used. 2-Aminoanthracene, 2-amino-acridine, N-methyl-N'-nitro-nitrosoguanidine and 2-nitrofluorene were used as positive controls.

PRIAZUL 2102 was cytotoxic 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. The positive controls behaved as expected. Under the test condition, PRIAZUL 2102 was not mutagenic in *S. typhimurium*.

8.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (11)

CD-1 mice (five/sex/dose) received an oral dose of 1250, 2500 or 5000 mg/kg bw of PRIAZUL 2102 in corn oil. Corn oil was used as the negative control. Cyclophosphamide was used as the positive control. Bone marrow cells were collected 24, 48 and 72 hours after administration for all groups, except the positive control group that were terminated after 24 hours.

There was no increase in the frequency of micronucleated polychromatic erythrocytes for treated groups compared to the negative control group. The positive control group showed an increased frequency of induced micronuclei. PRIAZUL 2102 did not induce micronuclei formation in bone marrow cells of mice.

8.4 Overall Assessment of Toxicological Data

The oral, inhalational and dermal acute toxicity of PRIAZUL 2102 were 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 3/4 and 4/4 rabbits, respectively. 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 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 *in vivo* and the gene mutation assay results PRIAZUL 2102 is thought to be non-genotoxic.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)] (12) in relation to irritant effects (skin and eye), acute lethal effects (oral and inhalation), sensitising effects (skin), repeated dose toxicity effects.

9. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Results of ecotoxicological tests supplied by the notifier.

Organism	**Test**	**Result**
Rainbow trout (*Oncorhynchus mykiss)*	Acute Semi-static 96 hours	PRIAZUL 2102 NOEL was 11 mg/L. 100% mortality 21 mg/L. Ethyl glucoside LC_{50} >1000 mg/L over 24 and 48 hours No adverse effects observed at 1000 mg/L.
Daphnia magna	Acute immobilisation	EC_{50} (calculated) 260 mg/L over 48 hours. (95% confidence limit 220 - 310 mg/L). NOEL (<10% immobilisation) (calculated) 100 mg/L over 48 hours. Ethyl glucoside EC_{50} >1000 mg/L over 24 and 48 hours No adverse effects observed at 1000 mg/L.
Algae	No test performed	No results available.

Heterotrophic Activity	Acute	PRIAZUL 2102 EC_{50} (calculated) 13.6 mg/L (assimilation) EC_{50} (calculated) 18.0 mg/L (respiration) EC_{20} (calculated) 2.5 mg/L (assimilation) EC_{20} (calculated) 2.7 mg/L (respiration) Ethyl glucoside EC_{50} (calculated) 2.7 mg/L (assimilation) EC_{50} (calculated) 56.0 mg/L (respiration) EC_{20} (calculated) <2.7 mg/L (assimilation) EC_{20} (calculated) 5.0 mg/L (respiration). Ethyl glucoside exhibits high toxicity to assimilation.

Fish

Acute toxicity tests on fish were carried out according to the method specified in OECD Guideline No. 203. The notifier has reported an LC_{50} of 15 mg/L. Ecotoxicological data provided were unsuitable for a probit analysis of the dose-response curve for determination of LC_{50} values as there were no data points recorded between the 0% and 100% mortality limits. Any determination of LC_{50} levels will be statistically invalid and therefore have large errors associated with them. The values should only be taken as a rough guide to a range of concentrations and not as a specifically measured value. Although data is not suitable for an accurate determination of LC_{50} it is clear that the value will lie in the range of 11 - 21 mg/L (measured concentrations).

Daphnia magna

Daphnia magna acute immobilisation tests were carried out as described in OECD Test Guideline No. 202, Part 1 and EEC Directive 67/548 Annex V C.2 (as published in 84/449/EEC). Determination of the EC_{50} was based on nominal concentrations as the compound is unstable under the test conditions. Final concentrations varied between 0 and 80% of initial values. It was not considered valid to use final measured concentrations for the calculation of EC_{50} values as this would not take into consideration the effect of near nominal concentrations prevalent at the start of the exposure period. *Daphnia magna* reproduction tests were not carried out as instability of PRIAZUL 2102 in water makes it difficult to be accurately perform tests on aquatic organisms over long periods of time. There appears to be a sufficient safety margin with respect to the anticipated environmental levels to indicate that no chronic effect is to be expected.

Algae

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

Heterotrophic Activity

Acute toxicity tests on heterotrophic activity in secondary sewage were carried out using a tracer method as described in Williams and Askew (13). This test measures carbon metabolism by following the assimilation and respiration of a ^{14}C-labelled amino acid to identify any acute toxic effects on the non-adapted bacterial flora in secondary sewage.

The test is an indication as to the level at which heterotrophs are able to utilise the test material and how the presence of the test compound effects "normal" respiration and assimilation. Heterotrophs are those bacteria that cannot utilise CO_2 but must obtain carbon from the environment in a relatively complex, reduced form.

PRIAZUL 2102 showed slight toxicity to heterotrophic activity in secondary sewerage however the degradation product, ethyl glucoside, exhibits moderate toxicity to assimilation.

· Conclusions

Based on the above, PRIAZUL 2102 is expected to be slightly toxic to fish and slightly to moderately toxic to sewage organisms but practically non-toxic to *Daphnia magna*. The impurity and degradation product ethyl glucoside is non toxic to fish and *Daphnia magna* but is moderately toxic to heterotrophic activity.

10. ASSESSMENT OF PREDICTED ENVIRONMENTAL HAZARD

In determining the environmental risk presented by PRIAZUL 2102, the lowest reported LC_{50} values should be used in determining the worst case situation due to unreliable statistical values.

Nearly all the imported material will be discharged to sewer following application. Assuming that 100% of the material is used per year, 75 tonnes will be discharged per annum at its highest import level. This represents 205 kg/day if used on a daily basis. Assuming that the material was to be used only in Melbourne with a population of 3.5 million and sewage discharge of 720 ML per day with no treatment or degradation, the final concentration would be 0.285 mg/L in sewage effluent (Q=8.8 (EC20 for heterotrophic activity)) and 0.0285 mg/L in receiving waters (Q=380 for fish).

It is unlikely specialty products of this type would be targeted at only one major Australian city but would rather be marketed in all major cities around the country. Usage distributed over this population will result in a five fold reduction in the concentration in receiving waters.

This represents a worst case and neglects any loss of material to sludge in sewage treatment which would be expected to be significant as indicated by the octanol/water partition coefficient and ignores any biodegradation. This material is readily biodegraded as determined by a standard test.
On the basis of ecotoxicological results, spills of PRIAZUL 2102 might be expected to cause some mortality to aquatic organisms. PRIAZUL 2102 is readily biodegraded and it is expected that concentrations of PRIAZUL 2102 would be

reduced to below levels showing effects in short periods of time. Careful storage, handling and prompt response to accidental spillage should minimise potentially harmful amounts of PRIAZUL 2102 from entering the environment.
A Material Safety Data Sheet has been provided and contains warnings in regard to protection of the environment, containment and disposal of spillage. The MSDS should be reworded to indicate avoiding contamination of drains, surface and ground waters rather than minimising contamination. Although the material will ultimately find its way to sewers from normal usage, this is in a diluted form. Concentrations that could be present from spillage would be likely to be high enough to cause toxic effects and should be avoided. The MSDS should also be amended to indicate that the composition is a mixture of chemicals rather than a single chemical substance.

11. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified substance will be imported into Australia and then formulated into a variety of products.

PRIAZUL 2102 is likely to be of low oral (LD_{50} > 2000 mg/kg) and dermal toxicity (LD_{50} > 2000 mg/kg) in humans and to be slightly irritating to the eyes and skin. It is a non-sensitiser to the skin. Inhalation exposure is not likely due to the extremely low vapour pressure of the notified substance. 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.

Exposure to the notified chemical is possible via skin or eye contact. Exposure of manufacturing plant workers to PRIAZUL 2102 during formulation is minimised by isolation of the formulation system. During filling, PRIAZUL 2102 formulations are also usually contained within a closed system and placed directly into containers which are then sealed immediately. When the notified substance is handled at temperatures above room temperature during formulation, ventilation systems extract air directly from the formulation. Manufacturing plant workers will be required to wear gloves and eye protection. Drum cleaning workers will be required to wear protective clothing, gloves and safety glasses. Drum cleaning operations will be carried out in a well-ventilated building or in the open.

Hair/beauty industry workers will normally be handling dilute solutions of the notified substance and if required due to other additives in the formulations may wear skin and possibly eye protection. Skin and eye protection is not necessary for workers exposed to dilute solutions of PRIAZUL 2102 for short periods of time although gloves should be worn to protect the skin from becoming dry due to repeated exposure to water and surfactants.

Retail workers, transport workers and warehouse workers are only likely to handle PRIAZUL 2102 or its formulations in sealed containers or packages. Gloves may be worn to prevent skin from becoming dry and all areas of skin contacted with PRIAZUL 2102 would normally be washed after contact as skin will probably feel sticky.

Public exposure to the notified chemical is expected to be high as haircare and bodywash formulations will be available for domestic and salon use, and are applied to external surfaces of the body. PRIAZUL 2102 is of low acute oral, inhalational or dermal toxicity. It should be noted that PRIAZUL 2102 is a slight skin and eye irritant. However, it is unclear as to which component of the formulation is responsible for the observed irritancy. As PRIAZUL 2102 is present at levels up to only 5% in personal care products, and 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, if adequate precautions are taken.

Given the low intrinsic health hazard of the notified chemical together with expected low exposure, the occupational health risk arising from use is expected to be minimal.

However, due to the potential effects of both the notified chemical and its main impurity and degradation product on sewage micro-organisms and the lack of results for toxicity to algae, the notifier should undertake to inform the Director of NICNAS if reports of effects on these organisms are reported.

12. RECOMMENDATIONS

To minimise occupational exposure to PRIAZUL 2102 the following guidelines and precautions should be observed:

. particular care should be taken to avoid spillage or splashing of PRIAZUL 2102;

. production of mists in the workplace during mixing operations should be avoided;

. good personal hygiene should be practiced to minimise the potential for ingestion; and

. when handling PRIAZUL 2102 personal protective equipment which conforms to and is used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS/NZS 1337) (14,15), impermeable gloves (AS 2161) (16) and overalls should be worn.

. the notifier should inform the Director of NICNAS if report of effects on these organisms are reported

13. MATERIAL SAFETY DATA SHEET

The attached Material Safety Data Sheet (MSDS) for PRIAZUL 2102 was provided in a suitable format.

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

14. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of PRIAZUL 2102 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise, if the notified chemical is to be used in metal cleaning formulations.

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