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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PRIAZUL 2112

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PRIAZUL 2112

1. APPLICANT

Unichema Australia of 164 Ingles Street, PORT MELBOURNE Victoria 3207 has submitted a standard notification statement with their application for assessment of PRIAZUL 2112. The notified chemical is intended for use in haircare and bodywash formulations.

2. IDENTITY OF THE CHEMICAL

PRIAZUL 2112 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 about its use and exact estimated import quantities have been exempted from publication in the Full Public Report and the Summary Report.

Trade names: PRIAZUL 2112
Biosurf 12 (trade name used in Europe)

Method of detection and determination:

The notified chemical can be isolated by high pressure liquid chromatography and identified by ultraviolet/visual, infrared and nuclear magnetic resonance spectral analysis.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	viscous liquid or paste, yellow to brown in colour at ambient temperature and pressure
Odour:	odourless to slight fatty acid odour
Boiling Point:	> 209°C at 1.3 Pa (theoretical - reduced pressure distillation. Test guideline A.2 EEC Directive 84/449/EEC). The compound generally decomposes before boiling point is reached))
Pour point:	27°C
Viscosity:	21000 mPa at 40°C (approximately)
Density:	not determined (density of a similar product PRIAZUL 2102 is 1065 kg/m^3 at 40°C

Vapour Pressure:	this is a high molecular weight organic chemical, the vapour pressure of PRIAZUL 2112 is extremely low and cannot be measured by standard methods; an estimate of vapour pressure has been based on molecular weight and estimated boiling point (< 10^{-8} Pa at 20°C)
Water Solubility:	0.18 g/L max at 20°C for a visually clear solution; water solubility was determined by the flask method using gas chromatography; dispersible in water. PRIAZUL 2112 is a nonionic surfactant.
Fat Solubility:	up to a 1:1 Priazul 2112 mixes 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
Adsorption/Desorption:	not determined
Dissociation Constant pKa**:**	not determined; given the chemical structure of PRIAZUL 2112 it is not expected to dissociate
Flash Point:	not determined for PRIAZUL 2112; for a similar product PRIAZUL 2102 is 237°C
Flammability Limits:	not determined
Autoignition Temperature:	not determined
Explosive Properties:	not explosive
Reactivity/Stability:	stable and unreactive under normal conditions; may decompose at elevated temperatures or with strong oxidants
Particle size distribution:	not applicable (is a liquid or a paste at ambient temperature)

Comments on Physico-Chemical Properties

PRIAZUL 2112 is a surfactant (by EEC definition, a chemical has surface activity when the surface tension is less than 60 mN/m) [a]. Due to a high Tyndall effect and the formation of micelles (CMC = 0.032 g/l) solubility behaviour deviates from that of simple organics.

No hydrolysis data was available for the notified material. Hydrolysis of the material 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 result has been 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 was made. The notifier has indicated that they expect low mobility in soil, but that PRIAZUL 2112 should biodegrade and not persist in the environment.

4. PURITY OF THE CHEMICAL

Degree of purity:

Typical concentration:	85%
Lower limit:	80%
Upper limit:	100%

Toxic or hazardous impurities: none known

Non-hazardous impurities: 14%(> 1% by weight)
Additives/Adjuvants: None

5. 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 2112 is intended for use in haircare and bodywash formulations in Australia. These formulations are primarily for domestic use but may also be used in hair dressing and beauty salons. The proportion of PRIAZUL 2112 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. The secondary use of PRIAZUL 2112 is in metal cleaning formulations for industrial and commercial applications.

[a] EEC Directive 92/69, A.5. "Surface Tension" (1992)

6. 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 be exposed only in the event of accidental spillage.

Manufacturing plant workers (10-25) are required to open drums of PRIAZUL 2112 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 2112. A drum cleaning worker would be required to clean roughly 5 drums for every tonne of PRIAZUL 2112 imported to Australia. Retail workers are required to unpack sealed containers containing PRIAZUL 2112 formulations and pack containers on shelves. Retail workers will only be exposed to the notified substance through damaged and leaking containers. End users will generally be exposed to formulations containing the notified chemical for short periods of time. The exposure time will vary greatly between workplaces in hair care industries. Typically, a hair care worker may be expected to shampoo up to 20 customers per day.

7. PUBLIC EXPOSURE

Public exposure to the notified substance is expected to be high. The primary use of Priazul 2112 (est. 80%) will be in domestic hair care and bodywash formulations. The public may also be exposed to PRIAZUL 2112 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 2112 is in metal cleaning formulations for industrial and commercial applications. Public exposure to the notified substance via the metal cleaning formulations is unlikely.

8. ENVIRONMENTAL EXPOSURE

Release

During the formulation process material is lost to waste from cleaning of equipment and lines. The amount of PRIAZUL 2112 lost to waste is expected to be minimal and overall waste generation is expected to be <1%. All waste containing PRIAZUL 2112 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 2112 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 2112 at a concentration of 5% w/v. Under normal conditions of use PRIAZUL 2112 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 2112. 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 2112 was not determined. Biodegradability of a similar compound PRIAZUL 2102, of which PRIAZUL 2112 is the major component, was assessed using COD methods. The similar compound was found to be 83 - 84% biodegraded over 28 days under the test conditions and could be classed as readily biodegraded. It is likely that PRIAZUL 2112 is also 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 low to moderate water solubility [1] and its high fat solubility. It is however expected to be readily biodegradable and unlikely to persist in the environment.

9. EVALUATION OF TOXICOLOGICAL DATA

No data on the toxicity of PRIAZUL 2112 were presented. Toxicological data on the similar chemical PRIAZUL 2102 were presented. The monoesters in PRIAZUL 2102 have similar functional groups, and the mixture comprises 41.8% PRIAZUL 2112.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of PRIAZUL 2112

Test	Species	Outcome	Reference
Acute oral toxicity (Gavage)	Rat (Wistar)	LD_{50} > 2000 mg/kg, no deaths	(2)
Dermal toxicity	Guinea pig	LD_{50} > 2000 mg/kg, no deaths	(3)
Inhalation toxicity	Rat (SpragueDawley)	LC_{50} > 1980 mg/m3, no deaths	(4)
Skin Irritation	Rabbit (New Zealand White)	Slight irritation	(5)
Eye irritation	Rabbit (New Zealand White)	Slight irritation	(6)
Skin sensitisation	Guinea pig (Dunkin-Hartley)	Non-sensitiser	(7)

9.1.1 Oral Toxicity (2)

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.

9.1.2 Dermal Toxicity (3)

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.

9.1.3 Inhalation Toxicity (4)

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.

9.1.4 Skin Irritation (5)

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.

9.1.5 Eye Irritation (6)

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.

9.1.6 Skin Sensitisation (7)

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.

9.2 Repeated Dose Toxicity (8)

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 , two weeks after the discontinuation of the treatment,

but not at week four at the end of the treatment. 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.

9.3 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

9.3.1 Salmonella typhimurium Reverse Mutation Assay (9)

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*.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (10)

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.

9.4 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.

The applicant has stated that some drying or irritation of skin may occur after prolonged contact with PRIAZUL 2112, and this can be avoided by wearing gloves. The MSDS provided by the applicant stated that the notified substance is 'unlikely to be irritant' to the skin. There are no data in support of these statements.

There were no toxicological studies presented for PRIAZUL 2112. PRIAZUL 2102 contains about 42% PRIAZUL 2112 and therefore toxicology studies on the former provide some information on the hazard potential of the latter. Since PRIAZUL 2112 is formulated and sold as PRIAZUL 2102, the absence of studies on PRIAZUL 2112 is not a major concern in this instance.

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)] in relation to irritant effects (skin and eye), acute lethal effects (oral and inhalation), sensitising effects (skin), repeated dose toxicity effects.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity tests for PRIAZUL 2112 have not been carried out.

Results of ecotoxicological tests for a similar compound, PRIAZUL 2102 (NA/318), are included in the following table. PRIAZUL 2112 is a component of PRIAZUL 2102 constituting approximately 40% of the total active components. Comments on the tests are included in the related assessment.

Organism	Test	Result
Rainbow trout (*Oncorhyncus mykiss)*	Acute Semi-static 96 hours	PRIAZUL 2102 (Similar Compound NA/318) NOEL was 11 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 (Similar Compound NA/318) 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.

The notifier has indicated that based on the similar chemical properties of the components of PRIAZUL 2102 that PRIAZUL 2112 is expected to show no significant differences in toxicological behaviour. PRIAZUL 2102 is a mixture of ethyl glucoside esters containing approximately 86% saturated, C_8 to C_{18}, fatty acid esters and 14% unsaturated fatty acid esters.

Given that it is the major component, with an average chain length, the EPA agrees that PRIAZUL 2112 will show similar properties to PRIAZUL 2102 given the structure and chemistry of the compounds and the composition of PRIAZUL 2102.

Based on the above, PRIAZUL 2112 is expected to be slightly to moderately toxic to fish and sewage organisms but practically non-toxic to *Daphnia magna*, however, it is readily biodegradable and not expected to be a significant environmental contaminant.

11. ASSESSMENT OF PREDICTED ENVIRONMENTAL HAZARD

In determining the environmental risk presented by PRIAZUL 2112, by comparing the ecotoxicity of PRIAZUL 2112 to PRIAZUL 2102, we must assume that all of the toxic effects of PRIAZUL 2102 are due to the single component PRIAZUL 2112 and the lowest reported LC_{50} values should be used in determining the worst case situation. This means that PRIAZUL 2112 is potentially 2.5 times more toxic than PRIAZUL 2102 and would have an LC_{50} of 6 mg/L to fish.

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 discharged in sewage effluent (Q=3.5 (EC20 for heterotrophic activity)) and 0.0285 mg/L in receiving waters (Q=210 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 surface

activity, and ignores any biodegradation. The above concentration is well below the toxic levels to fish and *Daphnia magna*.

Further, any treatment of sewage will reduce the levels discharged to the environment to low ppb due to the expected ready biodegradability of the material. Also, if the components of PRIAZUL 2102, of which PRIAZUL 2112 is a component, are of equal toxicity, the toxic effects will be further reduced 2.5 times.
On the basis of ecotoxicological results, spills of PRIAZUL 2112 might be expected to cause some mortality to aquatic organisms. PRIAZUL 2112 is expected to be readily biodegraded and concentrations of PRIAZUL 2112 would be reduced to below effect levels in short periods of time. Careful storage, handling and prompt response to accidental spillage should minimise potentially harmful amounts of PRIAZUL 2112 from entering the environment.

If spillage occurs, care should be taken to avoid contamination of drains surface and ground waters. 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.

12. 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 (LD50 > 2000 mg/kg) and dermal toxicity (LD50 > 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 2112 during formulation is minimised by isolation of the formulation system. During filling, PRIAZUL 2112 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 2112 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 2112 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 2112 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.

13. RECOMMENDATIONS

To minimise occupational exposure to PRIAZUL 2112 the following guidelines and precautions should be observed:

. particular care should be taken to avoid spillage or splashing of PRIAZUL 2112;

. 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 2112 personal protective equipment which conforms to and is used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS/NZS 1337) (12,13), impermeable gloves (AS 2161) (14) protective clothing (AS 2919) (15) should be worn.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for PRIAZUL 2112 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.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of PRIAZUL 2112 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise and if the notified chemical is going to be used in metal cleaning formulations.

Due to the potential effects of both the notified material 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.

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