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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Blue N-RM 2114

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Blue N-RM 2114

1. APPLICANT

Clariant (Australia) Pty Ltd of 675-685 Warrigal Rd CHADSTONE VIC 3148 has submitted a limited notification statement in support of their application for an assessment certificate for Blue N-RM 2114.

2. IDENTITY OF THE CHEMICAL

Blue N-RM 2114 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name:	Sandolan Blue MF-BLN SGR (contains 39% of the notified chemical)
Molecular Weight:	600

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	fine blue granules
Melting Point:	> 260°C
Density:	1 494 kg/m^3 at 20°C
Vapour Pressure:	not provided
Water Solubility:	2 2100 mg/L at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} 0.8445 ±0.1514
Hydrolysis as a Function of pH:	not provided

Adsorption/Desorption:	not provided
Dissociation Constant:	not provided
Surface Activity:	at 2.2 g/L = 46.7 mN/m (after 36 hours) 46.3 mN/m (after 48 hours) at 11 g/L = 48.3 mN/m (after 36 hours) 48.2 mN/m (after 72 hours)
Fat Solubility:	0.099 g/kg fat at 37 ±0.5°C
Flash Point:	not available
Flammability Limits:	not flammable
Autoignition Temperature:	> 400°C
Explosive Properties:	not explosive
Reactivity/Stability:	not oxidising

Comments on Physico-Chemical Properties

The notifier claims the vapour pressure of the notified chemical will be negligible. It is a solid at room temperature, has a high melting point and relatively high molecular weight. The chemical is imported as non-dusting granulated formulation. Particle size was not supplied which is acceptable.

The notifier claims that the notified chemical is stable in water and it is technically desirable that it does not hydrolyse. The presence of a sulfonamide functionality is noted. However, hydrolysis of this group is not expected to occur in the environmental pH range.

The notifier expects the notified chemical to have a low affinity for soil. High water solubility and a low log partition coefficient indicate that the chemical should have a low affinity for soil and sediment. Note, however, its surface activity.

The dye is a sodium salt of a sulphonic acid and has good water solubility. It can be assumed that the molecule will dissociate to a high degree in the pH range of 4-9. It also contains a primary and a secondary amine functionality.

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). The fat solubility is low.

4. PURITY OF THE CHEMICAL

Purity: 94% (lower - 90%, upper - 96%)

Toxic or Hazardous Components: none

Non-Hazardous Impurities:

Name	*CAS Number*	*% Weight*
sodium chloride	7647-14-5	1-3%
water	7732-18-5	1-8%

Additives/Adjuvants: None.

5. USE, VOLUME AND FORMULATION

The notified chemical (an anthraquinone dye) is to be used as a textile dye for wool and nylon. It will be imported in polyethylene-lined cardboard boxes at a rate of 390 kg for the first year rising to 468 kg per year by the fifth year. It will be imported into Australia as a granulated formulation; this formulation contains the notified chemical at a concentration of about 39% and is known as Sandolan Blue MF-BLN SGR. The product maybe repacked into 5, 10 or 20 L plastic containers at the notifier's warehouse.

6. OCCUPATIONAL EXPOSURE

The imported formulation will be imported in boxes that will either be distributed to the notifier's customers or repackaged. Repackaging will be infrequent , accounting for less than 10% of the chemical. This will be undertaken at the notifier's premises and will be undertaken by a storeman.

Use of the dye will entail removal of the dye from the containers by scoop, it is then weighed into a mixing tank and dissolved by mechanical stirring. The dye will be added at a rate of 1% based on the weight of fabric to be dyed. The dye solution is pumped into the dye bath (closed bath). The notifier indicates a high fixation rate of 98%, resulting in a high dilution rate in waste water from the dyeing procedure. Some dye baths will have exhaust ventilation others will not. There will be some manual handling and therefore potential exposure to the dye solution on textiles in the dyebath. Up to 10 dyehouses will use the dye containing the notified chemical with one storeman and one operator potentially exposed to the notified chemical. Potential exposure will be for periods of approximately one hour during weighing and for unspecified periods during other operations such as removal of dyed textiles from dyebaths.

Occupational exposure is most likely to occur during weighing of the granulated formulation and during handling of textiles from the dyebath. As the formulation is granulated actual exposure during weighing will be reduced. The likely exposure

pathway during this process is inhalational and possible eye contact from any mobilised dust. The most significant exposure pathway when handling the dyed textile will be dermal.

7. PUBLIC EXPOSURE

The product will not be available to the public directly but exposure to materials dyed with the product will be widespread. As the dye in its final form is chemically bound to the fibres, the biological availability of the dye will be minimal.

Minimal or no public exposure is anticipated from industrial processes utilising the notified chemical.

8. ENVIRONMENTAL EXPOSURE

Release

The bulk of the dye will become chemically fixed to the wool or nylon fibres, and in this state is not expected to impact on the environment. The notifier claims that the dye has a fixation rate of 98%, though a test report to support this claim was not supplied. It is the ionic attraction between the sulphonic acid group and the basic groups in wool that causes the adsorption of the dyestuff to the wool fibre. However, this resulting link can be easily broken. Therefore, it is believed that in the cases where good fastness performance is achieved, fibre attachment depends mainly on the non-polar van der Waals forces (2). In nylon, high wet fastness properties occur due to its hydrophobic nature. The greater the proportion of free amino groups in the nylon, the greater the affinity for acid dyes (2).

The major environmental exposure to dye will come from effluent discharge from dyehouses and waste water treatment systems. Other releases will be limited to traces remaining from repacking operations and clean-up of any spills, and from trace residues in empty packaging. The notifier claims that the packages should be effectively empty and will be disposed of to landfill.

All clean up of spills and disposal of empty packaging should be carried out according to the Material Safety Data Sheet (MSDS).

Fate

The dye normally released in the water as effluent from the dyehouse is expected to be the major environmental exposure. The dye is not likely to partition to sediment/sludge, but remain in the aquatic phase due to its high water solubility and low K_{OW}, though the extent of this is unclear due to its surface activity. Tests to determine the amount of dye removed from wastewater through the adsorption to activated sludge reported highly variable results for acid dyes (3). It is also unclear

whether the dye will hydrolyse during the waste water treatment process, as hydrolysis of the sulphonamide group is possible.

The biochemical oxygen demand (BOD) of the dye was tested and the five day study showed the BOD_5 was 0 mg O_2/100 mg. The dye was found to be non-degradable in sludge from a domestic waste water treatment process. This study indicates that the chemical is unlikely to significantly degrade in sewage treatment plants due to the relatively short retention time.

After treatment in the sewage plant, the dye will enter either freshwater or marine environments in solution. The dye should remain mainly in the aquatic environment and accumulation in sediment is unlikely. Although the dye is not likely to readily biodegrade, the potential for bioaccumulation is low due to low water partition coefficient, low fat solubility and high water solubility. Hydrophilic dyes with
log P_{OW} < 3 have been shown not to bioaccumulate (4).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Blue N-RM 2114

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	5
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	6
skin irritation	rabbit	not an irritant	7
eye irritation	rabbit	slight to moderate irritant	8
skin sensitisation	guinea pig	not a sensitiser	9

9.1.1 Oral Toxicity (5)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	by oral gavage; vehicle: 2% carboxymethylcellulose
Clinical observations:	sedation, dyspnoea, curved body position, ruffled fur in the 5 000 mg/kg dose group; all animals recovered within 5 observation days

Mortality:	none
Morphological findings:	none
Test method:	OECD Guidelines for Testing of Chemicals (10)
LD_{50}:	> 5 000 mg/kg
Result:	the notified chemical was of low oral toxicity in rats

9.1.2 Dermal Toxicity (6)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	notified chemical in 2% carboxymethylcellulose under occlusive dressing for 24 hours
Clinical observations:	ruffled fur on days 3 and 4
Mortality:	none
Morphological findings:	none
Test method:	OECD Guidelines for Testing of Chemicals (10)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Skin Irritation (8)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males, 1 female
Observation period:	72 hours
Method of administration:	0.5 g of the notified chemical, moistened with water, was applied under occlusive dressing for 4 hours

Test method: OECD Guidelines for Testing of Chemicals(10)

Result: the notified chemical was not a skin irritant in rabbits; no erythema or oedema were observed at 1, 24, 48 or 72 hours post-treatment

9.1.4 Eye Irritation (9)

Species/strain: rabbit/New Zealand white

Number/sex of animals: 2/sex

Observation period: 72 hours

Method of administration: 0.1 g of the notified chemical was placed in the conjunctival sac of the left eye of each rabbit

Draize scores (11) of unirrigated eyes:

	Time after instillation									
Animal	**1 hour**		**1 day**		**2 days**		**3 days**		**7 days**	
Cornea										
1	2[1]		2		2		1		0	
2	1		1		0		0		0	
3	2		2		2		1		0	
4	1		1		1		0		0	
Iris										
1	0		0		0		0		0	
2	0		0		0		0		0	
3	0		0		0		0		0	
4	0		0		0		0		0	
Conjunctiva	**r[c]**	**c[d]**	**r[c]**	**c[d]**	**r[c]**	**c[d]**	**r[c]**	**c[d]**	**r[c]**	**c[d]**
1	1	2	3	1	2	0	1	0	0	0
2	1	3	2	1	1	0	0	0	0	0
3	1	2	3	0	2	0	1	0	0	0
4	1	2	3	1	2	1	1	0	0	0

[1] see Attachment 1 for Draize scales
[c] redness [d] chemosis

Test method: OECD Guidelines for Testing of Chemicals (10)

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

9.1.6 Skin Sensitisation (9)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 10/sex (test group), 5/sex (control group)

Induction procedure: three pairs of intradermal injections (0.1 mL) in the scapular region:

- Freund's complete adjuvant (FCA), 1:1 with tap water
- the notified chemical, diluted to 5% with tap water
- the notified chemical at 5%, emulsified in a 1:1 mixture of FCA and tap water;

one week after the injections, the same region was treated with 25% notified chemical in tap water under occlusive dressing for approximately 48 hours

Challenge procedure: two weeks after the topical induction, challenge the left flank of each animal was treated with 25% notified chemical under occlusive dressing for 24 hours; re-challenge was performed in the same manner, one week later

Challenge (and re-challenge) outcome:

	Test animals		***Control animals***	
Challenge/ rechallenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	0/20**	0/20	0/10	0/10

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

Test method: OECD Guidelines for Testing of Chemicals (10)

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

9.2 Repeated Dose Toxicity (12)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex/group
Method of administration:	a 25% suspension of the notified chemical in 2% carboxymethylcellulose was applied under occlusive dressing for 6 hours per day over 28 days
Dose/Study duration::	0, 1 000 mg/kg/day for 28 days
Clinical observations:	none
Clinical chemistry/Haematology	no treatment-related changes
Histopathology:	no treatment-related changes
Test method:	OECD Guidelines for Testing of Chemicals (10)
Result:	no specific organ toxicity was noted in rabbits when the notified chemical was administered dermally at 1 000 mg/kg/day for 28 days; no indications of systemic toxicity were noted in the clinical laboratory investigations

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay

4 different reverse mutation studies were submitted by the notifier and are individually summarised below:

9.3.1.1 1st study (13)

Strains:	TA 98, TA 100, TA 1535, TA 1537 and TA 1538
Concentration range:	1.58 - 5 000 μg/plate
Test method:	OECD Guidelines for Testing of Chemicals (10)
Result:	the notified chemical was not mutagenic in *S. typhimurium* in the presence or absence of metabolic activation provided by rat liver S9 fraction

9.3.1.1 2nd study (14)

Strains:	TA 98, TA 100, TA 1535, TA 1537 and TA 1538
Concentration range:	1.58 - 5 000 μg/plate
Test method:	OECD Guidelines for Testing of Chemicals (10)
Result:	the notified chemical was not mutagenic in *S. typhimurium* in the presence or absence of metabolic activation provided by rat liver S9 fraction; precipitation of the notified chemical at high concentrations meant that only doses up to 500 μg/plate could be evaluated

9.3.1.3 3rd study: Nylosan Blue N-BLN/PK OP 4104 (15)

Strains:	TA 98, TA 100, TA 1535, TA 1537 and TA 1538
Concentration range:	1.58 - 5 000 μg/plate
Test method:	OECD Guidelines for Testing of Chemicals (10)
Result:	the notified chemical was mutagenic in *S. typhimurium* strains TA 98, TA 1538 and TA 100 in the presence but not in the absence of metabolic activation provided by rat liver S9 fraction; the mutagenic potencies were 0.29, 0.24 and 0.15 mutants per μg, respectively with mutagenicity being observed at 158 and 500 μg/plate in each strain; results at higher doses were discarded due to precipitation of the notified chemical

9.3.1.4 4th study: Nylosan Blue N-BLN/PK OP 4104 (16)

Strains:	TA 98, TA 100, TA 1535, TA 1537 and TA 1538
Concentration range:	1.58 - 5 000 μg/plate
Test method:	OECD Guidelines for Testing of Chemicals (10)

Result:	the notified chemical was mutagenic in *S. typhimurium* strains TA 98, TA 1538 and TA 100 in the presence but not in the absence of metabolic activation provided by rat liver S9 fraction; the mutagenic potencies were 0.29, 0.24 and 0.15 mutants per μg, respectively with mutagenicity being observed at 158 and 500 μg/plate in each strain; results at higher doses were discarded due to precipitation of the notified chemical

9.3.2 Mutagenesis in Chinese Hamster V79 Cells (17)

Concentration range:	measurement of mutagenicity of the notified chemical was conducted in the presence of metabolic activation (provided by rat liver S9 fraction) at doses up to 250 μg/mL for 2 hours and at doses up to 70 μg/mL for 24 hours in the absence of S9
Test method:	OECD Guidelines for Testing of Chemicals (10)
Result:	the notified chemical was not mutagenic in Chinese hamster V79 cells in the presence or absence of metabolic activation provided by rat liver S9 fraction

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (18)

Species/strain:	mouse/NMRI KFM
Number and sex of animals:	18/sex/treatment group
Doses:	4 000 mg/ kg
Method of administration:	by gavage - vehicle: distilled water
Test method:	OECD Guidelines for Testing of Chemicals (10)
Result:	no significant increase in the frequency of micronucleated polychromatic erythrocytes was detected at 24, 48 or 72 hours post-treatment

9.4 Overall Assessment of Toxicological Data

The notified chemical has a low oral and dermal toxicity in rats with respective LD_{50} values in excess of 5 000 and 2 000 mg/kg. In a skin irritation study in rabbits no evidence of skin irritation potential was found. An eye irritation study in rabbits resulted in effects on the cornea and conjunctiva. These effects were in evidence for 72 hours after application in the majority of rabbits but were resolved by day seven. The effects were reversed and were below the levels considered to be irritant according to the Worksafe Australia *Approved Criteria for the Classification of Hazardous Substances* (19).

In a guinea pig skin sensitisation study there was no evidence of sensitisation. A 28 day repeat dose dermal toxicity study using rabbits produced no treatment related changes or deleterious effects at doses up to 1 000 mg/kg/day.

Both *in vivo* and *in vitro* genotoxicity studies were submitted. Four *S. typhimurium* reverse mutation assays were submitted. All used the same strains of bacteria and the same maximal concentration of the notified chemical. The first two tests appear to be identical (maximum dose 5 000 μg/plate) and gave negative results both with and without S9 activation. The other two test used Nylosan Blue N-BLN/PK OP 4104 which was identified by the notifier as the notified chemical. Both these tests gave positive results for specific strains only and only with S9 activation, the strains were TA 98, TA 100 and TA 1538. Mutagenic effects were evident at 158 and 500 μg/plate. Results at higher concentrations were discarded due to precipitation of the test chemical. Another *in vivo* test for mutagenesis using Chinese hamster V79 cells was negative both with and without S9 activation. An *in vitro* mouse micronucleus test was negative for clastogenesis. There is some potential for mutagenesis as indicated by the Ames test results however the chemical would not be classified as mutagenic according to the Worksafe criteria (19) due to the negative results in the other Ames tests and the Chinese hamster V79 study.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicological data is not required for chemicals with import volumes of less than 1 tonne per year according to the Act. However, the notifier has supplied the following test reports.

Test	Species	Results (Nominal)
Acute Toxicity [a] (Static) OECD TG: 203	Rainbow Trout (*Salmo gairdneri*)	96 h LC_{50} = 4.9 mg/L
Acute Toxicity [b] (Static) OECD TG: 203	Carp (*Cyprinus carpio*)	96 h LC_{50} = 2.4 mg/L
Acute Immobilisation [b] (Static) EEC Dir 79/831 5.1.2	Water Flea (*Daphnia magna*)	24 h EC_{50} > 1 000 mg/L
Acute Toxicity ETAD Method #103	Aerobic Waste-Water Bacteria	10 min IC_{50} > 100 mg/L

a. Formation of sediment was observed at all test concentrations (0.8, 2, 5, 9 & 14 mg/L) after 24 hours. The concentrations after 2 hours of exposure accounted on average 105.3 ± 56.8% of the nominal; and
b. No testing was undertaken to determine actual concentrations.

Although not reported, the test media were probably highly coloured which may have hampered observations. The results are based on nominal concentrations. It is noted that the concentration testing results of the test media in the acute toxicity (Rainbow Trout) test, where concentrations were found to vary 105.3 ± 56.8% of the nominal. This result shows that the notified chemical is not stable during the test period.

The ecotoxicity data for the notified chemical shows that the dye is moderately toxic to rainbow trout and carp. It was found to be practically non-toxic to water fleas, though the test was limited over a 24 hour period, and the EC_{50} value determined may have been lower if testing was conducted over 48 hours.

Reports containing toxicity tests on algae were not supplied (though as noted previously are not required under the Act). Nabholz (20) notes that of over 200 acid dyes tested, all showed moderate toxicity to green algae. However, analysis of the data suggested that the effects to algae were not the result of direct toxicity but represented an indirect effect due to shading, *ie* effects on growth were due to changes in the quality and/or the quantity of light.

The notified chemical was found to inhibit the respiration rate (oxygen consumption) of aerobic waste-water bacteria by 42.6% when exposed at a concentration of 100 mg/L. The 10 minute IC_{50} is reported as greater than 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The Predicted Environmental Concentration (PEC) is estimated below.

Calculation Factor	Metropolitan Dyehouse
Maximum use of dye expected per day @ 2 kg dye/100 kg fabric, 2 t fabric/day	40 kg
Quantity of notified chemical in wastewater (active concentration 39%; fixation rate 98%)	312 g
Quantity of water used, incl. wash-off water (@ 100 L/kg)	200 000 L
Effluent concentration in dye-specific wash-water	1.56 mg/L
Dilution factor in dyehouse by other wash-waters, etc	1:10
Influent concentration	0.16 mg/L
Dilution factor in sewage treatment plant	1:100
Concentration in effluent from sewage treatment plant	1.56 µg/L
Dilution factor in receiving waters (ocean outfall)	1:10
PEC in receiving waters	0.16 µg/L (or 0.16 ppb)

The environmental hazard through the use of the notified chemical is rated as low. In determining this, the following were considered:

- a worst case scenario was assumed in calculating the PEC, where the dye was used in dyeing batches for the whole day. Also, no dye is removed in the waste water treatment process;
- a dye addition rate of 2% was used in the PEC calculation, which the notifier claims will be the maximum and used in no greater than 5% of the dyeings. A more usual dye addition rate is 1%;
- the notifier has specified that a limited number of dyehouses in metropolitan Sydney (3) and Melbourne (7) will be using the dye formulation, thus the environmental hazard has been determined for a city based dyehouse; and
- imports of the notified chemical are estimated by the notifier to remain below 1 tonne per year.

The PEC calculation shows that the exposure to fish and water flea is at levels unlikely to cause any significant effect. The effluent containing the dye is unlikely to result in significant inhibition of algal growth, as concentrations at this level are unlikely to decrease the light intensity or change the light quality by a significant amount. Release of coloured effluent would generally be of concern to textile and dye manufacturing industries and waste water authorities (3, 20). In any event, the dye's high water solubility suggests that once released to the waterways, dilution would be expected to swiftly reduce the environmental concentration to undetectable levels. It has been shown that algae grow quickly as soon as the dye is diluted (20).

The only other source of environmental contamination is from accidental spills and disposal of packaging. The MSDS is adequate to limit the environmental exposure and therefore limit the environmental effects.

It is noted that the notified chemical is surface active. However, significant effects are not expected in the environment due to the predicted low concentrations in the aquatic compartment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical has a molecular weight of less than 1 000. However the molecular weight is high enough to significantly limit transmission across biological membranes. In addition the water solubility and low fat solubility and resultant low log partition coefficient indicate a reduced potential for bioaccumulation. The notifier indicates that the notified chemical has a negligible vapour pressure. The chemical will be imported as a 39% component of a granulated formulation. This will result in a lower level of dust and therefore a reduced potential for inhalational exposure when handling the formulation.

The notified chemical has a low oral and dermal toxicity when tested with rats. A repeat dose study indicated no dose related and/or deleterious effects at a dose of 1 000 mg/kg/day. Studies on the irritation potential indicate that no evidence of skin irritation was detected there was some effects on the conjunctiva and cornea in a rabbit study. These effects were reversible and were below the level requiring a hazard classification according to the Worksafe Australia *Approved Criteria for Classifying Hazardous Substances* (19). A skin sensitisation study in guinea pigs gave no evidence of sensitisation potential. The notified chemical is not genotoxic according to the Worksafe criteria although positive results were found in selected strains of *S.typhimurium* in the reverse mutation assay; all other genotoxicity studies including an *in vivo* mouse micronucleus assay were negative. On the basis of the toxicity tests described the notified chemical would not be classified as hazardous.

Occupational exposure will be greatest during handling of the dye formulation and dyed textiles in the dye baths. Dermal exposure during handling of wet textiles is possible as is inhalational exposure during weighing and addition of the formulation to the mixing tank. The latter will be limited by the granulated form of the formulation. The toxicological profile and mode of use of the notified chemical indicate that significant risks through occupational exposure to the notified chemical are unlikely. The potential for eye irritation is the most significant concern, the use of suitable eye protection during handling of the dye formulation and where there is the potential for splashing from the dye bath will reduce this.

The dye is chemically bonded to the textiles it is used to dye. As a consequence of the properties of the chemical and its intended application, significant exposure of the public to the free chemical under normal circumstances is unlikely. As the eye irritancy of the notified chemical is the primary hazard and this will not be manifested by material bound into textiles, adverse effects following public exposure to dyed textiles are unlikely.

13. RECOMMENDATIONS

To minimise occupational exposure to Blue N-RM 2114 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (21) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (22);
- Industrial clothing should conform to the specifications detailed in AS 2919 (23);
- Impermeable gloves or mittens should conform to AS 2161 (24);
- All occupational footwear should conform to AS/NZS 2210 (25);
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then 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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the imported formulation containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (26).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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4. Yen, C.P., Perenich, T.A., & Baughman, G.L. 1991. "Fate of Commercial Disperse Dyes in Sediments". *Environmental Toxicology and Chemistry,* 10: 1009-1017.

5. Ullmann, L. 1983. *Acute oral toxicity study with Blue N-RM 2114 in rats*. Report No. 016672, Research and Consulting Company Ltd, Itingen, Switzerland.

6. Ullmann, L. 1983. *Acute dermal toxicity study with Blue N-RM 2114 in rats*. Report No. 016650, Research and Consulting Company Ltd, Itingen, Switzerland.

7. Ullmann, L. 1983. *Primary skin irritation following a single 4-hour occlusive application with Blue N-RM 2114 in rabbits*. Report No. 016683, Research and Consulting Company Ltd, Itingen, Switzerland.

8. Ullmann, L. 1983. *Primary eye irritation after single application with Blue N-RM 2114 in the rabbit*. Report No. 025244, Research and Consulting Company Ltd, Itingen, Switzerland.

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

11. Draize, J. H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* 49.

12. Ullmann, L. 1983. *28-day dermal toxicity study with Blue N-RM 2114 in rabbits*. Report No. 016514, Research and Consulting Company Ltd, Itingen, Switzerland.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe