File No: NA/355

Date: June 1996

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

DYMSOL UWB COMPONENT

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

DYMSOL UWB COMPONENT

1. APPLICANT

Henkel Australia Pty Ltd of 83 Maffra St BROADMEADOWS VIC 3047 has submitted a standard notification statement in support of their application for an assessment certificate for Dymsol UWB Component.

2. IDENTITY OF THE CHEMICAL

For commercial reasons, the identity of the notified chemical has been granted exemption from publication in the Full Public Report and the Summary Report.

Dymsol UWB Component is considered to be an eye irritant when classified in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)]. According to Regulation 7 of the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005(1994)] (Model Regulations), substances which are classified as eye irritants can be identified by a generic name if the identity of the substance is commercially confidential. Therefore the identity of the notified chemical has been exempted from publication in the Full Public Report and the Summary Report. The conditions of this being permitted are:

- A descriptive generic name be used to identify the substance in public reports, labels and Material Safety Data Sheet (MSDS) where its concentration exceeds 20% in a formulation,

- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,

- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc in the case of a legitimate need,

- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,

- The chemical be identified as a irritant in the Health Effects section of the MSDS, and that reference to assessment by NICNAS be made on the MSDS under circumstances where the level of the notified chemical exceeds 20%.

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is manufactured in a 50% aqueous formulation and is never isolated. The following physico-chemical data are for the formulation.

Appearance at 20°C and 101.3 kPa:	light yellow, viscous liquid
Melting Point:	25°C (at 101.3 kPa)
Density:	1130 kg/m^3
Vapour Pressure:	not determined
Water Solubility:	soluble in water in any proportion at 20°C
Partition Co-efficient (n-octanol/water):	log K_{ow} = 1.77
Hydrolysis as a Function of pH:	the notified chemical is used in alkaline detergent formulations in the USA and is stated to be stable between pH 4-14
Flash Point:	> 93°C (closed cup)
Flammability Limits:	not flammable
Explosive Properties:	not explosive
Reactivity/Stability:	stated to be stable and non-reactive but can decompose to oxides of carbon when mixed with strong acids and oxidising agents or when exposed to fire

Comments on Physico-Chemical Properties

The value given by the notifier for melting point corresponds to point at which the product is able to be poured (pour point). The value of the partition coefficient given by the notifier was determined for the product. This is not a pure compound. It contains the notified substance as a mixture of compounds. The product also contained organic and inorganic salts. The value was estimated by measuring the concentrations of only one component of the mixture.

The stability range (pH range 4-14) quoted for the notified chemical is based on a claim of caustic stability in the Technical Data Sheet for APG Glycoside Surfactants. Based on the known stability of this class of compounds a pH range of 3-12 is more realistic (1).

No information was provided on the adsorption/desorption properties of the chemical. Given the polymer's high water solubility and low partition coefficient it is anticipated that it will not strongly adsorb.

The notified chemical contains no dissociable hydrogens or basic functionalities.

4. PURITY OF THE CHEMICAL

Degree of purity: approximately 80%

Toxic or hazardous impurities: none

Non-hazardous impurities (> 1% by weight): see table below

Chemical Name	*CAS No.*	*Weight %*
N-butyl glucoside	31387-97-0	15%
oligo saccharides	n/a	
sodium p-toluene sulfonate	n/a	1.0%
sodium sulfate	7727-73-3	1.0%
sodium chloride	7647-14-5	1.0%

Additives/Adjuvants: the imported formulation contains 0.012% glutaraldehyde (CAS No. 111-30-8)

5. USE, VOLUME AND FORMULATION

The notified chemical is intended to be used as a surfactant in waterborne architectural coatings and will be imported at a rate of 5 tonne per year for the first year rising to 10 tonne per year by the fifth year. The notified chemical will be imported as a 50% aqueous solution.

6. OCCUPATIONAL EXPOSURE

The notified chemical in its aqueous imported formulation will be transported in 200 L plastic lined drums and 20 L plastic pails to a single site for blending into paint. At the reformulation site, reformulation may be carried out by either research and development or paint makeup personnel. In the former case only small amounts of the imported formulation would be tested. Quality control personnel may

also test small amounts for viscosity and pH. Research and development and quality control is estimated to have a duration of 6 hours per day, 10 days per year.

The paint makeup, conducted for 4 hours per day, 20 days per year, involves

insertion of a spear into a drum and pumping the contents into a high speed disperser. Following dispersion, other ingredients are added and the contents blended at low speed followed by filtering and drumming off into 1 L to 20 L tins. Exposure is possible when removing drum bungs and coupling and uncoupling lines for pumping. Spillage is possible during pumping, batch adjusting and testing and during drum filling although the system is largely enclosed and fitted with fume extraction. Exposure from drips, splashes and spills is expected to be infrequent and the amounts involved relatively small.

The notified chemical is at 1% in the final paint formulation and may be used by a large number of trade and DIY painters. Exposure to the paint may be frequent, is expected to be via the skin and may be prolonged.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to the notified substance arising from importation, transportation and formulation into paint products. Similarly, the potential for public exposure to the chemical during transport and disposal of process waste and clean up waste after a spill is very minor. This is minimised by the recommended practices during storage, transportation and waste disposal. There is likely public exposure from the end use application of the chemical as a water based surface coating, particularly during domestic application, but the notified substance is at a low concentration (1%) in these coatings. The chemical will finally be immobilised as part of a cross linked hardened paint film and while there will be significant public contact with the notified chemical in this inert form, there seems no likely route of exposure and absorption.

8. ENVIRONMENTAL EXPOSURE

Release

Environmental release during transportation will result only in the event of accidental spill or mishandling. All clean up of spills and disposal should be carried out according to the MSDS.

The notifier states that chemical released into the factory environment during paint manufacture will be trapped by the standard engineering controls in place. The release of chemical into the factory comes from two sources: (a) accidental spillage; (b) cleaning of mixers and mills. The notifier has estimated that 60 kg of the notified chemical will be lost annually as a result of the reformulation process. Aqueous waste will be handled by the site waste treatment plant, and solid waste is disposed of in approved landfill.

The architectural coatings containing the notified chemical will be stored and transported in epoxy lined paint cans, probably in 1, 2, 4, 10 and 20 litre sizes. The architectural coatings are water-based air drying formulations. They will be applied using a brush, roller or spray gun. The coatings will be applied by both tradesmen and "do-it-yourself" painters.

Release to the environment resulting from the use of the architectural coatings may occur to the sewer (washing of tools used to apply formulations containing the notified chemical), or to landfill (disposal of residual quantities of the formulations within used containers). The notifier has estimated that a maximum 140 mg (~1.5%) of the notified chemical will be lost in washing equipment. Empty containers may contain up to 5% of the contents.

Losses from spray application of the coatings may be up to 5% for well ventilated confined spaces, 5-10% for outdoor applications in static air and over 20% in windy conditions. This is likely to remain where it falls, mainly on the ground.

Fate

The substance was examined for biodegradation potential using the modified Screening test (OECD Test Guideline 301C)(2). The substance exhibited a 90-93% loss of Dissolved Organic Carbon after 28 days, indicating that it is readily biodegradable under the conditions of the test. The test solution became cloudy after seven days suggesting the formation of a water insoluble degradation product(s). The cloudiness of the solution faded toward the end of the test indicating biodegradation of intermediate product(s) formed. These intermediate product(s) are likely to be oligo saccharides and fatty acids.

No testing of the bioaccumulation potential was conducted. The low partition coefficient and high water solubility of the notified chemical would indicate it is not be likely to bioaccumulate.

The fate of the majority of the notified chemical will share that of the architectural coatings into which it is formulated, which when cured will share the fate of the building materials to which they are applied. The final environmental fate will be mostly landfill with some incineration. Any incineration of the notified chemical is expected to produce water and oxides of carbon.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

The acute toxicity tests, except for skin sensitisation, were conducted with the formulation designated APG 325, which contains the notified chemical. The skin sensitisation test was conducted with APG 600 which differs slightly from the notified chemical.

Summary of the acute toxicity of Dymsol UWB Component

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(3)
acute dermal toxicity	rabbit	LD_{50} > 2000 mg/kg	(4)
skin irritation	rabbit	slight irritant	(5)
eye irritation	rabbit	moderate irritant	(6)
skin sensitisation	guinea pig	non-sensitiser	(7)

9.1.1 Oral Toxicity (3)

Species/strain:	rat, Sprague-Dawley
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	gavage
Clinical observations:	no toxicologically significant observations
Mortality:	one death unrelated to treatment
Morphological findings:	none
Test method:	in accordance with OECD Guidelines (2)
LD_{50}:	> 5000 mg/kg
Result:	the notified chemical was of low oral toxicity in rats

9.1.2 Dermal Toxicity (4)

Species/strain:	rabbit, New Zealand White
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	occlusive gauze dressing, 24 hours duration
Clinical observations:	no effects of toxicological concern; essentially non-irritating
Mortality:	no deaths
Morphological findings:	none
Test method:	in accordance with OECD Guidelines (2)
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rabbits

9.1.4 Skin Irritation (5)

Species/strain:	rabbit, New Zealand White
Number/sex of animals:	3 males, 3 females
Observation period:	7 days
Method of administration:	0.5 mL of undiluted test material under an occlusive gauze patch for 4 hours

Draize scores (8):

Time after treatment (hrs)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
½ -1	1[i]	2	2	2	2	2
24	1	1	2	1	2	1
48	0	1	1	1	1	1
72	0	1	0	1	1	1
Day 7	0	0	0	0	0	0
Oedema						
½ -1	0	1	1	0	0	0
24	0	0	0	0	0	0
48	0	0	0	0	0	0
72	0	0	0	0	0	0
Day 7	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales

Test method: in accordance with OECD Guidelines (2)

Result: slight skin irritant in rabbits

9.1.5 Eye Irritation (6)

Species/strain: rabbit, New Zealand White

Number/sex of animals: 3 males, 3 females

Observation period: 21 days

Method of administration: 0.1 mL undiluted test material into the conjunctival sac of one eye; eye not rinsed

Draize scores (8) of unirrigated eyes:

	Time after instillation									
Animal	***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***
1	2[i]	4	2	4	2	4	2	4	2	3
2	1	4	1	4	2	3	2	3	2	4
3	2	4	2	4	2	4	2	4	2	4
4	2	4	2	3	2	3	2	3	2	3
5	2	4	2	3	2	3	2	4	3	4
6	2	4	2	4	2	4	2	4	3	4
Iris										
1	1		1		1		1		0	
2	1		1		0		0		0	
3	1		1		0		0		0	
4	1		1		0		0		1	
5	1		1		1		0		0	
6	0		0		0		0		0	
Conjunctiva	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***
1	2	3	2	2	3	2	3	3	2	3	3	2	2	3	0
2	2	3	2	2	3	1	3	3	2	3	3	2	3	4	2
3	2	4	2	2	3	2	3	3	1	3	2	2	2	2	2
4	2	3	2	2	2	1	2	2	1	2	2	0	2	3	1
5	2	3	2	2	2	2	3	2	1	3	2	1	2	2	1
6	2	3	2	3	3	1	3	2	1	3	2	0	2	2	0

[i] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Test method: in accordance with OECD Guidelines (2)

Result: the notified chemical is a moderate eye irritant in rabbits

9.1.6 Skin Sensitisation (7)

Species/strain: Pirbright white guinea pig

Number of animals: 36 (2x3 pre-experiments, 20 test, 10 control)

Induction procedure: three pairs of injections of Freunds Complete Adjuvant (FCA) in distilled water (1:1); 1% test

substance in distilled water; 1% test substance, 50% FCA in distilled water; topical induction: at day 7 60% test substance for 48 hours (occlusive)

Challenge procedure: 10% test substance, 24 hour, occlusive dressing

Challenge outcome:

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

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

Test method: Magnusson and Kligman (1969) (9)

Result: not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (10)

The following study was conducted with HL-BE-9, a close analogue of the notified chemical.

Species/strain: rat, Sprague-Dawley

Number/sex of animals: 50 males, 50 females

Method of administration: orally by gavage

Dose/Study duration:: 10 females/10 males dosed at 0, 250, 500 or 1000 mg/kg/day for 90 days; in addition 5 males and 5 females dosed at 0 and 1000 mg/kg/day for 90 days given a recovery period (in total 106-133 days)

Clinical observations: 2 mortalities were observed, 1 male in the low dose group and 1 female in the mid dose group; there were no treatment-related variations in body weight

Clinical chemistry/Haematology high dose males at the sixth week had increased numbers of thrombocytes

Histopathology: decreased gonad weight in all test group males exposed to the test substance was in concert with body weight and therefore not

	significant; high dose group had ulceration and oedema restricted to the forestomach
Test method:	in accordance with “Ermittlung der toxicologischen Eigenschaften von Chemikalen empfohlen” (11)
Result:	NOEL 250 mg/kg/day; effects at higher doses were not systemic apart from increased thrombocytes in males and this was considered not to be compound-related

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (12)

The test substance was HL-BE-9, a close analogue of the notified chemical.

Strains:	TA 98, TA 100, TA 1535, TA 1537 and TA 1538
Concentration range:	8 - 5000 μg/plate
Test method:	in accordance with OECD Guidelines (2)
Result:	toxic effects seen above 200 μg/plate; no increases in mutation frequency above background in any strain in the presence or absence of metabolic activation provided by rat liver S9

9.3.2 *In vitro* Mammalian Cytogenetic Test in Chinese Hamster V79 Cells (13)

This test was conducted with Plantaren-1200 UP, a close analogue of the notified chemical.

Cell line:	chinese hamster V79
Doses:	without metabolic activation (rat liver S9): 16 μg/mL at each of the time points - chromosomes prepared at 7, 20 and 28 hours after the start of treatment with the treatment interval 4 hours; in addition at the 20 hours time cells were treated with 2 and 8 μg/mL; with metabolic activation at 7 hours the dose was 40 μg/mL; at 20 hours, 10, 40 and 80 μg/mL and at 28 hours, 80 μg/mL
Test method:	in accordance with OECD Guidelines (2)
Result:	no induction of chromosomal aberrations by the test substance; in the absence of metabolic activation no reduction in mitotic index was observed; in the presence of metabolic activation at the highest concentration nearly no mitoses were observed

9.4 Overall Assessment of Toxicological Data

A close analogue of the notified chemical was found to have low acute oral toxicity in rats (LD_{50} > 5000 mg/kg) and low acute dermal toxicity in rabbits (LD_{50} > 2000 mg/kg). The analogue was a slight skin irritant and a moderate eye irritant in rabbits. A second close analogue of the notified chemical was not a skin sensitiser in guinea pigs and was not clastogenic in chinese hamster V79 cells *in vitro*. A third close analogue of the notified chemical did not exhibit organ toxicity in a 90-day oral repeat dose study except for irritation at the site of application. This third analogue was not found to be mutagenic in bacteria.

On the basis of the analogue data, the notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (14) in relation to acute lethal effects (oral, dermal), irritant effects (skin), sensitising effects (skin) or severe effects after repeated or prolonged exposure (oral route). However, the notified chemical would be classified as hazardous in relation to eye irritant effects.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has provided ecotoxicological data for a structurally related product Glucopon 600 UP. It is expected that the notified chemical should have similar properties, with marginally higher water solubility.

Species	***Test***	***Result***	***Ref***
Zebra fish (*Brachydanio rerio*)	Acute Toxicity (96 h), OECD Guideline 203 (2)	2 mg/L < LC_{50} < 8 mg/L	(15)
Daphnia magna	Daphnia Reproduction Test OECD Guideline 202 (2)	NOEC (reprod) = 2 mg/L (21 d) NOEC (mort) = 1 mg/L (21 d) LOEC (mort) > 2 mg/L (21 d)	(16)
Daphnia magna	Acute Daphnia Toxicity (48 h), EU Guideline 92/69/EWG OECD Guideline 202, part 1 (2)	2 mg/L < LC_{50} < 16 mg/L	(17)
Scenedesmus subspicatus	Algal, Growth Inhibition (72 h), OECD Guideline 201 (2)	NOEC (growth) = 4 mg/L (72 h) E_bC_{50} = 12 mg/L (72 h) E_rC_{50} = 38 mg/L (0-72 h)	(18)
Micro-organisms from activated sludge (*Pseudomonas putida*)	Acute Bacterial Toxicity, OECD Guideline 209 (2)	500 mg/L < 10% effect (30 min)	(19)

* NOEC - no observable effect concentration

Reports were provided and these indicate the above tests were satisfactorily conducted according to OECD Guidelines. The test reports indicate the notified chemical is moderately toxic to fish, *Daphnia* and algae, and practically non-toxic to sewerage micro-organisms.

In the semistatic Acute Fish Toxicity test (OECD Guideline 203) (2) the effect of Glucopon 600 UP was investigated at only three concentrations of the active ingredients (2, 4 and 8 mg/L), these data were used to calculate an LC_{50} (2.9 mg/L) reported by the notifier. The lowest concentration resulted in no fish mortality, while in the highest concentration all the fish died. Hence, these data cannot be used to calculate the LC_{50} for fish and the true LC_{50} value most likely lies between the two extremes (ie 2 mg/L < LC_{50} < 8 mg/L). At 4 mg/L of the active ingredient 20% mortality was observed along with sublethal effects (balance disturbances).

Concentrations ranging from 0-16 mg/L were examined in the Acute Daphnia Toxicity test (OECD Guideline 202, part 1)(2). The LC_{50} value of 7 mg/L provided by

the notifier, was based on only three concentrations (2, 8 and 16 mg/L), and like the Acute Fish Toxicity test the true LC_{50} value most likely lies between the two extremes (ie. 2 mg/L < LC_{50} < 16 mg/L).

The algal species tested (*Scenedesmus subspicatus*) is considered to be relatively insensitive (20).

In the Acute Bacterial Toxicity test (OECD Guideline 209)(2) the effect on the bacteria was quantified by measuring the difference between the oxygen consumption of bacterial suspensions containing the test substance and a control (glucose). The notifier quotes an EC_0 of 500 mg/L, which they define as the highest measured substance concentration with an effect below 10%.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The hazard posed by the use of the end product appears to be small in that it will be incorporated at a small percentage (~1%) in a range of architectural coatings the use of which might be expected to be widespread across Australia. The total quantity estimated by the notifier to be released through the sewer system annually Australia wide through washing of equipment is 150 kg (1.5% of 10 tonnes imported).

Taking the worst case assumption that 10% of the chemical imported reaches the aquatic compartment, remains dissolved and is thus discharged to receiving waters, a predicted environmental concentration (PEC) for the substance in sewage water across Australia can be estimated from the following assumptions: 1 tonne maximum annual use an Australian population of 18 million and a daily per capita waste water discharge (a conservative estimate) of 150 L. This provides a PEC of approximately 1 ppb in sewage water. At 1 ppb the PEC is three orders of magnitude below the concentrations of the notified chemical at which toxic effects are observed. Assuming only 150 kg is released into effluent the level would be reduced by an order of magnitude.

Normal use of the end products appear to be unlikely to cause undue load on water and sewage treatment plants that treat and biodegrade effluent. Leaching of the chemical from landfills is not expected to be significant as the chemical will be trapped in the matrix of the solidified architectural coating.

The overall environmental hazard posed by the notified chemical can be rated as negligible when incorporated into architectural coatings.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

On the basis of analogue data, the notified chemical would not be classified as hazardous according to the Approved Criteria (14) in relation to acute lethality, skin irritation, skin sensitisation and severe effects after repeated or prolonged exposure. The notified chemical is also not expected to be genotoxic. However, the notified chemical would be classified as an eye irritant.

The imported formulation, containing 50% of the notified chemical in an aqueous solution is reformulated into paint at a final concentration of 1%. The reformulation and drumming off of the paint is largely automatic and enclosed with the use of fume extraction to control exposure to vapours and aerosols. Dermal exposure to spills, drips and splashes is possible during transfer operations but is likely to be infrequent.

During use of the formulated paint there is potential for widespread exposure to the skin and the paint may remain on the skin for long periods until it is removed by washing.

The occupational health risk posed by the notified chemical is expected to be limited to eye irritation and is most likely to occur during transfer of the imported aqueous solution from the drums in which it is imported to the paint mixing apparatus. The health risk in other operations and during use of the paint is expected to be minimal.

There is negligible potential for public exposure to the notified substance arising from importation, transportation and formulation into paint products. There is likely public exposure from the end use application of the chemical as a water based surface coating, particularly during domestic application, but the notified substance is at a low concentration (1%) in these coatings. The chemical will finally be immobilised as part of a cross linked hardened paint film and while there will be significant public contact with the notified chemical in this inert form, there seems no likely route of exposure and absorption.

Based on the available information, it is unlikely that the Dymsol UWB aqueous formulation containing 50% of the notified chemical will pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- If engineering controls and work practices are insufficient to reduce exposure to a safe level, then the following personal protective equipment which conforms to Australian Standards (AS) or Australian/New Zealand Standards (AS/NZS) should be worn;

  safety goggles should be selected and fitted in accordance with AS 1336 (21) to comply with 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 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.

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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