File No: NA/694

3 February 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Silylated Polyglycol

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Silylated Polyglycol

1. APPLICANT

Dow Corning Australia Pty Ltd of 21 Tattersall Rd. BLACKTOWN NSW 2148 has submitted a standard notification statement in support of their application for an assessment certificate for Silylated Polyglycol.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the composition have been exempted from publication in the Full Public Report and the Summary Report.

Other Name:	Silylated polyglycol
Marketing Name:	Dow Corning 3-8214 Adhesion Promoter

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Colourless liquid
Boiling Point:	Not determined
Specific Gravity:	1.00 at 25°C
Vapour Pressure:	< 0.133 x10^{-3} kPa at 25°C (see comments below)
Viscosity:	1.00 cst
Water Solubility:	Reacts with water and the hydrolyzed product will polymerize, therefore no significant solubility.
Particle Size:	Not applicable to the liquid formulation

Partition Co-efficient (n-octanol/water):	Not determined
Hydrolysis as a Function of pH:	Not determined
Adsorption/Desorption:	Not determined
Dissociation Constant:	Not determined
Flash Point:	54 °C (closed cup)
Flammability Limits:	Upper Explosive Limit = 3.3 % Lower Explosive Limit = 19.0 %
Autoignition Temperature:	363°C
Explosive Properties:	Not determined
Reactivity/Stability:	Reacts with water and moisture

Comments on Physico-Chemical Properties

Tests were not performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice. No laboratory analysis reports were provided for any of the physico chemical data presented above.

Determinations of the partition coefficient, adsorption/desorption behaviour and the dissociation constant for the notified chemical were not attempted because the notified chemical reacts with water to form ethanol and silicic acid. There is no indication of the expected rate of hydrolysis. The notified chemical is predicted to be relatively insoluble, which would slow the rate of hydrolysis.

4. PURITY OF THE CHEMICAL

Degree of Purity:	Approximately 100%
Hazardous Impurities	None
Non-hazardous Impurities (> 1% by weight):	None
Additives/Adjuvants:	None

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. The formulated sealant, containing the notified chemical (2-3%), will be imported in moisture resistant, sealed 1, 7.5 or 36.5 kg steel drums. Annual import of the notified chemical over the next five years is projected to be up to one tonne per annum.

The notified chemical will be supplied to industrial consumers as a component of a pre-formulated, two part silicone encapsulant for electronic devices. The notified chemical functions as a silicone adhesion promoter and may be used in a number of formulations. An example of one such formulation (Dielectric Tough Gel) has been provided by the notifier. This product is a general purpose encapsulant. It can be used in a variety of electronic encapsulating applications which will protect electronics from dust, moisture and mechanical shock. The gel is catalysed by mixing parts A and B and pouring the mixture into a box containing the electrical wiring/connections which require insulation. During thermal cure, the adhesion promoter reacts with polymer components to form a crossed silicone elastomer.

6. OCCUPATIONAL EXPOSURE

Transport and Storage (20 to 50 workers)
The notified chemical will be imported in sealed metal containers. Product degradation is to be limited under the conditions proposed to transport and store this material. Occupational exposure is not expected during transport and storage except in the event of a spill.

Formulation Site (100 to 500 workers)
The mixing of part A and part B is normally conducted in an open system. Mixing can occur via manual methods or automated methods. Manual methods are used when small amounts are required to be mixed. The two parts of the encapsulant are manually poured and mixed using a metal rod or knife in a small metal, plastic or glass container. Larger amounts (up to 5 - 10 liters) are mixed mechanically by an immersion mixer in an open metal or plastic container. The notifier claimed that the mixing operation including the pouring of the two parts will take about 5 minutes because of the short pot life of the mixture. Alternatively mixing may be carried out by automated/airless mixing, metering and dispensing equipment. The mixed encapsulant is then poured into a box (or similar enclosure) where insulation of electrical wiring/connections are required. It is expected that workers may be exposed to the notified chemical during manual procedures by manual handling during charging and mixing. However, due to the fast cure nature of the encapsulant workers exposure will be limited to 5 - 10 minutes for each mix. The notifier recommends general ventilation and safety glasses for procedures where workers are exposed to the encapsulant. The substance cures at room temperature or using slightly elevated temperatures, 50°C. The latter curing method was not described.

Worker Education and Training
The notifier states that workers receive instruction in the use of all protective equipment and encapsulant mixing techniques. The Material Safety Data Sheet (MSDS) is available for workers.

7. PUBLIC EXPOSURE

The 2-part silicone encapsulant is intended for use by experienced operators, consequently according to the notifier, there should be no public exposure.

It is expected that during transport, storage and use, exposure of the general public to the notified chemical will be minimal, except in the event of an accidental spill. According to the MSDS supplied, all ignition sources should be extinguished and ignition of vapours may occur from static electricity. Spills should be collected for salvage or disposal into suitable containers, sealed and labelled for recovery, or disposal in accordance with state/territory and local regulations.

8. ENVIRONMENTAL EXPOSURE

Release

The notified chemical will be imported as a 2-part silicone encapsulant constituent and stored in the Dow Corning Australia warehouse. Storage will also take place in customer warehouses and at final work sites, which are likely to be electronic/electric workshops located throughout Australia.

The notifier has not estimated release following transfer, mixing and application. However, this assessment estimates annual release to be low at about 1% (a maximum of 10 kg) of import volume.

The notifier expects that end users will keep residues in the empty sealant containers to a minimum due the high cost of the sealant. This rationale is accepted and residue remaining in empty containers is expected to be approximately 2% (a maximum of 20 kg per annum). Empty containers are expected to be cleaned out with detergent before disposal to land fill. The detergent wash liquid will be handled as a liquid industrial waste by a licensed waste contractor.

Cleaning practices for dispensing and mixing equipment were not identified by the notifier but release as a result of cleaning is estimated for this assessment at 1% (a maximum of 10 kg per annum).

Uncured encapsulant is expected be disposed of as a liquid industrial waste product by a licensed waste contractor, sent to landfill or incinerated.

The cured encapsulant is a solid rubbery material and will be disposed of to landfill or incineration.

The risk of release as a result of transport accident is expected to be moderate due to container size and the liquid nature of the notified chemical.

The MSDS instructions for clean up and disposal of accidental spills are adequate.

Fate

The vast majority of the silicone sealant will be released in a cured, crosslinked state. The incineration products of the cured encapsulant will depend on the product with which it is mixed. The notifier provided no information on the nature of the components of the second part of the two part solution therefore it is not possible to predict all combustion products of the cured encapsulant. However, incineration may liberate water, formaldehyde and oxides of carbon, nitrogen and silicon.

If disposed of to landfill in the cross linked state, the notified chemical is expected to remain immobile within the sealant matrix. No data has been provided on the biodegradability of the notified chemical. However, it is anticipated that the cured product will degrade slowly via biotic and abiotic processes.

The notifier indicates that chemical released in the uncured state will preferentially bind to sediment and most mineral surfaces. This is supported by Lehmann *et al.* (1995) who indicate that based on calculated sorption constants, polydimethylsiloxane (PDMS) is essentially immobile in soils.

Literature cited by the notifier indicates that in general PDMS is not biodegradable. However data from Lehmann *et al*. (1995) suggests that PDMS degrades to low molecular weight, water soluble products in all soils tested across several moisture contents (0-100% of available water). Rates of degradation were not provided. The main degradation product was dimethylsilanediol (DMSD). After four months at 25°C DMSD had decreased by 25-50% as a result of either volatilisation from the soil, covalent bonding with the soil or oxidation to CO_2.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Silylated Polyglycol

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity	Rat	LD_{50}> 2 000 mg/kg	(Findlay, 1995c)
Acute dermal toxicity	Rabbit	LD_{50}> 2 000 mg/kg	(Findlay, 1995b)
Acute inhalation toxicity	Rat	LC_{50}> 3.87 mg/L/4h	(Leonatti, 1995)
Skin irritation	Rabbit	Not irritating	(Findlay, 1995a)
Eye irritation	Rabbit	Moderate irritant	(Blazscak, 1998)
Skin sensitisation	Guineapig	Not sensitising	(Findlay, 1996)

9.1.1 Oral Toxicity (Findlay, 1995c)

Species/strain: Rat/Sprague-Dawley

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: A single dose of 2 000 mg/kg bw test substance administered by gavage

Test method: OECD TG 401

Mortality: Two female rats died during the study, one at day 1 and another at day 12 after dosing

Clinical observations: Salivation, discoloration around mouth and wet or red discolored inguinal fur were seen in one or two surviving rats but these recovered 2-3 days following dosing; the above signs plus redness around nose, red nasal discharge, discolored paws, labored breathing, coldness to touch and emaciation were observed in one or both of the rats that died; body weight increased in all 8 survived animals during the study.

Morphological findings: No abnormalities were found in survivors; findings in the dead rats were consistent with autolytic changes and lesions in the lungs (dark/dark red area and/or puffiness) indicating possible aspiration of the test substance

LD_{50}: > 2 000 mg/kg

Result: the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Findlay, 1995b)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A single, 24 hour occluded application of 2 000 mg/kg bw test substance to the dorsal shorn skin
Test method:	OECD TG 402
Mortality:	Nil
Clinical observations:	No obvious signs of toxicity were observed
Morphological findings:	Nil
Comment:	Erythema and/or edema were observed in all rabbits following unwrapping and persisted for 4-5 days; superficial flaking of the skin was observed in all rabbits 4-5 days after dosing and persisted in four animals till the termination of the study.
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of very low dermal toxicity in rats

9.1.3 Inhalation Toxicity (Leonatti, 1995)

Species/strain:	Rat/Fischer 344
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	mean aerosol concentration (maximum attainable concentration) in chamber air was 3.87 mg/L; whole body exposure for 4 hours
Particle size distribution:	Mean aerodynamic diameter was 1.70 μm
Test method:	OECD TG 403
Mortality:	Nil
Clinical observations:	Rough coat and red material around the nose were observed in all animals and dyspnea and red material around eyes observed in several rats on the day of exposure and on days

	1 and 2; all animals had recovered by day 4
Morphological findings:	No treatment-related findings
LC_{50}:	> 3.87 mg/L/4hour (maximum attainable concentration)
Result:	the notified chemical was of low acute inhalational toxicity in rats

9.1.4 Skin Irritation (Findlay, 1995a)

Species/strain:	Rabbit/Albino
Number/sex of animals:	2 females, 1 male
Observation period:	3 days
Method of administration:	A single, 4 hour, semi occluded application of 0.5 mL of test material applied to intact, shorn dorsal skin
Test method:	OECD TG 404
Comment:	Skin reactions were not observed at any observation period; all individual scores were zero.
Result:	the notified chemical was non-irritating to the skin of rabbits

9.1.5 Eye Irritation (Blazscak, 1998)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3 females
Observation period:	7 days
Method of administration:	0.1 mL of test material was instilled in the lower conjunctival sac of the right eye of each animal; the left eye remained untreated and served as control
Test method:	OECD TG 405 EC Directive 67/548/EEC

Draize scores[1] *of unirrigated eyes:*

	Time after instillation														
Animal	***1 hour***			***1 day***			***2 days***			***3 days***			***7 days***		
Cornea	***o***	***a***	***u***	***o***	***a***	***u***	***o***	***a***	***u***	***o***	***a***	***u***	***o***	***a***	***u***
1	0	0	0	+	4	0f	+	4	1f	0	0	0f	0	0	0f
2	0	0	0	0	0	0f	0	0	0f	0	0	0	0	0	0
3	0	0	0	0	0	0f	0	0	0f	0	0	0			
Iris															
1		0			+			+			+			0	
2		0			+			+			0			0	
3		0			+			+			0				
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	1	2	2	1	3	2	1	3	1	1	0	0	0	0
2	2	1	1	2	1	3	2	0	1	1	0	1	0	0	0
3	2	0	1	1	1	2	1	0	0	0	0	0			

[1] see Attachment 1 for Draize scales
o = opacity a = area u = ulceration r = redness c = chemosis d = discharge
f = observation was confirmed with fluorescein
+ = 0.5 (scoring system from Huntingdon Life Sciences' Guideline: for cornea opacity = slight dulling of normal luster; for iris = slight deepening of the rugae or slight hyperemia of the circumcorneal blood vessels)

Comment: Slight to moderate conjunctival redness, slight chemosis, slight to marked clear discharge and slight changes to the iris were observed in all 3 animals and resolved by day 7; one animal also had slight dulling of the corneal surface and a small area of corneal ulceration but recovered within 72 hours.

Result: The notified chemical was a moderate irritant to the eyes of rabbits.

9.1.6 Skin Sensitisation (Findlay, 1996)

Species/strain: Guinea pig/Hartley

Number of animals: Test group: 20 males
Vehicle control group: 10 males
Positive control group: 10 males

Induction procedure:

Test group:

Day 1 — Three pairs of intradermal injections (0.1 mL) into the dorsal midline skin of the scapular region:
- 5% test substance in sunflower seed oil;
- Freund's complete adjuvant (FCA) in 0.9% saline (1:1);
- 5% test substance in a mixture of FCA and sunflower seed oil.

Day 8 — Webril Appli-Pad saturated (1.5 mL) with 10% test substance/sunflower seed oil formulation applied to the scapular area and wrapped with an adhesive bandage for 48 hours.

Control group: Treated similarly to the test animals omitting the test substance from the intradermal injections and topical application

Challenge procedure:

Day 22 — Test and vehicle control group:
Upper left shorn flank of each animal was treated with 0.3 mL of test substance in 1.0% v/v in sunflower seed oil and upper right site treated with 0.3 mL undiluted sunflower seed oil.

The dosing material was applied using a Hill Top Chamber and animals were wrapped with an adhesive bandage for 24 hours.

Test method: OECD TG 406

Challenge outcome:

	Test Animals				***Vehicle Control Animals***			
Challenge Concentration	***Incidence[1]***		***Severity[2]***		***Incidence***		***Severity***	
	24 h*	***48 h****	***24 h***	***48 h***	***24 h***	***48 h***	***24 h***	***48 h***
1.0%	4/20	7/20	5/20	10/20	0/10	6/10	0/10	7/10

* time after patch removal.

1 number of animals exhibiting positive response (score of ≥1)/ number of animals tested.

2 sum of scores / number of animals tested.

Comment:	The incidence and severity indices of positive skin responses for the test substance exposed group were similar to those of the vehicle control group.
Result:	the notified chemical was not sensitising to the skin of guinea pigs

9.2 Repeated Dose Toxicity

The notifier stated that on the basis of low acute oral, dermal and inhalation toxicity, the notified chemical was not considered to induce adverse health effects and repeat dose testing was not conducted.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Wagner, 1996)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100; *Escherichia coli* WP2 *uvr*A and WP2.
Concentration range:	0, 100, 333, 1 000, 3 333 and 5 000 μg/plate with and without S9 mix; each dose was tested in triplicate in two independent experiments: a preliminary toxicity study and main study. Test substance was delivered in acetone which was used as a negative control; appropriate strain specific positive control reference substances were used.
Metabolic activation:	Liver fraction (S9) from rat pretreated with Aroclor 1254
Test method:	OECD TG 471 – pre-incubation method TSCA 799.9510
Comment:	In both experiments precipitate was observed at and above 3 333 μg/plate. No appreciable toxicity was observed. No positive responses were observed in all strains tested with and without S9 activation, in either experiment.
Result:	The notified substance tested in acetone showed no evidence of mutagenic activity in strains of *Salmonella typhimurium* and *E.coli.*

9.3.2 *Salmonella typhimurium* Reverse Mutation Assay (Wagner, 1998)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100 and *Escherichia coli* WP2 *uvr*A and WP2
Concentration range:	0, 100, 333, 1 000, 3 333 and 5 000 μg/plate with and without S9 mix; each dose was tested in triplicate in two independent assays (initial and confirmatory); Test substance was delivered in acetone which was also used as a negative control; appropriate strain specific positive control reference substances were used.
Metabolic activation:	Liver fraction (S9 mix) from rat pretreated with Aroclor 1254
Test method:	OECD TG 471 – pre incubation method TSCA 799.9510
Comment:	Neither precipitate nor toxicity was observed in either experiment. No positive responses were observed in all strains tested with and without S9 activation.
Result:	The notified substance tested in acetone showed no evidence of mutagenic activity in strains of *Salmonella typhimurium* and *E.coli.*

9.3.3 Chromosome Damage

The notifier stated that on the basis of negative findings in bacterial mutagen assays investigations of clastogenic potential were not considered necessary.

9.4 Overall Assessment of Toxicological Data

The notified chemical has very low acute oral toxicity (LD_{50} > 2 000 mg/kg) in rats and very low dermal toxicity (LD_{50} > 2 000 mg/kg) in rabbits. In an acute inhalation study the LC_{50} was established at greater than 3.87 mg/L/4h which was the maximum attainable concentration. Skin irritancy was manifested in the acute dermal irritation study, following a 24 hour exposure to the notified chemical. However, these findings were not observed in the skin irritation study. The notified chemical was a moderate eye irritant. The notified substance was not sensitising to guinea pig skin.

Repeat dose oral testing has not been conducted on the notified chemical.

The notified chemical did not exhibit mutagenic activity in the bacterial system tested. No other genotoxicity data was provided.

Based on the data provided the notified chemical would not be classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity data for the notified chemical have not been provided. However, given the reactive nature of the chemical (forming ethanol and silicic acid on contact with water), the proposed import volume and the very limited potential exposure to the aquatic compartment, this data gap is acceptable.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical is a component of pre-formulated, two part silicone encapsulants for a number of formulations and functions as a silicone adhesion promoter. During thermal cure, the adhesion promoter reacts with polymer components to form a crossed silicone elastomer. The vast majority of the silicone sealants, containing the notified chemical crosslinked within the sealant matrix, will eventually be disposed of to landfill, where the notified chemical is expected to remain crosslinked and immobile and eventually degrade via biotic and abiotic processes. If disposed of by incineration, combustion products may include water, formaldehyde and oxides of carbon, nitrogen and silicon.

Release of approximately 2% of the notified chemical is expected from container residues and spills prior to mixing (in the uncured state). In the uncured state, the main degradation product is expected to be dimethylsilanediol (DMSD). This degradation product is expected to decrease over several months as a result of either volatilisation from the soil, covalent bonding with the soil or oxidation to CO_2. Approximately 2% (in the cured state) is expected to be released during mixing, equipment cleaning and application. In the cured state the cross linked polymer is expected to slowly degrade via biotic and abiotic processes. In either state, the notified chemical is expected to be immobile in the soil and, due to its high molecular weight, is not expected to bioaccumulate.

The potential environmental hazard of the notified chemical incorporated into formulated sealant products is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notifier provided an incomplete toxicological data package.

The notified chemical is of very low acute oral toxicity and dermal and low inhalation toxicity. The notified substance was not a skin irritant but was a slight to moderate eye irritant in rabbits. The notified substance was not sensitising to guinea pig skin.

A repeat dose oral study was not provided. The notified chemical did not exhibit mutagenic activity in bacteria. No other genotoxicity data were provided.

Under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), the notified chemical does not meet the criteria for classification as a hazardous

substance.

Occupational Health and Safety
Exposure by inhalation and dermal routes is possible but no measured exposure data are available. The sealant is imported in two ready to use parts of a silicone encapsulant. The notified chemical is present at 2 to 3% in Part A which is mixed at approximately 1:1 with Part B. The mixture cures within minutes of mixing, when the chemical is no longer available for exposure or absorption. Occupational exposure may occur where the two parts of the encapsulant are mixed for end use. Exposure via the lungs is unlikely because of the low volatility (vapour pressure = 0.133×10^{-3} kPa at 25°C) of the notified chemical. Dermal exposure is expected to be the main route for occupational exposure at formulation site during charging and mixing by manual methods. However, the risk of acute health effects following dermal exposure is expected to be low given the low acute lethal dermal toxicity and low concentration of chemical.

In the absence of data on long term systemic effects, it is not possible to characterise the long term health risk in relation to repeated dose toxicity.

The notified chemical will be handled in a non-dispersive manner, that is, worker exposure will be limited to 5 to 10 minutes for each mix due to the fast cure nature of the encapsulant. An alternative to the manual procedure is to use automated/airless mixing, metering and dispensing equipment with options for de-airing by vacuum, which will reduce worker exposure to the notified chemical. Workers at the formulation site should be instructed to follow good hygiene practices and wear eye protection and impervious gloves when handling the chemical.

After mixing, the notified chemical undergoes extensive crosslinking reactions with other chemical components present in the encapsulant formulations. Under these circumstances the notified chemical is essentially unavailable for skin contamination and exposure and any subsequent risk of adverse health effects is expected to be negligible.

The risk of adverse health effects to workers involved in transport and storage is considered to be negligible except in the case of accidental spillage when topical irritation may be experienced with prolonged contamination. Spill clean up workers should follow the instructions on the product MSDS.

Public Health
The 2-part silicone encapsulant is intended for use by experienced operators in the electronic/ electrical industries. Once the silicone encapsulant is fully cured, the notified chemical forms part of a crosslinked polymer/encapsulant network and is likely to be biologically unavailable. Consequently, public exposure to the notified chemical throughout all phases of its life-cycle is considered low.

13. RECOMMENDATIONS

To minimise occupational exposure to Silylated Polyglycol the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia, 1998);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion; and

- A copy of the MSDS should be easily accessible to employees.

If the conditions of use are varied, such as products containing the notified chemical enter the public domain, then greater exposure of the public may occur. In such circumstances, further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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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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