File No: PLC/189

August 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in DOW CORNING 9040 Silicone Elastomer Blend

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Family Services.

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Polymer in DOW CORNING 9040 Silicone Elastomer Blend

1. APPLICANT

Dow Corning Australia Pty Limited of 21 Tattersall Rd., BLACKTOWN NSW 2148 (ACN 008 444 166) has submitted a Polymer of Low Concern notification statement in support of their application for an assessment certificate for Polymer in DOW CORNING 9040 Silicone Elastomer Blend.

2. IDENTITY OF THE CHEMICAL

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

Trade names: DOW CORNING 9040 Silicone Elastomer Blend

Molecular weight (MW):

Number-average MW	Weight-average MW	% MW < 1000	% MW < 500	Method
> 15500	not stated	0	0	based on starting materials

The notifier did not supply a GPC trace or slice data but indicated that the polymer has a high number average molecular weight (expected to be around 1,000,000 g/mol) and that the all material is expected to have molecular weight greater than 15,500 g/mol.

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

Purity (%): 12 % in commercial product

Additives/adjuvants:

Chemical name	Synonym	CAS no.	% weight
decamethylcyclopentasiloxane	cyclomethicone	541-02-6	88

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	clear to slightly translucent paste	
Boiling point	not determined	no well defined melting or boiling point exists (see comments below)
Density	960 kg/m^3 at 25°C	
Water solubility	not soluble	based on solubility data for polymers of similar structure and molecular weight, the water solubility is expected to be less than 1 mg/L (see comments below)
Particle size	not applicable	the polymer is only used in liquid form
Flash point	76°C	polymer formulation
Explosive properties	not explosive	
Stability/reactivity	stable under normal environmental conditions	
Hydrolysis as function of pH	not determined	see comments below
Partition coefficient	not determined	see comments below
Adsorption/desorption	not determined	see comments below
Dissociation constant	no dissociable groups are present	see comments below

5.1. Comments on Physico-Chemical Properties

The polymer particles have a wide molecular weight distribution (15,500 to > 1,000,000 g/mol), so a sharp melting point is unlikely. In any case, when dispersed in decamethylcyclopentasiloxane the particles are in the form of a swollen gel for which melting point has little significance.

Although no data was supplied with the notification, the water solubility of silicone polymers such as the notified material is usually very low and the notifier indicated that the water solubility of a polydimethylsiloxane with molecular weight 1,200 g/mol was determined as 1.6 mg/L, while for a similar polymer with molecular weight 25,000 g/mol the water solubility was 0.17 mg/L and on further increase in MW to 56,000 g/mol the water solubility was 0.076 mg/L (Watanabe, 1984). As the average MW of the new polymer is stated as around 1,000,000 g/mol the water solubility is expected to be significantly less than 0.076 mg/L. Also, the new polymer will be used with a high proportion of decamethylcyclopentasiloxane in cosmetic preparations, and a report provided by the notifier (Chu, 1987) indicated that the solubility of the closely related octamethylcyclotetrasiloxane was determined as 0.05 mg/L.

The notifier supplied some information concerning the partition coefficient which is briefly commented on here. Chu (1987) determined the value of Log P_{ow} for octamethylcyclotetrasiloxane as around 5.1, which could be expected for a compound of this chemical nature which contains a high proportion of hydrocarbon and is essentially non polar. Although the new polymer is of a much greater molecular weight and is essentially linear, it contains the same silane groups and it is considered that on a molecular level the physical interactions between water and the polymer would be similar to those between water and octamethylcyclotetrasiloxane. Consequently, it is likely that Log P_{ow} for the polymer would also be around 5, indicating strong preference of the material for organic phases compared with water.

No adsorption/desorption data for soil (Log K_{oc}) were provided in the submission, but there are well established correlations between the value of Log P_{ow} and Log K_{oc} for a wide variety of chemical classes. For example, Lyman et al (1990) list a number of Quantitative Structure Activity Relationships (QSAR s) between Log K_{oc} and Log P_{ow}. Although none of the equations quoted by Lyman et al (1990) are strictly applicable for silicone polymers, it is generally true that high values for Log P_{ow} imply correspondingly large values for Log K_{oc}. Consequently, since Log P_{ow} is expected to be around 5 for the new polymer it is likely that Log K_{oc} will also be high, indicating that the polymer will have high affinity for the organic component of soils and sediments.

The compound contains no acidic or basic functionalities, so dissociation constant data are not applicable. The Si-O bonds are stable under most environmental conditions, and the polymer is not expected to be easily degraded when released.

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer will be used as a viscosity modifier in personal care products, such as antiperspirants and deodorants. It will be imported in the formulation DOW CORNING 9040 Silicone Elastomer Blend, which contains 12 % notified polymer in cyclomethicone. The finished personal care products will contain between 0.1 and 1 % notified polymer.

Manufacture/Import volume:
The notifier estimates that the import volume will be up to 10 tonnes notified polymer in the first year, increasing to 40-50 tonnes per annum after three years.

Formulation details:
The notified polymer will be imported as a formulation DOW CORNING 9040 Silicone Elastomer Blend, containing 12 % notified polymer (w/w) in cyclomethicone. The formulation will be stored by the notifier before transport to personal care product manufacturers. The product will be reformulated at a number of sites in Australia to produce consumer personal care products, containing up to 1 % (w/w) notified polymer. The resin dispersion will be imported in 18.1 kg and 181 kg steel drums. The imported formulation will be poured into open or enclosed mixing equipment and incorporated usually with a paddle mixer. The finished personal care products will be packaged for consumer use.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
Formulation		
Personal care product formulation (20-50 workers)		
dermal	12 % solution, 8 h/day on a daily basis; workers may be exposed to drips and spill of polymer solution	exhaust ventilation safety eyewear
Transport and storage		
Stevedoring industry (10-30 workers)		
none	12 % solution, up to 8 h/day on a daily basis; no exposure expected except in case of accident; exposure to 0.1 – 1 % notified polymer may occur during packaging of personal care products.	none
Transport workers (5-10 workers)		
none	12 % solution, up to 8 h/day on a daily basis; no exposure expected except in case of accident	none
Warehouse workers (5-10 workers)		
none	12 % solution, up to 8 h/day on a daily basis; no exposure expected except in case of accident	none

8. PUBLIC EXPOSURE

It is expected that during transport, storage and formulation into personal care products, exposure of the general public will be low.

Personal care products containing the notified polymer at 0.1 – 1 % will be sold to the public. Application of one or more of the products containing the notified polymer is likely to occur on a daily basis, consequently the only limit on exposure is likely to be the commercial success of these products. Exposure during use of antiperspirants and deodorants will occur primarily via the dermal route, with the chances of accidental ocular, oral and inhalation exposure being largely determined by the mode of application, eg spray aerosol or roll-on.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

The notifier indicated that an estimated 1 % of residual polymer would remain in the drums and in the mixing equipment after use. Assuming a maximum annual importation of 50 tonnes of notified polymer, around 500 kg of the polymer would remain in the empty drums and mixing vessels. The notifier stated that this material would probably be released into the sewer system, and due to its hydrophobic nature would become associated with sewer sludge. Periodically this sludge is removed from sewer lines and placed into landfill or incinerated.

The polymer will be used in a variety of personal care products, and it is likely that some residual formulation will be left in containers and disposed of with domestic garbage. The notifier did not provide any estimates of the quantity of polymer likely to be released in this manner, but this could be quite high, and 25 % may be typical. Assuming annual imports of 50 tonnes of the polymer, this indicates disposal of around 12.5 tonnes of polymer with garbage. The garbage would be either placed into landfill or be incinerated.

Almost all of the polymer will be released as a consequence of use in personal care products, mostly to sewer systems.

Consequently up to 75 % of the notified polymer (annually 37.5 tonnes) may be released to sewer. Most of the remainder (12.5 tonnes) would be placed into landfill with domestic garbage, although some may be incinerated.

As the new polymer is always used in association with decamethylcyclopentasiloxane, this will have the same release patterns. Consequently up to 420 tonnes of silicone material will be released to the environment each year.

9.2. Fate

The majority of the notified polymer will be used in cosmetic applications, and consequently most is expected to be released into the environment – primarily into sewer systems. The polymer has little affinity for water and is consequently likely to become associated with the

sediments in sewer trunks or in sewage sludge at treatment works. Most sewer sludge is placed into landfill, although some may be incinerated. Incineration will destroy the polymer with production of water vapour and oxides of carbon while the silicon component will be converted to silica then become associated with ash or furnace slag.

No data on biodegradation were submitted and the notifier indicated in the Material Safety Data Sheet (MSDS) for the 9040 Silicone Elastomer Blend that, due to very low water solubility, standard tests for biodegradation were not applicable. Silicone materials are not expected to be biodegradable, and it is likely that the released polymer (together with the associated decamethylcyclopentasiloxane) will be reasonably persistent once released.

The very low water solubility and hydrophobic nature of polydimethylsiloxanes indicates that material placed into landfill would be immobilised through association with soil and sediment particles (Hamelink, 1992; Lehmann et al., 1994a). However, over time the polymer and its degradation products could be expected to decompose to simpler species, with eventual production of silicate and landfill gases such as methane and carbon dioxide. Polydimethylsiloxanes are unstable in landfill situations (Hamelink, 1992; Lehmann et al., 1994a; Lehmann et al., 1994b), and in dry conditions clay minerals catalyse their hydrolytic decomposition to smaller molecules, some of which may be volatile and enter the atmosphere. When released to the atmosphere, low molecular weight organosilanes are apparently rapidly degraded through photolysis (Hamelink, 1992).

Due to its insolubility in water and high molecular weight, the polymer will have little potential for bioaccumulation.

10. EVALUATION OF HEALTH EFFECTS DATA

The health hazards of the constituents and hazardous impurities, additives and adjuvants are tabulated below.

Chemical	Health hazards	Regulatory controls
Constituents		
the identities of residual monomers have been exempted from publication in the Full Public Report	all are present at below the cutoffs for classification of the notified polymer as hazardous	none
Hazardous impurities		
none present		
Additives/adjuvants		
cyclomethicone	low toxicity and irritant potential (Rowe, 1948)	none

10.1 Acute Toxicity

Summary of the acute toxicity of Polymer in DOW CORNING 9040 Silicone Elastomer Blend (12 % notified polymer)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(Dow Corning, 1999d)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(Dow Corning, 1999b)
skin irritation	rabbit	non-irritating	(Dow Corning, 1999a)
eye irritation	rabbit	slight irritant	(Dow Corning, 1999c)
skin sensitisation	guinea pig	non-sensitising	(Dow Corning, 1999e)

10.1.1 Oral Toxicity (Dow Corning, 1999d)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	gavage; dose 2000 mg/kg
Test method:	OECD TG 401
Mortality:	no deaths occurred during the study
Clinical observations:	no clinical signs of toxicity were observed
Morphological findings:	no macroscopic abnormalities were observed
Comment:	one animal had a slight weight loss during the second week of the study
LD_{50}:	> 2000 mg/kg
Result:	the product containing the notified polymer was of very low acute oral toxicity in rats

10.1.2 Dermal Toxicity (Dow Corning, 1999b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex

Observation period:	15 days
Method of administration:	semi-occlusive patch; 24 hr exposure; material used as supplied; dose 2000 mg/kg
Test method:	OECD TG 402
Mortality:	no deaths occurred during the study
Clinical observations:	no clinical signs of toxicity were observed
Morphological findings:	no macroscopic abnormalities were observed
Comment:	one female had a slight weight loss during the first week of the study
LD_{50}:	> 2000 mg/kg
Result:	the product containing the notified polymer was of low dermal toxicity in rats

10.1.3 Skin Irritation (Dow Corning, 1999a)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 female
Observation period:	3 days
Method of administration:	semi-occlusive patch; 4 hr exposure; material used as supplied; dose 0.5 mL
Test method:	OECD TG 404
Comment:	all animals were free of dermal irritation throughout the study; all Draize scores were zero
Result:	the product containing the notified polymer was not irritating to the skin of rabbits

10.1.4 Eye Irritation (Dow Corning, 1999c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 male
Observation period:	3 days

Method of administration: a single dose of 0.1 mL of test substance was placed in the conjunctival sac of one (right) eye of each of the test animals; the untreated eye served as control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Cornea	all Draize scores were zero											
Iris	all Draize scores were zero											
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	0	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	1	0	0	1	0	0	0	0	0
3	1	0	0	1	0	0	1	0	0	0	0	0

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

Comment: no iris or corneal effects were observed; corneal observations were confirmed with fluorescein

Result: the product containing the notified polymer was a slight irritant to the eyes of rabbits

10.1.5 Skin Sensitisation (Dow Corning, 1999e)

Species/strain: guinea pig/Dunkin Hartley

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

Induction procedure:

test group:
day 1, 8, 15 neat test material was applied to a clipped area on the back for 6 hr, using an occlusive chamber; excess material was wiped off at the conclusion of each exposure

control group: no induction procedure was used

Challenge procedure:

test and control groups:
day 29 neat test material was applied to a clipped area on the back which had not previously been exposed for 6 hr, using an occlusive chamber

Positive control:	hexylcinnamic aldehyde (HCA)
Test method:	OECD TG 406 (Buehler method)
Comment:	five test animals and two control animals had a score of 0.5 at the 24 hr observation only; no dermal responses were observed at 48 hr; no significant difference between the responses of the test and control animals was seen
Result:	the product containing the notified polymer was not sensitising to the skin of guinea pigs

10.2 Genotoxicity

10.2.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Dow Corning, 1999f)

Strains:	*Salmonella typhimurium* TA98, TA100, TA1535 and TA1537; *Escherichia coli* WP2*uvr*A(pKM101) and WP2 (pKM101)
Metabolic activation:	10 % rat liver S9 fraction (Aroclor 1254-induced) in standard cofactors
Concentration range:	0, 1.0, 3.3, 6.7, 10, 33, 67, 100, 333, 667, 1000 μg/plate, dissolved in tetrahydofuran and plated as a 25 μL aliquot
Positive controls:	with S9: TA98, TA100, TA1535, TA1537: 2-aminoanthracene 1.0 μg/plate WP2*uvr*A: 2-aminoanthracene 10 μg/plate WP2: sterigmatocystin 100 μg/plate without S9 TA98: 2-nitrofluorene 1.0 μg/plate TA100,TA1535: sodium azide 1.0 μg/plate TA1537: 9-aminoacridine 75 μg/plate WP2*uvr*A, WP2: methyl methanesulphonate 1000 μg/plate
Test method:	OECD TG 471 and 472 (plate incorporation method)
Comment:	all concentrations were tested in triplicate and concurrent positive and negative controls responded appropriately, except for an unacceptable positive control value in the initial test of TA100 in the presence of S9; this assay was repeated

	no precipitation or reduction in background lawn was observed in any of the tests
	increases of 2.3 fold were observed for TA1537 both in the presence (at 1000 μg/plate) and absence (at 33 and 100 μg/plate) of S9 in the initial assay; no dose response was observed and no equivalent increases were observed in the confirmatory assay
Result:	the product containing the notified polymer was non mutagenic under the conditions of the test

10.3 Toxicological Information on Related Silicones

A number of published studies on the toxicology of commercial silicones were provided by the notifier. These are closely related to the notified polymer.

High molecular weigh dimethylsilicone fluids were found to be very low in acute oral toxicity (Rowe, 1948), and repeated feeding for one month at doses up to 20 g/kg did not cause discernable ill effects; administration by intraperitoneal, intradermal and subcutaneous effects showed these materials to be essentially inert. No skin irritation or corneal damage was observed, although transitory conjunctival irritation was seen. Low toxicity was observed for formulated silicone compounds and crosslinked resins.

Similar results were reported in a study of polydimethylsiloxane fluids (Calandra, 1976). It was stated that no evidence of carcinogenicity was observed in long term studies (up to 2 years in rats and dogs). Skin sensitisation was not observed in a number of human repeated insult patch tests. No ill effects were reported for several inhalation studies of aerosols of high molecular weight silicones.

In a number of reproductive studies on high molecular weight dimethylsilicones (Kennedy, 1976), an apparent dose related incidence of dose related foetal mortality was observed in rats, and a slight increase in a foot deformity (non dose related) in rabbits were observed. Other studies in rats, mice and rabbits showed no teratogenic effects or induction of dominant lethal mutations.

10.4 Overall Assessment of Toxicological Data

The notified polymer is of very low acute oral toxicity and low dermal toxicity. It is not a skin irritant or a skin sensitiser, and ocular irritant effects are slight and were found to clear after two days. No evidence of mutagenicity was observed in a bacterial assay.

Published information about the general class of polymer including the notified polymer indicates that these are of low toxicity.

The notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

12. ENVIRONMENTAL RISK ASSSESSMENT

Almost all of the new polymer is expected to be released to the environment as a consequence of its use in personal care products. Most is expected to be released to the sewer, although some may be placed directly into landfill with domestic garbage. The polymer is not biodegradable and that portion released to the sewer (estimated as up to 37.5 tonnes per annum) will become associated with sewer sludge due to its hydrophobic nature. Although all the polymer is expected to be released, the use pattern is such that the release will be diffuse and at relatively low levels. For example, if all the annual import of 50 tonnes were to be released to the sewer system, assuming that each individual in Australia produced 150 L of sewage each day, and taking the national population as 19,000,000 the Predicted Environmental Concentration (PEC) in the sewage is estimated as 48 μg/L. However, as indicated previously this will become associated with sludge, and this will ultimately also be placed into landfill, although some may be incinerated. It is also expected that around 12.5 tonnes of polymer may be directly released to the soil compartment through disposal of partly emptied containers in domestic garbage.

Silicone polymers are stable under moist conditions, but it is expected that prolonged residence in dry landfills would eventually degrade the polymer to landfill gases and silica, while incineration would destroy the material, also with production of silica.

No ecotoxicity data were supplied, but silicone polymers are not known to be toxic to aquatic organisms, and in any case the low rate of release and expected association of the polymer with sediments would mitigate any toxic effects. The polymer is not expected to bioaccumulate.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

The notified polymer is of very low acute oral toxicity and low dermal toxicity. It is not a skin irritant or a skin sensitiser, and a very slight ocular irritant. No evidence of mutagenicity was observed in a bacterial assay. The notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

13.2. Occupational health and safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage of the polymer solution or the personal care products containing this polymer, or during retail sale of the products. There will be exposure during production of the personal care products.

During the reformulation and packaging processes, the main exposure route for the notified polymer will be dermal. The polymer solution and final products will be viscous, and ready formation of aerosols is not expected. The polymer is not expected to be hazardous by dermal exposure as the high molecular weight will preclude absorption through the skin. The engineering controls and personal protective equipment specified in the notification (local exhaust ventilation and protective eyewear) will provide protection against the notified polymer. No significant OHS risks are expected due to the low toxicity of the notified polymer.

13.3. Public health

An analogous chemical to the notified polymer showed some evidence of effects on reproduction in rats, following subcutaneous administration (Kennedy, 1976). The use of the notified polymer at 0.1 – 1 % in personal care products means that a small amount will be applied to the skin for each use. Likely skin application sites, such as underarms, possess large numbers of sweat glands, and consequently there is potential for increased dermal absorption at these sites. This is not of concern in this case, as the notified polymer is of high molecular weight (NAMW > 15500) and is unlikely to penetrate biological membranes, suggesting limited systemic absorption following normal use.

The low concentration and limited systemic absorption would eliminate any potential toxic hazard from normal use of the polymer in personal care products. There will be minimal public exposure during transport, storage and formulation into personal care products.

Based on the above information, it is considered that Polymer in DOW CORNING 9040 Silicone Elastomer Blend is unlikely to pose a significant hazard to public health when used in the proposed manner.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994b). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC,

1994a). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

To minimise occupational exposure to Polymer in DOW CORNING 9040 Silicone Elastomer Blend, the following guidelines and precautions should be observed:

- Safety eyewear should be used during occupational use of the products containing the notified polymer;
- 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.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with State and territory hazardous substances regulations must be in operation.

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992).

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the Director of Chemical Notification and Assessment must be informed if the polymer characteristics cease to satisfy the criteria under which it has been accepted as a Synthetic Polymer of Low Concern, and secondary notification may be required under subsection 64(1). The Director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified polymer may be required. No other specific conditions are prescribed.

17. REFERENCES

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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

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