File No: PLC/148

April 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Ceramer 67 Polymer

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Ceramer 67 Polymer

1. APPLICANT

Plastral Fidene Pty Ltd of 11B Lachlan Street, Waterloo NSW 2017 has submitted a Polymer of Low Concern notification statement in support of their application for an assessment certificate for Ceramer 67 Polymer.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name:	Neptune 5223T
Characterisation as a Synthetic Polymer of Low Concern	
Number-Average Molecular Weight (NAMW):	>1000
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	<1%
Molecular Weight < 1 000:	6%
Reactive Functional Groups	No reactive groups present
Polymer Stability	Stable up to 150°C
Charge Density	Not likely to be charged in the environmental pH range.
Method of Detection and Determination	The polymer was identified by infrared (IR) spectroscopy and characterised by gel permeation chromatography.

The polymer meets the criteria for assessment as a synthetic polymer of low concern under Regulation 4A of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Amber, free flowing fine powder.
Particle Size:	Polymer is manufactured as 3mm granules. Mean particle size for imported polymer blend is 12μm.
Water Solubility:	Water solubility was not quantitated, but a visual estimation of solubility (based on insoluble material after stirring) suggests low water solubility (<1 g/L).
Melting Point:	97°C
Density:	0.94g/cm^3 at 20°C
Vapour Pressure:	Not determined; expected to be low.
Partition Co-efficient (n-octanol/water):	Not determined due to low water solubility. The polymer is expected to partition into *n*-octanol rather than water, and may be expected to become associated with the organic component of soil and sediments.
Hydrolysis as a Function of pH:	Not determined. The polymer contains ester groups which may undergo hydrolysis under extreme conditions but is unlikely to occur in the environmental pH range of between 4 and 9.
Adsorption/Desorption:	Not determined due to low water solubility. The polymer is expected to become associated with the organic component of soil and sediments.
Dissociation Constant:	The polymer contains free carboxylic acid groups which are expected to have a pK_a of 4.2. The dissociation constant data provided was based on malonic acid.
Flash Point:	>175°C (closed cup)
Flammability Limits:	Not flammable.
Autoignition Temperature:	Not applicable.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Stable under normal conditions of storage.

Comments on Physico-Chemical Properties

No additional comments.

4. PURITY OF THE CHEMICAL

Degree of Purity:	>99%
Maximum Content of Residual Monomers:	There are essentially no residual reacting species remaining after polymerisation.
Hazardous Impurities:	None
Non-hazardous Impurities (> 1% by weight):	None
Additives/Adjuvants:	None

5. USE, VOLUME AND FORMULATION

The notified polymer will be used as a thickener in water-based paint at 0.25-1.0%. It will be imported in a paint additive blend at 50% w/w. Five to 10 tonnes will be imported annually for the first 5 years. The notified polymer will be imported as a polymer blend in powder form in 70kg polyethylene-lined fibreboard drums.

6. OCCUPATIONAL EXPOSURE

Import, Transport and Storage

Following import, the notified polymer will be transported by road to a single customer site. The mean particle size of the blend containing the notified polymer is 12μm. Therefore, it is likely that a significant proportion of the polymer blend consists of particles 7μm or less, in the respirable range.

Fifteen personnel working 1-2 hours/day for 10 days/year will be engaged in these transport operations. At the customer warehouse, 5 staff working 2 hours/day for 100 days/year will be responsible for storage of the imported drums. These workers engaged in initial transport and storage routinely will only handle unopened drums and so exposure to the notified polymer would only occur following accidental puncture of the drums.

Laboratory Research and Development

Two to 4 laboratory staff working 4 hours/day for 100 days/year will prepare trial paint batches by mixing the blend containing the notified polymer with other paint additives for laboratory analysis. Exposure to the notified polymer in the laboratory environment is controlled by laboratory coats and safety glasses worn by staff and sampling and mixing conducted under local exhaust ventilation.

Paint Formulation

At the customer site, plant operators will pre-weigh batch lots of polymer manually into pails which will then be added manually to a 10,000L mixing vessel. After mixing, a sample will be collected for quality assurance analysis by automatic decanting from the mixing vessel in an enclosed system after which the paint will then be loaded into 0.25, 1, 2, 4, 10 and 20L epoxy lined steel cans.

For the 12 operators who will be engaged in these activities 8 hours/day for 100 days/year, it is possible that dermal, ocular and pulmonary exposure to the polymer may occur. Given that the polymer will be significantly diluted in paint, the most likely exposure to the polymer will occur via spillage to the skin and eyes and inhalation during batch weighing of particulate polymer. Exposure will be controlled by local and general exhaust ventilation to capture dust and vapours and personal protective equipment consisting of long-sleeved overalls, head covering, safety glasses, safety boots, dust masks and impervious gloves.

Paint Distribution

Forty warehouse staff each working up to 8 hours/day for 200 days/year will pack paint products containing the notified polymer for distribution. At this stage, paint containers normally remain sealed until end use and so exposure to the notified polymer would only occur as a result of accidental opening.

The finished paint products containing the notified polymer will be sold through numerous retail and wholesale paint outlets by more than 200 paint salespeople. These salespeople will be exposed potentially to the polymer during tinting with colourants. Assuming the upper limit of import volumes and 200 salespeople handling the paint containing the notified polymer, a salesperson may handle on average a total of 50kg of the polymer per year.

It is likely that paint tinting may be conducted in the absence of local ventilation or personal protective equipment and so exposure to the notified polymer during these activities may occur via dermal, oral, ocular and pulmonary routes. Given the likely low volatility of the polymer, exposure via the skin and eyes following accidental spillage is more likely than from inspiration of aerosols.

End Use

Exposure to the polymer may occur for the more than 200 contract painters and 5000 do-it-yourself (DIY) painters who will apply paint containing 0.25-1% of notified polymer. Painting will be conducted by brush or roller and exposure would occur predominantly via the skin and eyes following splashes and spills. Although the paints will be spread to a large surface area, the expected low vapour pressure of the polymer means that inhalation exposure is unlikely. Given the wide availability of the paint, it is likely that the location of application of the paint as well as the level of personal protective equipment used during application will vary from worker to worker and, consequently, the possibility of exposure to the notified polymer may also vary. Exposure may be higher in some situations such as with a DIY painter using minimal personal protection in a poorly ventilated indoors application.

7. PUBLIC EXPOSURE

Customers will use the notified polymer in the formulation of water-based paint products. The finished paint products will be sold to the general public for domestic use. These paint

products will be applied by brush or roller and dermal and ocular exposure are likely as a result of splashes and spills.

The potential for public exposure to the notified polymer during transport and use or from disposal is assessed as negligible. Exposure to the notified polymer after paint has dried will be negligible because the notified polymer will be bound within a cured paint film.

8. ENVIRONMENTAL EXPOSURE

Release

There is potential for release during paint formulation and application. The product containing the notified polymer is imported in 70 kg polyethylene lined fibre drums and is stored and reformulated by the paint manufacturer. Residues remaining in imported drum liners are expected to be 0.5% of the annual import volume of 10 tonnes (up to 50 kg per annum).

Paint containing the notified polymer will be packaged into 0.25, 1.0, 2.0, 4.0, 10 or 20 L epoxy lined steel cans. Spills occurring as a result of reformulation will be contained within the plant through bunding. The notifier estimates the quantity of spillage to be up to 200 kg per annum (2% of annual import volume). Washings from the cleaning of manufacturing equipment will be recycled and reused in subsequent paint batches. Paint samples collected for quality assurance will either be returned to subsequent paint batches or disposed of as waste. All waste will be taken off-site by a licensed industrial waste contractor for treatment and disposal at a licensed landfill site.

The majority of release to the environment is expected to occur as a result of paint application and the cleaning of application equipment (e.g. brushes, rollers). In most cases, it is expected that washings will be disposed of inappropriately to the sewer. The notifier expects approximately 5% (maximum of 500 kg per annum) of the notified polymer to be released in this way and has provided a Predicted Environment Concentration (PEC). However, it is anticipated that an unknown proportion may be discarded directly to the storm water system.

An additional 2% of the notified polymer will remain as residues in cans. This will be disposed of to land fill and is expected to be in a solid, inert form. The notifier has also stated that unused waste paint remaining in cans will be disposed of at liquid waste collection points at waste management centres. However, it is anticipated that much of this paint will ultimately be disposed of to landfill.

The total release of polymer (assuming an annual import volume of 10 tonnes and the above release estimates) is estimated to be no greater than 900 kg per year for the next five years. Of this, approximately 5% may be released to the sewer.

Fate

Solid waste generated during the formulation of the paint coating will be disposed of to landfill. Import and retail containers and their residues are also expected to be disposed of in this way. Once in landfill, soil mobility of the polymer is anticipated to be low and it is not expected to migrate through to the aquatic compartment. The polymer is expected to dry and slowly degrade via aerobic, anaerobic and abiotic processes. Degradation products are

expected to be carbon dioxide and water.

The notifier has indicated that wash water containing the polymer may be released to the sewer where it is expected to bind to sewage sludge, and ultimately disposed of to landfill. However, is expected that some wash water will be released, untreated, to stormwater. In this circumstance, the polymer is expected to eventually bind to sediment and be slowly degraded by biotic and abiotic processes.

Once applied to the internal surfaces of houses and other domestic structures, the notified polymer will be incorporated in a hard, durable, inert paint film and would not present a significant hazard. Any fragments, chips and flakes of the paint will be of little concern as they are expected to be inert. The polymer is not expected to cross biological membranes, due to high molecular weight, and should not bioaccumulate (Connell, 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Ceramer 67 Polymer

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000mg/kg	Sanders (1997b)
eye irritation	rabbit	Slightly irritating	Sanders (1997a)
skin sensitisation	guinea pig	Not sensitising	Sanders (1997c)

9.1.1 Oral Toxicity (Sanders, 1997b)

Species/strain:	Rat, Sprague-Dawley CD
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Gavage using test material ground to a fine powder and suspended in arachis oil BP.
Test method:	OECD TG 401 (Limit test)
Mortality:	None
Clinical observations:	No signs of systemic toxicity were observed and all animals showed expected gain in bodyweight during the study.
Morphological findings:	No abnormalities were found at necroscopy.
LD_{50}:	> 2000mg/kg

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

9.1.2 Eye Irritation (Sanders, 1997a)

Species/strain: Rabbit, New Zealand White

Number/sex of animals: 3, Males

Observation period: 3 days: 1, 24, 48 and 72 hours following application.

Method of administration: Test material was ground to a fine powder. In the first animal, 0.1 ml of test material was applied to the conjunctival sac of the right eye. The left eye remained untreated. In the second and third animals, the test material was applied in a similar fashion but 1-2 minutes after ocular application of 1-2 drops of local anaesthetic 0.5% proxymetacaine hydrochloride.

Draize scores of unirrigated eyes:

	Time after Instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	0		0	0		0	0		0	0		0
2	0		0	0		0	0		0	0		0
3	0		0	0		0	0		0	0		0
Iris												
1	0			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	1	2	1	0	0	0	0	0	0	0	0
2	2	1	2	1	0	0	0	0	0	0	0	0
3	2	1	2	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Test method: OECD TG 405

Comment: Moderate conjunctival redness and discharge and

mild chemosis were noted in all animals one hour after application. Mild redness persisted for 24 hours.

Result: The notified chemical was mildly irritating to the eyes of rabbits.

9.1.3 Skin Sensitisation (Buehler test) (Sanders, 1997c)

Species/strain: Guinea pig, Dunkin Hartley

Number of animals: 20 treatment, 10 control

Induction procedure: On days 0, 7 and 14: To the clipped area of the left flank, each animal was affixed with an adsorbent cotton lint patch loaded with powdered test material at 50% w/w in petroleum jelly. After 6 hours, the patch was removed and the treatment sites decontaminated using diethyl ether and marked. Control animals were similarly treated with vehicle alone.

Challenge procedure: Day 28: To two clipped areas of the right flank, each animal was affixed with an adsorbent cotton lint patch loaded with powdered test material at 25% and 50% w/w in petroleum jelly. After 6 hours, the patches were removed and the treatment sites decontaminated using diethyl ether and marked. Control animals were similarly treated with vehicle alone.

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	0/20**	0/20	0/10	0/10
50%	0/20	0/20	0/10	0/10

* time after patch removal

** number of animals exhibiting positive response

Test method: OECD TG 406

Comment: Application of test material or control vehicle failed to induce positive responses in any animal.

Result: The notified chemical was not sensitising to the skin of guinea pigs.

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Thompson, 1997)

Strains:	*Salmonella typhimurium* TA 1535, TA1537, TA98, TA 100; *Escherischia coli* WP2 uvrA
Concentration range:	0, 50, 150, 500, 1500 and 5000 μg/plate
Metabolic activation:	Aroclor 1254-induced rat liver homogenate, S9 fraction
Test method:	OECD TG 471, 472
Comment:	A precipitate was observed at 1500 and 5000μg/plate. This did not prevent scoring of revertant colonies. The test material was not cytotoxic at any dose level.
Result:	The notified chemical was not mutagenic at doses up to 5000μg/plate in bacteria in the presence or absence of metabolic activation induced by rat liver S9 homogenate.

9.3 Overall Assessment of Toxicological Data

Acute oral toxicity of the notified polymer was found to be very low, with a rat LD_{50} > 2000mg/kg.

In an acute eye irritation study in rabbits, the notified chemical was shown to be slightly irritating. A Buehler skin sensitisation study in guinea pigs failed to show positive responses in any animal indicating that the notified chemical was not sensitising.

In an Ames test, the notified polymer was non-mutagenic. No mutagenicity was observed in a *Salmonella typhimurium* and *Escherischia coli* reverse mutation assay at doses up to 5000μg/plate neither in the presence nor absence of metabolic activation. No significant, reproducible increase in numbers of revertant colonies were found.

From the toxicological data, the notified chemical is not classified as a hazardous substance according to the NOHSC Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were submitted.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Approximately 5% of the notified polymer may be discharged to sewer during equipment cleaning.

As the product will be used throughout the country and sent to sewage treatment plants in both city and country locations, a PEC based on maximum projected level of use across the continent has been calculated:

Maximum Import Volume per annum	10000 kg
Amount discharged to sewer	5%
Volume discharged per day	1.36 kg
Sewer output per day*	2 700 ML
Concentration in Sewage Treatment Plant	0.51 µg/L
Further diluted (1:10) in receiving waters	0.05 µg/L

*Sewer output based on an Australian population of 18 million, each using 150 L water per day. The PEC submitted by the notifier assumed a population of 19 million with daily per capita water use of 190 L per day resulting in a concentration in sewer effluent of 0.38 µg/L. Ecotoxicity data are not available for the notified polymer. However, non-ionic polymers that have a NAMW >1000 and are of relatively low solubility are considered to be of limited concern for aquatic ecotoxicity (Nabholz et al., 1993).

The majority of the waste polymer is expected to ultimately be released to landfill. The polymer is unlikely to be mobile in the soil environment and would be expected to slowly degrade to carbon dioxide through abiotic and biotic processes. The environmental hazard of the notified polymer in landfill is expected be low.

In the event of release of the polymer into waterways, the polymer is expected to disperse into the water then slowly settle out onto sediments where it would slowly degrade. The environmental hazard of the notified polymer in the aquatic environment is expected to be low.

The polymer's large molecular weight and relatively low water solubility should prevent bioaccumulation. Given the above, the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified polymer possesses physicochemical properties to be considered as a Synthetic Polymer of Low Concern. The mean particle size of the blend containing the notified polymer is 12µm. Therefore, it is likely that a significant proportion of the polymer blend consists of particles 7µm or less, in the respirable range.

Toxicity data submitted for the polymer indicates that it is of very low acute oral toxicity, is non-mutagenic and is not a skin sensitiser. In eye irritation studies, the polymer causes only

mild, transient irritation. Based on these toxicological data, the polymer substance can be assessed against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) as non-hazardous. Therefore, the health hazard represented by the polymer is low.

Occupational Health and Safety

The notified polymer will be imported as a polymer blend in 70kg polyethylene-lined fibreboard drums and transported by road to a single customer site. Workers will be involved in initial import, transport and storage of the notified polymer. After paint formulation, warehouse staff will pack paint products containing the notified polymer for distribution. Given the low hazard of the polymer and the potential for exposure during these activities only following accidental puncture of the import drums and paint containers, the health risk for workers engaged in import, transport, storage and distribution would be assessed as low.

At the customer site, the polymer is made up into trial paints, then formulated into commercial batches. Laboratory staff will prepare trial paints for quality control analysis by mixing the blend containing the notified polymer with other paint additives. Staff exposure to the polymer in the laboratory environment will be controlled by local exhaust ventilation and the use of personal protective equipment consisting of laboratory coats and safety glasses.

Paint formulation staff will manually weigh and add the polymer to the paint mixing vessel. During mixing and loading, worker exposure will be controlled by local and general exhaust ventilation to capture particles and vapours. Workers will also wear personal protective equipment consisting of long-sleeved overalls, head covering, safety glasses, safety boots, dust masks and impervious gloves. Given these exposure controls and low polymer hazard, the health risk to workers engaged in these paint formulation and quality control processes would be assessed as low.

The finished paint products containing the notified polymer will be sold through numerous retail and wholesale paint outlets by more than 200 paint salespeople. These salespeople will be exposed potentially to the polymer during tinting with colourants. It is likely that paint tinting may be conducted in the absence of local ventilation or personal protective equipment and so dermal exposure from spillage is likely during these activities. Despite the frequency of these operations, given the low toxicity profile of the notified polymer and its low levels in paint (0.25-1%), the health risk for paint salespeople would be assessed as low.

End Use

Paints containing the notified polymer will be conducted by brush or roller and exposure may occur via the skin and eyes following splashes and spills. In addition, since the paints will be spread and given a large surface area, exposure to volatile paint components may also occur from inhalation of vapours. However, given the expected low volatility of the notified polymer, exposure to the notified polymer by this route is unlikely. Because of the wide availability of the paint, it is likely that the location of application of the paint as well as the level of personal protective equipment used during application will vary from worker to worker and, consequently, the possibility of exposure to the notified polymer may vary. Despite this variability in exposure, the low toxicological profile of the notified polymer renders the health risk low.

Public Health

Paint products containing the notified polymer will be available for sale to the general public. Although members of the public may make dermal and ocular contact with paints containing the notified polymer, the risk to public health from the notified polymer will be negligible because of its high NAMW and low concentration in paint products. Exposure to the notified polymer in dried paint is negligible since it is bound within a cured paint film.

13. RECOMMENDATIONS

To minimise occupational exposure to Ceramer 67 Polymer, 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); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); impermeable gloves or mittens should conform to AS 2161 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- 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* (National Occupational Health and Safety Commission, 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 subsection 64(1) of the Act, secondary notification will be required if the polymer characteristics cease to satisfy the criteria under which it has been accepted as a Synthetic Polymer of Low Concern. Secondary notification of the notified polymer 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

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: D. W. Connell ed. Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton.

Nabholz JV, Miller P & Zeeman M (1993) Environmental Risk Assessment of New Substances under the Toxic Substances Control Act Section Five. In: W. G. Landis, J. S. Hughes and M. A. Lewis ed. Environmental Toxicology and Risk Assessment,
American Society for Testing and Materials. ASTM STP 1179, Philadelphia, **:** 40-55.

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.

Sanders A (1997a) ENV 97-0501: Acute eye irritation test in the rabbit. Safepharm Laboratories Limited, Derby, UK.

Sanders A (1997b) ENV 97-0501: Acute oral toxicity (limit test) in the rat. Safepharm Laboratories Limited, Derby, UK.

Sanders A (1997c) ENV 97-0501: Buehler delayed contact hypersensitivity study in the guinea pig. Safepharm Laboratories Limited, Derby, UK.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia, Sydney.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia, Sydney.

Thompson P.W. (1997) ENV 97-0501 Reverse mutation assay “Ames test” using Salmonella Typhimurium and Escherichia Coli. Safepharm Laboratories Limited, Derby, UK.

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