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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Copolymer in Polyquaternium-34

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polyquaternium-34

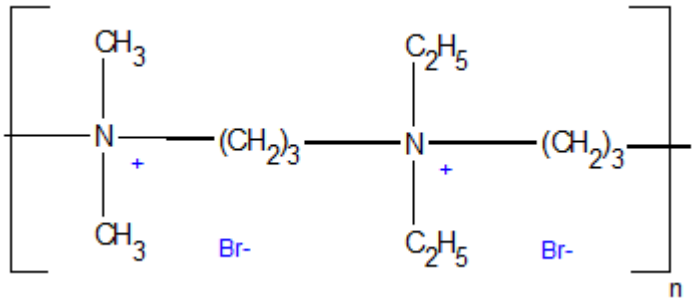
1. APPLICANT

L'Oreal Paris has submitted a limited notification statement in support of their application for an assessment certificate for Polyquaternium-34. No claims for exempt information were made by the notifier, and the assessment report is published here in its entirety.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	1,3-propanediamine, N,N-diethyl-N',N'-dimethyl-, polymer with 1,3-dibromopropane
Chemical Abstracts Service (CAS) Registry No.:	143747-73-3
Other Names:	copolymer of 1,3-dibromopropane and N,N-diethyl-N',N'-dimethyl-1,3-diaminopropane
Trade Name:	Polyquaternium-34 (50 % aqueous solution) Mexomere PAK (50 % aqueous solution)
Molecular Formula:	$[(C_{12}H_{28}N_2)Br_2)]_n$

Structural Formula:



where n = average of 6-7

Number-Average Molecular Weight (NAMW): 2 340 (n = 6.5)

Maximum Percentage of Low Molecular Weight Species
Molecular Weight < 500: not available
Molecular Weight < 1 000: not available

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*
N,N-diethyl-N,N'-dimethyl-1,3-diaminopropane	62478-82-4	50
1,3-dibromopropane	109-64-8	50

Method of Detection and Determination: identification by infrared (IR) spectroscopy, organic components determined by gas-liquid chromatography (GLC), total bromine by $AgNO_3$ titration

Spectral Data: major IR peaks at 1 400, 1 449, 1 474, 1 491, 1 629, 2 666, 2 977, 3 420 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: yellow liquid with negligible odour (50% aqueous solution)

Boiling Point: 100°C (50% aqueous solution)

Density: 1 15o kg/m^3 at 20°C

Vapour Pressure: 0.0075 kPa at 25°C

Water Solubility: completely soluble in all proportions

Partition Co-efficient (n-octanol/water): log P_{ow} = -4.19 at 25°C

Hydrolysis as a Function of pH: not available

Adsorption/Desorption: not available

Dissociation Constant: not available

Surface Tension 72.8 mN/m at 20°C (of 72.8% sol^n) (1).

Fat Solubility	0.05 mg/100g at 37ºC (2)
Flash Point:	> 110°C
Flammability Limits:	not flammable
Autoignition Temperature:	> 400°C
Explosive Properties:	not explosive
Reactivity/Stability:	stable under normal storage, handling and usage conditions

Comments on Physico-Chemical Properties

Tests were performed according to EEC test guidelines (1) in compliance with OECD Principles of Good Laboratory Practice. Water solubility, partition coefficient, surface tension and fat solubility tests were performed on Mexomere PAK (the notified polymer 50% and water)

It is claimed that the notified polymer is soluble with water in all ratios resulting in visually clear solutions. In the test, 10.22 g was brought into solution (with 5.0 mL of water) with a Vortex mixer, then stirred in a water bath at 20ºC for one hour. All solutions were visually clear after this time.

The notified polymer does not contain any hydrolysable functionalities. Due to its very high water solubility and as it is practically insoluble in fat, the polymer would be expected to have a low K_{OC} and not be strongly adsorbed to sediments. However, quaternary ammoniums are known to react with dissolved organic carbon in water to form part of the sediments, and become completely inactivated on contact with soils (3, 4).

Due to its charged nature, the notified polymer will be highly dissociated at environmental pH values. The notified polymer is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (1)

4. PURITY OF THE CHEMICAL

Degree of Purity:	98%
Toxic or Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	none
Maximum Content	

of Residual Monomers: < 0.72%

Chemical Name	*CAS No.*	*Weight %*
N,N-diethyl-N,N'-dimethyl-1,3-diaminopropane	62478-82-4	0.09
dibromopropane	109-64-8	< 0.005

Additives/Adjuvants: commercial formulation is a 50% aqueous solution

5. USE, VOLUME AND FORMULATION

The notified polymer is a hair conditioning agent. It will be imported as the commercial formulation Polyquaterium-34, a 50% aqueous solution. The notified polymer is used at a concentration of 3% in retail rinse-out, hair conditioners. It is also included as a component of a range of hair colourants for domestic use.

The import volume will be less than or equal to one tonne per annum for each of the first five years.

6. OCCUPATIONAL EXPOSURE

The notified polymer is imported as a 50% solution. The imported formulation, Polyquaternium-34, will be reformulated at the notifier's factory in Sandringham, Victoria. Polyquaternium-34 is classified as a class 9 dangerous good according to the *Australian Code for the Transport of Dangerous Goods by Road or Rail* (5). The classification is for an Environmentally Hazardous liquid. This classification will affect the type of packaging and transport requirements, but is not expected to pose an occupational risk. Occupational exposure during transport and warehousing will not routinely occur. It will only occur in the event of leakage or accidental release from the shipping containers.

Occupational exposure will be most significant during reformulation of Polyquaternium-34 into hair colourants. Employees handling products containing the notified polymer will be exposed to the notified polymer at its highest concentration (50%). Employees handling the reformulated products will only be exposed to formulations containing 3% of the notified polymer. Four main groups of employees will be potentially exposed. These include 1 storeman, 2 laboratory technicians, 1 compounder and 1 linesetter. The storeman will potentially be exposed when sampling the formulation for chemical testing by the laboratory technicians. Exposure for these employees will be intermittent and for short periods only. The compounder is likely to have the highest potential exposure. The compounder will weigh and blend the ingredients of the hair colourants, including the Polyquaternium-34 and then clean the equipment. There is significant potential for dermal exposure and more limited potential for ocular exposure during handling of the liquid formulation, Polyquaternium-34.

The linesetter will prepare and maintain the automatic filling line. Exposure will be lower as there will only be potential exposure to a formulation containing 3% of the notified polymer.

7. PUBLIC EXPOSURE

As the notified polymer is to be used in products to be sold directly to the public for the colouring and conditioning of hair, significant, widespread public exposure is probable. Exposure will be limited only by the commercial success of products in which Copolymer in Polyquaternium-34 is included and by the frequency of application, which is stated by the applicant to be every four to six weeks for hair colours.

Unintentional exposure to significant quantities of Copolymer in Polyquaternium-34 from the manufacturing process or transport of it, or products including it, is unlikely given the single manufacturing site and the low concentration of the compound in formulated products.

8. ENVIRONMENTAL EXPOSURE

Release

The hair colouring product will come in a 40 mL PVC bottle that contains approximately 1.2 g of notified polymer. Approximately 833 000 units can be manufactured per year at the maximum import rate.

The notifier claims that the average loss of the notified polymer in a 200 kg manufactured batch of hair colourant, containing a maximum of 3% notified polymer, is 45 g. This includes the residues rinsed from the raw material drums. The wastes are flushed with water during the in-process cleaning of the manufacturing tank and associated pipework. They are collected in the effluent treatment tank. No more than 135 g of manufactured hair colourant (4.05 g of polymer) will be washed into each 10 000 L batch of effluent. Effluent from this tank is released to the Melbourne Waste Treatment Plant when full.

Spills will be mixed with an absorbent material and collected in sealed drums for safe disposal. Any polymer entering drains on site will be directed to the effluent storage tank.

It is anticipated that customers will use the colouring product every four to six weeks. The notifier claims that although the notified polymer has a high substantivity (adsorption) to human hair, it is expected that a certain proportion of it, depending on hair length, will be washed out during treatment. Also, the polymer only provides a temporary conditioning effect, and since it is used every four to six weeks, it is assumed that 100% of it will be washed out gradually over that time. Empty containers, with residues, will probably be disposed of to landfill.

Fate

The vast majority of notified polymer will be discharged to sewer. Here the notified polymer is expected to rapidly react with the dissolved organic carbon (DOC) in the water column, forming an insoluble flocculent that should be removed with the sludge (3). The sludge will either be landfilled or incinerated. Incineration products will include oxides of carbon and nitrogen, together with bromine salts in the ash.

Minor amounts remaining as residues in product containers disposed of to landfill should be contained. Should leaks occur, these will quickly become immobile absorbing to soil.

The biochemical oxygen demand (BOD) and chemical oxygen demand (COD) of Mexomere PAK (containing 3% of the notified polymer) were determined by methods similar to EEC Test Guidelines C8 and C9 (1). However, BOD could not be determined as after 20 days the oxygen consumption was strongly inhibited by the test substance, i.e. Mexomere PAK inhibited the bacterial activity in the test medium. The COD was found to be 0.305 mg O_2/mg. The biodegradability of the notified polymer was not determined which is acceptable for polymers with import volumes less than one tonne per year according to the Act.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

While not required for polymers which will be imported in quantities less than one tonne per annum, according to the Act, the following toxicity studies have been supplied by the notifier:

Summary of the acute toxicity of Copolymer in Polyquaternium-34

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(6)
acute dermal toxicity	rabbit	LD_{50} > 2 000 mg/kg	report not sighted
skin irritation	rabbit	non-irritant	(7)
eye irritation	rabbit	slight irritant	(8)
skin sensitisation	guinea pig	non-sensitiser	(9)

9.1.1 Oral Toxicity (6)

Species/strain:	rat/SPF Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	by gavage in distilled water
Clinical observations:	nil
Mortality:	nil
Morphological findings:	nil;
Test method:	similar to OECD guidelines (2)
LD_{50}:	< 2 000 mg/kg
Result:	the notified polymer was of low oral toxicity to rats in a limit test

9.1.2 Skin Irritation (7)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/male
Observation period:	72 hours
Method of administration:	0.5 mL of test substance on a dry compress applied to clipped skin for 4 hours under a semi-occlusive dressing
Draize scores (10):	all scores were zero

Test method: similar to OECD guidelines (2)

Result: the notified polymer was not a skin irritant in rabbits

9.1.3 Eye Irritation (8)}

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/sex not stated

Observation period: 72 hours

Method of administration: test substance placed in conjunctival sac of the left eye of each rabbit, right eye served as the control

Draize scores (10) of unirrigated eyes: no iridial lesions or corneal opacity noted.

	Time after instillation											
Animal	***1 hour***			***1 day***			***3 days***			***4 days***		
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]***
1	0	0	0	0	0	0	0	0	0	0	0	0
2	1	0	2	1	0	0	0	0	0	0	0	0
3	1	0	1	0	0	0	0	0	0	0	0	0

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

Test method: similar to OECD guidelines (2)

Result: the notified polymer was a slight eye irritant in rabbits

9.1.4 Skin Sensitisation (9)

Species/strain: guinea pig/Hartley

Number of animals: 5 negative controls
5 positive controls (dinitrochlorobenzene)
10 treated with test substance

Induction procedure: preliminary investigation indicated that maximal slightly-irritating intradermal dose was test substance diluted 1/10 with thick paraffin oil (TPO); preliminary investigation indicated that maximal non-irritating

epicutaneous dose was test substance diluted 1/2 with TPO; induction of animals treated with test substance was as follows
(day 1):site 1: 0.1 mL of Freund's Complete Adjuvant (FCA) diluted 1/2 with isotonic NaCl solution.
site 2: 0.1 mL of test substance at 1/10 with TPO.
site 3: 0.1 mL of equal volumes of FCA 1/2 in NaCl solution with test substance diluted 1/10 with TPO

Challenge procedure: day 8, 0.5 mL of sodium lauryl sulfate 1/10 in paraffin oil
day 22, 0.5 mL of test substance diluted 1/2 with TPO

Challenge outcome:

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

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

Test method: similar to OECD guidelines (2)

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

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium*/*Escherichia coli* Reverse Mutation Assay (11)

Strains: *S.typhimurium* strains -TA 1535, TA 1537, TA 1538, TA98 and TA 100
E.coli strain - WP2 uvrA
with or without Aroclor induced rat liver S9 fraction

Concentration range: 312.5 - 5 000 μg/plate

Test method: similar to OECD guidelines (2)

Result: the notified polymer was not mutagenic in this system

9.3 Overall Assessment of Toxicological Data

The notified polymer was of low oral toxicity in a rat limit test (LD_{50} > 2 000 mg/kg), it also had low dermal toxicity in a study using rabbits (LD_{50} > 2 000 mg/kg), however the primary reports for this study was not sighted. No systemic effects were evident in either study. In studies using rabbits the polymer was not a skin irritant however there were slight conjunctival responses evident up to 24 hours after application in a rabbit eye study. No repeat dose or acute inhalation toxicity data were available for the notified polymer. The notified polymer was not mutagenic in a *Salmonella typhimurium/Escherichia coli* reverse mutation assay.

On the basis of the submitted toxicological data summarised above, the notified polymer would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (12).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data is required for polymers with import volumes less than one tonne per year according to the Act. However, the notifier did provide the following ecotoxicity data:

Test	Species	Results
Acute Toxicity Nominal[#] Static system (1)	Zebra fish (*Brachydanio rerio*)	96 h LC_{50} = 80 mg/L NOEC = 48 mg/L
Acute Immobilisation Nominal* Static system (1)	Water Flea (*Daphnia magna*)	48 h EC_{50} = 0.68 mg/L NOEC < 0.35 mg/L

[#]. Nominal concentrations tested were 48, 62, 80, 100, 130, 170, 220, 290, 370 & 480 mg/L.
*. Nominal concentrations tested were 0.35, 0.45, 0.60, 0.80, 1.0, 1.3, 1.7, 2.2, 2.9, 3.7, 4.8 & 6.3 mg/L.

Tests were conducted on Mexomere PAK (notified polymer 85.2% and water 14.8%) in compliance with OECD Principles of Good Laboratory Practice. Therefore, actual LC_{50} and EC_{50} values will be slightly lower than those indicated above (by approximately 14.8%).

The ecotoxicity data indicate that the notified polymer is only slightly toxic to fish but highly toxic to aquatic invertebrates.

No data were presented on the notified polymer's toxicity to algae. It is known that algae are the most sensitive species during acute exposure to cationic surfactants, which includes quaternary ammonium compounds (3). These polymers react with biological membranes. However, aquatic toxicity is highly mitigated by the presence of dissolved organic carbon (DOC) in water (3). Therefore, while initial considerations indicate that the polymer will be very highly toxic to algae, actual

toxicity without test data is difficult to determine. It is predicted based on the toxicity shown to other aquatic organisms, that the notified polymer is probably at least highly toxic to algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The vast majority of notified polymer will be discharged to sewer through product use. As the product will be used all around the country, and sent to sewage treatment plants in both city and country locations, a predicted environmental concentration (PEC) based on continental use has been calculated:

Import Volume	1 tonne
Amount discharged to sewer	100%
Volume discharged per day	2.74 kg (1 000 kg/365 days)
Sewer output per day*	2 700 ML
Concentration in Sewage Treatment Plant	1.01 μg/L(ppb)

* Sewer output based on an Australian population of 18 million, each using 150 L water per day.

If this scenario was limited to Melbourne, with a population greater than three million and 500 ML of waste water treated per day, the PEC would still only be approximately 5.50 ppb (safety factor of 134 for EC_{50} of most sensitive aquatic organism tested, *Daphnia magna*). Both PECs are prior to any removal through adsorption to sludge in the sewage treatment process or further dilution in receiving waters.

During product manufacturing, the notifier has indicated that a maximum 4.05 g of notified polymer will be released with every 10 000 L of effluent from the plant. Therefore, the maximum concentration of polymer discharged to the Melbourne sewer from the plant is ~0.4 mg/L. In the sewage treatment system, the polymer will undergo further dilution (500 ML of waste water treated per day) and adsorption to sludge. This will result in a PEC of less than 1 ppt (or ~$8x10^{-10}$ mg/L).

The minor amount remaining as residues in product containers after use should be confined to landfill. Any leaking polymer will be rapidly and completely adsorbed to soil.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Copolymer in Polyquaternium-34 has a low oral toxicity in rats and a low dermal toxicity in rabbits. It is not a skin irritant in rabbits however, it had some potential for eye irritation. These effects in rabbits were low level and transitory. It is not a skin sensitiser in guinea pigs or a mutagen in an Ames test.

The NAMW should preclude transmission across biological membranes. The low levels of residual monomers and lack of hazardous or toxic impurities further reduces the hazard associated with the introduction of this polymer.

Occupational exposure will be limited. Exposure during transport and storage is considered unlikely. The greatest exposure is likely to occur during reformulation and then only when handling the 50% concentrate, Polyquaternium-34. Exposure when handling the colourant formulations will be limited as the notified polymer is at a level of only 3%. Exposure during reformulation is most likely to be dermal with a limited possibility of ocular exposure. The toxicological profile, relatively low concentrations in final formulation, and expected low exposure indicates that the occupational risk to workers handling Polymer in Polyquaternium-34 will be low.

Significant numbers of the public will be exposed to Copolymer in Polyquaternium-34 on the scalp, neck and face, as a component of hair colourants. However the risk to the public is expected to be low. The low systemic and topical toxicity and low concentration in finished products (approximately 3%), provides an acceptable safety margin. Additionally as the compound is freely soluble in water, with a partition coefficient (log P_{ow}) of -4.19, very little residual material would be expected to be associated with the scalp after application, with excess readily washed away.

13. RECOMMENDATIONS

To minimise occupational exposure to Copolymer in Polyquaternium-34 the following guidelines and precautions should be observed:

- Industrial clothing should conform to the specifications detailed in AS 2919 (13);
- All occupational footwear should conform to AS/NZS 2210 (14);
- Spillage of the notified polymer or products containing it 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 Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the formulation containing the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (15).

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 polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. An algal growth inhibition test result and report will be required if annual import quantities are to rise above one tonne.

16. REFERENCES

1. European Economic Community (EEC) 1992, 'Methods for the Determination of Physico-Chemical Properties', in *EEC Directive 92/69, Annex V, Part A, EEC Publication No. L383*, EEC.

2. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.

3. Nabholz, J.V., Miller, P. & Zeeman, M. 1993, 'Environmental Risk Assessment of New Substances under the Toxic Substances Control Act Section Five', in *Environmental Toxicology and Risk Assessment, American Society for Testing and Materials*, ASTM STP 1179, Philadelphia, pp. 40-55.

4. Tomlin, C., ed. 1994, *The Pesticide Manual*, 10th edition, , Crop Protection Publications, British Crop Protection Council and The Royal Society of Chemistry, UK.

5. Federal Office of Road Safety 1992, *Australian Code for the Transport of Dangerous Goods by Road and Rail*, 5th edn, Australian Government Publishing Service, Canberra.

6. Richard, S. 1991, *Safety Study in the Rat by Oral Dosing*, Project no., 910268 E, Centre de Recherches Biologiques, Baugy, France.

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9. Richard, S. 1992, *Study of Cutaneous Sensitisation using the Magnusson and Kligman Maximization Test in Guinea Pigs.*, Project no., 910269 E, Centre de Recherches Biologiques, Baugy, France.

10. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.

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13. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australia, Sydney.

14. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

15. 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.

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