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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Liquitint Violet

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT 4
1. APPLICANT 4
2. IDENTITY OF THE CHEMICAL 4
3. PHYSICAL AND CHEMICAL PROPERTIES 4
3.1 Comments on Physico-Chemical Properties 5
4. PURITY OF THE CHEMICAL 6
5. USE, VOLUME AND FORMULATION 6
6. OCCUPATIONAL EXPOSURE 6
7. PUBLIC EXPOSURE 7
8. ENVIRONMENTAL EXPOSURE 7
9. EVALUATION OF TOXICOLOGICAL DATA 8
9.4 Overall Assessment of Toxicological Data 10
10. ASSESSMENT OF ENVIRONMENTAL EFFECTS 11
11. ASSESSMENT OF ENVIRONMENTAL HAZARD 13
12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS 13
13. RECOMMENDATIONS 14
14. MATERIAL SAFETY DATA SHEET 15
15. REQUIREMENTS FOR SECONDARY NOTIFICATION 15
16. REFERENCES 15

FULL PUBLIC REPORT

Liquitint Violet

1. APPLICANT

Wom International of 7/195 O'Sullivan Beach Road, Lonsdale, SA 5160 (ABN 14 002 708 832) and Asia Pacific Specialty Chemicals Limited of 15 Park Road, Seven Hills, NSW 2147 (ABN 32 000 316 138) have submitted a limited notification statement in support of their application for an assessment certificate for Liquitint Violet.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name: Liquitint Violet
Liquitint Royal Blue
Experimental Violet PP03

3. PHYSICAL AND CHEMICAL PROPERTIES

Unless specified, the following data refer to a 70% aqueous solution of notified polymer (Liquitint Violet).

Appearance at 20°C & 101.3 kPa: Dark violet liquid with sweet odour.

Boiling Point: 100°C (water)

Specific Gravity: 1.2 (polymer 1.16 – calculated)

Vapour Pressure: Not determined. See comments below.

Water Solubility: Soluble. See comments below.

Partition Co-efficient (n-octanol/water): log K_{ow} = 1.23

Hydrolysis as a Function of pH: $t_{1/2}$ at pH 9 & 20°C = 114 days

	$t_{1/2}$ at pH 9 & 40°C = 10 days $t_{1/2}$ at pH 4 & 7, 50°C > 5 days $t_{1/2}$ at pH 4 & 7, 20°C > 1 year (for the equivalent dichloride salt of the notified polymer)
Adsorption/Desorption:	Not determined. See comments below.
Dissociation Constant:	Not determined. See comments below.
Flash Point:	> 260°C (notified polymer)
Flammability Limits:	Not applicable. Notified polymer is combustible.
Autoignition Temperature:	Not applicable.
Explosive Properties:	Not explosive.
Reactivity/Stability:	May react in the presence of oxidising agents.

3.1 Comments on Physico-Chemical Properties

The polymer's vapour pressure is expected to be low due to its high molecular weight and ionic nature.

The polymer is highly water soluble and is imported in a product Liquitint Violet as a 70% aqueous solution. Solubilities as high as 442 mg/L were tested in the fish toxicity study (Geger & Bucksath, 1996).

Due to the coloured nature of the imported product Liquitint Violet, hydrolysis was monitored and measured by the absorption of a solution of the material, as measured on a spectrophotometer. Preliminary testing, performed at 50°C, indicated a $t_{1/2}$ greater than 1 year at 20°C at pH 4.0 and 7.0. Further testing was carried out to determine the half life at pH 9.0. These results indicate the polymer is stable at the lower pH, but is slowly hydrolysed under more alkaline conditions.

The octanol-water partition coefficient of Liquitint Violet was determined using the liquid chromatography method of the ASTM (American Society for Testing and Materials) method E1147-92 under the guidance and conditions of OECD method 117. The low partition coefficient reflects the ionic nature and high water solubility of the polymer.

Due to the high water solubility and delocalised charge, the polymer would not normally be expected to adsorb to soil. However, quaternary ammonium species are known to react with colloidal organic matter in water, and eventually become assimilated into aquatic sediments (Nabholz, Miller & Zeeman, 1993).

Due to its chemical structure, the polymer will not undergo basic reactions in aqueous solutions.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 97%

Hazardous Impurities:

Chemical name:	Hydroquinone
CAS No.:	123-31-9
Weight percentage:	< 3.0%
Toxic properties:	Conc ≥ 25%: Xn; R20/22

Non-hazardous Impurities (> 1% by weight): None

Maximum Content of Residual Monomers: Information not provided.

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified polymer will be used as a dye for domestic soaps and detergents and industrial cleaning and sanitising solutions. The polymer will not be manufactured in Australia but will be imported as a 70% aqueous solution in 20 L pails and 205 L steel drums. The polymer will be used in domestic products at < 0.5% and typically at 0.01-0.05%.

Up to 2 tonnes of the notified polymer will be imported annually for the first 5 years.

6. OCCUPATIONAL EXPOSURE

Import and Transport

Containers of notified polymer will not be opened prior to reformulation. Therefore, for the 12–20 workers who will be involved in initial import and transport for up to 20 days per year, exposure to the notified polymer is only envisaged following accidental puncture of the import drums or pails.

Product Manufacture (Formulation)

Warehouse workers (6-10 workers, 1hour/day, 20 days/year) will lance import containers and pump the imported solution to closed storage tanks. The solution is either weighed and transferred manually to a closed blending tank or pumped automatically via a metering system. After blending, the final product is transferred via automatic filling machines into containers – 1 and 2 L for domestic laundry products and 5, 10 and 20 L for industrial cleaning products.

For warehouse workers and blending room operators (10 workers, 8 hours/day, 50 days/year),

dermal and ocular contamination from spills and splashes would be the main route of occupational exposure and this may occur during initial opening of import containers. Exposure is unlikely during automatic transfer and blending processes but there may be exposure during the filling of product containers if overfilling occurs. For blending room operators who may conduct manual blending, dermal and ocular contamination with the notified polymer may occur during the transfer, mixing and filling operations. Five maintenance workers may also be exposed dermally to the notified polymer during equipment cleaning and maintenance.

The vapour pressure of the notified polymer is expected to be low due to its high molecular weight and the form (aqueous solution) in which it is handled. Thus, inhalation exposure during product manufacture is considered to be negligible.

Worker exposure during product manufacture and maintenance will be controlled by personal protective equipment consisting of cotton overalls, safety boots/shoes, PVC/latex gloves, safety glasses and safety helmets.

End Use

Cleaning staff, possibly numbering in the thousands, will use products containing the notified polymer and dermal and ocular occupational exposure is possible. For reasons indicated above, inhalation exposure would be negligible. Although the extent of use of personal protective equipment such as rubber gloves by cleaning workers is likely to be highly variable, the notified polymer is present typically at 0.01-0.05% in products and so only low level dermal exposure is envisaged.

7. PUBLIC EXPOSURE

There is likely to be widespread dermal exposure to the notified polymer by the public when used as a dye in standard domestic laundry products.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Little or no release of the notified dye is anticipated during product manufacture. As industry practice is not to clean equipment between product batches, residues in blending vessels will become part of the next product batch. Emptied containers will be rinsed before disposal in landfill, with the rinse solution added to the product being formulated. Should a spill occur, the product will be washed to a trade waste sewer with copious volumes of water.

The notified polymer is used to colour domestic laundry products. It will be almost entirely released to sewer after use. Product containers will be either recycled or sent to landfill with other household garbage. Small amounts of unused detergent and fabric softeners may remain in emptied consumer containers, and so a small proportion of the polymer may be released to landfill with the used containers. However, this release would be very disperse and is unlikely to exceed 1% of the total, amounting to a maximum of 20 kg annually.

8.2 Fate

Due to its cationic nature, polymer discharged to sewer is expected to rapidly associate with negatively charged colloidal organic material which is ubiquitous in sewage, and would eventually assimilate into sewage sediments (Nabholz et al., 1993). Polymer disposed of to landfill should also associate with negatively charged humic material and consequently be effectively immobilised despite the high water solubility.

The inherent biodegradability of the chloride analogue of the notified polymer was determined according to OECD Test Guideline 302B (Modified Zahn-Wellens Test) (Lebertz, 1993). Under the conditions of the test, 25% of the material was degraded within 42 days calculated on the basis of DOC elimination, indicating an "inherent biodegradability" of the material. The test was prolonged as at 28 days an increase in degradation was measured. However, no further degradation was observed after day 28, through to day 42. There is no indication in the report if the material inhibited the activity of the inoculum in the test medium.

Sewage sludge will either be sent to landfill or incinerated. Incineration products will include water vapour, oxides of carbon and nitrogen. When associated with sediments or humic material in soils, the polymer is expected to be slowly degraded through biological action and under aerobic conditions eventually mineralise to water and oxides of carbon and nitrogen, and to methane and ammonia in anaerobic environments.

The high water solubility of the polymer will preclude bioconcentration (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

Summary of the acute toxicity of Experimental Violet PP03.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	$LD_{50} > 5\ 000$ mg.kg^{-1}	(Lemen, 1987a)
skin irritation	rabbits	slightly irritating	(Lemen, 1987b)
eye irritation	rabbit	non-irritating	(Lemen, 1987c)

9.1.1 Oral Toxicity (Lemen, 1987a)

Species/strain:	Rat, Sprague-Dawley
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Oral (gavage)
Clinical observations:	Coloured urine and faeces
Mortality:	None

Morphological findings: No gross lesions

Test method: Limit test, OECD TG 401

LD_{50}: > 5000 mg/kg

Result: The test substance was of very low acute oral toxicity in rats.

9.1.2 Skin Irritation (Lemen, 1987b)

Species/strain: Rabbit, New Zealand White

Number/sex of animals: 6 males

Observation period: 72 hours

Method of administration: Test substance (0.5 mL) was applied to intact and abraded skin for 24 hours.

Draize scores - Erythema

Erythema	***Time after Treatment***					
	Intact Skin #			***Abraded Skin***		
Animals	***24hours***	***48 hours***	***72 hours***	***24hours***	***48 hours***	***72 hours***
1	0[a]	0	0	1	1	0
2	0	0	0	1	0	0
3	1	0	0	1	0	0
4	1	0	0	1	0	0
5	0	0	0	1	0	0
6	1	0	0	1	1	0

[a] see Attachment 1 for Draize scales

Clinical Observation: Draize scores for oedema were zero for all rabbits during days 1 to 3.

Test method: OECD TG 404

Result: The test substance was slightly irritating to the skin of rabbits.

9.1.3 Eye Irritation (Lemen, 1987c)

Species/strain: Rabbit, New Zealand White

Number/sex of animals:	6 males
Observation period:	72 hours
Method of administration:	Test substance (0.1 mL) was applied in the everted lower lid of the left eye, with the right eye serving as the untreated control. Treated eyes remained unwashed.
Test method:	OECD TG 405
Clinical Observation:	Upon instillation of the test substance, in one animal excessive rubbing and blinking was observed with some test substance still remaining in the conjunctival sac at 24 hours.
Draize scores:	Draize scores for corneal and iridal irritation were zero for all the animals during the study. Scores for conjunctival irritation (redness, chemosis and discharge) were zero for all except for a single rabbit which had a score of 1 for redness at 24 hours.
Result:	The test substance was not irritating to the eyes of rabbits.

9.4 Overall Assessment of Toxicological Data

The notified polymer was of very low acute oral toxicity in rats (LD_{50} > 5 000 mg/kg). It was a slight skin irritant but not an eye irritant in rabbits.

Irritation was of insufficient severity to classify the notified polymer 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

The following ecotoxicity studies for a chloride salt analogue of the notified polymer were provided for assessment. Both were performed according to US EPA test methods and US EPA Good Laboratory Practice Standards. All results are based on mean measured concentrations, with measured values indicating that the test solutions were stable in the test systems under the test conditions.

Test	Species	Results (95% conf. limits)	Reference
Acute Toxicity [a] 96 hour flow through US EPA 797.1400	Rainbow trout (*Oncorhynchus mykiss*)	LC50 = 390 mg/L (217-442 mg/L) NOEC = 109 mg/L	Geger & Bucksath (1996)
Growth Inhibition [b] 96 hour Static US EPA 797.1050	Algae (*Selenastrum capricornutum*)	EC50 = 1.7 mg/L (1.5-1.9 mg/L) NOEC = 0.45 mg/L	Ziegler & Bucksath (1996)

a) Mean measured concentrations were control, 33.0, 63.6, 109, 217 and 442 mg/L
b) Mean measured concentrations were control, 0.12, 0.24, 0.45, 0.87, 1.8 and 3.7 mg/L

Fish

The mean-measured concentrations represented 96±9.2% of the nominal test concentrations. The controls were clear throughout the test, while all the test concentrations were a dark blue colour and increased in darkness with concentration. All test chambers were free of precipitate and surface film during the study.

Due to the concentration of the dye in the test chambers it was not possible to observe the fish. Therefore, fish were randomly netted and held near the surface to determine behaviour. For this reason, accurate biological observations of sublethal effects could not be made until the end of the study when fish were placed in clear water.

At concentrations up to and including 109 mg/L, all fish were all assumed normal throughout the test and found to be normal at 96 hours, except one fish at 33.0 mg/L and 96 hours which displayed a loss of equilibrium. Effects after 48 hours were noted in test concentrations higher than 109 mg/L. At 271 mg/L, 7 fish were observed surfacing and displaying laboured respiration. However, at 96 hours all fish bar one (which displayed dark discolouration) were found to be normal in this test concentration.

Fish deaths were observed in the 442 mg/L test concentration (maximum concentration tested), with 6 at 72 hours and another 7 at 96 hours (cumulative total of 13). One fish was observed as normal at 96 hours, with the remaining six displaying surfacing behaviour, loss of equilibrium and/or quiescence.

The data was analysed using accepted statistical methodology (Stephan et al, 1978) to provide the LC_{50} of 390 mg/L.

Daphnia

A Daphnid study was not supplied. Nabholz, et al. (1993) claim that water soluble, cationic (quaternary ammonium) polymers with molecular weights greater than 1000 are of concern. These polymers interact with biological membranes and destroy the ability of gill membranes and other oxygen transfer organisms to facilitate respiration. While algae are assumed to be the most sensitive species during acute exposures, fish and aquatic invertebrates are more sensitive during chronic exposure (Nabholz, et al., 1993).

However, it is also understood that colloidal organic material[1] (which usually carries negative ionic charges) binds with cationic polymers and this renders the cationic chemical less bioavailable and less toxic, ie. the toxicity is highly mitigated in the presence of colloidal organic material (Nabholz, et al, 1993).

Therefore, while initial considerations indicate that the polymer will be highly toxic to Daphnids, actual toxicity without test data is difficult to determine.

Algae

The mean-measured concentrations represented 91±3.1% of the nominal test concentrations. The 0.45, 0.87, 1.8 and 3.7 mg/L test solutions were observed to be purple in colour with no visible precipitate, with colour intensity increasing with the increase in test concentrations. The 0.12 and 0.24 mg/L test solutions, and control were observed not to have a purple colour.

Cell counts were conducted at 24, 48, 72 and 96 hours for each replicate of the control and each test concentration. The multiple means test showed a significant inhibition effect ($p > 0.05$) on growth in the 0.87, 1.8 and 3.7 mg/L test concentrations as compared to the control. The 96 hour EC_{10} and EC_{90} were calculated to be 0.30 mg/L (95% confidence limits = 0.19 and 0.41 mg/L) and greater than 3.7 mg/L, respectively.

As the test material is a dye and all solutions above 0.24 mg/L were purple in colour, a primary factor in the inhibition of the growth of the algae is the reduction of available light. The notifier has not performed a modified growth inhibition test to differentiate between a reduced growth of algae due to real toxic effects of the notified polymer on the algal cells, or due to an indirect effect, a reduced algal growth by light absorption in coloured test solutions. As deleterious effects can be caused by the interception of light (shading effect) necessary for algal growth, the authors claim that the toxicity observed may have been due to physical rather than chemical factors.

However, it should be noted that for environmental purposes, growth inhibition, whether due to chemical or physical factors, is still of relevance. Algistatic effects may still lead to an undesirable environmental impact if exposure is continuous.

Summary

The ecotoxicity data for the notified chemical indicate that it is practically non-toxic to fish and moderately to highly toxic to algae. It is unclear how toxic the polymer will be to aquatic invertebrates, although it may exhibit significant toxicity towards these species.

[1] Such organic matter in natural waters and sewage is often referred to as “Dissolved Organic Carbon” or DOC.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is expected that the polymer will have wide distribution in the aquatic environment because of its use as a component of household soaps and detergents. As the product will be used throughout Australia 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	2000 kg
Amount discharged to sewer	100%
Volume discharged per day	5.48 kg (2 000 kg/365 days)
Sewer output per day *	2 700 ML
Concentration in Sewage Treatment Plant	2.02 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 3 million and 500 ML of waste water treated per day, the PEC would be ~11 ppb (safety factor of 155 for EC_{50} of most sensitive aquatic organism tested, *Selenastrum capricornutum*). However, these are very much worst case PECs and assume no biodegradation and no removal of the polymer from the water through adsorption into sludge in the sewers or during sewage treatment, expected to be significant in most release scenarios. Also, further dilution on discharge of the sewage effluent to receiving waters will also significantly decrease the PECs in receiving waters.

The high water solubility of the new dye will preclude bioconcentration.

The minor amount remaining as residues in product containers after use should be confined to landfill. Any leaking polymer will associate with the organic component of soils and sediments where it is expected to be slowly degraded and mineralised through biological processes.

In conclusion, the notified chemical is not likely to present a hazard to the environment when it is stored, transported and used in the typical manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified polymer was of very low acute oral toxicity in rats (LD_{50} > 5 000 mg/kg). It was a slight skin irritant but not an eye irritant in rabbits. The polymer has a molecular weight >1000 and so is unlikely to cross biological membranes readily. Based on available data, the notified polymer would not be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

Occupational Health and Safety

Given no requirement for opening import containers prior to reformulation and exposure to the notified polymer only in the event of an accident, the health risk for transport and warehouse workers handling the polymer would be assessed as low.

Dermal and ocular exposure to the polymer is possible during reformulation into industrial and domestic cleaning products and during maintenance of processing plant. Workers involved in product manufacture and maintenance will wear personal protective clothing that will limit exposure. As the polymer is coloured, any dermal contact will be clearly visible so it is likely that the exposed workers will wash it off immediately as recommended in the Material Safety Data Sheet (MSDS). Additionally, due to its high molecular weight, the notified polymer is unlikely to be absorbed through the skin. Therefore the health risk for workers during product manufacture is expected to be low.

Cleaning staff will use products containing the notified polymer and dermal and ocular occupational exposure is possible. The use of personal protective equipment such as rubber gloves by cleaning workers is likely to be highly variable but as the notified polymer is present typically at 0.01-0.05% in products and is unlikely to cross biological membranes readily, the health risk to cleaning workers from the notified polymer is assessed as low.

Public Health

There is likely to be widespread dermal exposure to the notified polymer by the public when used as a dye in standard domestic laundry products. However, since it will be used at very low levels and has a high molecular weight (and therefore unlikely to be able to readily cross biological membranes), the notified polymer is unlikely to present a toxicological hazard. Hence, the potential for harm to the public through this exposure is considered low.

13. RECOMMENDATIONS

To minimise occupational exposure to Liquitint Violet, the following guidelines and precautions should be observed:

For manufacture and maintenance workers:

- Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during formulation of products containing the notified polymer;

For end-users of products:

- Where frequent dermal exposure is likely, rubber gloves should be worn during the use of products containing the notified polymer;

For all workers:

- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

Guidance in selection of protective eyewear 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); for industrial clothing, guidance may be

found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994) or other internationally accepted standards.

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

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* (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, the Director must be informed if any of the following circumstances arise:

- The annual import volume of the notified polymer is greater than 2 tonnes; or
- Daphnia ecotoxicity data become available; or
- The notified polymer is released to water in a more concentrated form (> 0.5%). In this case, daphnia ecotoxicity data will be required for assessment.

Under subsection 64(2) of the Act, the Director must be informed if any of the circumstances stipulated under that subsection arise.

Secondary notification of the notified chemical may be required.

16. 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.
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

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