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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Copy Charge PSY

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Copy Charge PSY

1. APPLICANT

Hoechst Australia of 606 St. Kilda Road, MELBOURNE, VIC 3004 and Brother Industries Pty. Ltd. of 7 Khartoum Road, North Ryde, NSW 2113 have submitted a limited notification statement in support of their application for an assessment certificate for Copy Charge PSY.

2. IDENTITY OF THE CHEMICAL

Copy Charge PSY is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of toner composition and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

2. IDENTITY OF THE CHEMICAL

Trade Name:	Copy Charge PSY Copy Charge PSY VP 2038
Molecular Weight:	< 1 000
Method of Detection and Determination:	Infrared (IR) ultraviolet (UV), nuclear magnetic resonance (NMR)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white powder
Melting Point:	250°C
Density:	D_4^{20} =1 150 kg/m^3

Vapour Pressure:	< 3.4 x 10^{-9} kPa at 20°C (calculated)
Water Solubility:	175 mg/L at 20°C and pH 4.4
Fat Solubility:	< 3 mg/100 g fat at 37°C
Partition Co-efficient (n-octanol/water):	log P_{ow} -1.8/-0.7 at 25°C
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 = > 1 year $T_{1/2}$ at pH 7.0 = > 1 year $T_{1/2}$ at pH 9.0 = > 1 year
Adsorption/Desorption:	no data available
Dissociation Constant:	pK_a1 = 2.25 and pK_a2 = 5.91; where 1 is the dissociation of one hydroxyl group followed by 2, the dissociation of the second group
Flash Point:	not available
Flammability Limits:	not flammable
Autoignition Temperature:	> 240°C
Explosive Properties:	not explosive under the effect of heat, shock or friction
Reactivity/Stability:	generally stable, possibility of a dust explosion
Surface Tension:	67.7 mN/m at 20°C

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

The octanol/water partition coefficient is low [Log P_{ow} = -1.8], indicating a preference for the aqueous phase. However, the value of P_{ow} could not be unambiguously determined due to non linear effects which were dependent both on pH and on concentration.

Adsorption/desorption data were not provided by the notifier. However, the chemical nature of the compound suggests that it may absorb onto some soil types. Without specific data it is not possible to rigorously estimate mobility, but the compound should be treated as moderately mobile. The relatively low oil/water partition coefficient supports this assertion.

The notified chemical is not surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

Non-hazardous Impurities (> 1% by weight): low concentration

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a charge control agent in toners for photocopiers, laser printers and plain paper fax machines. These toners will contain a low level of the notified chemical.

It is estimated that less than ten tonne/year of the notified chemical will be imported into Australia. It will only be imported as a preformulated toner. There will be no manufacture or reformulation of the notified chemical in Australia.

6. OCCUPATIONAL EXPOSURE

Occupational exposure to the notified chemical will only occur with exposure of the formulated toner containing low levels of the notified chemical. The toner formulations are imported in sealed cartridges; there is no repackaging, filling or refilling of cartridges in Australia. The cartridges contain between 50 and 200 g of toner. Exposure to the notified chemical during transport and warehousing will be insignificant even if a cartridge is broken and releases its contents.

The cartridges are inserted into the electrographic device after first removing the sealing strip. This task will be undertaken by office staff; potentially thousands of office staff could undertake this task. Maintenance workers will have a higher potential for exposure when repairing and cleaning photocopiers etc. Up to one hundred maintenance workers will potentially be exposed to the notified chemical. The likely exposure pathways will be dermal and inhalational. Occupational exposure to the notified chemical once it is fused to paper will be minimal as it will incorporated into a water insoluble resin complex.

7. PUBLIC EXPOSURE

Exposure of the public to the notified chemical will be possible when printed sheets are handled or when toner cartridges are changed and disposed of. Toner when fused to paper becomes immobilised. Toner cartridges are sealed when manufactured, the seal being removed after insertion into printers and copiers.

Although contact with toner will be possible during the exchange operation the level of exposure under normal circumstances is expected to be low.

8. ENVIRONMENTAL EXPOSURE

Release

There are two principal pathways of release of the notified substance into the environment. Firstly residual unused toner - ie that remaining in the spent cartridges after most of the material has been used - will be disposed of as office waste and will be either incinerated or disposed of to landfill. In the normal course of usage, this should be minimal, since it is expected that only 5-40 g (depending on toner cartridge size) of toner product would remain in the spent cartridges, and since the notified chemical constitutes a maximum of 5% of the product it is estimated that each spent cartridge has the potential to contribute from between 0.25 and 2 g of Copy Charge PSY to the environment via this route. It is anticipated that the spent toner cartridges would be disposed of into landfill. However, release of the residual toner should occur only after destruction of the integrity of the cartridge.

In normal use the product will be incorporated into a thermo-cured resin (ie the print) and firmly bound to the paper substrate, and hence would be released to the environment through disposal of the waste paper. The anticipated fate of the material would be associated with that of the paper, and is described below.

Fate

The majority of the Copy Charge PSY will be associated with the print and bound strongly to paper. Waste paper disposal is effected either through high temperature incineration, recycling or deposition into landfill.

High temperature incineration would destroy the compound - with evolution of oxides of carbon, nitrogen and sulphur -, while it is expected that during the extensive repulping and bleaching procedures implied by paper recycling the material would be either destroyed chemically or be incorporated into waste sludge. Given that the compound has appreciable water solubility, it is possible that some of the notified chemical could also partition into aqueous waste streams generated during recycling. Waste sludge from the recycling plants would be either incinerated or disposed of to landfill, while aqueous waste would be comprehensively treated prior to discharge.

Again some waste paper may be disposed of directly to landfill, and although only slowly hydrolysable and not readily bio-degradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade the Copy Charge PSY. Aqueous leachate from a landfill could conceivably contain low concentrations of non-degraded compound, which would be received into the wider environmental water compartment. However the relatively low toxicity of the material (see further below) appears to precludes major detrimental effects to the

environment. The same considerations will apply for effluent discharged (after treatment) from paper recycling facilities.

The material is not readily biodegradable, as the Modified Sturm test [method OECD 301B] indicated only 15% degradation after 28 days.

Despite the low molecular weight, the ionic nature of the substance, relatively high water solubility and low oil/water partition coefficient indicate that the compound will not accumulate appreciably in biological tissue.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Copy Charge PSY

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	> 2 000 mg/kg	{Walker, 1991 #43}
acute dermal toxicity	rat	> 2 000 mg/kg	{Walker, 1991 #44}
skin irritation	rabbit	slight irritant	{Walker, 1991 #45}
eye irritation	rabbit	slight irritant	{Walker, 1991 #46}
skin sensitisation	guinea pig	non-sensitiser	{Walker, 1991 #47}

9.1.1 Oral Toxicity {Walker, 1991 #43}

Species/strain:	rat, Sprague-Dawley
Number/sex of animals:	5 males/ 5 females
Observation period:	14 days
Method of administration:	by gavage in arachis oil B.P. at a dose level of 2 000 mg/kg
Clinical observations:	surviving animals showed expected weight gains
Mortality:	one animal died at day 2
Morphological findings:	dead animal at necropsy revealed haemorrhagic lungs and liver and kidneys; no abnormalities in all other animals

Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
LD_{50}:	> 2 000 mg/kg
Result:	low acute oral toxicity in rats, single mortality unlikely to be related to test article

9.1.2 Dermal Toxicity {Walker, 1991 #44}

Species/strain:	rat, Sprague Dawley
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	semi-occluded dermal application of 2 000 mg/kg
Clinical observations:	none, expected weight gains occurred
Mortality:	nil
Morphological findings:	none
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
LD_{50}:	> 2 000 mg/kg
Result:	low acute dermal toxicity in rats

9.1.4 Skin Irritation {Walker, 1991 #45}

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	3 male
Observation period:	72 hours
Method of administration:	single 4 hour semi-occluded application of test material moistened with distilled water; then swabbed with distilled water

Draize scores {Draize, 1959 #4} all scores at day one and three were zero; at one hour one rabbit exhibited very slight erythema (score 1)
see Attachment 1 for Draize scales

Test method: in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: slight irritant in rabbits

9.1.5 Eye Irritation {Walker, 1991 #46}

Species/strain: rabbits/New Zealand white

Number/sex of animals: 3 male

Observation period: 72 hours

Method of administration: 0.1 ml of test material placed in conjunctival sac of right eye

Draize scores {Draize, 1959 #4} of unirrigated eyes: all scores at day one and three were zero; at one hour all rabbits redness of the conjunctiva (score 1) and two rabbits also exhibited chemosis and discharge (score 1)
see Attachment 1 for Draize scales

Test method: in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: slight eye irritant in rabbits

9.1.6 Skin Sensitisation {Walker, 1991 #47}

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 30, 20 test and 10 control

Induction procedure: day 1, 3 intradermal injections:
Freund's Complete Adjuvant (FCA)/distilled water 1:1
5% (w/v) test material in arachis oil B.P.
5% (w/v) suspension of test material in a 1:1 preparation of FCA plus arachis oil B.P.
day 7, same area treated with test material (50% w/w in arachis oil B.P.) occluded for 48

	hours; control similar to above with no test material in intradermal injections and test material only in topical application
Challenge procedure:	day 21, 0.1 - 0.2 ml of test material (50% w/w in arachis oil B.P. occluded for 24 hours
Challenge outcome:	nil response
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	not a sensitiser in guinea pigs

9.2 28-day Repeated Dose Toxicity {Wragg, 1992 #48}

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5 males and 5 females per dose group
Method of administration:	by gavage using polyethylene glycol as vehicle
Dose/Study duration:	150, 400, 1 000 mg/kg/day and vehicle control; 28 days
Clinical observations:	increased salivation in high and intermediate dose animals
Clinical chemistry/Haematology	no treatment related effects
Histopathology:	kidneys showed epithelial basophilia and degeneration in the medullary proximial tubules in high dose animals and 3 intermediate dose animals; this was mirrored by absolute and relative increases in kidney weight in high dose animals and intermediate dose males
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	dose related effects evident on kidneys at 400 mg/kg/day

9.3 Genotoxicity

9.3.1.1 *Salmonella typhimurium* Reverse Mutation Assay {Thompson, 1991 #49}

Strains:	TA 1535, TA 1537, TA 1538, TA 98, TA 100
Concentration range:	5 - 5 000 μg/plate with and without rat liver S9 fraction; solvent, dimethyl sulphoxide
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	non-mutagenic in this system

9.3.1.2 *Salmonella typhimurium* Reverse Mutation Assay {Thompson, 1992 #50}

Strains:	*S. typhimurium* - TA 1535, TA 1537, TA 1538, TA 98, TA 100 *Escherichia coli* - WP2*uvrA*
Concentration range:	5 - 5 000 μg/plate with and without rat liver S9 fraction; solvent dimethyl sulphoxide
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	non-mutagenic

9.3.2 Metaphase Analysis in Chinese hamster lung (CHL) Cells *in vitro* {Wright, 1992 #51}

Species/strain:	Chinese hamster lung cell line
Doses:	625 - 5 000 μg/ml for 6 hour treatment with and without rat liver S9 fraction 312.5 - 2 500 μg/ml for 12, 24 and 48 hour continuous treatment with rat liver S9 fraction
Method of administration:	in suspension in Eagle's Minimal Essential medium with Earle's Salts (MEM); positive controls - mitomycin C and cyclophosphamide
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result:	non-clastogenic; positive controls had significant increases in the frequency of aberrations; poor response in cyclophosphamide without S9 and cyclophosphamide group from the 12 hour treatment with S9 may be due to cell cycle delay induced by cyclophosphamide

9.4 Overall Assessment of Toxicological Data

The notified chemical has a low acute oral and dermal toxicity in rats with no evidence of toxicity at the maximum dose rates tested of 2 000 mg/kg. The chemical has some potential to cause skin and eye irritation, however the effects were slight, with low level erythema and conjunctival redness being observed in the respective studies. These effects were only apparent one hour after application and had resolved by 24 hours. The chemical was not a sensitiser in a guinea pig maximisation study at challenge and induction concentrations up to 50%.

The notified chemical produced dose related systemic effects in a 28 day oral repeat dose rat study. The effects were limited to the renal system and were in part degenerative. The effects included changes in relative and actual kidney weight as well as degeneration of medullary proximial tubules. The target organ and system was therefore the kidney and excretory system. These effects were apparent in doses of 400 mg/kg/day and above. No other effects were apparent and there was no mortality at the highest dose of 1 000 mg/kg/day.

The notified chemical was considered to be non genotoxic in a number of *in vitro* studies. These included reverse mutation assays using *Salmonella typhimurium* and *Escherichia coli* with and without rat liver S9 activation. There was no evidence of clastogenesis in a Chinese hamster lung (CHL) study to assess effects on chromosomal aberration induction.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

While not required for materials to be imported in quantities less than one tonne per annum, the following ecotoxicity studies have been supplied by the notifier. The tests were carried out using OECD Test Guideline Methods.

Test	Species/ Method	Results (Nominal)
Acute Toxicity (static test)	Zebra Fish (method OECD TG 203)	LC_{50} (96h): > 1,000 mg/L (see note below)
Acute Immobilisation (static test)	*Daphnia magna*. STRAUS (method OECD TG 202)	Immobilisation. - EC_{50}(48h) = 68 mg/L
Growth Inhibition (Biomass) method	Algae *Scenedesmus subspicatus* (method OECD TG 201)	E_bC_0 (72h): 100 mg/L[1] E_bC_{10} (72h): 106 mg/L E_bC_{50} (72h): 172 mg/L
Respiration Inhibition (static test)	Aerobic Waste Water Bacteria (method OECD TG 209	LOEC (3h): 719 mg/L EC_{50} (3h): 877 mg/L (see note below)

The stated LC_{50} (96 h) for Zebra fish exceeds water solubility of compound (175 mg/L), and this was acknowledged in the investigation report. The investigators stated that a cloudy precipitate persisted in the test vessel during the test using this level of compound.

During the respiration inhibition test, the test material was also present at well above the solubility limit and was presumably kept in suspension with the activated sludge through stirring.

For all the above biological tests, the calculated concentrations of the test substance were based on nominal concentrations, since quality control data for all tests (except that for inhibition of microbial respiration) confirmed that actual concentrations differed by no more than 20% of the nominal ones.

In the tests on Zebra Fish, no mortality occurred over the 96 h test period, and the investigators noted no adverse effects on the fish.

When the pH was raised to around 7.5 in order to increase the concentration of the compound above 175 mg/L, no adverse pH related effect was observed on the zebra fish and water fleas, nor on the algal growth rate.

The ecotoxicity data for the notified chemical indicate that the material is practically non toxic to the fish and algae species tested, although it is slightly toxic to water fleas.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical appears to be minimal, and in the light of the ecotoxicological data provided, even gross spillage of the individual toner containing cartridges (eg transport related accident) should cause little environmental damage from the contained Copy Charge PSY.

In the event of accidental spillage or release of the toner, the cleanup operation would probably entail disposal to landfill.

The “long term” fate of the majority of the notified material is expected to be either through paper recycling, landfill disposal or incineration of waste paper. In all three cases it is anticipated that the material would be destroyed either through the agency of a vigorous chemical environment or through (admittedly slow) biological or abiotic processes. Even in the absence of substantial degradation, the relatively low usage rate and diffuse nature of disposal patterns would indicate very slow release into the wider environment, and this at low concentrations.

At concentrations likely to arise as a consequence of normal disposal procedures for the residual toner product and waste paper, the notified compound appears to offer little cause for concern in respect of the aquatic environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical will only be imported as a low level component of electrographic toner. It will only be imported in sealed cartridges containing up to 200 g of toner. The molecular weight of the notified chemical is below 1 000 and transmission across biological membranes is therefore possible. The notified chemical is moderately water soluble but less soluble in fat. The octanol water partition coefficient is not optimal for bioaccumulation. The notified chemical has a very low vapour pressure is not flammable or explosive, however, when in the form of a powder there is the possibility of dust explosion.

The notified chemical has a low oral and dermal acute toxicity in rats. It is not classified as an irritant or sensitiser according to the Worksafe criteria {National Occupational Health and Safety Commission, 1994 #9} although in eye and skin studies low level irritation was apparent. Systemic effects were evident in a 28 day repeat dose study with rats. The organ effected was the kidney where degeneration was evident at doses as low as 400 mg/kg/day. The notified chemical was not genotoxic *in vitro*. On the basis of these toxicity studies the notified chemical would not be classified as hazardous according to the Worksafe criteria {National Occupational Health and Safety Commission, 1994 #9}.

Occupational exposure to the notified chemical will be low. This is because it is only imported as a low level component of toners which are in sealed cartridges with limited potential for release. There is the potential for exposure to office workers however this will be negligible. Greater exposure would be anticipated with personnel maintaining the electrographic equipment. The main routes of exposure will be dermal and inhalational, however significant exposure is unlikely and effects are unlikely. The risk through occupational exposure to the notified chemical in Australia is low.

Public exposure to the notified chemical will occur primarily through contact with printed documents where the notified chemical will be bound to the paper as a fused, water-insoluble polymer matrix, thus the notified chemical is expected to represent a low risk to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Copy Charge PSY the following guidelines and precautions should be observed:

- Spillage and mobilisation of the toners containing the notified chemical should be avoided, spillages should be cleaned up promptly and 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 #13}.

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. Walker, D.J. 1991, *Copy Charge PSY: Acute oral toxicity (limit test) in the rat*, Project no., 10/573, Safepharm Laboratories Limited, Derby, U .K.
2. Walker, D.J. 1991, *Acute dermal toxicity (limit test) in the rat*, Project no., 10/587, Safepharm Laboratories Ltd., Derby, U.K.
3. Walker, D.J. 1991, *Copy Charge PSY: Acute dermal irritation test in the rabbit.*, Project no., 10/574, Safepharm Laboratories Ltd., Derby, U.K.
4. Walker, D.J. 1991, *Copy Charge PSY: Acute eye irritation test in the rabbit*, Project no., 10/575, Safepharm Laboratories Ltd., Derby, U.K.

5. Walker, D.J. 1991, *Copy Charge PSY: Magnusson and Kligman maximisation study in the guinea pig*, Project no., 10/576, safepharm Laboratories Ltd., Derby, U.K.

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

7. 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.

8. Wragg, M.S. 1992, *Copy Charge PSY: Twenty-eight day sub-acute oral toxicity study in the rat*, Project no., 10/588, Safepharm Laboratories Ltd., Derby, U.K.

9. Thompson, P.W. 1991, *Copy Charge PSY: Reverse mutation assay "Ames test" using Salmonella typhimurium*, Project no., 10/577, Safepharm Laboratories Ltd., Derby, U.K.

10. Thompson, P.W. 1992, *Copy Charge PSY: six strain reverse mutation assay "Ames test" using Salmonella typhimurium and Escherichia coli*, Project no., 10/577A, Safepharm Laboratories Ltd., Derby, U.K.

11. Wright, N.P. 1992, *Copy Charge PSY: Metaphase analysis in CHL cells in vitro*, Project no., 10/608, Safepharm Laboratories Ltd., Derby, U.K.

12. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.

13. 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