File No: NA/460

Date:January 1997

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Abil EM90

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Abil EM90

1. APPLICANT

Salkat Australia Pty Ltd of 262 Highett Road HIGHETT Victoria 3190 has submitted a limited notification statement in support of their application for an assessment certificate for Abil EM90.

2. IDENTITY OF THE CHEMICAL

Abil EM90 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 the polymer composition and exact use have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	modified polyether-polysiloxane/dimethicone copolyol
Trade Name:	Abil EM90, CL 530
Number-Average Molecular Weight:	> 1 000
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	5.5%
Molecular Weight < 1 000:	9.0%

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	clear colourless and nearly odourless viscous liquid
Boiling Point:	not available
Specific Gravity:	0.941 g/ml at 25°C (estimated)

Vapour Pressure:	not available
Water Solubility:	8 mg/L at 25°C
Partition Co-efficient (n-octanol/water):	not available
Hydrolysis as a Function of pH:	not available
Adsorption/Desorption:	not available
Dissociation Constant:	not available
Flash Point:	> 120°C
Flammability Limits:	not available
Autoignition Temperature:	not available
Explosive Properties:	not available
Reactivity/Stability:	relatively stable

Comments on Physico-Chemical Properties

The vapour pressure of the was not determined because of the high molecular weight of the polymer. Related chemicals such as dimethicone have a relatively high vapour pressure and evaporate readily (1).

Data such as solubility and partition coefficient are not particularly relevant to surface active compounds, which prefer to reside at or on the interface between polar and apolar media, rather than partitioning between them. This type of molecule is generally extremely hydrophobic. The structure of the notified polymer would increase this hydrophobicity.

The siloxane and ether linkages of the polymer are not expected to hydrolyse in the pH range 4-9. At pH values below 2 and above 11 and temperatures above 90°C cleavage of the Si-O-Si bonds in the chemical will occur. The extent to which hydrolysis would occur in the environment is unclear, given that silicones adsorb strongly to surfaces.

The notified chemical contains no dissociable hydrogens or basic functionalities.

Low flammability indicates that the autoignition temperature will be high.

4. PURITY OF THE CHEMICAL

Degree of Purity: ~95%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities

None of the non-hazardous impurities are listed on Worksafe Australia's *List of Designated Hazardous Substances* (2). One is listed as a possible sensitiser in Sax and Lewis (3) and in Toxline (4) use of the chemical in dental fittings and jewellery can result in a sensitised state in some individuals. None of the other impurities are listed as having significant toxicological effects on Toxline (4).

Maximum Content of Residual Monomers: < 1 ppm

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as an emulsifier in cosmetic preparations. It will be imported in quantities in excess of one tonne per annum. In the first year of import approximately two tonnes will be imported; the ultimate market potential could be as high as ten to fifteen tonnes per year. The chemical will be imported in 50 kg plastic drums which will be used to reformulate cosmetics.

Abil EM90 is already in the USA and Europe for the same use as is intended for Australia.

6. OCCUPATIONAL EXPOSURE

The notified polymer will not be manufactured in Australia but will be imported in palletised 50 kg drums. Occupational exposure during transport and warehousing is unlikely and will only occur in the event of accidental release. There is no repackaging in Australia and the pails will be delivered direct to the cosmetic manufacturer.

The Abil EM90 will be transferred to sealed containers by weigh room staff (1-3 personnel) prior to transfer to a production vessel. Between 3 and 5 employees are responsible for transferral of Abil EM90 to the production vessel. This procedure is unlikely to occur on a daily basis. The raw materials are poured into funnels for introduction to the sealed production vessel.

The production room meets specific conditions required for the TGAC licence,

these include the provision of ventilation with Class 7 000 filtered air.

The finished cosmetic formulation, containing 5 % of the notified polymer, is automatically dispensed into tubes for distribution and retail sale. These machines are cleaned daily, one worker to each machine.

The main routes of occupational exposure to the notified polymer will by via dermal contact with the possibility of eye contact through splashing or unintentional transfer; the provision of the appropriate safety equipment and clothing will minimise this possibility.

7. PUBLIC EXPOSURE

The imported notified polymer will be transported for reformulation as required by customers. Public exposure is possible following accidents, however the likelihood is low in view of the quality accredited transport services used by the notifier and clean up and disposal protective measures described.

Public exposure to the notified polymer during reformulation into cosmetics and skin care products is unlikely. The public will be exposed to the notified polymer through use of the cosmetic formulations and skin care products that contain concentrations of the notified polymer up to a maximum concentration of 5%.

8. ENVIRONMENTAL EXPOSURE

Release

The polymer will be transported to customer sites in 50 kg drums. Empty drums will be disposed of to an approved chemical dump site. This would account for 150 kg per annum of the polymer at the maximum import rate, assuming that 1% remains in the drum.

Formulation of the cosmetic will occur at up to four sites throughout Australia. It will take place in a closed production system. The washing of machinery would result in the loss of 0.5% of the polymer (75 kg per annum). Washings would go either to a sullage treatment works (washing volumes > 15 L) or washed down a drain to the sewer (washing volumes < 10 L) against a licence from a water authority.

The use of cosmetic products containing the polymer would be widespread but diffuse as it is applied in small quantities to the skin. The majority of the product will be rubbed off ie, onto clothing, etc or washed off while users are swimming or paddling. This will occur in either pools or natural waterways. Cosmetic remaining on users after swimming or paddling will be removed through washing resulting in its release to the sewer.

Fate

The environmental properties of polydimethylsiloxane fluids have been well reviewed in the literature (5).

Silicone fluids are very surface active because the flexible siloxane linkages permit alignment of the hydrophobic methyl substituents towards the non-polar phase, and of the polysiloxane backbone towards the polar phase.

The polar medium is generally water, and apolar media to which polydimethylsiloxanes become attached may be textiles, sewage sludge, algae, sediment, etc. In aqueous environments, strong, complete and permanent adsorption of high molecular weight silicone fluids to sediment may be assumed. Hence, this modified silicone will be removed from solution by adsorption onto sediment or sludge with little, if any, likely to be contained in natural or treated waste waters. Sludge containing the notified substance may then be incinerated or landfilled. Incineration would destroy the substance and liberate water and oxides of carbon and silicon, while disposal to landfill would immobilise it.

Polydimethylsiloxanes are thought to be unstable in terrestrial environments, where clays can catalyse cleavage of the siloxane linkage, but are probably more permanent in aquatic sediment as the catalytic action of clays is inversely related to their degree of hydration (5).

As noted above, the hydrolytic stability of this modified silicone in the environment is unclear. However, hydrolysis products do not appear to be of significant ecological concern.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Abil EM90

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	6
acute dermal toxicity	rat	not available	-
skin irritation	rabbit	* irritant potential	7
eye irritation	rabbit	* irritant potential	8
skin sensitisation	guinea pig	not a sensitiser	9

* not classified as an irritant according to Worksafe Australia, *Approved Criteria for Classifying Hazardous Substances* (10)

9.1.1 Oral Toxicity (6)

Species/strain: rat, Wistar

Number/sex of animals: 5 male/5 female

Observation period: 14 days

Method of administration: gavage, single dose 5 000 mg/kg

Clinical observations: one animal had ano-genital staining at day 1

Mortality: nil

Morphological findings: nil

Test method: According to U S Federal Hazardous Substances Control Act (FHSA) Guidelines (11), 16 CFR 1500.3

LD_{50}: 5 000 mg/kg

Result: low acute oral toxicity

9.1.2 Skin Irritation (7)

Species/strain: rabbit, New Zealand white

Number/sex of animals: 6/not specified

Observation period: 72 hours

Method of administration: 0.5 ml of test chemical applied to clipped test site (2.5 cm^2) and occluded for 24 hours; test site then wiped clean

Draize scores (12): intact skin

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
1	[a]2	2	2	2	1	2
3	1	0	1	1	0	2
Oedema						
1	1	1	1	1	1	1
3	0	0	0	1	0	1

[a] ee Attachment 1 for Draize scales

Test method: According to U S Federal Hazardous Substances Control Act (FHSA) Guidelines (11), 16 CFR 1500.41

Result: some irritant potential, however below threshold for classification as hazardous (irritant) according to Worksafe criteria (10)

9.1.3 Eye Irritation (8)

Species/strain: rabbit, New Zealand white

Number/sex of animals: 6/female

Observation period: 72 hours

Method of administration: 0.1 ml in one eye

Draize scores (12) of unirrigated eyes: no corneal opacity or iritis in any test animal

Time after instillation

Animal	***1 day***			***2 days***			***3 days***		
Conjunctiva	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***
1	[1]2	1	2	2	1	2	1	0	0
2	2	1	2	1	1	1	1	0	0
3	2	1	2	2	1	2	1	0	0
4	1	1	2	1	1	2	0	0	0
5	2	1	2	2	1	2	0	0	0
6	2	1	2	2	2	2	2	0	0

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

Test method: According to U S Federal Hazardous Substances Control Act (FHSA) Guidelines (11), 16 CFR 1500.42

Result: conjunctival effects only; with the exception of redness, all absent at 72 hours; not classified as an eye irritant according to Worksafe criteria (10)

9.1.4 Skin Sensitisation (9)

Species/strain: guinea-pig, Hartley

Number of animals: 20 test animals, 10 naive control, 10 naive rechallenge, 10 positive control, 5 positive naive control, 5 positive naive control rechallenge

Induction procedure: **intradermal induction**:
Freund's complete adjuvant (FCA) (50% in distilled water), distilled water, test substance at 100% (determined to be non-irritating in preliminary screen), test substance (10% in distilled water) 1:1 with FCA, distilled water 1:1 with FCA, positive control - mercaptobenzothiazole (60% w/w in ethanol), 95% ethanol, 10% mercaptobenzothiazole in 95% ethanol 1:1 FCA 50% in distilled water, 95% ethanol 1:1 FCA 50% in distilled water
topical induction:
test substance (100%), dry Hilltop chamber applied at dose site, mercaptobenzothiazole (60% w/w in ethanol), 95% ethanol

Challenge procedure: 24 hours before challenge treated with 10% sodium lauryl sulfate
test substance (100%), mercaptobenzothiazole (60% w/w in ethanol),

Rechallenge procedure: test substance (100%), mercaptobenzothiazole (60% w/w in ethanol),

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
100%	**0/20	0/20	0/20	0/20

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

Test method: in accordance with OECD guidelines (13) with minor deviations

Result: not a skin sensitiser in guinea-pigs; controls gave appropriate responses

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (14)

Strains:	TA 98, TA 100, TA 1535, TA 1537 and *Escherichia coli* strain WP2*uvrA*
Concentration range:	250, 500, 1 000, 5 000 μg/plate with or without S-9 activation
Test method:	similar to OECD guidelines (13)
Result:	not mutagenic in this system; controls gave appropriate response

9.4 Other Toxicological Data

A review of dimethicone copolyols (a component of the notified chemical) was provided by the notifier (1), it refers to a number of toxicology studies that support the data described above. In addition the tests which are absent from the above suite (dermal toxicity, inhalational toxicity and repeat dose studies) are described for various dimethicone copolyols. A dermal 28-day percutaneous toxicity study using dimethicone copolyol "A" 190 at 200 mg/kg/day resulted in nil mortality or behavioural effects. Slight to moderate erythema and oedema were found at the application sites after day 2. There was no weight loss in test animals and the only histopathological result of significance was a depression in spermatogenesis in one of the 10 test rabbits (all males). Inhalation toxicity studies in rats are described for a range of dimethicone copolyols. Mortality only occurred at elevated temperatures to concentrations of dimethicone copolyol "B" 7500 of 23.47 mg/L (33% of test animals after 4 hours) and at an unspecified concentration (100% mortality after 8 hours). The same dimethicone copolyol produced nil mortality at lower temperature and/or for shorter time periods.

When rats were fed dimethicone copolyol "B" at a dose rate of 640 and 2 880 mg/kg/day for 89 days there were no mortalities or any deleterious effects

9.5 Overall Assessment of Toxicological Data

There is only a limited toxicological data set available for the notified polymer which is acceptable for a limited notification. It has a low oral toxicity in rats with an LD_{50} in excess of 5 000 mg/kg. There is no dermal or inhalational toxicity data available for the notified polymer. In a rabbit skin irritation study, although there was some evidence of irritation (erythema) it was minimal and below the level requiring a hazardous classification (10). It should also be noted that the test protocol differed from the OECD (13) method as the notified chemical was in contact with the skin for 24 hours rather than the 4 hours recommended in the OECD protocol. An eye irritation study in rabbits produced conjunctival effects but these were below the threshold requiring a hazardous classification. The notified polymer was not a

sensitiser in a guinea pig sensitisation study. It was not mutagenic in a *Salmonella typhimurium* reverse mutation assay with or without S9 activation.

A summary of toxicological information on dimethicone copolyols, a group that includes a component of the notified chemical, indicated a similar level of toxic response to those described for the notified polymer. A dermal 28-day percutaneous toxicity study using dimethicone copolyol "A" 190 at 200 mg/kg/day produced only slight to moderate erythema and oedema at the application sites and a depression in spermatogenesis in one of the 10 test rabbits (all males). Inhalation toxicity studies in rats are described for a range of dimethicone copolyols. Mortality only occurred at elevated temperatures, nil mortality occurring at lower temperature and/or for shorter time periods at elevated temperatures. A repeat dose study using dimethicone copolyol "B" for a duration of 89 days resulted in no mortalities or deleterious effects at a dose of 2 880 mg/kg/day.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of number average molecular weight (NAMW) >1 000 according to the Act. The high molecular weight of the substance suggests that it will not cross biological membranes, and will therefore be of low toxicity and not bioaccumulate. It is well accepted that polydimethylsiloxane fluids become permanently adsorbed to sediment and should not exert adverse environmental effects. Physical effects such as surface entrapment has been observed when testing aquatic invertebrates in clean laboratory water. Similar effects are not expected in natural environments where a large variety of other surfaces provide opportunities for deposition (5).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified polymer is a minor component of cosmetic products and as such will be released to the environment in small amounts through washing from the skin. As a worst case, an environmental concentration of 15 ppb is predicted if all the imported polymer remains suspended in sewage waters (assuming: 14 800 kg are discharged annually to the sewer, by an Australian population of 18 million with a daily per capita waste water discharge of 150 L). However, most is expected to adsorb to sediment or sewerage sludge that will be landfilled or incinerated. In landfill the substance is not expected to be mobile or degrade due to its low water solubility. Hence, the overall environmental hazard of the chemical can be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Abil EM90 is a high molecular weight (NAMW, in excess of 1 000) modified polyether polysiloxane. It contains a significant level of low molecular weight

species below 1 000 (< 9%) and below 500 (< 5%). The high molecular weight of the polymer precludes transmission across biological membranes although the low molecular weight species which the notifier indicates are largely paraffins are not so limited. None of these paraffins or the other impurities listed with the exception of one are listed as having significant toxicological attributes. The latter is a residue of the catalyst used in the production of the polymer, is at such low levels that it is unlikely to be of significance. It can result in a sensitised state in some individuals. The bioaccumulative capacity of the notified polymer is unknown as an octanol water partition coefficient was not provided. The inability to cross biological membranes reduces any concerns regarding bioaccumulative potential or possible systemic effects through gross exposure to the polymer.

The toxicological data submitted was limited but confirms the notified polymer as having a low oral toxicity with no indications of systemic effects in an acute study. It was not a classifiable eye or skin irritant according to Worksafe Australia's *Approved Criteria for the Classification of Hazardous Substances* (10) although there were some minor indications of irritant potential. A guinea pig sensitisation study was negative as was an Ames test for mutagenicity. The dermal toxicity, inhalational toxicity and sub chronic effects of Abil EM90 are unknown, however a summary provided by the notifier for dimethicone copolyols, one of which is a component of the notified polymer, indicate that they are of limited toxicological significance in these test systems.

Occupational exposure to the notified polymer will normally only occur during reformulation unless there is accidental release during transport and warehousing. During reformulation (weighing, transferral, mixing and packaging of the formulation) exposure is possible but will be limited by the use of appropriate safety equipment such as eye protection and clothing. Exposure will be further limited by the use of ventilation and closed mixing and dispensing systems. Occupational exposure will be limited and the risk through such exposure will be low.

There will be widespread public contact with the notified polymer from use of cosmetic formulations and skin care products. Skin and eye irritation are slight in animals and products containing up to 5% of the notified polymer are likely to have negligible irritant potential. While public exposure to the notified polymer is possible following an accident, the likelihood is low in view of the quality accredited transport services and clean up and disposal protective measures.

13. RECOMMENDATIONS

To minimise occupational exposure to Abil EM90 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (15) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (16);

- Industrial clothing should conform to the specifications detailed in AS 2919 (17) and AS 3765.1 (18);
- Impermeable gloves or mittens should conform to AS 2161 (19);
- All occupational footwear should conform to AS/NZS 2210 (20);
- 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 Material Safety Data Sheet (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* (21).

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

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3. Sax, N. I. & Lewis, R. J. 1989, *Dangerous Properties of Industrial Materials*, Van Nostrand Reinhold, New York.
4. Toxline Silver Platter 1995, *Toxline SilverPlatter CD-ROM database, January 1994-June 1996*, Silver Platter International N.V.

5. Hamelink, J. L. 1992. Silicones. In: N T de Oude (ed), *The Handbook of Environmental Chemistry*, Volume 3 Part F, Anthropogenic Compounds: Detergents. Springer-Verlag, p 383-394.

6. Shapiro, R. 1990, FHSA acute oral toxicity limit test- Abil EM-90. Report No. T-102, Product Safety Labs, East Brunswick, New Jersey, U S A.

7. Shapiro, R. 1990, FHSA dermal irritation test- Abil EM-90. Report No. T-104, Product Safety Labs, East Brunswick, New Jersey, U S A.

8. Shapiro, R. 1990, FHSA primary eye irritation test- Abil EM-90. Report No. T-103, Product Safety Labs, East Brunswick, New Jersey, U S A.

9. Shapiro, R. 1995, Dermal sensitisation test - Magnusson-Kligman method- Abil EM 90. Report No. E50516-1R, Product Safety Labs, East Brunswick, New Jersey, U S A.

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11. Federal Hazardous Substances Act (FHSA) Regulations, guidelines.

12. Draize, J. H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49**.

13. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris.

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15. Standards Australia 1994, *Australian Standard 1336-1994*, *Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.

16. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

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

18. Standards Australia 1990, *Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals,* Standards Association of Australia Publ., Sydney.

19. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves),* Standards Association of Australia Publ., Sydney.

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

21. 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