File No: NA/481

Date:March 1997

## NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION

## AND ASSESSMENT SCHEME

## FULL PUBLIC REPORT

Polymer in AS 4000

This Assessment has been compiled in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

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Director Chemicals Notification and Assessment

FULL PUBLIC REPORT NA/481

#### **FULL PUBLIC REPORT**

#### Polymer in AS 4000

#### 1. APPLICANT

G E Plastics Australia Ltd of 175 Hammond Road DANDENONG VIC 3175 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer in AS 4000.

#### 2. IDENTITY OF THE CHEMICAL

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

Other Names: methyl silicone polymer

silicone hardcoat

SHC 3000

**Trade Names:** AS 4000 (Commercial Product)

Number-Average

Molecular Weight (NAMW): > 1 000

Maximum Percentage of Low Molecular Weight Species

**Molecular Weight < 500:** < 5.0% **Molecular Weight < 1 000:** < 10.0%

**Method of Detection** 

and Determination: ultraviolet/visible (UV/Vis) spectrometry

**Spectral Data:** infrared spectra were provided for the notified

chemical

#### 3. PHYSICAL AND CHEMICAL PROPERTIES

Tests to determine the physico-chemical properties of the notified polymer were performed on the dry polymer, after evaporation of the solvents

Appearance at 20°C

and 101.3 kPa: pale yellow powder

Melting Point: > 315°C

Specific Gravity: 1.35 at 22.5°C

Vapour Pressure: not determined (see below)

Water Solubility: insoluble

**Partition Co-efficient** 

(n-octanol/water): not provided, water insoluble polymer

Hydrolysis as a Function

of pH: not determined (see below)

Adsorption/Desorption: not determined (see below)

**Dissociation Constant:** not determined (see below)

**Flash Point:** 27.2°C (commercial product containing polymer)

**Flammability Limits:** not determined; (lower limit 1.7°C, upper limit

36.5°C for the commercial product)

**Autoignition Temperature:** > 400°C (estimated)

**Explosive Properties:** not determined (see below)

Reactivity/Stability: considered to be unreactive

#### **Comments on Physico-Chemical Properties**

The vapour pressure is expected to be low due to the large molecular weight of the polymer.

The notifier has provided references (1, 2) which report that silicone resins are insoluble in water (they are water repellent). Therefore, the notifier claims that the notified polymer will be insoluble in water. The water solubility will be very low due to the large molecular weight of the polymer and the fact that silicone polymers are claimed to be insoluble in water (3).

The notified polymer is not likely to hydrolyse due to its expected low water solubility. The polymer does not contain any readily hydrolysable groups.

The partition coefficient is expected to be high due to the expected low water solubility. Given the polymer's low water solubility and expected high partition coefficient, it is anticipated that the polymer will strongly adsorb to, or be associated

with, soils and sediments.

The notified polymer does not contain any dissociable groups.

#### 4. PURITY OF THE CHEMICAL

Degree of Purity: high

**Non-hazardous Impurities** 

(> 1% by weight): none

**Maximum Content** 

of Residual Monomers: very low

#### Comments on the Residual Monomer

The residual monomers are present at very low concentrations, and are unlikely to be of toxicological significance.

## 5. USE, VOLUME AND FORMULATION

The notified polymer will be used as hard coating for polycarbonate, engineering plastic articles in the automotive industry. The coating imparts hardness to the surface of the plastic and provides resistance to abrasion, solvents and UV radiation.

The notified polymer will be imported in a ready to use form as a 20% solution in methanol, n-butanol, isopropanol, toluene and water.

It is estimated that up to 5 tonnes of the notified polymer will be imported each year for the first five years.

#### 6. OCCUPATIONAL EXPOSURE

AS 4000, containing the notified polymer at 20%, will be imported in 200 L steel drums. The product will be transported from the wharf to the notifier's warehouse it will then be distributed by road to the customer(s).

Repackaging, if any, will be carried out at the notifier's warehouse and a maximum of 2 people would be involved. It is estimated that less than 100 kg will need to be repacked each year. This would not occur for more than 20 minutes each day for up to 10 days per year. Repackaging will be carried out in a well ventilated area.

Reformulation of AS 4000 may occur at up to four customer sites. No details regarding reformulation processes were available to the notifier.

AS 4000 will be applied at one vehicle production location by dip, spray or flow-coating. After coating, the article is allowed to air dry until 'tack-free'. The coating is

then cured at 130°C for 30 to 60 minutes.

Exposure may occur when workers are decanting AS 400 into application vessels, during coating of articles and and when purging the application equipment. There is also the potential for occupational exposure during repackaging. As described above these operations will be conducted under local exhaust ventilation, thus minimising the potential for inhalational exposure. The most likely route of exposure will be dermal during each of the procedures detailed above.

Workers should be aware that the commercial form of the notified polymer, AS 4000, contains a range of solvents including methanol, n-butanol and isopropanol, which are known to cause adverse effects following dermal and inhalational exposure. These effects are reported in the product Material Safety Data Sheet (MSDS). These solvents also render AS 4000 flammable and a Class 3 Dangerous Good (4). Further details about the formulation are provided in Section 12 of the report.

#### 7. PUBLIC EXPOSURE

The public may come into contact with the automotive parts which are coated with AS 4000. However, the polymer, which has a high NAMW will be immobilised in the protective layer of the coated part. Public exposure is therefore likely to be minimal. The potential for minor public exposure exists during transport and disposal of AS 4000. This is minimised by adherence to the recommended practices during storage and transport provided in the MSDS.

## 8. ENVIRONMENTAL EXPOSURE

#### Release

The generation of waste is limited to losses through application, cleaning of application equipment, residues in empty packaging and traces remaining from the clean-up of any spill. The notifier claims that losses through the application methods, dip and flow coating, are minimised by continuous reticulation. Spray application on to plastic parts is rare in the automotive industry. Where spray applications are used, overspray is collected in a water curtain in the spray booths. Manufacturers have generally adopted the practise of recycling the solvent used in equipment cleaning cycles into the next batch to be applied.

Wastes containing the notified polymer will be sent to the plant's effluent treatment system where oily contaminants will be separated, before the aqueous phase is discharged to the sewer. The majority of the polymer should be removed with the skimmed oils, which should be disposed of by a licensed waste contractor. The notified polymer is of such viscosity that it will easily drain from the 200 L drums into application vessels. Residues in these drums are estimated to be 50-100 g before rinsing with application solvent. Disposal of empty containers containing residues of the notified polymer will be recycled by a contractor or crushed for steel recycling.

Should the notified polymer be repackaged, it will be done at the notifier's warehouses where there are adequate procedures to prevent release to the environment.

#### **Fate**

Almost all of the imported polymer will be cured as a coating with high affinity for the plastic articles to which is applied and would not be disposed of until the article is no longer required. The coating containing the polymer will share the fate of the article to which it is applied. When the polymerised polymer is disposed of, either as a residue or as a coating, no hydrolysis, movement, leaching, biodegradation or bioaccumulation of the polymer is expected.

Washings, containing the polymer will be sent to the automotive manufacturer's waste treatment plant. Effluent from this process will be sent to the sewer. The notified polymer is expected to partition to sediment/sludge of the waste water treatment plant, which is then landfilled or incinerated. In landfill, the polymer is expected to sorb to soil due to the expected low water solubility and high partition coefficient. Complete incineration of the polymer is expected to produce water and oxides of carbon and silicon.

Spillages will be contained and absorbed to dry adsorbent material which will be disposed of to landfill. Uncured (non-polymerised) polymer disposed of to landfill should remain immobile in the landfill due to the polymer's expected low solubility in water.

Any chips or flakes of the cured polymer coating that occur (due to stone chips, accidents, wear and tear, *etc*) will be inert, diffuse and form part of the soil/sediments.

No biodegradation data has been provided and is not required under the Act. However, the notifier does not anticipate that the polymer will be biodegradable. Siloxane bond redistribution within the polymer in dry soils is not expected to occur as this route of degradation seems to be limited to straight chain polydimethylsiloxane fluids. Bioaccumulation is not expected as biological membranes are not permeable to polymers and chemicals of very large molecular size (5, 6).

#### 9. EVALUATION OF TOXICOLOGICAL DATA

Although toxicological data are not required for a polymer of NAMW greater than 1 000, under the Act, the notifier has provided a number of toxicological studies to assist assessment. Tests were conducted on the notified polymer after removal of solvents from the commercial preparation, for all studies except the acute inhalation. These data are provided below:

## 9.1 Acute Toxicity

## Summary of the acute toxicity of Polymer in AS 4000

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD <sub>50</sub> > 5 000 mg/kg	(7)
skin irritation	rabbit	slight irritant	(8)
eye irritation	rabbit	slight irritant	(9)
			(10)
acute inhalation toxicity	rat	LC <sub>50</sub> > 3.2 mg/L	
skin sensitisation	guinea pig	not a skin sensitiser	(11)

## **9.1.1 Oral Toxicity (7)**

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: oral gavage of a single dose at 5 000 mg/kg;

the notified polymer was administered as a

suspension in propylene glycol

Clinical observations: lethargy and weakness was observed in all

males and 2 females in the first two hours after dosing; one male was prostrate and had irregular breathing in the first 4 hours after

dosing

Mortality: nil

Morphological findings: moderate distended pelvis of the right kidney

in one female; not considered to be treatment

related

Test method: similar to OECD Guidelines for Testing

Chemicals (12)

 $LD_{50}$ : > 5 000 mg/kg

Result: the notified chemical was of low acute oral

toxicity in the rat and would not be classified according to Worksafe Australia's Approved

Criteria for the Classification of Hazardous Substances (13) (Approved Criteria)

## 9.1.2 Skin Irritation (8)

Species/strain: rabbits/New Zealand White

Number/sex of animals: 3/sex

Observation period: 72 hours

Method of administration: the notified polymer was administered as a

paste (0.5 g) in physiological saline to intact and abraded sites under a semi-occluded

dressing for 4 hours

Test method: similar to OECD Guidelines for Testing

Chemicals (12); assessment of irritant effects

according to Draize (14)

Result: very slight erythema was observed at one

abraded site in one animal and in a second

animal at both abraded sites; each

observation was made at the 24-hour reading only; readings were not made at the 48-hour

time point

the notified chemical was a slight skin irritant in rabbits; but these effects were below the threshold for classification according to

Worksafe Australia's Approved Criteria for the Classification of Hazardous Substances (13)

(Approved Criteria)

## 9.1.3 Eye Irritation (9)

Species/strain: rabbits/New Zealand White

Number/sex of animals: group 1: 3 males and 3 females (unirrigated

eves)

group 2: 2 males and 1 female (irrigated eyes)

Observation period: 7 days

Method of administration: 0.1 gm of the notified polymer was

administered into the conjunctival sac of the right eye of each animal, the left eye serving

as control

Test method: similar to OECD Guidelines for Testing

Chemicals (12); assessment of irritant effects

according to Draize (14)

Results: group 1: one animal exhibited a Draize score

of 1 for redness at 24-hours; a second animal

in this group had Draize scores of 2 for

redness, chemosis and discharge at 24 hours; and a score of 1 for redness and chemosis at 48 hours; fluorescein stain retention was also seen in this animal with areas of 2 and 1 at 24

and 48 hours respectively; all other eye

irritation scores were 0;

in group 2, no signs of ocular irritation were observed in any animal, throughout the study

the notified chemical was a slight irritant to the rabbit eye; however the response was below the threshold for classification as hazardous according to the Approved Criteria (13)

## 9.1.4 Acute inhalation (10)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: aerosol of commercially available solution

containing a maximum feasible concentration

of 3.2 mg/L of notified polymer;

Test method: Similar to OECD Guidelines for Testing

Chemicals (12);

 $LC_{50}$ :  $LC_{50} > 3.2 \text{ mg/L}$ 

Result: the notified chemical was of low inhalational

toxicity in the rat; although the maximum concentration tested was below the threshold for classification, there were no mortalities or systemic toxicity to indicate that the LC<sub>50</sub> would not exceed the threshold requiring

classification (> 5 mg/L) (13)

## 9.1.5 Skin Sensitisation (11)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 20 test/10 control

Induction procedure: days 0 and 2: 0.2 mL of 50% (v/v) test

material in petrolatum; applied under an

occluded dressing

day 4: 0.1 mL of Freund's Complete Adjuvant FCA:saline (1:1 v/v) *i.d.*; followed by 0.2 mL of 50% (v/v) test material in petrolatum applied

under an occluded dressing

day 4: Controls; 0.1 mL of FCA:saline (1:1%

v/v) *i.d.* 

Challenge procedure: day 21: topical application of 50%, 25%, 10%

and 0% test material in petrolatum under an

occluded dressing

## Challenge outcome:

	Test a	nimals	Naive a	animals
Challenge concentration	24 hours*	48 hours*	24 hours	48 hours
0%	1/20**	0/20	1/10	0/10
10%	5/20	1/20	1/10	1/10
25%	7/20	0/20	4/10	0/10
50%	7/20	1/20	2/10	0/10

<sup>\*</sup> time after patch removal

Test method: OECD Guidelines for Testing Chemicals (12)

Result: significant responses were seen in test

animals at 24 hours; when the responses of naive animals were taken into account the threshold for classification was not reached (13); this response did not persist to the 48 hour reading and it is therefore likely that

these effects were due to irritation

## 9.2 Genotoxicity

#### 9.2.1 Salmonella typhimurium Reverse Mutation Assay (15)

*Strains:* S. typhimurium TA 1535, TA 1537, TA 1538,

TA 98 and TA 100

<sup>\*\*</sup> number of animals exhibiting positive response

Concentration range: 100, 333, 1 000, 3 330, 5 000 μg/plate in the

presence and absence of metabolic activation

(rat liver S-9)

Test method: similar to the OECD Guidelines for Testing of

Chemicals (12)

Result: the notified chemical was non mutagenic in

the strains tested

## 9.2.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (16)

Species/strain: mouse/Swiss SPF

Number and sex of animals: 5/sex

Doses: 2 000 mg/kg of test substance in corn oil

Method of administration: oral intubation

Test method: OECD Guidelines for Testing Chemicals (12)

Result: non clastogenic in the mouse micronucleus

test

## 9.4 Overall Assessment of Toxicological Data

The notifier submitted toxicological data from animal studies showing that the notified polymer is of low acute toxicity via oral and inhalational routes ( $LD_{50} > 5\,000\,\text{mg/kg}$ ,  $LC_{50} > 3.2\,\text{mg/L}$  respectively). Slight irritation was reported in rabbit skin and eye irritation studies. The notified polymer was not classified as a skin sensitiser in a guinea pig study. The notified polymer did not show mutagenic or clastogenic activity in two genotoxicity assays, including an *in vivo* mouse micronucleus assay.

On the basis of the data provided by the notifier, the notified polymer would not be classified according to Worksafe Australia's *Approved Criteria for the Classification of Hazardous Substances* (13).

#### 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were provided, which is acceptable for polymers of NAMW greater than 1 000 according to the Act.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of notified polymer will be incorporated into a cured hard-coating for plastic articles in the automotive industry. The coating containing the polymer will share the fate of the articles to which it is coated. Only a small number of vehicle manufacturing or parts plants will use the product containing the polymer. The environmental hazard through such a use is considered negligible since releases are low.

Waste polymer sent to the municipal waste water treatment plant will be handled as part of the normal solid waste recovery, and disposed of to landfill or through incineration. In landfill the polymer is not expected to be mobile or degrade due to its expected low water solubility. Incineration products are not expected to present a significant hazard to the environment.

# 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECT

The notified polymer will only be imported in a ready to use form as a component of AS 4000, used for plastic coating in the automotive industry. The notified polymer has low acute oral toxicity and would not be classified as an eye or skin irritant, although some signs of skin and eye irritation were observed in animal studies. It is not a skin sensitiser nor does it appear to have genotoxic potential. The notified polymer has a high molecular weight which will limit absorption across biological membranes and it is expected to have a negligible vapour pressure, therefore is unlikely to be of concern for workplace air contamination. Residual monomers are present at very low concentrations and are unlikely to be of toxicological significance. There are however, a relatively high percentage of low molecular weight (MW) species (MW below 1 000 < 10%, MW below 500 < 6%), that have the potential to cross biological membranes but this is unlikely to be of toxicological concern as the percentage of species will be significantly reduced in the final product to which workers may be exposed.

There is the potential for occupational exposure during repackaging, filling of application equipment and application of the product containing the notified polymer. The most likely route of exposure is dermal. All workplace procedures are conducted in exhaust ventilated areas and this will limit inhalational exposure. In addition, by protecting against the hazardous solvents in the formulation (see recommendations section), potential dermal, ocular and inhalational exposure to the notified polymer will be significantly reduced. Under normal conditions, given the physico-chemical properties, toxicological profile and low concentration in AS 4000, the notified polymer is considered to present a low occupational health risk.

AS 4000 contains a range of hazardous solvents to which there is the potential for exposure during each of the processes described above. These solvents include methanol, n-butyl alcohol and toluene. The hazards associated with these chemicals include harmful effects if ingested or inhaled, skin and eye irritation. Details of these hazards are contained in the product MSDS. Exposure to these solvents should be minimised for all routes of exposure. Workers should also take particular care when

opening drums containing AS 4000, as there may be a build up of volatiles in the headspace of the drum. Worksafe's Exposure Standards for *Atmospheric Contaminants in the Occupational Environment*, should be consulted (17) when working with these solvents.

The notified polymer is unlikely to be of significant risk to public health when used in the proposed manner.

#### 13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in AS 4000 the following guidelines and precautions should be observed:

- Safe practices for handling any chemical formulation, should be adhered to and include:
  - minimising spills and splashes:
  - practising good personal hygiene; and
  - practising good house keeping and maintenance including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal;

It is expected that in the industrial environment, protective clothing conforming to and used in accordance with Australian Standard (AS)2919 (18) and protective footwear conforming to Australian/New Zealand Standard (AS/NZS) 2210 (19)should be worn as a matter of course.

A copy of the MSDS should be easily accessible to employees.

In addition, Worksafe Australia's document *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards* (17) should be used as a guide in the control of any volatile components in AS 4000 containing the notified polymer. Workplace monitoring for these components should be carried out on a regular basis.

It is advisable when handling the commercial form of the notified polymer, AS 4000, containing potentially hazardous solvents, to wear chemical-type goggles (selected and fitted) according to AS 1336 (20) and meeting requirements of AS/NZS 1337 (21), and impermeable gloves AS 2161-1978 (22), to protect against any unforseen circumstances. Respiratory protection (selected and fitted) according to AS/NZS 1715 (23) meeting the requirements of AS/NZS 1716 (24), may be necessary if engineering controls are inadequate.

#### 14. MATERIAL SAFETY DATA SHEET

The MSDS for the product containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (25).

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. Anonymous 1982, 'Final Report on the Safety Assessment of Dimethicone Copolyol', Journal of the American College of Toxicology, vol. 1, no. 4.
- 4. Federal Office for Road Safety 1992, Australian Code for the Transport of Dangerous Goods by Road and Rail, 5th, Australian Government Publishing Service Publ, Canberra.
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- 18. Standards Australia 1987, Australian Standard 2919-1987, Industrial Clothing, Standards Association of Australia, Sydney.
- 19. 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.
- 20. Standards Australia 1994, Australian Standard 1336-1994, Eye protection in the Industrial Environment, Standards Association of Australia, Sydney.
- 21. Standards Australia/Standards New Zealand 1992, Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.
- 22. Standards Australia 1978, Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves), Standards Association of Australia, Sydney.

- 23. Standards Australia/Standards New Zealand 1994, Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.
- 24. Standards Australia/Standards New Zealand 1994, Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.
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## **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		

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Redness	Rating	Chemosis	Rating	Discharge	Rating
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely	1	Any swelling above	1 slight	Any amount different	1 slight
injected above normal	slight	normal		from normal	
More diffuse, deeper crimson red with individual vessels not	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
easily discernible		Swelling with lids	3 mod.	Discharge with	3
Diffuse beefy red	3	half-closed		moistening of lids and	severe
	severe	Swelling with lids	4	hairs and	
		half-closed to completely closed	severe	considerable area around eye	

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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