File No: NA/720

23 April 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

α-D-galactopyranuronic acid, O-6-deoxy-β-L-galactopyranosyl-1→3-O-α-D-galactopyranosyl-1→3-, homopolymer (9CI)
(Biosaccharide Gum-1)

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 the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

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(Biosaccharide Gum-1)

1. APPLICANT

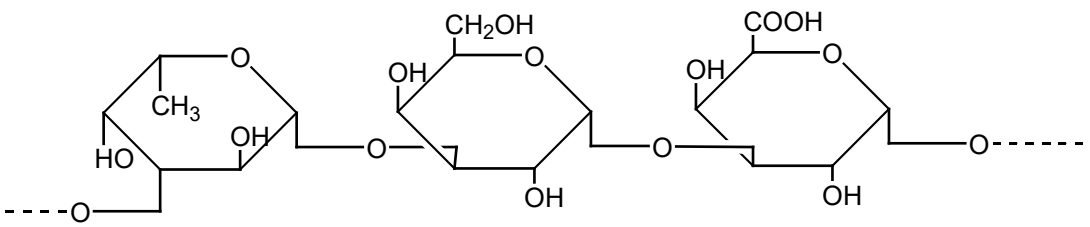
Marigny (Australasia) Pty Ltd of 266 Bay Road, SANDRINGHAM VIC 3191 (ACN 004 191 673) has submitted a Limited Notification statement in support of their application for an assessment certificate for the biopolymer, **Biosaccharide Gum – 1**.

No application was made by the notifier for any information relating to the notified biopolymer to be exempt from publication in the Full Public Report and Summary Report.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	α-D-galactopyranuronic acid, O-6-deoxy-β-L-galactopyranosyl-1→3-O-α-D-galactopyranosyl-1→3-, homopolymer (9CI)
Chemical Abstracts Service (CAS) Registry No.:	194237-89-3
Other Names:	Biosaccharide Gum-1
Marketing Name:	Fucogel 1000PP (aqueous solution that contains the notified biopolymer at 1%)
Molecular Formula:	$(C_6H_{12}O_6)_x$ $(C_6H_{12}O_6)_y$ $(C_6H_{10}O_7)_z$ where (L-Fructose)x + (D-Galactose)y + (Galacturonic acid)z ≈ 105 (see comments below)

Structural Formula:



Molecular Weight:	20 000
Method of Detection and Determination:	Infrared (IR) analysis
Spectral Data:	Major IR absorbance peaks were located between 1 600 to 700 cm^{-1}

Comments on Chemical Identity

The notified biopolymer is composed of disaccharides, (L-fructose and D-galactose) and galacturonic acid.

No molecular formula for the notified biopolymer was provided. The absence of information on the ratio of disaccharide to galacturonic acid prevented an independent determination of a molecular formula for the biopolymer for this assessment.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Pale yellow, slightly opalescent, viscous solution
Boiling/Melting Point:	Not determined
Density:	1.00 g/cm^3
Vapour Pressure:	Not determined
Water Solubility:	Not determined
Partition Co-efficient (n-octanol/water):	Not determined
Hydrolysis as a Function of pH:	Not determined
Adsorption/Desorption:	Not determined
Dissociation Constant:	Not determined
Flammability Limits:	Not determined
Autoignition Temperature:	Not determined
Explosive Properties:	Not determined
Reactivity/Stability:	Not determined

Comments on Physico-Chemical Properties

Other than a measurement of density no other investigation of physico-chemical properties were conducted on the notified biopolymer.

Based on its high molecular weight and polysaccharide nature, the notified biopolymer is expected to have low vapour pressure.

In the absence of physico-chemical data, the notifier has commented as follows:

The notified biopolymer is expected to be very soluble in water.

Hydrolysis of the notified biopolymer is not expected to occur in the environmental pH range due to the presence of stable glycosidic linkages. The literature indicates that abiotic breakdown of the glycosidic linkages is only expected to occur in the presence of an acid catalyst in aqueous solution where water is present in excess.

The n-octanol partition coefficient is expected to be low. The notified biopolymer is expected to partition to water due to its anticipated water solubility.

The notified biopolymer is not expected to sorb strongly to soil, sediments or organic material due to its anticipated water solubility.

The galacturonic acid component of the notified biopolymer has a carboxylic acid group which has the potential to dissociate.

4. PURITY OF THE CHEMICAL

Degree of Purity: >99%

Hazardous Impurities:

Chemical name:	Heavy metals (unidentified)
CAS No.:	Not assigned
Weight percentage:	≤0.002
Chemical name:	Arsenic
CAS No.:	7440-38-2
Weight percentage:	≤0.0002
Toxic properties:	R23/25 - Toxic by inhalation and if swallowed (NOHSC 1999)

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

Additives/Adjuvants: Fucogel 1000PP contains the notified biopolymer at 1% (aqueous solution) and is preserved with Phenoxyethanol (1%) and Phenonip (<0.3%).

Chemical name: 2-Phenoxyethanol
CAS No.: 122-99-6

Phenonip is comprised of:

Chemical name: Methylparaben
CAS No.: 99-76-3

Chemical name: Ethylparaben
CAS No.: 120-47-8.

Chemical name: Propylparaben
CAS No.: 94-13-3

Chemical name: Butylparaben
CAS No.: 94-26-8

Chemical name: Isobutylparaben
CAS No.: 4247-02-3

5. USE, VOLUME AND FORMULATION

The notified biopolymer will not be manufactured in Australia. It will be imported as a component (1%) of an aqueous solution, Fucogel 1000PP at approximately 50 kg per annum over the next five years in 25 kg plastic containers.

Fucogel 1000PP is an additive used in the formulation of skin moisturisers at concentrations of up to 5% (0.05% notified biopolymer).

Formulation of the finished moisturiser involves transfer of the notified biopolymer solution at the final stage of manufacture to other ingredients contained within a steam-jacketed, enclosed mixing vessel. The notifier states that the formulation process is automated.

6. OCCUPATIONAL EXPOSURE

Tabulated below is the maximum potential exposure duration of workers to the notified biopolymer and the personal protective equipment required to be worn by them during the performance of their tasks.

Category of Worker	*Nature of Work Done*	*Maximum Potential Exposure*	*Personal Protective Equipment & Engineering Controls*
Storeworker	Storage & transfer of 25 kg containers.	0.5 hour/day; 12 days/year.	Safety glasses, overalls & gloves;
Compounder	Dispensing of biopolymer solution into mixing vessel & cleaning of equipment.	2 hours/day; 24 days/year.	Safety glasses, overalls & gloves; Exhaust ventilation/dust extractors.
Linesetter	Setting, monitoring & maintaining filling line.	0.5 hour/day; 24 days/year.	Safety glasses, overalls & gloves; Exhaust Ventilation.
Laboratory Technician	Sampling & testing of the biopolymer solution prior to compounding.	0.5 hour/day; 24 days/year.	Safety glasses, overalls & gloves; Laboratory fume hoods.

Transport and Storage
The notified biopolymer solution is transported in hermetically sealed 25 kg containers. No exposure is anticipated during transport except in the event of a spill. One storeworker is responsible for delivery receipt and transfer of the containers to the storage area by forklift.

Formulation
Blending
Up to three compounders are involved in the formulation process. Within the dispensary, the notified biopolymer solution is weighed out by a compounder, then manually transferred to the 3 000 kg mixing vessel which already contains the other ingredients.

Packaging
At the end of the compounding process the mixing vessel is sealed to prevent contamination. The finished product (containing the notified biopolymer at 0.05%) is transferred to the packaging line where one linesetter feeds the product into the filler, which transfers the end use product to 50 mL jars.

Clean - up
After filling, the empty vessel is cleaned before returning to the manufacturing area. A third compounder steam cleans the vessel in the wash bay and stores it for future use. This compounder is also responsible for washing of the 25 kg containers prior to disposal.

Quality Control Analysis
Sampling of the biopolymer solution is performed by two laboratory technicians in a segregated, quarantine area of the store. Testing of samples is undertaken in the chemical laboratory.

7. PUBLIC EXPOSURE

Exposure of the public to the notified biopolymer is via cosmetic use. The notifier estimates that consumers will use the product once every 2 to 3 days, and therefore be exposed to 0.25 g of the biopolymer per application of skin moisturiser, equivalent to about 0.1 g per day.

Spillage of Fucogel 1000PP during transport will be controlled by following the recommended spill procedures given in the Material Safety Data Sheet (MSDS), which recommends that spillages should be collected by aspiration or absorption of the material onto sand or sawdust for disposal by incineration.

8. ENVIRONMENTAL EXPOSURE

Release

The notified biopolymer will be formulated at a factory site in Melbourne. Release of the notified biopolymer is expected to occur during formulation activities such as dispensing, mixing, quality testing, packaging and equipment and drum cleaning. Release is expected to total approximately 5% (2.5 kg) of total import volume. All liquid waste and spills are contained and directed to the in-house effluent plant. The effluent treatment process is a batch process involving 10 000 litres per treatment cycle. During this process the alkaline effluent is adjusted to a pH range of 6-10 using 32% (v/v) HCI. Ammonia stripping via aeration/evaporation is another feature of this process. The treated water is then released to the Melbourne Waste Water Treatment Plant.

The amount of end use product remaining as residues in the retail jars will depend on the design of the containers. The most likely container residue level is 5% volume, representing release of approximately 5% of import volume (2.5 kg) per annum. Retail containers will be disposed of to landfill through domestic garbage services.

The majority of release of the notified biopolymer is expected to be associated with end use of the consumer product. The high molecular weight of the notified biopolymer suggests that it will not pass biological membranes and will therefore remain on the skin to be subsequently washed off and into the sewer. The notified biopolymer has the potential to be degraded on the skin by bacteria but it is not known what percentage will be broken down and absorbed. Consequently, the Predicted Environmental Concentration (PEC) estimate

assumes all of the notified biopolymer applied to the skin will be washed off (see Environmental Hazard section).

Fate

The polysaccharide nature of the compound suggests at least inherent biodegradability. Glycosidic linkages between individual units of the biopolymer are likely to be stable to abiotic degradation under normal environmental pH, but under extreme pH these linkages may be destroyed. However the biopolymer has the potential to be readily degraded by bacteria and other microflora in the pH range of 4-9.

Notified biopolymer released to the sewer is expected to remain in solution rather than be removed during primary treatment. During biological or secondary treatment, the notified biopolymer is expected to be oxidised and degraded by anaerobic and aerobic microorganisms and ultimately mineralised to carbon dioxide and water.

The high anticipated solubility indicates the notified biopolymer may leach rapidly in landfill. However, the notified biopolymer is expected to be degraded by soil borne bacteria. Any undegraded biopolymer in landfill may eventually be transported to the aquatic compartment.

Due to the high molecular weight and anticipated high water solubility, the biopolymer is not expected to bioaccumulate or persist.

9. EVALUATION OF TOXICOLOGICAL DATA

The following tests were conducted on Fucogel 1000 (also known as Bioeurope 856), which is an aqueous solution that contains the notified biopolymer at 1% and the preservatives, Phenopip (phenoxy ethanol and parabens at 0.6%).

9.1 Acute Toxicity

Summary of the acute toxicity of Fucogel 1000

Test	*Species*	*Outcome*
Acute oral toxicity	Mouse	LD_{50} not established
Skin irritation	Rabbit	Slight irritant
Eye irritation	Rabbit	Slight irritant

9.1.1 Oral Toxicity (Universite D'Aix Marseille 1992)

Species/strain:	Mouse/OFI albino
Number/sex of animals:	10/group
Observation period:	8 days
Method of administration:	Oral gavage: 200, 500, 1 00 and 1 000 mg/kg
Test method:	Not stated
Mortality:	There were 2 deaths in the 1 000 mg/kg group and 3 deaths in the 1 500 mg/kg group. Also reported were 3 deaths in the control group.
Clinical observations:	Not reported
Morphological findings:	Not reported
LD_{50}:	Not established
Comment:	The study summary reports an LD_{50} of > 1 500 mg/kg bw. However, on the basis of deaths occurring in control animals with no explanation offered and in the absence of commentary on morphological findings this assessment rejects the quoted LD_{50} and concludes that an LD_{50} cannot be established.

9.1.2 Skin Irritation (Universite D'Aix Marseille 1992)

Species/strain:	Rabbit/albino
Number/sex of animals:	6, sex not specified
Observation period:	3 days
Method of administration:	Not satisfactorily described except that the test substance was applied in a volume of 0.5 mL to scarified and non-scarified zones on the sides of animals.
Test method:	Not stated

Draize scores:

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

[a] see Attachment 1 for Draize scales. NR – not reported.

Comment: Only an approximate assessment of the skin irritation effect of the notified biopolymer can be made on the basis of the quality of the data provided. The irritation scores for erythema and oedema were provided as combined scores, and the 48-hour observation point was not included. It was therefore not possible to calculate the mean scores for skin irritation from this study.

Result: The poor reporting quality of the study permits only an approximate assessment of eye irritation potential to be made. The available evidence suggests that the notified biopolymer solution may be a slight irritant to the skin of rabbits.

9.1.3 Eye Irritation (Universite D'Aix Marseille 1992)

Species/strain: Rabbit/albino

Number/sex of animals: 3, sex not specified

Observation period: 7 days

Method of administration: 0.1 mL of test substance instilled into the right eye of each animal

Test method: Not stated

Comment: No accurate assessment of the ocular irritation potential of the notified biopolymer can be made because no scores for ocular lesions were given for the first three days of observation. The report mentions conjunctival irritation in all three animals one hour after instillation, with slight oedema in one animal, with no evidence of any lesions by the fourth day.

Result: The poor reporting quality permits only an approximate

assessment of eye irritation potential to be made. The available evidence suggests that the biopolymer solution may be slightly irritating to the eyes of rabbits.

9.2 Overall Assessment of Toxicological Data

Toxicological data on the notified biopolymer are not available. However, the notifier provided findings on acute oral toxicity, and skin and eye irritation on Fucogel 1000 an aqueous solution that contains the notified biopolymer at 1% and less than 1% preservative. Interpretation of the results from these studies is hampered by the fact that the tests were not conducted according to established test guidelines and only summary reports were provided with very little detail given on methodology and test findings.

An acute oral LD_{50} could not be determined on the basis of mortality in the control group.

Irritation studies gave insufficient information to accurately determine the potential to adversely affect the skin and eyes but the available evidence suggests that only a slight reaction was elicited in both, with notified biopolymer solution.

Hazard Classification
On the basis of the limited data provided no determination of hazard can be made for Fucogel 1000PP against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999)

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified biopolymer is unlikely to present a hazard to the environment when formulated as described and used in the indicated manner. The great majority of the biopolymer will go through the sewerage system where it is expected to undergo biodegradation to carbon dioxide and water.

While no data are readily available for the biopolymer or related polymers neither the biopolymer or its degradation products are likely to be toxic to aquatic organisms. In any case all releases of the biopolymer will be widespread and diffuse at very low concentrations (see below).

This assessment assumes the cosmetic product will be sold throughout Australia, consequently release will be widespread and diffuse. The following assumptions are held in calculating the PEC: the formulation containing the new biopolymer is used nationwide; all is released to the sewer system; 150 L of waste water are generated each day by each person; and that the biopolymer remains in the water column.

Import rate	50 kg per annum
Release rate	50 kg per annum
Population (national)	18 000 000
Volume of sewerage per annum	18 000 000 x 150 L
Mean concentration in sewage per day	0.051 μg/L
PEC*	0.0051 μg/L

*On release to receiving waters (after treatment at the sewage treatment plant), it is assumed that the effluent is diluted by a factor of 10.

Many monosaccharides such as galactose and fructose act as substrates for both fermentation and respiratory metabolism (Zubay 1983). For this reason, and provided levels of release remain low, the notified biopolymer is not expected to be toxic and the risk posed to the aquatic environment is considered to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Summary reports on an acute oral toxicity study and skin and eye irritant studies were provided for an aqueous solution containing the notified biopolymer at 1% and preservatives at less than 1%. An LD_{50} for acute oral toxicity cannot be established on the basis of mortality in the control group. The descriptive findings indicate slight skin and eye irritancy in animals. Interpretation of the study results is severely hindered by the poor reporting quality of the studies and an assessment of hazard of the notified biopolymer against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999) is not possible.

Occupational Health and Safety

The formulation and final packaging of skin moisturisers containing the notified biopolymer (at 0.05%) occurs within an automated and partially enclosed system. Tasks requiring manual operations, such as handling of the 25 kg import containers containing the notified biopolymer (at 1%), weighing and addition of the notified biopolymer to mixing vessels and sampling for quality control purposes, could give rise to drips, spills and splashes. Contamination of the workplace atmosphere with aerosols of the notified biopolymer is not expected given the viscous nature of the polysaccharide and the presence of ventilation systems throughout the plant. The notifier states that all workers at the formulation site are required to wear coveralls, gloves and safety glasses, thereby limiting the occurrence of skin and eye contact. Formulation of the moisturisers is done batch wise and occurs about twice per month. Under the conditions described, exposure to the diluted notified biopolymer during manual tasks is expected to be intermittent and the potential risk of skin and eye irritant effects low. Other activities where exposure to the notified biopolymer could occur are during rinsing of the import containers for disposal and cleaning of plant equipment. However, the biopolymer is present in very dilute form (<1.0%) and the level of exposure is considered negligible.

Public Health
Exposure of the public to the notified biopolymer via cosmetic use is estimated to be 0.25 g of the notified biopolymer per application of skin moisturiser, equivalent to about 0.1 g per day. Since the biopolymer is present at a low final concentration in the finished product (0.05%), it is unlikely to pose a significant risk to the public when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified biopolymer, the following guidelines and precautions should be observed:

- Workers should receive regular instruction on good occupational hygiene practices in order to minimise personal contact, and contamination of the work environment with Biosaccharide Gum-1 and products that contain it.

- Personal protective equipment (PPE) should be used where exposure to Biosaccharide Gum-1 and products that contain it occurs. Workers should be trained in the proper fit, correct use and maintenance of their PPE. Guidance in the selection, personal fit and maintenance of PPE can be obtained from:

Protective eyewear:	AS 1336 (SAA 1994);
	AS/NZS 1337 (SAA/SANZ 1992).
Chemical impermeable	AS 3765.2 (SAA 1990).
clothing:	
Impermeable gloves:	AS 2161.2 (SAA/SANZ 1998).
Occupational footwear:	AS/NZS 2210 (SAA/SANZ 1994).

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

If products containing the notified biopolymer are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 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 biopolymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 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 the Act, the Director of Chemicals Notification and Assessment, must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

NOHSC (1994). National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Canberra, Australian Government Publishing Service.

NOHSC (1999). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, AusInfo.

NOHSC (1999). List of Designated Hazardous Substances [NOHSC:10005(1999)]. Canberra, AusInfo.

SAA (1990). Australian Standard 3765.2-1990, Clothing for Protection Against Hazardous Chemicals Part 2 Limited Protection Against Specific Chemicals. Sydney, Standards Association of Australia (SAA).

SAA (1994). Australian Standard 1336-1994, Eye Protection in the Industrial Environment. Sydney, Standards Association of Australia (SAA).

SAA/SANZ (1992). AS/NZS 1337-1992, Australian/New Zealand Standard Eye Protectors for Industrial Applications. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand (SAA/SANZ).

SAA/SANZ (1994). Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand (SAA/SANZ).

SAA/SANZ (1998). Australian/New Zealand Standard 2161.2-1998, Occupational Protective Gloves, Part 2: General Requirements. Sydney/Wellington, Standards Association of Australia /Standards Association of New Zealand (SAA/SANZ).

Universite D'Aix Marseille (1992). Acute Oral Toxicity - Bioeurope 856 (Summary Report - English translation). Marseille.

Universite D'Aix Marseille (1992). Eye Irritation Study - Bioeurope 856 (Summary Report - English translation). Marseille.

Universite D'Aix Marseille (1992). Primary Skin Irritation Study - Bioeurope 856 (Summary Report - English translation). Marseille.

Zubay, G. (1983). Biochemistry. Part II. Carbohydrate Metabolism and Chemical Energy, Addison-Wesley Publishing Co.

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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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

MSDS