File No: NA/598

May 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

"Eastman AQ" 1350 Copolyester

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Director

Chemicals Notification and Assessment

Eastman AQ Copolyester

1. APPLICANT

Eastman Chemical Limited of Level 8, 15 Talavera Road NORTH RYDE NSW 2113 has submitted a limited notification statement in support of their application for an assessment certificate for "Eastman AQ" Copolyester.

2. IDENTITY OF THE CHEMICAL

Eastman AQ Copolyester is considered not to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae have been exempted from publication in the Full Public Report and the Summary Report.

Trade Names: Eastman AQ 1950 Copolyester
Eastman AQ 14000 Copolyester

Eastman AQ 1045 Copolyester Eastman AQ 1350 Copolyester

PM 18009

Number-Average

Molecular Weight (NAMW): Up to 10 000

Maximum Percentage of Low Molecular Weight Species

Molecular Weight < 500: 0.6% Molecular Weight < 1 000: 2.6%

Polydispersity: 4.01

Method of Detection

and Determination: Size exclusion chromatography (SEC) was used to

determine the NAMW and low molecular weight

species; infrared (IR) spectroscopy

Spectral Data: major characteristic peaks were found in the

infrared spectrum at: 625, 760, 1 400, 1 450, 1 050, 1 130, 1 175, 1 250, 1 310, 1 725 and

2 950 cm⁻¹

Comments on Chemical Identity

The notified polymer products, EASTMAN AQ Copolyesters 1 045, 1 350, 14 000 and 1950, are all chemically identical, high molecular weight polymers (NAMW > 5000 g.mol⁻¹), with only some variation in the molecular weight to provide different melt viscosity values, ie. they vary in the length of the polymer chain. It is the notifier's intention to import any grades that are chemically identical.

An IR spectrometric trace was submitted for the identification of the notified substance. Combustion analysis of a sample indicated the following elemental content: 58.98% Carbon, 8.39% Hydrogen, 30.75% Oxygen, 1.09% Sulphur and 0.79% Sodium.

A SEC test report, including trace, was supplied to determine the NAMW and percentage of low molecular species (1). The polydispersity of the polymer is 4.01 which indicates a wide molecular weight distribution.

The notifier claims that residual monomers and starting materials are below 0.6% as the polymer contains this amount below 500 g.mol⁻¹.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C

and 101.3 kPa: yellow solid with a sweet odour

Melting Point: the polymer does not have a crystalline melting

point; softens and begins to flow at approximately

90°C

Density: $> 1 000 \text{ kg.m}^{-3}$

Vapour Pressure: not determined; expected to have a negligible

vapour pressure

Water Solubility: not determined; polymer is dispersible in water

but not soluble

Partition Co-efficient

(n-octanol/water): not determined

Hydrolysis as a Function

of pH: not determinable using OECD TG 111 (2)

Adsorption/Desorption: not determined

Dissociation Constant: not determined

Flash Point: not determined

Flammability Limits: not determined; polymer is combustible

Autoignition Temperature: not determined

Explosive Properties: not known

Reactivity/Stability: hazardous polymerisation will not occur; stable

under normal conditions but reacts with strong

oxidising agents

Particle Size: > 2.5 cm

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 notified polymer does not have a crystalline melting point. The notifier expects the polymer to have a negligible vapour pressure as it is a solid with a relatively high softening/flow point.

Hydrolysis testing indicated that the polymer was not soluble in the buffer solutions (detection limits of the polymer in water by the UV-visible spectrophotometer were approximately 100 mg.L⁻¹). However, the notifier claims that it is water dispersible, ie. the polymer is broken into particles small enough to remain in suspension in water and do not go into solution, mixing on a molecular level. This allows articles manufactured with this polymer as an adhesive component to be "repulped" with water which can be beneficial for recycling operations. However, the presence of 7% of 1,3-benzenedicarboxylic acid, 5-sulfo-bis(2-(2-hydroxyethoxy (ethyl) ester, sodium salt together with 26% 2,2'-oxybisethanol is noted. Both of these constituents could be expected to confer some degree of affinity for water on the resultant polymer.

The notified polymer was not soluble in the pH 4, 7 and 9 buffers at a high enough concentration for the estimated half-life to be calculated, using the analytical technique employed. Addition of organic solvents to enhance water solubility was unsuccessful, with the solubility not modified to a level that could be accurately determined. Hydrolysis of the ester linkages in the environmental pH range, although theoretically possible, should be precluded (or be very slow) due to the polymer's low water solubility.

The notifier did not supply any data for partition coefficient, adsorption/desorption and dissociation constant. The "sulfonic salt" functionalities are likely to remain in the ionic form under normal environmental conditions. However, due to the low solubility, the notified polymer is expected to partition to the organic phase and to adsorb to, or be associated with, soil and sediment.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

Non-hazardous Impurities

(> 1% by weight): none

Toxic or Hazardous

Impurities: None

Maximum Content

of Residual Monomers: < 0.1%

Additives/Adjuvants: The imported polymer normally does not contain

additives; stabilisers such as Irganox 1010 (CAS No. 6683-19-8) and/or DSTDP (CAS No. 693-36-7) may be added during the manufacture of the

polymer at a level below 0.5%

5. USE, VOLUME AND FORMULATION

The notified polymer is a thermoplastic and will be used as an adhesive, primarily for paper and plastic articles. The notified polymer normally will not make up 100% of the adhesive product, but will be melted and mixed with a variety of tackifiers, waxes and plasticisers to result in a final formulated hot melt adhesive. Formulations may contain up to 50 to 70% of the notified polymer. The use of the notified polymer as an adhesive will eliminate the use of solvents.

The notified polymer will be imported in the pure form as solid pellets.

It is estimated that 4.5 tonnes of the notified polymer will be imported in the first year rising to 18.5 tonnes per annum by the fifth year.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported in 20 kg or 136 kg polyethylene lined drums. The notified polymer will be transported from the wharf to the notifier's warehouse. It will then be distributed by road to customer sites. A maximum of 4 people would involved. Exposure during transport and handling would only be likely in the event of an accident.

Formulation of the notified polymer may occur at up to ten customer sites. No details regarding formulation processes at each site were available to the notifier. The polymer is weighed and charged to a hopper of a tumble blender where it is melted and mixed with other additives and water to form a hot melt adhesive. Weighing and introduction to the blender is carried out under local exhaust ventilation, to capture any fugitive dust. After formulation with other components the product containing the notified polymer is dried and applied as a melt, typically as a molten bead or spray depending on the adhesive of the manufactured article eg packaging, book binding, labels on containers etc. These operations are carried out under local exhaust ventilation. At each site 20 to 80 workers will be exposed to the

notified polymer.

Dermal and inhalational exposure to dusts and fumes of the notified polymer may occur when workers are weighing and introducing the notified chemical to the blender and during melt extrusion for substrate bonding. The majority of the particles are greater than 200 μm in size, which exceeds the cut-off limit considered to be inspirable. There is still the possibility that the workers might inhale fumes from the molten polymer product during bonding. As described above, these operations will be conducted under local exhaust ventilation, thus minimising the potential for inhalational exposure.

7. PUBLIC EXPOSURE

Consumer Articles

The extent of public contact with articles containing the notified polymer is indeterminate but may be high depending on the nature of the applications for which the notified polymer is used. Exposure in most circumstances however is likely to be negligible due to the solid nature of the polymer and its position between layers of material which it has been used to glue together.

Industrial Use

The notified polymer will be processed at approximately 10 sites. Although the process may result in the generation of dusts and fumes the quantity produced is unlikely to be substantial given the nature of the material and dusts should be constrained by normal industrial ventilation and filtration systems. Public exposure from the industrial processing of this polymer is expected to be negligible.

Transport

In the event of a transport accident, the notified polymer being a solid pellet dispersion will be minimal and recovery and disposal by landfill or incineration according to local government regulations should be readily achievable. Public exposure following a transport accident is likely to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

Because the polymer is shipped as solid pellets, there should be little contamination of the containers, which can be recycled.

The polymer is melted and mixed with other additives to form the hot-melt adhesive. Losses of the polymer are not expected to be significant as the polymer can be melted and reused. For example, should a formulation not be within specification, the batch will be re-worked by blending with subsequent batches. The notifier anticipates an overall material loss rate of below 1%, which will be collected and

disposed of by incineration or to landfill.

The polymer product is then applied as a melt, typically as a molten bead or spray depending on the adhesive need for the manufactured article, eg. Packaging, book binding and labels on containers. Application of the hot-melt adhesive is claimed as a generally efficient process. It is expected that less than 0.5% of the imported polymer volume will be required to be disposed of.

The notifier claims that the notified polymer is water dispersible, allowing bonded articles to be recycled by "repulping". Articles are soaked in water, dispersing and removing the adhesive. The substrate can then be dried and recovered for reuse. The adhesive can be removed from the water dispersion by adjusting the ionic strength of the dispersion, eg. addition of divalent calcium salts.

Fate

The vast majority of notified polymer will be used in manufacturing adhesives. The fate of the polymer adhesive is tied to the fate of the article to which it is applied. Environmental exposure of articles containing the polymer product through leaching in landfill is not expected due to its insolubility. Once the adhesive is dried, the notified polymer should become inert by the hardening process.

Should treated articles be recycled, the polymer adhesive will become dispersed in the water column. The polymer adhesive will then either be removed, as indicated above, or disposed of to sewer with the waste water. Should the polymer product be disposed of to sewer, it should partition to the sludge and be trapped in the solids at the sewage treatment works. The solids are disposed of by landfill or incineration. Incineration products will include water, oxides of carbon and sulphur, with a small amount of sodium salts in the ash.

The notified polymer was found to be not readily biodegradable in the OECD 301B Test for Ready Biodegradability "CO₂ Evolution/Modified Sturm Test" (3). A 28-day test for ready biodegradability using unacclimated micro-organisms as the inoculum showed 5% and 7% degradation of the notified polymer at 20 mg DOC.L⁻¹ (theoretical), based on carbon dioxide evolution. However, due to the stringency of the test, low CO₂ evolution does not necessarily mean that the test substance is not degradable under environmental conditions, or after waste water treatment. The polymer's inherent biodegradability was not measured.

Biological membranes are not permeable to polymers of very large molecular size and therefore bioaccumulation of the notified polymer is not expected (4,5).

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicity data are required for polymers of NAMW greater than 1 000, under the Act. However, the data summarised below were provided by the notifier.

9.1 Acute Toxicity

Summary of the acute toxicity of "Eastman AQ" 1350 Copolyester

| Test | Species | Outcome | Reference |
|---------------------|------------|--|-----------|
| acute oral toxicity | rat | $_{1}^{\text{LD}_{50}}$ > 5 000 mg.kg ⁻ | (6) |
| skin irritation | rabbit | slight irritant | (7) |
| eye irritation | rabbit | non-irritant | (8) |
| skin sensitisation | guinea pig | non-sensitiser | (9) |

9.1.1 Oral Toxicity (6)

Species/strain: rat/CD®(SD)BR

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: oral gavage of a single dose at

5 000 mg.kg⁻¹;the notified polymer was administered as a 25% solution in deionised

water

Clinical observations: discoloured (light brown) faeces were

observed in all males and 2 females in the first

twenty four hours

Mortality: nil

Morphological findings: none

Test method: similar to OECD guidelines (10)

 LD_{50} : > 5 000 mg.kg⁻1

Result: the notified chemical was of low acute oral

toxicity in rats

9.1.4 Skin Irritation (7)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 males

Observation period: 72 hours

Method of administration: the notified polymer was administered as a

paste (0.5 g) in water to abraded sites under a

semi-occluded dressing for 4 hours

Test method: similar to OECD guidelines (19)

Result: very slight erythema was observed at one

abraded site in one animal at 24 and 48 hours and in another animal at 48 and 72 hours

the notified chemical was a slight skin irritant

in rabbits

9.1.5 Eye Irritation (8)

Species/strain: rabbit/New Zealand White

0

Number/sex of animals: 3/sex

Observation period: 3 days

Method of administration: 0.1 g 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 (10)

Result: no signs of ocular irritation were observed in

any animal, throughout the study

the notified chemical was not an irritant to the

rabbit eye

9.1.6 Skin Sensitisation

9.1.6.1 Skin Sensitisation study in the Guinea Pig(9)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 20 test/10 control

Induction procedure: for the test group

day 0: three pairs of intradermal injections

(0.1 mL) in the scapular region:

Freund's complete adjuvant (FCA), 1:1 with

deionised water

the notified chemical, diluted to 5% with

deionised water

the notified chemical at 5%, emulsified in a 1:1 mixture of FCA and deionised water

for the control group

day 0: three pairs of intradermal injections (0.1 mL) in the scapular region:

FCA, 1:1 with deionised water

deionised water

FCA emulsion

day 6 after injections, the same region was treated with 0.5 mL of 10% sodium lauryl sulphate in petroleum (test and control groups)

day 7, the same region was treated with 25% of the notified polymer in deionised water under occlusive dressing for approximately 48 hours; the control group received only

deionised water

Challenge procedure:

day 21, the left flank of each animal (both test and control groups) was treated with 25% of the notified polymer under occlusive dressing; the right flank was treated with deionised

water only

Challenge outcome:

| | Test a | Test animals | | Control animals | | |
|-------------------------|-----------|--------------|----------|-----------------|--|--|
| Challenge concentration | 24 hours* | 48 hours* | 24 hours | 48 hours | | |
| 25% | **0/20 | 0/20 | 0/10 | 0/10 | | |

^{*} time after patch removal

Test method: similar to OECD guidelines (10)

Result: the notified chemical was not a skin sensitiser

in guinea pigs

9.1.6.2 Repeated Insult Patch Test for Skin Sensitisation (11)

Species/strain: Homo sapiens

Number of persons: 119 completed the study

^{**} number of animals exhibiting positive response

Dose: the notified chemical, diluted to 25% with

deionised water

Test method: Modified Draize procedure

all exposures were by 24+1 hour contact

under occlusive conditions

129 subjects started the study; 119

completed; 10 subjects withdrew for reasons

unrelated to use of the test substance

Result: mild transient erythema was observed in one

subject during induction and no responses were observed in any of the subjects during

challenge

no evidence of clinical sensitisation was observed in resulting from use of the notified

chemical

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (12)

Strains: TA 98, TA 100, TA 1535, TA 1537 and

TA 1538 and Escherichia coli strain

WP2*uvr*A(pKM101)

Concentration range: 100 - 5 000 μg.plate⁻¹

Test method: similar to OECD guidelines (10)

Result: the notified chemical not mutagenic in S.

typhimurium and Escherichia coli in the presence or absence of metabolic activation

provided by rat liver s9 fraction

9.4 Overall Assessment of Toxicological Data

The notified polymer was of low acute oral toxicity in rats (oral $LD_{50} > 5\,000\,\text{mg.kg}^{-1}$). It was a slight skin irritant but not an eye irritant in rabbits. It was not a skin sensitiser when tested in guinea pigs. A Human Repeat Patch Test performed using the notified polymer did not show any evidence of clinical sensitisation potential.

The notified polymer was not found to be mutagenic in bacteria.

In relation to the toxicity studies summarised above, the notified polymer would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (13).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data is required for polymers of NAMW > 1000 according to the Act. However, the notifier has supplied an "Activated Sludge Respiration Inhibition Test" report.

| Test | Species | Results |
|------------------------|------------------------------|--|
| Respiration inhibition | Aerobic waste water bacteria | 3 h EC ₅₀ >1 000 mg.L ⁻¹ (14) NOEC=1 000 mg.L ⁻¹ |

^{*} NOEC - no observable effect concentration

A 3-hour activated sludge respiration inhibition test was performed using activated sludge from a domestic waste water treatment plant. The sludge micro-organisms were exposed to five (theoretical) nominal concentrations of the test substance in the test vessels, 25, 50, 100, 500 and 1 000 mg.L⁻¹. Due to the low solubility of the notified polymer, it was added directly to the test beakers and was tested as a particulate in the test medium. Test results indicate that the notified polymer is not

expected to affect secondary waste treatment micro-organisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The main environmental exposure to the notified polymer could occur when the articles containing the adhesive are either recycled or disposed of. The final destination is likely to be either landfill, where the polymer can be expected to persist but remain immobile in the hardened form, or sewer, where the polymer is expected to become associated with the sludge and be incinerated. The polymer was found to be non-toxic to waste treatment micro-organisms up to the limit of its solubility.

During the holt-melt adhesive formulation process, the notifier claims that losses will be less than 1% (i.e. less than 200 kg per annum at maximum import rates). The final destination of this waste will be either incineration or landfill. Losses during application of the adhesive are difficult to determine and will vary depending on the method of application. However, these losses are expected to be localised within the manufacturing plant. The notifier expects that losses will be limited to 0.5% of all of the polymer imported, approximately 90 kg per annum at the maximum import rate. Any spillages will be easily cleaned up as the notified polymer is in a solid pellet form.

The low environmental exposure of the notified polymer as a result of the proposed use indicates that the overall environmental hazard should be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the toxicological data, the notified polymer is not expected to exhibit acute or systemic toxicity. It is not likely to be an eye irritant, a skin sensitiser or genotoxic. A Human Repeat Patch Test showed no evidence of clinical sensitisation potential in humans. It may be a slight skin irritant. The polymer would not be classified hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (13).

Exposure of transport and storehouse workers to the notified polymer is likely to occur only in the event of an accident.

Exposure to workers involved in reformulation of the notified polymer and substrate bonding is expected to be low. Formulation and substrate bonding will be carried out under local exhaust ventilation, which would reduce any exposure to fugitive dust and molten polymer product respectively.

In the event of exposure the main occupational health risk during formulation and substrate bonding of the notified polymer would be slight skin irritation. The risk can be minimised by the use of protective gloves and clothing as outlined below.

Although public exposure may be significant depending on the application to which the notified polymer is put, the risk of adverse effects following such exposure is likely to be negligible due to its low toxicity profile and high NAMW, which will largely prevent dermal or gastro intestinal absorption.

13. RECOMMENDATIONS

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

- If engineering controls are insufficient to reduce exposure to the molten product of the notified polymer to a safe level 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);
- Impermeable gloves or mittens should conform to AS 2161 (18);
- All occupational footwear should conform to AS/NZS 2210 (19);
- 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 Sheets (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (20).

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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- 2. Isaacs B, 1996b. "Copolymer of DMCD-CX13-DEG-CHDM-TNP: Abiotic Degradation: Hydrolysis as a Function of pH", Chemicals Quality Services Division, Eastman Kodak Company, Report No. HYD-00406.
- 3. Beglinger JM and Ruffing CJ, 1996b. "Sodiosulfopolyester: Activated Sludge Respiration Inhibition Test", Health and Environment Laboratories, Eastman Kodak Company, Study No. EN-620-165245-A
- 4. Anliker R, Moser P & Poppinger D (1988). "Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors". *Chemosphere* 17(8): 1631-1644.
- 5. Gobas FAPC, Opperhuizen A & Hutzinger O (1986). "Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation". *Environmental Toxicology and Chemistry* 5: 637-646.
- 6. K.P., Shepard 1995. Acute oral toxicity study with "Eastman AQ" 1350 Copolyester in rats. Report No. TX--0208, The Toxicology Science Laboratory, Eastman Kodak Company, Rochester, New York, USA.
- 7. K.P., Shepard 1995. *Primary Dermal Irritation study with "Eastman AQ" 1350 Copolyester in rabbits*. Report No. TX-95-135, The Toxicology Science Laboratory, Eastman Kodak Company, Rochester, New York, USA.
- 8. K.P., Shepard 1996. Acute Eye Irritation study with "Eastman AQ" 1350 Copolyester in rabbits. Report No. TX-96-236, The Toxicology Science Laboratory, Eastman Kodak Company, Rochester, New York, USA.
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- 11. R.A., Harper 1996. Repeated Insult Patch Test with "Eastman AQ" 1350 Copolyester in humans. Report No. 95-1706-70, Hill Top Research Inc., Miamiville, Ohio, USA.
- 12. Barber, E.D., 1997. Salmonella/mammalian-microsome mutagenicity test with "Eastman AQ" 1350 Copolyester. Report No. 17906-0-409R, Corning Hazleton Inc., Virginia, USA.
- 13. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.
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- 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 Australia Publ., Sydney.
- 18. Standards Australia, 1978. Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves), Standards Association of Australia Publ., Sydney.
- 19. Standards Australia/Standards New Zealand 1994, Australian/ New Zealand Standard 2210 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ. Wellington.
- 20. 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 | 3 severe |
| | Severe | Swelling with lids half-closed to completely closed | 4 severe | considerable area around eye | |

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 |