File No: PLC/142

February 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Diahold Me

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Diahold ME

1. APPLICANTS

PAX Australia Pty Ltd of 9 Williamson Rd Ingleburn NSW 2565 and Procter and Gamble Ltd of 99 Phillip St. Parramatta NSW 2150 have jointly submitted a Synthetic Polymer of Low Concern notification statement in support of their application for an assessment certificate for Diahold ME.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report.

Characterisation as a Synthetic Polymer of Low Concern

Marketing Name:	Diahold Me
Number-Average Molecular Weight (NAMW):	> 10 000
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	0.09%
Molecular Weight < 1 000:	0.27%
Polymer Stability	Designed to be stable in the environment.
Reactivity	Not Reactive.
Particle Size	Mean particle size is 185 µm. 5.39 % < 75 µm in diameter.
Charge Density	Polymer has no charge.

Water Solubility	Practically water insoluble due to high molecular weight and high silicon content.
Method of Detection and Determination:	Infrared absorption spectroscopy (IR).

The polymer meets the criteria or assessment as a synthetic polymer of low concern under Regulation 4A of the *Industrial Chemicals Notification and Assessment Act 1989.*

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	White free flowing powder
Melting Point:	no clear melting point
Specific Gravity:	1.1 at 20°C
Vapour Pressure:	Unlikely to have significant vapour pressure due to high molecular weight.
Water Solubility:	Practically water insoluble due to high molecular weight and high silicon content (<1.0 mg/L).
Particle Size:	> 850 µm 0 500-850µm 2.1 250-500µm 29.4 150-250µm 34.9 100-150µm 24.3 75-100µm 3.9 <75µm 5.4 mean 185 µm
Partition Co-efficient (n-octanol/water):	The notified polymer is expected to have negligible solubility in water based on the high silicon content.
Hydrolysis as a Function of pH:	The notified polymer contains an ester group and Si-O bond, which may undergo hydrolysis under extreme conditions.
Adsorption/Desorption:	Determination would be difficult due to the low water solubility.

Dissociation Constant:	The notified polymer has free carboxylic acid groups which are expected to have a pK_a of 4.0 (based on propanoic acid).
Flash Point:	Not applicable.
Flammability"	Polymer not flammable. May form flammable dust-air mixtures.
Autoignition Temperature:	Not applicable.
Explosive Properties:	Not explosive.
Reactivity/Stability:	The notified polymer will react with oxidizing materials.

Comments on Physico-Chemical Properties

The notified polymer as a powder is said to have negligible solubility in its pure state as the notifier claims the 20% acrylic acid functional groups are not neutralised and do not contribute enough water solubility to render the entire molecule soluble. In the finished hair styling product, the acrylic acid is neutralised and the notifier claims that the polymer should be almost totally soluble in water. In the environmental pH range of 4-9 most will be in the anionic form above pH5 as pK_a is expected to be around 4.9 (based on propanoic acid). However, the effect of the large insoluble *t*-butyl and silicone fraction on overall solubility is unclear.

The polymer contains ester groups which may undergo hydrolysis in extreme conditions but this is unlikely to occur within the environmental pH range.

The particle size distribution was the mean of two sieve analysis.

4. PURITY OF THE CHEMICAL

Degree of Purity:	98 %
Hazardous Impurities:	Residual Monomers: 0.03% combined
Non-hazardous Impurities (> 1% by weight):	2 % water
Additives/Adjuvants:	None.

5. USE, VOLUME AND FORMULATION

The notified polymer (Diahold ME) is to be used as a component of hair styling spray products. Initially it will be imported by PAX Australia as the raw polymer to be used in the formulation of a hair spray containing 4% Diahold ME that will be fully exported. The notified polymer will not be manufactured in Australia. Additionally, Proctor & Gamble intend to import from the US, beginning June 2000, a number of finished hair care products (sprays) containing the notified polymer at concentrations ranging from 4.5-6.5%, for the Australian market.

Volume and Formulation

The polymer will be imported in packaged 80 kg plastic drums at a rate of 2.5 tonnes/annum for the purpose of formulation of hair spray products and at 2.4 tonnes/annum as a component of ready to use hair styling products.

6. OCCUPATIONAL EXPOSURE

Transport, Storage and Retailing

The notified polymer will be imported in 80 kg plastic drums, transported to and reformulated at the PAX Australia site. Diahold Me is not classified as a dangerous good. The final product is produced in aluminum aerosol canisters of 150 mL capacity. Up to 10 workers are expected to be involved in the transport and storage of the notified chemical and *ca.* 100 workers in the retail sector (supermarket, pharmacy, variety stores). Transport and Storeman/Packer workers will wear overall and safety boots should only be exposed to the notified chemical in the event of an accident. Appropriate clean-up procedures will be instigated to minimise these effects. Supermarket workers (1-2 h/day, 10 day/year) will unload the hair spray products from cartons and stack them onto shelves. It is anticipated that they may only be exposed in the event of an accident.

Formulation

Formulation operators (10-20, 8h/day, 6 days/year) are involved in manually transferring 400 kg/batch of the notified polymer from the import containers into the mixing equipment (10 000 L capacity). It is stated that the notified polymer will be blended with other ingredients in a batchwise process. Sampling for QA purposes will be collected, and once the contents approved, will be pumped via an automatic filling line to a multihead filling machine where the final product will be transferred to aluminum aerosol canisters of 150 mL capacity. The concentration of the notified polymer at this stage is 4%. Local exhaust ventillation will be provided during the filling operation. Filling line staff (10-20) operate and clean the automated and enclosed filling equipment.

In the reformulation process, the primary source of exposure to the notified chemical will be skin contact and inhalation of fine polymer particle (*ca.* 30-35 % in the inspirable range). Control measures in place include engineering controls, with the automation of all processes except the transferal of the notified chemical from the 80 kg plastic drums into the mixing equipment. Where automation is not used, Personal Protective Equipment (PPE) for personnel are used. Typically, the formulation operators will wear long sleeved overalls, a head covering, safety glasses, safety boots

and impervious gloves during handling. Filling line workers will wear disposable gloves, safety glasses, safety shoes and uniforms.

Packaging operators at the formulation plant (30-50, 8h/day, 6 days/year) will pack the aerosol cans into cartons for export. They will only be exposed to the notified polymer during sampling and running laboratory trials. They would most likely handle small samples only and would be expected to wear laboratory coats and safety glasses.

End-Use
Hairdressers will be exposed to the notified chemical in formulation while spraying for *ca.* 30 seconds from a distance of 20-25 cm. The exposure would likely be multiple applications on a daily basis. Skin and eye contact are the most likely routes of exposure to the notified chemical.

7. PUBLIC EXPOSURE

The public will only be exposed to the unformulated polymer concentrate in the event of an accidental spill. Hair spray products containing the notified polymer at up to 6.5% will be used by hairdressers and by the public. It is estimated that at-home use by individuals will result in an approximate total exposure of 10 g hair spray, 1-2 times daily.

8. ENVIRONMENTAL EXPOSURE

Release

Release to the environment of the notified polymer as a result of reformulation at the PAX Australia plant is expected to be *ca.* 1% of the import volume as residues remaining in the 'empty' drums (25 kg/year), which will be disposed of to landfill. Accidental spills at the warehouse may account for an additional 1% release of the polymer to the environment (25 kg/year). The material safety data sheet (MSDS) information supplied by the notifier indicates that spilt product should be prevented from entering waterways and would be placed in covered containers presumably for disposal to landfill. Therefore, *ca.* 50 kg/year of polymer would be disposed to landfill from the reformulation process.

Cleaning of the processing equipment at PAX Australia is expected to produce 50 kg of final product, containing 4% notified polymer (2 kg of waste polymer/batch). The notifier intends to produce 6 batches/year, *i.e.* 12 kg of waste polymer in the washings which will be sent to the on-site treatment system before being discharged to the sewer.

None of the finished hair spray produced at the PAX Australia plant will be released to the Australian environment by end users as it all intended for export to south-east Asia.

The 2.4 tonnes of notified polymer that will be imported by Proctor & Gamble as the finished aerosol hair spray products will not undergo any reformulation or repackaging in Australia, but will be sent directly to the retail market. These products will contain the polymer at concentrations of 4.5-6.5% and will be sold in 150 mL aerosol canisters. The notifier estimates that *ca.* 50% of the product will be wasted into the air with the other 50%

being applied to the hair. All of the 1.2 tonnes/year of polymer will eventually be released to the sewer after the product is washed from the hair.

This notifier has estimated that 2% of the product will remain as residue in the 'empty' aerosol cans and will be disposed of to landfill with the domestic garbage.

Fate

Most of the waste polymer, *ca.* 50 kg/year, produced during the reformulation process at the PAX Australia plant would be deposited to landfill. The raw insoluble polymer is expected to remain associated with the soil and not undergo leaching into the waterways. The notifier claims that waste final product would be far more water soluble so would most likely become mobile in the aquatic environment through leaching from the landfill sites. However, the effect of the large insoluble silicon portion of the structure makes the fate unclear as the molecule may adhere to sediments and soil.

The wash water from the cleaning of the processing equipment will be released to the sewer after passing through the on-site waste water treatment system. The notifier claims that the polymer waste, *ca.* 12 kg/year is water soluble. However, it is unclear what the ultimate environmental fate would be and some adherence to soil particles would be expected.

All polymer imported in the finished hair styling sprays by Proctor & Gamble will be used in the Australian domestic market. The notifier has estimated that 2% of the product will remain as residue in the 'empty' aerosol cans after use and will be disposed of to landfill with the domestic garbage, from where it will gradually be released when the cans are destroyed. The notifier estimates that *ca.* 50% of the hair spray would adhere to the hair during use and it would all (1200 kg/ year) be released to the sewer when washed from the hair. However, some further hair spray would be expected to adhere to the clothing of the end users and also eventually enter the sewer when the clothing is washed (the assessment estimates that a further 700 kg/year is possible). This release would be in a very diverse manner, nationwide. Due to the potential water solubility of the polymer in the final product this material would not become associated with soil or sediments but would remain in the water until it was gradually broken down by slow environmental processes.

However, as noted above the effect of the silicone portion is unclear. Silicone polymers are generally not biodegradable, or susceptible to rapid abiotic degradation (*eg* hydrolysis) so the polymer could be expected to be persistent in the environment. However, some environmental processes, contact with dry clay soils in particular, create the potential for rearrangement of the structures causing the formation of volatile cyclic structures and water soluble siloxanols (Buch & Ingebrigtson, 1979).

Biodegradation is unlikely. The high molecular weight of the substance also means that bioaccumulation is not likely to occur (Gobas *et al.* 1986; Anliker *et al.* 1988).

9. EVALUATION OF TOXICOLOGICAL DATA

Several toxicological studies were provide by the notifier. Most were for the notified chemical, however, a number were for a hair spray formulation containing the notified chemical at 27.3 %.

Summary of the Acute Toxicity of Diahold ME and Diahold ME in Formulation

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity (Diahold Me)	Sprague-Dawley Rats	LD_{50} > 2000 mg/kg	Ikeda, 1995a
Acute oral toxicity (Hair spray formulation)	Sprague-Dawley Rats	LD_{50} > 2000 mg/kg	Ikeda, 1995b
Acute dermal irritation (Diahold Me)	Japanese White rabbits	Not irritating	Oigawa, 1995a
Acute dermal irritation (Hair spray formulation)	Japanese White rabbits	slightly irritating	Oigawa, 1995b
Acute eye irritation (Diahold Me)	Japanese White rabbits	Not irritating	Oigawa, 1995c
Acute eye irritation (Hair spray formulation)	Japanese White rabbits	slightly irritating	Oigawa, 1995d
Skin sensitisation	Hartley guinea pigs	non-sensitising	Ikeda, 1995c
Cumulative skin irritation	Japanese White rabbits	not irritating	Oigawa 1995e
Phototoxicity (Morikawa Method)	Hartley guinea pigs	No phototoxicity observed	Oigawa, 1995f
Phototoxicity (Modified Morikawa Method)	Hartley guinea pigs	No phototoxicity observed	Oigawa, 1995g
Photosensitisation	Hartley guinea pigs	No photosensitivity observed	Oigawa, 1995h

Summary of the Repeated Inhalational and Genotoxicity Studies of Diahold ME and Diahold ME in Formulation

Test	*Species*	*Outcome*	*Reference*
Repeated Dose Inhalation Toxicity	Fischer 344 rats	No treatment-related findings were observed on any parameter	Mandella, 1998
Ames Test	*S. typhimurium* (TA 1535, TA 1537, TA 1538, TA 100, TA98); *E. coli* WP2*uvrA*-	No mutagenic activity between 313 and 5000 µg/plate, either in the presence or absence of S9 metabolic activation.	Nishitomi, 1995a
Chromosomal Aberration Test *In Vitro*	Cell line CHL/IU from lungs of female Chinese hamster	No clastogenic activity was observed.	Nishitomi, 1995b
Micronucleus Test in Bone Marrow	ICR mice	At doses up to 2000 mg/kg, no clastogenicty or damage to mitotic apparatus in bone marrow cells observed.	Mizuno, 1995

9.1 Acute Toxicity

9.1.1 Oral Toxicity (Diahold Me) (Ikeda, 1995a)

Species/strain:	Rat/Sprague-Dawley albinos
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Gavage; 0.5 % (w/v) aqueous solution of carboxymethyl cellulose; dose 1.0 mL/100 g body weight.
Test method:	Limit test, OECD TG 401
Mortality:	There were no deaths during the study.
Clinical observations:	No signs of systemic toxicity were noted during the study.
Morphological findings:	No abnormalities were detected on day 14.
LD_{50}*:*	> 2 000 mg/kg.
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Oral Toxicity (Hair Spray Formulation) (Ikeda, 1995b)

Species/strain:	Rat/Sprague-Dawley albinos
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Gavage; 2000 mg/kg in 72.3% aqueous solution; dose 1.0 mL/100 g body weight.
Test method:	Limit test, OECD TG 401
Mortality:	There were no deaths during the study.
Clinical observations:	No signs of systemic toxicity were noted during the study.

Morphological findings: No abnormalities were detected on day 14.

LD_{50}: >2 000 mg/kg.

Result: The hair spray formulation was of low acute oral toxicity in rats.

9.1.3 Skin Irritation (Diahold Me) (Oigawa, 1995a)

Species/strain: Rabbits/Japanese White

Number/sex of animals: 3/female

Observation period: Animals were examined for dermal reactions 1, 24 and 48 hrs after test substance application.

Method of administration: 1g of the test material, as supplied, in 1:1 white vasoline was applied by a closed patch method to intact and abraded skin for 24 hrs.

Test method: Draize method (closed patch). The method differed from OECD TG 404 in the following areas:

- Exposure period was 24 hr instead of 4 hr maximum;
- Draize scores were taken after 1, 24 and 48 hrs after patch removal, *cf.* with 24, 48 and 72 hrs in the OECD method
- 1 g of the test substance was administered instead of 0.5 g.

Draize Scores:

Time after treatment (hours)	***Animal #***					
	1	***2***	***3***	***1***	***2***	***3***
	intact skin	***intact skin***	***intact skin***	***abraded skin***	***abraded skin***	***abraded skin***
Erythema						
1	1	0	0	0	0	0
24	0	0	0	0	0	0
48	0	0	0	0	0	0

Comments:	After exposure, slight erythema was observed on the intact skin of one animal one hour after patch removal (see table above). All Draize scores for oedema were zero. No other dermal reactions were observed.
Result:	Under the conditions of the study, the notified chemical was not irritating to the skin of rabbits

9.1.4 Skin Irritation (Hair Spray formulation) (Oigawa, 1995b)

Species/strain:	Rabbits/Japanese White
Number/sex of animals:	3/female
Observation period:	Animals were examined for dermal reactions 24, 48 and 72 hrs after test substance application.
Method of administration:	500 µL of the test material, containing 72.3 % denatured alcohol, was applied by a closed patch method to intact and abraded skin for 24 hrs in two methods: (i) 500 µL was placed on a gauze patch and applied immediately and (ii) the denatured alcohol component was evaporated at room temperature (35 min) from the patch and the remaining semidry material was then applied.
Test method:	Draize method (closed patch). The method differed from OECD TG 404 in the following areas: ▪ the exposure period was 24 hrs instead of 4 hrs maximum ▪ Draize scores were taken after 1, 24 and 48 hrs after patch removal, *cf.* to 24, 48 and 72 hrs in the OECD method.

(i) Draize scores: Liquid formulation

Time after Treatment (hours)	*Animal #*					
	1	*2*	*3*	*1*	*2*	*3*
	intact skin	*intact skin*	*intact skin*	*abraded skin*	*abraded skin*	*abraded skin*
Erythema						
1	0	0	1	1	0	1
24	0	0	0	0	0	0
48	0	0	0	0	0	0

All Draize scores for oedema were zero.

(ii) Dried formulation; all Draize scores for both erythema and oedema were zero.

Comment — For the liquid formulation, slight erythema was observed on the intact skin of one animal and on the abraded skin of two animals one hour after patch removal (see table above). No other dermal reactions were observed. It appeared that the slight irritation observed with the liquid formulation may have been due to the alcohol present.

Result: — Under the conditions of the study, the hair spray formulation containing the notified chemical was slightly irritating to the skin of rabbits.

9.1.5 Acute Eye Irritation (Diahold Me) (Oigawa, 1995c)

Species/strain: — Rabbit/ Japanese White

Number/sex of animals: — 3/female

Observation period: — Animals were examined for eye lesions 1, 24, 48 and 72 hrs after test substance application.

Method of administration: — 10 µL of the test material (7.9 mg) was applied as supplied on the cornea the right eye of each animal; the left eye served as the control; the treated eyes remained unwashed for 24 hrs.

Test method: — According to low volume eye irritation procedure (ASTM 1985).

Comments:	After administration, no eye irritation reactions were observed in any animal. No abnormal clinical findings or abnormal body weight changes ascribed to the application of the notified chemical were observed in any animal.
Result:	The notified chemical was tested under non-OECD guidelines; under the test conditions, the notified chemical was not irritating to the eye.

9.1.6 Acute Eye Irritation (Hair Spray Formulation) (Oigawa, 1995d)

Species/strain:	Rabbit/Japanese White
Number/sex of animals:	12/female
Observation period:	Animals were examined for eye lesions 1, 24, 48 and 72 hrs after the formulated hair spray application.
Method of administration:	10 µL of the test material was applied as supplied on the cornea the right eye of each animal in the test chemical and solvent control group; the left eye served as the control; 6 animals were in an eye-unwashed group, and 6 in a washed group.
Test method:	According to low volume eye irritation procedure (ASTM 1985).

Table 1a. Individual scores of ocular reactions: Diahold Me in formulation (Unwashed eye)

	Score of ocular reactions					
	Observation	***Cornea***	***Iris***	***Conjunctivae***		
	time (hrs)	***Opacity***	***Area***	*Redness*	*Chemosis*	*Discharge*
Animal #						
1	1	0	0	1	1	2
	24	0*/ -	0	1	1	1
	48	0 0	0	1	0	0
	72	0 0	0	0	0	0
		0 0				
2	1	0 0	0	1	1	2
	24		0	1	1	1
	48	0 0	0	1	0	0
	72	0 0	0	0	0	0
		0 0				
3	1	0	0	1	1	1
	24	0/-	0	1	1	1
	48	0 0	0	1	0	0
	72	0 0	0	1	0	0
		0 0				

*: Score without fluorescein / Score with fluorescein. -: no findings

Table 1b. Individual scores of ocular reactions: Diahold Me in formulation (washed eye)

	Score of ocular reactions					
	Observation	***Cornea***	***Iris***	***Conjunctivae***		
	time (hrs)	***Opacity***	***Area***	*Redness*	*Chemosis*	*Discharge*
Animal #						
7	1	1	0	1	1	0
	24	2*/2	0	1	0	0
	48	1	0	1	0	0
		1				
	72	0	0	1	0	0
		0				
		0				
		0				
8	1	0	0	1	1	0
		1				
	24		0	1	0	0
	48		0	1	0	0
			0			
	72		0	1	0	0
			0			
			0			
			0			
9	1	1	0	1	1	0
		1/1				
	24		0	1	0	0
	48	1	0	1	0	0
		1				
	72	0	0	1	0	0
		0				
		0				
		0				

*: Score without fluorescein / Score with fluorescein. -: no findings

Table 1c Individual scores of ocular reactions: Solvent (Unwashed eye)

	Score of ocular reactions						
	Observation	***Cornea***		***Iris***	***Conjunctivae***		
	time (hrs)	***Opacity***	***Area***		*Redness*	*Chemosis*	*Discharge*
Animal #							
4	1	1		0	1	1	1
	24	2*/-		0	1	0	3
	48	1	1	0	1	0	0
	72	0		0	1	0	0
	4 days	0		0	1	0	0
	7 days	0		0	0	0	0
		0					
		0					
		0					
5	1	0	2*/ -	0	1	1	2
	24	0	0	0	1	1	1
	48	0	0	0	1	0	0
	72	0	0	0	0	0	0
	4 days	0		0	1	0	0
	7 days	0		0	0	0	0
		0					
		0					
6	1	1		0	1	1	1
	24	2/-		0	1	1	1
	48	1		0	1	0	0
	72	1		0	1	0	0
	4 days	0		0	0	0	0
		0					
		0					
		0					

*: Score without fluorescein / Score with fluorescein. -: no findings

Table 1d. Individual scores of ocular reactions: Solvent (washed eye)

Score of ocular reactions							
	Observation	***Cornea***		***Iris***	***Conjunctivae***		
	time (hrs)	***Opacity***	***Area***		*Redness*	*Chemosis*	*Discharge*
Animal #							
10	1	1	2*/	0	1	1	0
	24	3		0	1	0	0
	48	0		0	1	0	0
	72	0		0	1	0	0
	4 days	0		0	0	0	0
		0					
		0					
		0					
11	1	1		0	1	1	2
	24	2/2		0	1	1	1
	48	1		0	1	0	0
	72	1		0	0	0	0
	4 days	0		0	1	0	0
		0					
		0					
		0					
12	1	1		0	1	1	0
	24	2/3		0	1	0	2
	48	1		0	1	0	0
	72	1		0	1	0	0
	4 days	0		0	0	0	0
		0					
		0					
		0					

*: Score without fluorescein / score with fluorescein. -: no findings

Comments:

For both washed and unwashed eyes, the Draize scores for the formulation (in Tables 1a and 1b) were similar to the corresponding scores for the solvent only (denatured alcohol). If anything, the scores for the solvent were slightly higher for both washed and unwashed eyes. These results indicate that irritation is due to the solvent alcohol rather than the notified chemical.

Result: Under the conditions of the study, the hair spray formulation containing the notified chemical was slightly irritating to the eyes of rabbits. The solvent in the formulation was also slightly irritating to the eyes of rabbits.

9.1.7 Skin Sensitisation (Buehler Method) (Ikeda, 1995c)

Species/strain: Guinea pig/ Hartley White

Number of animals: 25/male

Induction procedure: The animals were separated into 4 groups:

- Test substance group: Diahold Me (10% in 70 % ethyl alcohol): 10 animals
- Test substance control group: 70% ethyl alcohol: 5 animals
- DNCB (0.1 % 2,4-dinitrochlorobenzene) group: 5 animals
- Control group (acetone): 5 animals

One day before induction exposure, the fur was shaved on the left flank. On the day of exposure, a cotton flannel patch with 400 µL of the test material was applied and covered with an occlusive adhesive sheet. Induction was conducted three times at one-week intervals.

Challenge procedure:

- Test substance group: Diahold Me (10% in 70 % ethyl alcohol): 10 animals
- Test substance control group: 10% Diahold Me, 70% ethyl alcohol) 5 animals
- DNCB (0.1 %) group: 5 animals
- DNCB control group 0.1 % DNCB : 5 animals

One day before challenge exposure, the fur was shaved on the right flank. Fourteen days after the final induction, the test materials were applied and covered by an occlusive sheet (6 hrs) as described above.

Test method: According to OECD TG 406 test guidelines

Comments: No positive skin reactions were observed in any animal in the test substance group and the test

substance control group after challenge. In the DNCB group, positive skin reactions were observed in all animals, and no skin reactions were observed in any animal in the DNCB control group. No animals showed abnormal clinical signs or body weight change.

Result: The notified chemical was non sensitising to the skin of guinea pigs

9.1.8 Phototoxicity (Oigawa, 1995f) (Morikawa Method)

Species/strain: Guinea pig/ Hartley White

Number/sex of animals: 10/female

Method of administration: Diahold Me in ethyl alcohol and ethyl alcohol alone were applied topically to shaved surfaces. UV irradiation (UVA emitted light, 11.2 J/cm^2) was initiated 30 min after chemical application at *ca.* 10 cm from the skin. Irradiation was conducted through a 5 mm-thick glass filter to eliminate short-wave energy <320 nm), found to induce skin erythema.

Dose/Study duration: 30 µL of a paste containing 10 % Diahold Me in 70 % ethyl alcohol was placed on pre-shaved fore and hind legs on both irradiated and nonirradiated sides. Positive control 8-methoxypsoralen (8-MOP) was 0.005 % (w/v) in 70 % alcohol.

Test method: Diahold Me and solvent controls were applied according to Morikawa *et al.* (1974).

Clinical observations: Observations were made at 1, 2, and 3 days after irradiation. No abnormal clinical signs were noted during the study. No body weight loss was observed.

Comments: No skin reactions were observed at the sites treated with Diahold Me or solvent alone on either the irradiated or nonirradiated sites. All Draize scoring for these groups were 0. Positive scoring was observed with 8-MOP.

Result: Diahold Me has no phototoxicity potential on guinea pigs' skin under the stated conditions.

9.1.9 Phototoxicity (Modified Morikawa Method) (Oigawa, 1995g)

Species/strain: Guinea pig/ Hartley White

Number/sex of animals: 10/female

Method of administration: Diahold Me in ethyl alcohol and ethyl alcohol alone were applied topically to shaved surfaces. UV irradiation (UVA at 11.2 $J.cm^{-2}$ x 41 min and UVB at 0.15 $J.cm^{-2}$ x 15 min) was applied from 30 min after chemical application at *ca.* 50 cm from the skin. Irradiation was conducted through a 5 mm-thick glass filter to eliminate short-wave energy <320 nm), found to induce skin erythema.

Dose/Study duration: A paste containing 30 µL of 0.05 g of Diahold Me in 1 mL of ethyl alcohol (70 %) was placed on pre-shaved fore and hind legs on both irradiated and nonirradiated sides. Positive control 8-methoxypsoralen (8-MOP) was 0.005 % (w/v).

Test method: Diahold Me and solvent controls were applied according to the UVA and UVB modified method (Morikawa *et al.,* 1974).

Clinical observations: Observations were made at 1, 2, and 3 days after irradiation. No body weight loss or abnormal clinical signs were noted during the study.

Comments: No skin reactions were observed at the sites treated with Diahold Me or solvent alone on either the irradiated or nonirradiated sites. All Draize scoring for these groups were 0. Positive scoring was observed with 8-MOP.

Result: Diahold Me has no phototoxicity potential on guinea pigs skin under the stated conditions.

9.1.10 Photosensitisation (Harber Method) (Oigawa, 1995h)

Test substance:	Diahold Me
Controls:	solvent: 70% ethyl alcohol positive control: 3,5,4'-tribromosalcylanilide (TBS)
Species/strain:	Guinea pig/ Hartley White
Number/sex of animals:	20/male (10 for Diahold Me; 5 for each control group)
Induction procedure	0.1 mL of paste containing 2% Diahold Me in 70% ethyl alcohol was placed on pre-shaved sides of the midline of the back. After 30 min., a medium wavelength UV light (UVB, 1 $J.cm^{-2}$) was applied at a distance of *ca.* 20 cm, followed by long wavelength UV light (UVA, 30 $J.cm^{-2}$) at *ca.* 10 cm. The irradiation was repeated 3 times at 2-day intervals. The solvent and positive control (2% TBS in 70% ethyl alcohol) groups were treated similarly.
Challenge procedure:	21 days after the final induction exposure, 0.05 mL of 10% Diahold Me in 70% ethyl alcohol was applied as for induction. After 30 min., a long wavelength UV light (9 $J.cm^{-2}$) was applied at a distance of *ca.* 10 cm. The solvent control group was treated similarly with 10% Diahold Me in 70% ethyl alcohol. The positive control group was challenged with 1% TBS in 70% ethyl alcohol.
Test method:	Diahold Me and solvent controls were applied according to Harber & Shalita (1975).
Clinical observations:	Observations were made at 1, 2, and 3 days after irradiation. No body weight loss or abnormal clinical signs were noted during the study.
Comment:	No skin reactions were observed at the sites treated with Diahold Me or solvent alone on either the irradiated or nonirradiated sites.

Result:	Diahold Me has no photosensitivity potential on guinea pigs' skin under the stated conditions.

9.2 Repeated Dose Toxicity Studies

9.2.1 28-Day Cumulative skin irritation (Oigawa 1995e)

Species/strain:	Rabbit/Japanese White
Number/sex of animals:	10/female
Method of administration:	Diahold Me was applied on the clipped skin without occlusion
Dose/Study duration:	300 µL in a 1:1 (wt/wt) mixture of white vaseline once daily for 28 days. Vaseline was applied to the control group in the same manner.
Test method:	No method cited, however the Draize scoring method was used
Clinical observations:	No abnormal signs were noted during the study.
Clinical chemistry/Haematology	None reported.
Comments:	In the test substance group, an erythema score of 1 was observed in all animals. In the control group, an erythema Draize score of 1 or 2 was observed in all animals. In some cases, the erythema disappeared temporarily. Papules were also observed in three animals, which disappeared temporarily mid-phase of the application period. Papules were observed in one animal and red spots in another. At the final observation, the integrated mean score of erythema (maximum value: 112) was 25.6 in the vaseline applied group and 10.8 in the Diahold Me applied group.
Histopathology:	After the final skin examination, inflammatory changes were shown on the applied sites of both groups. It was stated that these observed changes in the control and the test substance groups were ascribed to vaseline being used as a vehicle as the findings and their degree were found similar.

Result:	It was observed that the notified chemical has no cumulative skin irritation ascribed to repeated application under the conditions of this study.

9.2.2 Repeated Dose Inhalation Toxicity (Mandella, 1998)

This study was designed to assess the potential testicular effects of Diahold Me, in particular, the weights and histopathology of the testes and epididymides after 13-weeks of inhalation in rats via whole body exposure at exposure levels of 1, 2 and 6 mg/m^3.

Species/strain:	Rat/Fisher 344
Number/sex of animals:	40/male (10/group)
Observation period:	13 weeks.
Method of administration:	Whole-body exposure via inhalation. The notified chemical was generated as a dust of particle size *ca* 2 µm at target doses of 0, 1.0, 3.0 and 6 mg/m^3 (measured concentrations were 0, 1, 3 and 5.9 mg/m^3). Duration of exposure was 6 hrs/day, generally 5 day/week for a total of 65 exposures.
Test method:	There were no guidelines for this clarification study. The original 13-week study followed USEPA 1-3 and OECD guidelines. Complete macroscopic postmortem examinations were performed, examining the external surfaces and all orifices, the external surfaces of the brain and spinal cord, the organs and tissues of the cranial, thoracic, abdominal and pelvic cavities and neck; and the remainder of the carcasses for any macroscopic morphological abnormalities. Statistical analyses were performed for body weight, cumulative body weight change, food and water consumption and organ weights. No clinical chemistry/haematology was performed.
Mortality:	There were no deaths during the study.

Clinical observations:	Observations included chromodacryorrhea and nasal discharge. Laboured breathing was observed in one high-exposure (6 mg/m^3) animal on day 20, in an isolated case. There were no test material-related abnormalities observed during weekly physical examinations. Mean body weights and body weight gains from Day 0 in all groups exposed to the test material were non-dose related and a statistically significant 5 % higher than the control group at various intervals throughout the study.
Pathology:	There was a statistically significant (5 %) increase in the mean ratio of the combined testes weight to brain weight in mid-exposure (3 mg/m^3) *cf.* to the control group. Additionally, there was a statistically significant increase in the right testes in the high-exposure (6 mg/m^3) group. However, the weights relative to body and brain weights were comparable to the control values and was hence concluded not toxicologically significant. No abnormalities were detected on Day 98. There were statistically significant increases in organ weight ratios, however these variations were not dose-related and/or were comparable to control values and historical control values.
Histopathology:	All organs were preserved, however only the brain, epididymides and testes from 0, 6 and one of 1 mg/m^3 test animals were examined. Degradation/atrophy of germinal epithelium was observed in 4 rats- one from the higher dose, two from the low-dose and one control. In 2 cases (1 high-dose, I low-dose), the effect was severe and accompanied by multinucleated spermatids. The historical control values reported for this strain and effect were 20-30 %.
Comment:	Microscopic findings, including degeneration /atrophy of the germinal epithelium, were observed. However, these effects were not dose-related and were similar to historical control values reported

for Fisher 344 rats. In general, testes and epididymides weights were similar to control values or within the historical control range.

Result: There were no significant dose-related adverse effects on the weights and histopathology of the testes and epididymides of the rat after 13-weeks inhalation via whole-body exposure up to the max 6 mg/m^3 dose for Diahold Me.

9.3 Genotoxicity

9.3.1 *S. typhimurium* and *E. coli* Reverse Mutation Assay (Nishitomi, 1995a)

Strains: *S. typhimurium* strains:TA98, TA100, TA1535, TA1537 and E. *coli* WP2*uvrA*-

Concentration range: 313, 625, 1250, 2500 and 5 000 µg/plate

Metabolic activation: Rat liver S9 fraction from animals pretreated with phenobarbital and β-napthoflavone.

Test method: OECD TG 471 and 472

Comments: In each tester strain, the number of revertant colonies was less than double the solvent control value, hence was judged negative. Precipitation was observed at concentrations at ≥ 1250 µg for both test substance and solvent controls. There was no evidence of cytotoxicity at the highest concentration of 5000 µg.

Result: The notified chemical was not considered mutagenic in the bacterial strains tested in the absence or presence of metabolic activation provided by rat liver S9 fraction.

9.3.2 Chromosomal Aberration Test *In Vitro* (Nishitomi, 1995b)

Cells:	CHL/IU from the lungs of a female Chinese hamster
Doses:	test group 1: 1250, 2500 and 5000 µg/mL of Diahold Me (24 and 48 hr treated groups without metabolic activation) test group 2: 1250, 2500 and 5000 µg/mL (6 hr treated group with S9 metabolic activation) Control groups: (i) negative control: Sodium carboxymethylcellulose (ii) positive controls: Mitomycin C (MMC) and Benzo [a] pyrene (BP)
Metabolic Activation System:	rat liver S9 fraction from animals pretreated with phenobarbital and β-napthoflavone
Test method:	OECD TG 474
Treatment Regime:	test group 1: test material or positive control was preincubated to cell cultures in serum free medium, with 50 µL/mL S9 mix (4 hrs); the cells were then washed and cultured in fresh complete medium for a total time of 18 or 28 hrs. test group 2: test material or positive control was added to cell cultures in complete medium for a total time of 18 or 28 hrs without a change of medium. Colcemid was added to all cultures 2.5 hrs before harvest to arrest cells in metaphase.
Comments:	The notified substance did not increase the number of cells with chromosome aberrations or polyploids as compared with the negative control, either in the absence or presence of metabolic activation, at concentrations of up to 5000 µg/mL
Results:	Diahold Me is not clastogenic under the test conditions employed.

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Mizuno, 1995)

Test substance:	Diahold ME
Species/strain:	Mice/ICR: Crj:CD-1
Number and sex of animals:	5/Male
Doses/Method of administration:	Test substance 500 mg/kg (low), 1 000 mg/kg (mid) or 2 000 mg/kg (high); twice at 24-hour intervals Vehicle control olive oil; (orally, 10 mL/kg/day) Positive control Cyclophosphamide 40 mg/kg was administered intraperitoneally once only.
Sampling schedule:	Vehicle control, low, mid and high dose animals were sacrificed 24 hrs after dosing. The remaining animals of the vehicle control group and high dose animals were sacrificed 48 hrs after dosing. The positive control group animals were sacrificed 24 hrs after dosing.
Clinical observations:	No mortality or clinical signs of toxicity.
Test method:	OECD TG 475
Micronuclei score:	No significant increase in micronucleated polychromatic erythrocytes (PCEs) due to treatment with test substance at either sampling time; the positive control caused a significant increase in micronucleated PCEs.
Result:	Diahold Me did not induce a significant increase in micronucleated PCEs in bone marrow cells of the mouse *in vivo*.

9.4 Overall Assessment of Toxicological Data

Toxicological data were provided for the notified chemical and a hair spray formulation containing 27.3% of the notified chemical.

Diahold Me
The notified chemical was of very low acute oral toxicity in the rat (LD_{50} > 2000 mg/kg). It was not a skin or eye irritant in the rabbit, however, the applied dose was lower than the OECD set guidelines and the exposure time was longer. No cumulative skin irritation was observed in a 28-day repeated dose study. In guinea-pig studies, it was not a skin sensitiser, phototoxic agent or photosensitiser. In genotoxicity studies, Diahold Me tested negative in an Ames test and was not clastogenic *in vitro* and *in vivo*.

A 13-week repeated dose inhalational study focussed on the effects of Diahold Me on the testes and epididymes of the male rat. No effects were observed at the maximum dose of 6 mg/m^3 (0.006 mg/L). This dose is low and apparently the study was carried out to clarify observations from an earlier study, however, details of the earlier study were not provided.

Based on the studies provided, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994).

Hair Spray Formulation
The formulation was of very low acute oral toxicity in the rat (LD_{50} > 2000 mg/kg). It was a slight skin and eye irritant in the rabbit, however, the studies indicated that irritation was due to ethyl alcohol in the formulation, that is the notified chemical did not add to the toxicity of the solvent.

Based on the studies provided, the formulation is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided which is acceptable for polymers of low concern with a NAMW greater than 1000 according to the *Industrial Chemicals (Notification and Assessment) Act 1989.*

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The waste raw polymer produced in the reformulation process at PAX Australia will be disposed of to landfill. It is practically insoluble and will only be slowly degraded by biological and bacteriological processes. Any waste of the final product in which the polymer is claimed to be water soluble will also be deposited to landfill and will very gradually leach into the water compartment as the containers break down.

The wash water used to clean the processing equipment will be released to the sewer after treatment on-site. This accounts for 12 kg/year or 2 kg/batch of the notified polymer and will be diluted with water during the washing process.

If it is assumed that 80% of the imported hair spray adheres to the hair and clothing and eventually enters the sewer, *ca.* 1900 kg of notified polymer will be expected to enter the aquatic environment. This would be released in very low concentrations and in a very diffuse manner across Australia. The following Predicted Environmental Concentration (PEC) assumes that 150 L of sewage are generated each day/person. The high water solubility of the polymer in the final product indicates that the polymer would remain in the water compartment and little would become associated with the organic component of soils, sediments or sludge from the treatment plants.

The resultant PEC in receiving waters would be:

Amount released to sewer	1900 kg
Population (national)	18 000 000
Sewage Volume (national)/year	985 x 10^9 L/year
Mean Concentration in sewerage	1.9 µg/L

On release to receiving waters after treatment at the sewage treatment plant, the effluent is assumed to be diluted by a factor of 10. This gives a final PEC of 0.19 µg/L. Although the notifier has not submitted any ecotoxicological data, the compound contains no functional groups known to be toxic to aquatic organisms. Consequently release of the polymer to the water compartment at the estimated levels is unlikely to present a hazard to the environment. However, silicone polymers are generally not biodegradable or susceptible to rapid abiotic degradation (*eg* hydrolysis) so the polymer could be expected to be persistent in the environment.

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

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Toxicological data were provided for the notified chemical and a hair spray formulation containing 27.3% of the notified chemical.

Diahold Me

The notified chemical was of very low acute oral toxicity in the rat (LD_{50} > 2000 mg/kg). It was not a skin or eye irritant in the rabbit, however, the applied dose was lower than the OECD set guidelines and the exposure time was longer. No cumulative skin irritation was observed in a 28-day repeated dose study. In guinea-pig studies, the notified chemical was not a skin sensitiser, phototoxic agent or photosensitiser. In genotoxicity studies, Diahold Me tested negative in a battery of Ames tests and was not clastogenic *in vitro* and *in vivo*. A 13-week repeated dose inhalational study focussed on the effects of Diahold Me on the testes and epididymes of the male rat. No effects were observed at the maximum dose of 6 mg/m^3 (0.006 mg/L). This dose is low and apparently the study was carried out to clarify

observations from an earlier study, however, details of the earlier study were not provided.

The notified polymer is practically insoluble in water and has a high number average molecular weight (26800), which is sufficiently high to prevent passage across biological membranes. The level of lower NAMW species is small (0.27 % below 1000 and 0.09 %. Below 500). In particulate form, *ca.* 30-35 % of the polymer is in the inspirable range, however the population of respirable particles is expected to be well below 5 %.

Based on this information, the formulation is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1994).

Hair Spray Formulation
The formulation was of very low acute oral toxicity in the rat (LD_{50} > 2000 mg/kg). It was a slight skin and eye irritant in the rabbit, however, the studies indicated that irritation was due to ethyl alcohol in the formulation. Based on the studies provided, the test chemical in formulation is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1994).

Occupational Health and Safety

Transport And Storage
The ready-to-use hair spray products will contain the notified polymer at a maximum concentration of 6.5%. Risk of exposure during transport and storage from these ready-to-use products or the notified chemical is considered negligible in the absence of an accident. In the event of a spill, exposure would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier. The risk of adverse health effects for transport and storeman/packer workers transport is considered low.

Formulation
In the reformulation process, the primary source of exposure to the notified chemical will be its manual transferal from 80 kg plastic drums when the powdered chemical is opened and emptied into the mixing equipment. The remaining processes are automated. However, exposure to the chemical may occur during connection/disconnection of containers to transfer lines and during cleaning and maintenance of mixing and filling equipment. There exists potential for exposure by inhalation and/or skin and eye contact with dust particles with the associated health effects of respiratory and eye irritation. Skin absorption is unlikely due to the high molecular weight of the polymer. Given this risk of adverse health effects during this stage of the formulation process, local exhaust ventilation and dust extraction need to be maintained over mixing areas to capture dust and aerosols at source, and minimise exposure to airborne particulates generated from the notified chemical and any other ingredients. The provision of engineering controls will also serve to reduce the likelihood of potentially flammable dust clouds in the work area. Personal Protective Equipment (PPE) for workers should be used. Typically, the formulation operators will wear long sleeved overalls, a head covering, safety glasses, safety boots and impervious gloves during handling to minimise skin contact. The wearing of an air purifying dust respirator with P3 particulate filter may be

required. The NOHSC exposure standard for inspirable dust (10 mg/m^3 TWA) will need to be adhered to in the workplace.

Filling operators are potentially exposed to the notified polymer at a lower concentration and by skin contact only, hence the risk of adverse effects arising from the polymer is low. Similarly, laboratory personnel will usually be exposed to small amounts of polymer for brief periods only and packaging operators will only be exposed in the event of spillage. Therefore, the health risk to these workers is low and will be minimised by the wearing of the standard protective equipment required to address routine hazards in the workplace.

The risk of adverse health effects to retail outlet workers is expected to be due to the low toxicity of the polymer and the low probability of exposure.

End use
Hairdressers are likely to receive frequent, repeated or prolonged dermal contact to hair setting agent containing the notified chemical. As above, there is negligible risk of systemic toxicity following repeated or prolonged exposure. However, the risk of skin irritation cannot be excluded, particularly so as hairdressers by occupation are likely to have a compromised skin barrier function. Good hygiene practices, such as prompt removal of contaminants from the skin will be required to reduce the risk of adverse skin effects.

Although the notified chemical is present at a low concentration of 4.0%, there exists a risk of skin sensitisation, and possibly eye irritation from prolonged exposure.

Public Health
The public will only be exposed to the unformulated polymer concentrate in the event of an accidental spill. There will be inhalational exposure to the formulated hair spray products during home use. However, the low toxicity, high NAMW and relatively large particle size of the polymer suggests that potential hazard from inhalational exposure to the notified polymer in hair spray products is likely to be low. Therefore, it is considered that the notified polymer will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Diahold ME, the following guidelines and precautions should be observed:

Formulation workers:

- The generation of dust clouds should be prevented to avoid the risk of inhalation and fire. Appropriate respiratory devices should conform to AS 1337 [Standards Australia/Standards New Zealand, 1994];

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992) industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990) impermeable gloves or mittens should conform to AS 2161 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- 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;

Hairdressers:

Hairdressers are encouraged to consult guidance documents for identifying and managing health risks in hairdressing that have been published by some state occupational health and safety authorities (Division of Workplace Health and Safety, 1994); [WorkCover NSW, 1997); [WorkCover Corporation, 1996). The notifier should advise the hairdressing industry of the availability of state government publications in addition to any current industry codes.

All workers:

- Good personal hygiene should be practiced to minimise the potential for ingestion;

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (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 subsection 64(1) of the Act, secondary notification may be required if the polymer characteristics cease to satisfy the criteria under which it has been accepted under subsection 64(2) of the Act as a Synthetic Polymer of Low Concern.

Secondary notification of the notified polymer may be required if

(i) any of the circumstances stipulated under that subsection arise.

(ii) If the conditions of use are varied such that greater exposure of the public may occur. Further information may be required to assess the hazards to public health.

(iii) If the method of use changes in such a way as to greatly increase the environmental exposure of the notified polymer, or if additional information becomes available on adverse environmental effects of the polymer.

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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		

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