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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Luviquat Hold

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in Luviquat Hold

1. APPLICANT

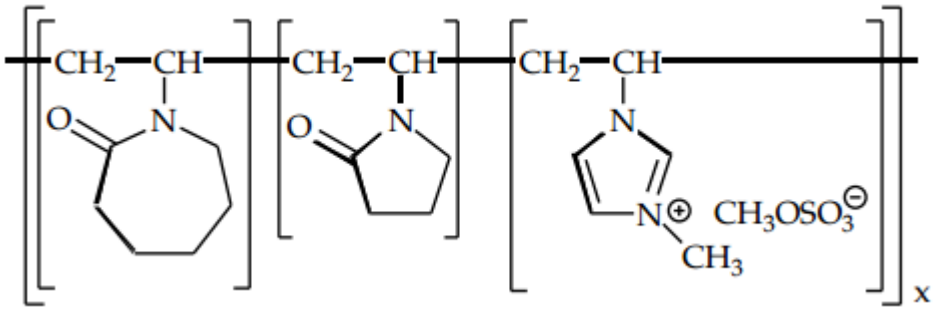
BASF Australia Ltd of 500 Princess Highway NOBLE PARK VIC 3174 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer in Luviquat Hold.

2. IDENTITY OF THE CHEMICAL

Polymer in Luviquat Hold is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the molecular weight, quantity imported, details of the polymer composition and information of release to environment have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Name:	1H-imidazolium, 1-ethenyl-3-methyl-, methyl sulphate, polymer with 1-ethenylhexahydro-2H-azepin-2-one and 1-ethenyl-2-pyrrolidinone
Chemical Abstracts Service (CAS) Registry No.:	174761-16-1
Other Names:	Luviquat CPI; Polyquaternium-46; 2-pyrrolidone, 1-ethenyl-, polymer with 1-ethenylhexahydro-2H-azepin-2-one and 1-ethenyl-3-methyl-1H-imadazolium methyl sulphate; 2H-azepin-2-one, 1-ethenylhexahydro-, polymer with 1-ethenyl-3-methyl-1H-imadazolium methyl sulphate and 1-ethenyl-2-pyrrolidinone
Trade Name:	Luviquat Hold
Molecular Formula:	$(C_8H_{13}NO.C_6H_9N_2.C_6H_9NO.CH_3O_4S)_x$

Structural Formula:



Method of Detection and Determination:	gel permeation chromatography (GPC) and infrared (IR) spectroscopy
Spectral Data:	GPC and IR spectra were provided; the IR spectrum had major characteristic peaks at 580, 653, 1 293, 1 446, 1 464, 1 487, 1 616, 1 653, 2 937 and 3 421 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

The following information was generated from Luviquat Hold, a 20% aqueous solution of the notified polymer:

Appearance at 20°C and 101.3 kPa:	clear, colourless to yellowish viscous liquid with no odour
Boiling Point:	approximately 100°C (as for water)
Specific Gravity:	1 020 $kg.m^{-3}$ at 20°C
Vapour Pressure:	2.3 kPa at 20°C (as for water)
Water Solubility:	miscible with water (see comments below)
Partition Co-efficient (n-octanol/water):	not available (see comments below)
Hydrolysis as a Function of pH:	not available (see comments below)
Adsorption/Desorption:	not available (see comments below)
Dissociation Constant:	not available (see comments below)
Flash Point:	> 100°C

Flammability Limits:	not applicable for a water based dispersion of the polymer
Autoignition Temperature:	approximately 500°C
Explosive Properties:	not available
Reactivity/Stability:	not available

Comments on Physico-Chemical Properties

The notifier states that the product containing the notified polymer is a clear solution which can be diluted with water in all proportions. One of the monomers has a quaternary ammonium functionality. Depending on the proportion of this monomer, it could potentially impart significant solubility to the polymer.

It is unclear whether the notified polymer is likely to undergo hydrolytic decomposition of the cyclic amides in the environmental pH range of 4 to 9, due to its solubility. The notifier has indicated that analogous products containing similar copolymers are stable over several years.

The notified polymer is not expected to permeate through biological membranes due to its large molecular size. Thus, the partition coefficient test was not requested. Given the polymer 's high water solubility, it is anticipated that the value of partition coefficient will be low.

Based on the anticipated partition coefficient the polymer would not be expected to strongly adsorb to sediments. However, quaternary ammoniums are known to react with dissolved organic carbon (DOC) in water to form part of the sediments, and become completely inactivated on contact with soils [Nabholz, 1993 #8]. Additionally, the notifier has presented a study [Schwarz, 1995 #73] which showed a 70% reduction in the DOC content of a solution of the polymer containing activated sludge over a 48 hour period.

The notified polymer contains no dissociable hydrogen atoms or basic functionalities.

The molecular structure of the notified polymer does not indicate an explosion hazard particularly when manufactured as an aqueous solution in water.

Luviquat Hold is a stable liquid and is not considered reactive. The polymer will not degrade, decompose or depolymerise when handled properly.

4. PURITY OF THE CHEMICAL

Degree of Purity:	> 99.9%

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia. It will be imported into Australia as a 20% aqueous solution in the product Luviquat Hold.

The notified polymer is intended for use in hair care products. The polymer forms a cationic film which provides both conditioning and setting effects. The polymer will be formulated into emulsions, lotions and gels at up to approximately 1%. The gel will be packaged in 150 g polyethylene tubes. Other hair care products will be packed in aerosol cans or non-aerosol bottles.

6. OCCUPATIONAL EXPOSURE

The vapour pressure of Luviquat Hold is close to that of water. Therefore, inhalation exposure is expected to be low, dermal contact will be the main route for occupational exposure.

Luviquat Hold, a viscous liquid containing 20% of the notified polymer, will be imported into Australia by sea in sealed 120 kg plastic drums. After unloading, the drums will be transported by road to the warehouse and formulation plant. Exposure of receivers and transport workers to the notified polymer would occur only in the event of accidental spillage.

At the formulation site, operators will weigh Luviquat Hold and mix it with other ingredients to prepare an aqueous solution. Laboratory technicians will sample the polymer before and after formulation for quality control. The finished products will contain up to 5% of Luviquat Hold or 1% of the notified polymer.

The mixing process occurs in a closed system. If a propellant is to be used, the final solution is then mixed with propellant which comprises either propane/butane or propane alone. There is an automated system for the filling, capping and labelling of aerosol and non-aerosol containers. Therefore, the possible occasions for workers to be exposed to the notified polymer will be during weighing and addition. However, it is estimated that operators will handle the notified polymer for up to only 15 minutes per day, for each mixing operation. Occupational exposure to the notified polymer during other processes such as mixing, filling, capping and labelling is expected to be negligible in the automatic operation.

7. PUBLIC EXPOSURE

As the notified polymer is to be used in hair care products, widespread public exposure, primary dermal, is possible, limited only by the commercial success of products containing it. Depending on the presentation of the products containing the notified polymer, ingestion and eye contact will be possible through overspray, splashing, hand to mouth and hand to eye transfer.

In the event of a transport accident, significant dispersal is unlikely and spilt material will be readily recoverable through adsorption onto sand or other dry

material. Industrial processing of the notified polymer will be limited to blending and container filling operations. These processes are unlikely to produce significant dispersal of the material beyond the confines of the industrial site.

8. ENVIRONMENTAL EXPOSURE

Release

Product Manufacturing
Hair care products containing the notified polymer will be made by only one manufacturer. The hair care product comes in 150 g polyethylene tubes that contain less than 10 g of notified polymer.

The notifier claims that the total loss during the formulation of the hair care products containing the notified polymer (including unused residues in containers, washings from equipment and batch residues) will be approximately 0.2%. Container and batch residues will be disposed of to landfill. Equipment washings will be processed through the wastewater treatment system of the plant.

Product Use
The products containing the notified polymer are for use on hair in conditioning gels. Thus, it is anticipated the almost all of the imported polymer will find its way into the sewer as a result of washing from hair.

Empty containers, with residues, will probably be disposed of to landfill.

Fate

The vast majority of notified polymer will be discharged to sewer. Here it is expected to rapidly react with the suspended or dissolved organic carbon (DOC) in the water column, forming an insoluble flocculant that should be removed with the sludge [Nabholz, 1993 #8]. The sludge will either be landfilled or incinerated. Incineration products will include oxides of carbon, nitrogen and sulfur.

Additionally, the notifier has provided a study on adsorption of the notified polymer to activated sludge in a static system over 48 hours [Schwarz, 1995 #73]. The disappearance of the polymer from solution was monitored by determining the DOC content of the solution. Samples were prepared containing 116 $mg.L^{-1}$ and activated sludge concentration of 1 g of dry matter per litre of solution. A 70 % reduction in the DOC of the test samples was observed over the 48 hour period of the test.

Minor amounts remaining as residues in product containers disposed of to landfill should be contained. Should leaks occur, these will quickly become immobile through absorbing to soil.

The biodegradability of the notified polymer was not determined which is acceptable for polymers with import volumes less than 1 tonne per year according to the Act. Biological membranes are not permeable to polymers of very large molecular size and therefore bioaccumulation of the notified polymer is not

expected [Anliker, 1988 #2] [Gobas, 1986 #6].

9. EVALUATION OF TOXICOLOGICAL DATA

The notified polymer is produced as a 20% solution in water (Luviquat Hold) and will not be isolated. Although toxicity data are not required for chemicals with NAMW greater than 1 000 according to the Act, some toxicological data for Luviquat Hold, generated from an identical substance, Luviquat CPI, were provided and are summarised below.

9.1 Acute Toxicity

Summary of the acute toxicity of Luviquat CPI.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg.kg^{-1}	[Gelbke, 1995 #31]
skin irritation	rabbit	a slight skin irritant	[Gelbke, 1995 #32]
eye irritation	rabbit	a slight eye irritant	[Gelbke, 1995 #33]
skin sensitisation	guinea pig	not skin sensitiser	[Gelbke, 1995 #34]

9.1.1 Oral Toxicity [Gelbke, 1995 #31]

Species/strain:	rat/Wistar/Chbb:Thom (SPF)
Number/sex of animals:	3/sex
Observation period:	14 days
Method of administration:	oralgavage
Clinical observations:	no signs of systemic toxicity related to the treatment were noted
Mortality:	nil
Morphological findings:	no abnormality related to the treatment was noted
Test method:	based on EEC Directive [European Economic Community, 1992 #36]
LD_{50}:	> 2 000 mg.kg^{-1}

Result: Luviquat CPI was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity

Test not performed.

9.1.3 Inhalation Toxicity

Test not performed.

9.1.4 Skin Irritation [Gelbke, 1995 #32]

Species/strain: rabbit/New Zealand White (SPF)

Number/sex of animals: 2 males, 1 female

Observation period: 8 days

Method of administration: a test patch moistened with 0.5 mL undiluted Luviquat CPI was applied to the intact skin with a semiocclusive dressing for 4 hours

Draize scores [Draize, 1959 #4]:

Time after treatment (days)	***Animal #***			
	1	***2***	***3***	***8***
Erythema				
1	1[a]	1	0	0
2	2	2	1	0
3	2	1	0	0

[a] see Attachment 1 for Draize scales

Test method: based on OECD Guidelines [Organisation for Economic Co-operation and Development, 1995-1996 #15]

Clinical observations: Draize scores for oedema were zero in all animals; erythema presented till day 3

Result: Luviquat CPI was a slight skin irritant in rabbits

9.1.5 Eye Irritation [Gelbke, 1995 #33]

Species/strain:	rabbit/ New Zealand White
Number/sex of animals:	3 males
Observation period:	3 days
Method of administration:	Luviquat CPI (0.1 mL undiluted) was applied to the conjunctival sac of the right eyelid; the substance was washed out with tap water about 24 hours after application
Observations:	Draize scales for cornea and iris were zero up to 3 days after installation in all animals; redness was observed in one rabbit after one hour and 24 hours; discharge was observed after 1 hour in one rabbit
Test method:	based on OECD Guidelines [Organisation for Economic Co-operation and Development, 1995-1996 #15]
Result:	Luviquat CPI was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation [Gelbke, 1995 #34]

Species/strain:	guinea pig/Pirbright White, Dunkin-Hartley Cr1:(HA) BR [SPF]
Number of animals:	15 females (5 control, 10 test)
Induction procedure:	on day 1, intradermal induction consisted of three pairs of injections (0.1 mL per site): Freund's complete adjuvant (FCA) and 0.9% NaCl (1:1); 5% Luviquat CPI aqueous solution; and 5% Luviquat CPI emulsion in 0.9% NaCl solution and FCA (1:1) on day 8, percutaneous induction was carried out; a filter paper strip soaked in Luviquat CPI (0.3 g, 100%) was applied to the shoulder skin with an occlusive dressing for 48 hours
Challenge procedure:	on day 21, a filter paper soaked in Luviquat CPI (0.15 g, 100%) was applied on the flank skin with an occlusive dressing for 24 hours

Challenge outcome:

	Test animals	***Control animals***
Challenge concentration	***24 hours****	***24 hours***
75%	**0/10	0/5

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

Test method:	similar to OECD Guidelines [Organisation for Economic Co-operation and Development, 1995-1996 #15]
Result:	Luviquat CPI was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity

Test not performed.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay [Gelbke, 1995 #35]

Strains:	TA 1535, TA 1537, TA 98 and TA 100
Concentration range:	1 560 to 25 000 μg per plate using water as the diluent for the test substance
Test method:	based on OECD Guidelines [Organisation for Economic Co-operation and Development, 1995-1996 #15]
Result:	Luviquat CPI was not mutagenic in bacteria either with or without metabolic activation provided by rat liver S-9 fraction

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse

Test not performed.

9.4 Overall Assessment of Toxicological Data

No toxicological data are required under the Act for polymers with a NAMW greater than 1 000 and volumes less than 1 tonne per annum. However, the notifier did provide some toxicity data on Luviquat CPI.

Luviquat CPI was of low acute oral toxicity (LD_{50} greater than 2 000 $mg.kg^{-1}$) in rats, and was a slight eye and skin irritant in rabbits. It was not a skin sensitiser in guinea pigs. In the presence or absence of metabolic activation, Luviquat CPI was not mutagenic in bacteria. Acute dermal toxicity, repeat toxicity and cellular genotoxicity studies were not conducted. This was considered acceptable for this notification.

On the basis of the submitted data, Luviquat CPI would not be classified as hazardous in accordance with National Commission's *Approved Criteria for Classifying Hazardous Substances* [National Occupational Health and Safety Commission, 1994 #9] in relation to acute lethal effects (oral), irritation effects (eye and skin) and sensitising effects (skin).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data are required under the Act for polymers with a NAMW greater than 1 000 and volumes less than 1 tonne per annum. However, the notifier did provide the following ecotoxicity data.

Test	*Species*	*Results (Nominal)*	*Ref.*
Acute Toxicity (96 h) Nominal Static system OECD Guideline No. 203	Zebra fish (*Brachydanio rerio*)	10 $mg.L^{-1}$ < LC_{50} < 21.5 $mg.L^{-1}$ NOEC = 4.64 $mg.L^{-1}$	[Munk, 1995 #74]

* NOEC - no observable effect concentration

The test was conducted according to OECD Guideline 203 [Organisation for Economic Co-operation and Development, 1995-1996 #15]. The effect of the chemical was examined at 6 concentrations (1.0, 2.2, 4.6, 10.0, 21.5 and 46.4 $mg.L^{-1}$). After 96 hours 10% and 100% mortality were observed at 10 $mg.L^{-1}$ and 21.5 $mg.L^{-1}$, respectively. Hence, the LC_{50} lies somewhere between 10 $mg.L^{-1}$ and 21.5 $mg.L^{-1}$.

The ecotoxicity data indicate that the notified polymer is moderately toxic to fish. No data have been provided for the toxicity of the notified polymer to algae. Polymers containing quaternary functionalities are known to be around 6 times more toxic to algae than fish [Nabholz, 1993 #8].

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The vast majority of notified polymer will be discharged to sewer through product use. As the product will be used all around the country, and sent to sewage treatment plants in both city and country locations, a predicted environmental concentration (PEC) based on continental use has been calculated:

Import Volume	< 1 000 kg
Amount discharged to sewer	100%
Sewer output per day*	2 700 ML
Concentration in Sewage Treatment Plant	< 1 $\mu g.L^{-1}$ (ppb)

*Sewer output based on an Australian population of 18 million, each using 150 L water per day.

Allowing for a ten fold increase in the sensitivity of algae to the polymer compared to fish [Nabholz, 1993 #8], ie an LC_{50} approximately 1 $mg.L^{-1}$, the PEC is over 1 000 times lower than the estimated LC_{50}. Additionally, the PEC would be further reduced by adsorption to sewerage sludge and dilution in receiving waters.

The minor amount remaining as residues in product containers after use should be confined to landfill. Any leaking polymer will be rapidly and completely adsorbed to soil.

Hence, the overall environmental hazard of the polymer can be rated as negligible when used in hair care products at the proposed levels.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

With a high NAMW of greater than 10 000, the notified polymer is unlikely to be bioavailable and significant systemic toxicity is therefore unlikely. The toxicological studies with Luviquat CPI revealed that it was of low acute oral toxicity, it was a slight eye and skin irritant but not a skin sensitiser. It was not a mutagen in the Ames test. Based on the submitted data, the notified polymer would not be classified as hazardous according to *Approved Criteria for Classifying Hazardous Substances* [National Occupational Health and Safety Commission, 1994 #9].

A hazardous residue at a maximum concentration of 50 ppm is presented . This monomer is a severe eye irritant, has an oral LD_{50} in rats of 1 470 $mg.kg^{-1}$, an LC_{50} in rats of 3 200 $mg.m^{-3}$ (4 hours), and a dermal LD_{50} in rabbits of 560 $mg.kg^{-1}$ [Registry of Toxic Effects of Chemical Substances database, 1993 #62]. At 50 ppm in the polymer and substantially less in products, however, this impurity will not pose a significant hazard.

Luviquat Hold contains three adjuvants at the concentration from approximately 0.05% to 0.2%. Although the acute oral toxicity of these compounds range from low to moderate, and the irritant properties from slight to severe [Registry of Toxic Effects of Chemical Substances database, 1993 #62], their contribution to the overall toxicity of Luviquat Hold at the concentrations at which they are present will be not of significant concern.

The occupational health risk to waterside, warehouse and transport workers will be negligible except in the event of accident. Workers at the formulation site could be exposed to the notified polymer through dermal contact or contamination while weighing and during addition. However, the occupational health risk for these workers is considered to be low on the basis of the toxicological profile of the polymer and the limited duration of exposure. The occupational exposure during mixing, filling capping and labelling is negligible as automatic machines are used in the plant.

Although widespread public exposure is likely, the notified polymer is present at approximately 1% (5% of Luviquat Hold) in the product so the magnitude of individual exposure will be low (150 to 300 mg per use). The acute toxicological hazard is minimal and the chronic hazard is likely to be low. The neutral pH, absence of skin or eye irritant properties and the high molecular weight, make the generation of significant topical toxicity unlikely. Similarly although ingestion of small quantifies is probable, dependent on the nature of the products in which it is present, the toxicological hazard is low, the exposure will be negligible at the indicated concentrations, and the risk to the public will consequently also be low.

13. RECOMMENDATIONS

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

- Spillage of the notified polymer 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 MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product containing the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* [National Occupational Health and Safety Commission, 1994 #13].

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 polymer 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

1. Nabholz, J.V., Miller, P. & Zeeman, M. 1993, 'Environmental Risk Assessment of New Substances under the Toxic Substances Control Act Section Five', in *Environmental Toxicology and Risk Assessment. American Society for Testing and Materials*, ASTM STP 1179, Philadelphia, pp. 40-55.

2. Schwarz, H. 1995, *Test for the adsorbability of VERS.ZK 87/142 on activated sludge using the short-term adsorption test*, Project Number 95/0229/49/1, BASF Aktiengesellschaft Emission Monitoring and Ecology laboratory for Microbiology, Ludwigshafen Germany.

3. Anliker, R., Moser, P. & Poppinger, D. 1988, 'Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors', *Chemosphere*, vol. 17, no. 8, pp. 1631-1644.

4. Gobas, F.A.P.C., Opperhuizen, A. & Hutzinger, O. 1986, 'Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation', *Environmental Toxicology and Chemistry*, vol. 5, pp. 637-646.

5. Gelbke, H.P., Poelloth. & Hellwig. 1995, *Study on the acute oral toxicity of Luviquat CPI in rats*, Project No 10A0171/951057, Department of Toxicology, BASF Aktiengesellschaft, Ludwigshafen/Rheein, FRG.

6. Gelbke, H.P., Poelloth. & Hellwig. 1995, *Study on the acute dermal irritation/corrosion of Luviquat CPI in the rabbit*, Project No 18H0171/952093, Department of Toxicology, BASF Aktiengesellschaft, Ludwigshafen/Rheein, FRG.

7. Gelbke, H.P., Poelloth. & Hellwig. 1995, *Study on the acute eye irritation of Luviquat CPI in the rabbit*, Project No 11H0171/952094, Department of Toxicology, BASF Aktiengesellschaft, Ludwigshafen/Rheein, FRG.

8. Gelbke, H.P., Polloth. & Hellwig. 1995, *Report on the Maximization Test for the sensitizing potential of Luviquat CPI in guinea pigs*, Project No 30H0171/952095, Department of Toxicology, BASF Aktiengesellschaft, Ludwigshafen/Rheein. FRG.

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10. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.

11. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.

12. Gelbke, H.P., Engelhardt, G. & Hoffmann, H.D. 1995, *Report on the study of Luviquat CPI (ZHT Test Substance No 95/171) in the Ames Test (Salmonella/Mammalian-Microsome Mutagenicity Test - Standard Plate Test and Preincubation Test)*, Project No 40H0171/954125, Department of Toxicology, BASF Aktiengesellschaft, Ludwigshafen/Rheein, FRG.

13. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.

14. Munk, R. 1995, *Acute toxicity study on the zebra fish (Brachydanio rerio HAM. and BUCH.) of Luviquat CPI in a static system (96 hours)*, Project Number 17F0171/955025, BASF Aktiengesellschaft Department of Toxicology, Ludwigshafen/Rheein, Germany.

15. Registry of Toxic Effects of Chemical Substances database 1993, 'RTECS'.

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

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

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

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe