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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Luviquat Care (Polyquaternium 44)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Luviquat Care (Polyquaternium 44)

1. APPLICANT

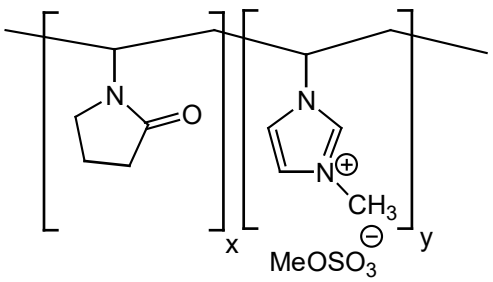
Johnson and Johnson Pacific Pty Ltd of Stephen Rd, Botany, NSW 2019 (ABN 73 001 121 446) and BASF Australia Pty Ltd of 500 Princes Highway, Noble Park, VIC 3174 (ABN 62 008 437 867) have submitted a limited notification statement in support of their application for an assessment certificate for Luviquat Care (Polyquaternium 44).

No requests for exempt information were made.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	1H-imidazolium, 1-ethenyl-3-methyl-, methyl sulphate, polymer with 1-ethenyl-2-pyrrolidinone
Chemical Abstracts Service (CAS) Registry No.:	150599-70-5
Other Names:	Polyquaternium 44 Copolymer of vinylpyrrolidone and quaternised vinylimidazole
Marketing Name:	Luviquat Care
Molecular Formula:	$C_6H_9NO.(C_6H_9N_2.CH_3O_4S)$

Structural Formula:



where ratio of x:y is 80:20

Molecular Weight:	approximately 1×10^6 (by light scattering)
Number-Average	not determined

Molecular Weight (NAMW):

Weight-Average Molecular Weight: not determined

Maximum Percentage of Low Molecular Weight Species not determined

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*
1-ethenyl-3-methyl-1H-imidazolium, methyl sulphate	26591-72-0	20
1-ethenyl-2-pyrrolidinone	88-12-0	80

Method of Detection and Determination: Infrared (IR) spectroscopy, ^{1}H nmr spectroscopy

Spectral Data: IR: Peaks at - 3453(br), 3145, 3095, 2954, 1668, 1495, 1462, 1437, 1424, 1374, 1290, 1274, 1164, 1012, 743 cm^{-1}

^{1}H nmr: Peaks at - 7.97, 7.65, 7.58, 7.50, 7.41, 7.08, 6.97, 4.80, 4.17, 3.90, 3.77, 3.68, 3.33, 2.49, 2.38, 2.09, 1.77 ppm

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physical and chemical properties were determined for Luviquat Care, a solution of 6 - 7 % notified polymer in water, unless otherwise specified.

Appearance at 20°C & 101.3 kPa: clear colourless or yellow liquid

Boiling Point: 100°C

Specific Gravity: 1.013

Vapour Pressure: 2.7 kPa at 23°C

Water Solubility: 70 g/L at 25°C (notified polymer)

Particle Size: not applicable as the notified polymer is only used in Australia in liquid form

Partition Co-efficient (n-octanol/water): not determined (see comments below)

Hydrolysis as a Function of pH: not determined (see comments below)

Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	not flammable
Explosive Properties:	not expected to be explosive
Reactivity/Stability:	stable under normal environmental conditions

3.1 Comments on Physico-Chemical Properties

The values given for vapour pressure and boiling point are those for water. The notified polymer, having a very high molecular weight, is not expected to be appreciably volatile.

The notifier has provided a brief description of the method by which the water solubility of the notified polymer was determined. The notifier indicates that during manufacture at a maximum concentration of 7 g/100 mL the polymer solution is clear, but increasing the solid content results in precipitation of the polymer and a turbid solution. The notifier's website indicates that the notified polymer is miscible in water and ethanol in all proportions. A high water solubility is consistent with the notified polymer's polar structure.

The partition coefficient has not been determined due to the high water solubility of the notified polymer and its apparent hydrophilic nature, indicative of partitioning into the aqueous phase.

The notified polymer contains an amide linkage that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.

As a consequence of its cationic nature, the notified polymer is expected to associate with the soil matrix and sediments and as such will be immobile in soil. This is confirmed by the strong adsorption found in the activated sludge test (BASF, 1998a).

Although no dissociation tests were conducted, the notified polymer will be fully dissociated under all pH conditions due to the presence of quaternary ammonium groups.

4. PURITY OF THE CHEMICAL

Degree of Purity:	> 99.9 %
Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	none
Maximum Content of Residual Monomers:	

Chemical Name	*Synonym*	*CAS No.*	*Weight %*
1-ethenyl-2-pyrrolidinone	N-vinylpyrrolidone	88-12-0	50 ppm

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia. It will be imported into Australia as a component of the ready-to-use hair shampoo in 300 mL containers. The concentration of the notified polymer in shampoo will be 0.28 %. Import volumes for the notified polymer are expected to be less than 1 tonne per annum over the first five years.

6. OCCUPATIONAL EXPOSURE

As the notified polymer is imported in the final consumer use packages, occupational exposure will be limited to handling of the closed packages in the transport, distribution and retail sectors. A large number of workers in these sectors will handle the product containing the notified polymer for brief periods, with no exposure expected except in the case of an accident. Warehouse staff involved in distribution at the notifier's premises will be expected to have the greatest exposure to the product, with 5 workers handling the sealed packages for 30 minutes per day, 15 days per year. The notifier states that personal protective equipment for eyes or skin will be not used, due to the low hazard posed by the finished consumer product.

7. PUBLIC EXPOSURE

Public exposure to the notified polymer is possible but unlikely following the rupture of the shampoo containers as a result of a transport accident.

All of the imported polymer will eventually pass to the environment, either from residues in discarded containers sent to landfill or as a component of used shampoo entering sewage. In the environment the notified polymer is expected to be highly diluted and immobile in sediment or soil. Public contact with the notified polymer as an environmental contaminant is therefore also unlikely.

As the notified polymer is an ingredient in children's shampoo products, public exposure during end use will be widespread. The main route of exposure will be via dermal contact during hair washing. It is estimated that approximately 3-5 mL product, containing 0.28 % notified polymer, will be used 2 – 7 times per week.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The products containing the notified polymer will be used in shampoos. Thus it is anticipated that virtually the entire import volume of the notified polymer will find its way into the sewer as a result of it being washed from hair.

The notifier estimates that 10 mL of shampoo will remain in the empty shampoo containers, which equates to less than 1 g of the notified polymer per container. The empty containers and any residues they contain will be disposed of in domestic landfill.

8.2 Fate

The majority of the notified polymer will be released into the sewer following washing of hair. Here, despite its water solubility, the notified polymer is expected to adsorbed to sediments and be immobile due to its cationic nature. In landfill, the notified polymer is not expected to escape from the 300 mL containers, however, if it did it would also adsorbed to soil and be immobile.

The notifier has provided results of two biodegradation tests in an aerobic aqueous media for a related polymer, Luviquat FC 905. This differs from the notified polymer in that it has a greater proportion of the quaternized imidazolium monomer (95 vs 20 %). The first test followed EEC Directive 79-831 Annex V (equivalent to OECD TG 301F, Manometric Respirometry Test) (BASF, 1985a). The biodegradation of a solution of the test substance at a concentration of 100 mg/L was determined by the measurement of biological oxygen demand after the medium was inoculated with a mixed population of aquatic microorganisms and stored between 20-25ºC for 28 days. Aniline was used as the standard material. The results indicated that 0 % of the polymer had degraded over this time, while approximately 76 % of the standard degraded in 28 days. The results indicate that the polymer is not readily biodegradable.

The second test provided was for inherent biodegradation conducted following OECD TG 302B (Zahn-Wellens Test) (BASF, 1985b). The biodegradation was determined by the measurement of dissolved organic carbon removed from a solution containing 1064 mg/L of the test substance after the medium was inoculated with a mixed population of aquatic microorganisms over a period of 28 days. The results indicated that 42 % of the polymer had degraded in 28 days while 32 % had adsorbed in 3 h. The results indicate that notified substance is not biodegradable as less than 70 % had degraded. However, a reasonable degree of inherent biodegradability may be predicted in water and soils suggesting the notified polymer may degrade slowly under similar conditions.

The notifier has also submitted a test for adsorption on activated sludge for the notified polymer (BASF, 1998a). The polymer, at a concentration of 1913 mg/L, was incubated with activated sludge obtained from BASF's wastewater treatment plant. During the test, samples were taken and analysed for dissolved organic carbon (DOC) content. The study found a 95 % decrease in DOC after 3 h and 100 % after 48 h, suggesting the polymer is eliminated rapidly from the aqueous phase.

The notified polymer should not bioaccumulate as it is highly water soluble and has a molecular weight much greater than 1000 (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Summary of Toxicological Investigations

The following studies were carried out for the product, Luviquat Care, a 7.4 % solution of the notified polymer in water. No adjustment for the concentration of notified polymer was applied.

Endpoint & Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test.	no evidence of sensitisation.
Genotoxicity - bacterial reverse mutation	non mutagenic

9.2 Acute Toxicity

9.2.1 Acute Oral Toxicity

TEST SUBSTANCE	7.4 % notified polymer in water
METHOD	OECD 423 Acute Oral Toxicity – Acute Toxic Class Method EC Directive 96/54/EEC B.1.tris Acute Toxicity (Oral) – Acute Toxic Class Method.
Species/Strain	Rat/Wistar chbb:thom (SPF)
Vehicle	Water, dose volume 10 mL/kg bw.
Remarks - Method	The notified polymer was first tested against the females; as no mortality was observed, the males were treated with the same dose level.

RESULTS

Group	*Number & Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 female	2000	0/3
II	3 male	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity were observed.
Effects in Organs	No treatment related abnormalities were observed.
Remarks - Results	All animals gained weight during the study.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	BASF Akteingesellschaft Department of Toxicology

(1999a)

9.2.2 Skin Irritation

TEST SUBSTANCE	7.4 % notified polymer in water
METHOD	OECD 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/Himalayan Chbb: HM
Number of Animals	3
Observation Period	7 days
Vehicle	Used as received.
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.3	1.7	2.0	2	< 7 days	0
Oedema	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, & 72 hours for EACH animal.

Remarks - Results	Slight to well defined erythema was observed in all animals on days 1 to 3.
CONCLUSION	The test substance is slightly irritating to skin.
TEST FACILITY	BASF Akteingesellschaft Department of Toxicology (1999b)

9.2.3 Eye Irritation

TEST SUBSTANCE	7.4 % notified polymer in water
METHOD	OECD 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/Himalayan Chbb: HM
Number of Animals	3
Observation Period	3 days
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Conjunctiva: redness	0.66	0	0	2	2 days	0
Conjunctiva: chemosis	0	0	0	1	1 hr	0
Conjunctiva: discharge	0	0	0	1	1 hr	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, & 72 hours for EACH animal.

Remarks - Results: All animals showed conjunctival redness at the 1 hr observation; discharge and chemosis were each observed in one animal at this observation.

CONCLUSION: The test substance is slightly irritating to the eye.

TEST FACILITY: BASF Akteingesellschaft Department of Toxicology (1999c)

9.2.4 Skin Sensitisation

TEST SUBSTANCE: 7.4 % notified polymer in water

METHOD: OECD 406 Skin Sensitisation – Buehler Test.
EC Directive 96/54/EC B.6 Skin Sensitization - Buehler Test.

Species/Strain: Guinea pig/Hsd Poc: DH(SPF)

PRELIMINARY STUDY: Maximum non-irritating concentration:
topical: 75 %

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 10

INDUCTION PHASE: Induction Concentration
topical: 100 %

Signs of Irritation: No irritation reactions were observed at 24 hr after removal of patches.

CHALLENGE PHASE: topical application: 100 %

Remarks - Method: No significant protocol deviations.

RESULTS

Remarks - Results: No dermal reactions were seen after challenge with undiluted test substance in either the test or control groups.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.

TEST FACILITY	BASF Akteingesellschaft Department of Toxicology (1999d)

9.3 Genotoxicity

9.3.1 Genotoxicity-Bacteria

TEST SUBSTANCE	7.4 % notified polymer in water
METHOD	OECD 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	10 % Aroclor 1254 induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 20 – 70000 µg/plate. b) Without metabolic activation: 20 – 70000 µg/plate.
Vehicle	Water.
Remarks - Method	An initial test was carried out with and without metabolic activation, in triplicate, by the plate incorporation procedure, and doses up to 5000 µg/plate. A repeat test was carried out for the same dose range with and without metabolic activation, in triplicate, using the pre-incubation procedure. The experimental procedure was then repeated for a higher dose range.
RESULTS	
Remarks - Results	No increases in the number of revertant colonies was observed for any strain in the presence or absence of metabolic activation. At high doses, decreases in the number of revertant colonies were seen in a number of tests. No precipitation was observed under any conditions. Appropriate positive controls in all cases resulted in large increases in the number of revertant controls, indicating that the test system responded appropriately.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF Akteingesellschaft Department of Toxicology (1999e)

9.4 Overall Assessment of Toxicological Data

The toxicological tests for which reports were provided by the notifier were conducted using a 7.4 % solution of the notified polymer in water. This substance was of low acute oral

toxicity in rats, non-sensitising to the skin of guinea pigs, and non-mutagenic in a bacterial reverse mutation assay. it was a slight irritant to rabbit eyes, with slight conjunctival irritation occurring in all animals on instillation, but clearing in two out of three by 24 hr. It was a slight skin irritant in rabbits; erythema persisted in all three test animals beyond 72 hr. based on this result, the notified polymer would not be classified as a skin irritant in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (Approved Criteria) (NOHSC, 1999). However, it is possible that higher degrees of skin irritation would be observed if higher concentrations were to be tested.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has provided a full test report on the ecotoxicity of the notified polymer towards Zebra Fish.

Test	*Species*	*Results*
96 h Acute Toxicity OECD TG 203	Zebra Fish *Brachydanio Rerio*	LC_{50} = 10 - 100 mg/L NOEC = 1 mg/L

* NOEC - no observable effect concentration

The test on fish (BASF, 1998b) was performed on Luviquat Care using a static methodology. Observations were performed at 1, 4, 24, 48, 72 and 96 hours. The test was performed using ten specimen fish per loading rate using notified polymer made up at nominal concentrations of 1, 10 and 100 mg/L. The results of the definitive study showed that sub-lethal effects such as apathy and swimming near the bottom of the tank were experienced at all test substance concentrations. After 96 h, 10 % mortality was observed at a test substance concentration of 10 mg/L and 100 % mortality was observed at nominal concentrations above 100 mg/L after 24 h. The 96-hour LC_{50} for the chemical to *Leuciscus idus* is between 10-100 mg/L.

The ecotoxicity data for the notified polymer indicates that it is slightly toxic to fish. Polycationic polyamines which have molecular weights above 1000 and are water soluble are known to be approximately six time more toxic to algae that they are to fish (Nabholz, 1993). Therefore assuming worst case, it is expected that the notified polymer will have an algal EC_{50} of approximately 1.5 mg/L.

The notifier has also submitted full test reports on the ecotoxicity of a related polymer, Luviquat FC 905, which contains 95 % of the monomer containing the quaternary group, compared with 20 % in the notified polymer.

Test	*Species*	*Results*
96 h Acute Toxicity OECD TG 203	Golden Orfe *Leuciscus idus*	LC_{50} = 0.22 - 0.46 mg/L NOEC = 0.1 mg/L
Bacterial Growth Inhibition Test	*Psedomonas putida*	EC_{50} (17 h) = 1 mg/L
Inhibitory Effect OECD TG 209	Activated Sewerage Sludge	EC_{20} (30 min) = 1400 mg/L

The test on fish (BASF, 1987) was performed on Luviquat FC 905 using a static methodology. Observations were performed at 1, 4, 24, 48, 72 and 96 hours. The test was performed using ten specimen fish per loading rate at a temperature of 20ºC. The tests were conducted using Luviquat FC 905 made up at nominal concentrations of 0.046, 0.1, 0.215, 0.464, 1.0, 2.15 and 4.64 mg/L. The results of the definitive study showed that sub-lethal effects such as apathy were experienced at nominal concentrations of 0.215 mg/L. After 96 h, 10 % mortality was observed at a test substance concentration of 0.215 mg/L and 100 % mortality was observed at nominal concentrations above 0.464 mg/L. The 96-hour LC_{50} for the polymer to *Brachydanio Rerio* is between 0.22-0.46 mg/L depending on the significance level (1 and 5 % respectively).

The notifier has provided a summary of a bacterial growth inhibition test (BASF, 1999f). The test was conducted according to the method detailed in draft DIN 38412 part 8. To the test medium in 10 mL flat bottom reagent tubes was added the notified polymer and a bacterial suspension. The resulting suspension was incubated at 20°C with shaking for 17 h after which the optical density of a sample was determined. The 17 h EC_{50} for Luviquat FC 905 to *Psedomonas putida* was determined to be 1 mg/L.

The activated sludge study was conducted on Luviquat FC 905 using sludge obtained from a BASF wastewater treatment plant (BASF, 1985c). The definitive study was conducted on nominal concentrations of 889, 4443 and 8885 mg/L. Activated sludge (1 g/L dry weight) was added to the aqueous solutions of the test substance to give the required concentrations. Activated sludge at the nominal concentrations of 889, 4443 and 8885 mg/L after 3 h experienced 11, 44 and 28 % inhibition, respectively. The 30 min EC_{20} for the test substance to activated sludge is stated to be 1400 mg/L, determined by an unknown method.

The ecotoxicity data supplied for the structurally similar polymer, Luviquat FC 905, suggests the notified polymer is likely to be highly toxic to fish and bacteria, practically non-toxic to activated sludge but potentially highly toxic to daphnia and algae. It seems clear that while the monomer contents are the same, the higher quaternary group content (95 vs 20 %) results in the much higher toxicity. The much lower MW of 40000 according to the BASF Technical Information sheet (BASF, 2001) may also be partly responsible.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The intended use pattern of the notified polymer is expected to result in the majority of the polymer being eventually released to the environment. However, this will be in dilute manner as the notified polymer contained within the hair care products will be released from domestic use at low concentrations. The ecotoxicity data for the notified polymer indicates that it is slightly toxic to fish but no other data was available.

In a worst case based on maximum annual imports of 983 kg per annum, all of which is released to sewer and assuming that none is removed during sewage treatment processes, assuming a national population of 19 million and that each person contributes an average 150 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 0.95 μg/L.

Amount of polymer entering sewer annually	983 kg
Population of Australia	19 million

Amount of water used per person per day	150 L
Number of days in a year	365
Estimated PEC	0.95 μg/L (0.95 ppb)

When released to receiving waters the concentration is generally understood to be reduced by a further factor of at least 10, and so the Predicted Environmental Concentration (PEC) is around 0.095 μg/L.

In view of the absence of data to indicate the toxicity of the notified polymer to daphnia and algae, it is assumed that the algal toxicity will be six times greater the that experienced for fish (LC_{50} = 10 mg/L assuming worst case in range for Luviquat Care result; Nabholz *et al.* 1993). Furthermore, due to the uncertainty an extra safety factor of 10 has been applied in addition to the 1000 recommended by the OECD.

The nationwide PEC estimate indicates that after discharge to receiving waters the environmental concentration of the notified polymer will be one order of magnitude below the estimated most sensitive toxicity (LC_{50} = 1 μg/L). However, the risk to aquatic organisms will be further mitigated by the removal of the notified polymer through association with dissolved organic carbon from soils and sediment. This is expected to bind to the notified polymer, neutralising its positive charge and removing it from the aquatic compartment thus making it less bioavailable and less toxic to aquatic organisms (Nabholz, 1993). Therefore even though the notified polymer is soluble in water, its concentration in the aquatic compartment is expected to be significantly less than the calculated PEC because it will adsorbed to soil and sediment due to its cationic nature and be removed from the aquatic compartment. If a total of 95 % of the notified polymer is adsorbed to soil and sediment as indicated after 3 h in the test for Luviquat Care the revised PEC would be 0.0048 μg/L, which is 3 orders of magnitude below the estimated toxicity to algae.

Wastes containing the notified polymer including residues from import containers will also be disposed of in landfill where it is expected to adsorbed to soil and sediment due to its cationic nature.

Given the large safety factor applied, the environmental exposure and overall environmental hazard from the notified polymer is expected to be acceptable.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
A 7.4 % aqueous solution of the notified polymer was found to be of low acute oral toxicity in rats, not sensitising to guinea pig skin, and not mutagenic in a bacterial assay. The solution was found to be slightly irritating to rabbit eyes and skin, and the skin reactions observed indicated that high concentrations of the notified chemical may be hazardous. The 7.4 % solution is not classified as a hazardous substance in accordance with the Approved Criteria.

Occupational Health and Safety
The notified polymer will only be introduced as a constituent of a ready to use shampoo, in consumer packaging. Therefore minimal occupational exposure to the notified polymer is expected during transport, storage, distribution and retail sale. Exposure would only occur on

breakage of packages. Due to the small amounts of shampoo involved and the low concentration (0.28 %) of the notified polymer in the shampoo, the risk to occupational health and safety is expected to be very low.

Public Health
The notified polymer is present in the shampoo at a concentration of 0.28 %. At this concentration it is not expected to cause irritation of the skin or eyes, nor is it a skin sensitiser. The notified polymer has a high molecular weight and is unlikely to penetrate biological membranes. The low concentration of the notified polymer in hair care shampoo products and the low toxicity of the notified chemical suggest that the notified polymer will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

13.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the importation volume increases above 1 tonne per annum, in which case standard notification, including a full suite of ecotoxicity testing including tests against aquatic invertebrates and algae, will be required;
  - the notified polymer is introduced in a form containing more than 25 % quaternised monomer, or in a form where the Number Average Molecular Weight is lower than 250000, in which case skin and eye irritation tests and ecotoxicity tests against fish, aquatic invertebrates and algae for the form to be introduced will be required.

or

(2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REFERENCES

BASF Akteingesellschaft (1985a) Determination of the Biodegradability or the Elimination of Luviquat FC 905 in the Manometric Respirometry Test, Project No. 58/003/26/1, BASF Laboratory of Emission Control and Ecology, Ludwigshafen, Germany. (unpublished report)

BASF Akteingesellschaft (1985b) Determination of the Ultimate Aerobic Biodegradability or the Elimination of Luviquat FC 905 in the Zahn-Wellens Test, Project No. 58/003/26/1, BASF Laboratory of Emission Control and Ecology, Ludwigshafen, Germany. (unpublished report)

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Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

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

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

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

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
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

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