File No: NA/818

September 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Jaguar C-162

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.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, Plaza level, Alan Woods Building, 25 Constitution Avenue, Canberra ACT 2600 between 9 AM and 5 PM Monday to Friday.

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Section at:

Street Address: 334-336 Illawarra Rd MARRICKVILLE NSW 2204, AUSTRALIA
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA
Telephone: (61) (02) 8577 8816 FAX (61) (02) 8577 8888

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Jaguar C-162

1. APPLICANT

Rhodia Australia Pty Ltd (ABN 24 050 029 000) of 352 Ferntree Gully Rd, Notting Hill VIC 3168 has submitted a standard notification statement in support of their application for an assessment certificate for the modified biopolymer Jaguar C-162.

Marketing Name:	Jaguar C162; Jaguar C2000
Method of Detection and Determination:	The notified polymer has been characterised by infrared spectroscopy.

2. IDENTITY OF THE CHEMICAL

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

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Creamy-white powder with little odour.
Boiling Point:	Product decomposes at temperatures > 150°C.
Specific Gravity:	700 – 850 kg/m^3
Vapour Pressure:	Not applicable due to the high molecular weight of the notified polymer.
Water Solubility:	Soluble in water, gives a clear solution upon acidification.
Partition Co-efficient (n-octanol/water):	Not possible to obtain as the notified polymer is a surfactant.

Hydrolysis as a Function of pH:	Results of testing for hydrolysis as a function of pH is not available. There are no functional groups likely to hydrolyse in the environmental pH range 4-9.
Adsorption/Desorption:	Not available. However, while soluble the notified polymer can be expected to be adsorbed to suspended solids and dissolved organic carbon due to the presence of a positively charged N ion.
Dissociation Constant:	No acidic or basic functional groups are present. Polymer will remain fully dissociated.
Particle Size:	Particles retained at 20 mesh: maximum 0.2 % Particles retained at 140 mesh: maximum 25 %
Flash Point:	>93°C (closed cup). Not flammable.
Flammability Limits:	Not applicable as the notified polymer is a non-flammable, but combustible solid which decomposes above 150°C (see comments below).
Autoignition Temperature:	Decomposes > 150°C.
Explosive Properties:	Combustible solid. Finely divided particles may form explosive mixtures with air. Also risk of ignition of dust cloud (see comments below).
Reactivity/Stability:	Reacts with strong oxidising agents, and acids.

Comments on Physico-Chemical Properties

On combustion or on thermal decomposition (pyrolysis) the notified polymer releases highly flammable gases which generate fire or explosion hazards, flammable vapours which may generate fire or explosion hazards, toxic gases (nitrogen oxides) and hazardous dusts (silica and carbon oxides).

4. PURITY OF THE CHEMICAL

Degree of Purity:	90 – 92 %
Hazardous Impurities:	None
Non-hazardous Impurities (> 1% by weight):	Water, < 10 %.
Residual Monomers:	None known
Additives/Adjuvants:	None

5. USE, VOLUME AND FORMULATION

Use and Import Volume

The notified polymer will be used as a thickener for cosmetic formulations and as a conditioning agent in shampoos. Jaguar C-162 will normally be present in hair care preparations at concentrations of 0.1 % – 0.2 %, although the manufacturer recommends use at up to 1 %. The notified polymer has been in use in Australia during 1999 and 2000 under a NICNAS Commercial Evaluation permit granted under section 21G of the Act and in 2000 and 2001 under a NICNAS Commercial Evaluation Permit extension granted under section 21H of the Act. Jaguar C-2000 (differing from Jaguar C-162 in the levels of functional groups present) has been in use in Australia under the permit but is not proposed to be introduced under the assessment certificate.

The notified polymer will not be manufactured in Australia, but will be imported in 25 kg fibreboard cartons lined with plastic bags. Annual import volumes will be in the range of up to 10 tonnes Jaguar-C162 per annum.

Formulation

The process of formulation of the hair care preparations is as follows: on receipt at the site of reformulation, Jaguar C-162 will be placed in the quarantine section of the warehouse, where a sample of approximately 100 g will be taken and sent to the laboratory for chemical and microbiological testing. If the samples meet specification, Jaguar C-162 will be approved for use in manufacture and transferred to the manufacturing department.

In the manufacturing department, the notified polymer will be dispensed as required into plastic bags, which will be sealed and transferred to the compounding area. Jaguar C-162 will be used in shampoo formulations at levels around 20 kg per 10000 kg batch. They will be added to the batch through a hatch at the top of the 10000 kg mixing vessel. On completion of compounding a sample from the batch will be sent to the laboratory for testing. Once approval for the compounded product is obtained, it will be packed into 250 mL or 400 mL bottles as required. These bottles will be placed in fibreboard shippers of 24 units, transferred to the distribution warehouse and released for sale.

6. OCCUPATIONAL EXPOSURE

There is potential for the exposure of workers involved in the transport and the storage of Jaguar C-162, workers involved in formulating and testing the hair preparations and those involved in packaging the hair preparations for sale.

Worker Category (number of workers)	*Nature of work*	*Exposure*
Warehouse Staff (5)	Handling, transport and storage of notified polymer	2 hours/day, 20 days/year
Quality Assurance (5)	Sampling and testing of notified polymer	4 hours/day, 3 days/year

	Sampling and testing of product containing the notified polymer	4 hours/day, 20 days/year
Manufacturing Operators (10)	Dispensing of notified polymer	1 hour/day, 20 days/year
	Compounding of product containing notified polymer	4 hours/day, 20 days/year
Packaging Operators (20)	Filling product containing notified polymer into bottles	8 hours/day, 20 days/year

Transport and Storage
The notified polymer will be transported inside and outside the site of formulation in drums designed to withstand impact and minimise breakage in the event of an accident. Occupational exposure for warehouse staff involved in handling, transporting and storing Jaguar C-162 is not expected, except in the case of an accident.

Formulation and Quality Control
During formulation, Jaguar C-162 will be handled in relatively small quantities. Approximately 20 kg of Jaguar C-162 will be used per 10000 kg batch of hair preparation. Dispensing and compounding will occur in closed systems, or in a system designed not to create aerosols or a spill hazard. Manufacturing operators may have dermal, ocular or respiratory exposure to the notified polymer if there are spills during dispensing to plastic bags or during addition of the notified polymer to the mixing vessel. Manufacturing operators will wear impervious gloves and safety goggles.

Quality assurance workers may have dermal, ocular or respiratory exposure to the notified polymer through spills which may occur during sampling of the notified polymer in powder form. They may also have dermal or ocular exposure to the notified polymer at concentrations of between 0.1 % and 0.2 % through spills or splashes which may occur when sampling the formulated product. Sampling will occur in a closed system, or in a system designed not to create aerosols or a spill hazard.

Packaging
Packaging workers will not be exposed to neat Jaguar C-162. They may, however, have ocular or dermal exposure to the notified polymer at concentrations of between 0.1 % and 0.2 % through spills or splashes that may occur when transferring the formulated product to the bottles. Once packaged, it is not expected that these workers will be further exposed to the notified polymer.

7. PUBLIC EXPOSURE

Public exposure to the notified polymer is possible but unlikely following the rupture of product 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 or skin care products 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 shampoo and skin care products, public exposure during end use will be widespread. The main route of exposure will be via dermal contact during hair, hand and body washing. It is estimated that, during shampooing or body washing, approximately 3-5 mL product, containing up to 0.2 % notified polymer, will be used 2 – 7 times per week. Contact during hand washing may be more frequent.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

8.1.1 Release at Site

About 15 kg of the notified polymer is expected to be disposed of to landfill as container residues each year. The amount of polymer residue in the manufacturing tank and the filling machine were estimated to be 0.04 kg and 0.1 kg, respectively. The estimated concentrations of the notified polymer in the effluent discharge to the manufacturer's treatment plant from cleaning these were 0.016 g/L (0.0002 %) and 0.4 g/L (0.04 %), respectively. The products are manufactured in 10000 kg batches approximately every two months. The total load to the manufacturer's effluent treatment system is approximately 0.3 kg every two months. The liquid waste is treated using a continuous biological system consisting of a 25000 L pre-treatment tank (anaerobic degradation) and a 125000 L balancing and final treatment tank (aerobic degradation) prior to discharge into the sewer.

As the polymer will be in packed in containers designed to withstand impact, the notifier does not anticipate release during transport. Due to the relatively low level of use and being dispensed and compounded in closed systems, the release during storage and product compounding will not be significant. Where accidental spillage occurs, the notified polymer will be disposed of at an approved landfill. The notifier estimates the accidental spillage to be considerably less than 100 kg per annum Australia wide.

8.1.2 Release from Use

All of the notified polymer will enter the sewer when the shampoo is washed off the consumer's hair in the shower. The notifier estimated that approximately 40 % of the product containing the polymer would be sold in the Sydney region. Based on an estimated import volume of 10000 kg per annum and the 90 % purity of the notified polymer, approximately 3600 kg of the notified polymer would enter the Sydney sewerage system per annum (9.86 kg per day).

8.2 Fate

In the sewage treatment facilities, most of the polymer is expected to become associated with the water compartment due to its relatively high water solubility. The notification dossier did not provide adsorption data and stated that it was not possible to obtain the partition coefficient, as the notified polymer is a surfactant. The notified polymer is not expected to exhibit significant adsorption to organic matter or sediment in the water compartment given its ready water solubility. However, cationic polymers are known to be adsorbed to suspended

solids and dissolved organic carbon. Due to the presence of the positively charged N ion the notified polymer can be expected to partition to sludge to some extent. The notified polymer does not volatilise, hence can not be expected to partition into the atmosphere from water. Any remaining polymer in the sewage system after treatment is expected to enter the marine and freshwater environments mainly in solution.

The two following tests on biodegradability of the notified polymer were provided.

8.2.1 Ready biodegradability (Institut Fresenius, 1993, IF-93/15448-01)

Test Substance:	Jaguar C-162
Method:	OECD TG 301D Ready Biodegradability: Closed Bottle Test.
Inoculum	A composite inoculum using secondary effluent from a predominantly domestic sewage plant and a mixture of three soil samples
Exposure period	28 days
Auxiliary solvent:	None
Analytical monitoring:	Dissolved oxygen determination using O_2 electrode (WTW; FRG; Model OXI 530 with electrode model TriOxamatic EO 200)
Remarks –Method:	In addition to the test substance, blank samples and samples containing a reference substance were measured.

Results:

Jaguar C-162		***Sodium Benzoate***	
Day	***% degradation***	***Day***	***% degradation***
7	1	7	62
14	0	14	64
21	7	21	64
28	5	28	67

Remarks – Results:	The test substance attained 5 % degradation by 28 days. Degradation of the reference substance indicates the viability of the culture and test conditions.
Conclusion:	The notified polymer is not readily biodegradable according to the OECD criteria requiring > 60 % degradation.

8.2.2 Inherent biodegradability (Rhone-Poulenc, 1995, BD 86)

Test Substance:	Jaguar C-162
Method:	OECD TG 302B (Zahn-Wellens Test)
Inoculum	Activated sludge from the aeration tank of a purification plant.
Exposure period	28 days
Auxiliary solvent:	None
Analytical monitoring:	DOC
Remarks –Method:	The test report stated that the test was conducted in accordance to regulation 133/99 Published in the Journal

Officiel Des Communautes Europeenes of 30 May 1988 (Test of Zahn and Wellens). In addition to the test substance, blank samples and samples containing a reference substance were measured. A control for monitoring the inhibition was tested.

Results:

	% Degradation		
Incubation time Days	***Jaguar C-162 Test Vessel 1***	***Jaguar C-162 Test Vessel 2***	***Ethylene glycol***
0	0	0	0
2	0	0	2
5	0	0	45
7	0	0	63
12	0	0	70
14	0	0	73
20	0	0	76
28	0	0	84

Remarks – Results: The test substance attained 0 % degradation by 28 days. Degradation of the reference substance indicates the viability of the culture and test conditions.

The percentages of biodegradation calculated according to the concentrations of Dissolved Organic Carbon at the beginning and at the end of the test are 67 % and 59 % for the two vessels of the substance after 28 days of incubation. This implies transformation of the initial substance into a less soluble substance, since no release of CO_2 was noted.

Conclusion: According to the OECD guidelines, the notified polymer is not inherently biodegradable.

8.2.3 Bioaccumulation

No bioaccumulation data were provided. The high molecular weight and water solubility suggests that the polymer has a poor affinity to lipids and hence is not likely to diffuse across biological membranes and bioaccumulate (Connell 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Jaguar C-162

Test	***Species***	***Outcome***	***Reference***
Acute oral toxicity	Rat	LD50 > 2000 mg/kg	(Toxicol Laboratories Limited, 1987c)

Skin irritation	Rabbit	Non irritating	(Toxicol Laboratories Limited, 1987a)
Eye irritation	Rabbit	Slight irritant	(Toxicol Laboratories Limited, 1987b))
Skin sensitisation	Guinea pig	Non sensitising	(Centre International de Toxicologie, 1995b)

Summary of the acute toxicity of Jaguar C-2000

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity	Rat	LD50 > 2000 mg/kg	(Centre International de Toxicologie, 1997d)
Skin irritation	Rabbit	Non irritating	(Centre International de Toxicologie, 1997b)
Eye irritation	Rabbit	Slight irritant	(Centre International de Toxicologie, 1997c)
Skin sensitisation	Guinea pig	Non sensitising	(Centre International de Toxicologie, 1997e)

9.1.1.1 Oral Toxicity (Toxicol Laboratories Limited, 1987c)

Test Substance:	Jaguar C-162
Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2000 mg/kg by gavage in a dose volume of 10 mL/kg.
Test method:	OECD TG 401
Mortality:	One female died on day 3, another female died on day 8.
Clinical observations:	Piloerection and hypoactivity were observed in all females 1, 2, and 4 hours after dosing, continuing to day 2 in one female.
Morphological findings:	Perinasal staining was observed in one in-study decedent, however autolysis of the carcass prevented further investigation. Blood and blood clots were observed in the stomach and duodenum in the other female, with the

	remaining tissues being pale due to gastric haemorrhage. No abnormalities were noted at necropsy of surviving animals on termination at day 14.
Comment:	The test substance had some toxic effect, as 20 % mortality was observed.
LD50:	> 2000 mg/kg
Result:	Jaguar C-162 was of low acute oral toxicity in rats.

9.1.1.2 Oral Toxicity (Centre International de Toxicologie, 1997d)

Test Substance:	Jaguar C-2000
Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2000 mg/kg by gavage in a dose volume of 20 mL/kg.
Test method:	OECD TG 401; EEC TG B1
Mortality:	Nil
Clinical observations:	No clinical signs of systemic toxicity were observed during the study. Body weight gains were reduced in males and females when compared to historical controls.
Morphological findings:	No abnormalities were noted at necropsy.
LD50:	> 2000 mg/kg
Result:	Jaguar C-2000 was of low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Stillmeadow Inc, 1995)

AG-RHO DR-2000 is a chemical analogue of Jaguar C-162 and Jaguar C-2000. A summary only was provided.

Test Substance:	AG-RHO DR-2000
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	14 days

Method of administration:	2020 mg/kg in corn oil using patches.
Test method:	Not stated.
Mortality:	**Nil**
Clinical observations:	Not stated.
Morphological findings:	Not stated.
LD50:	> 2020 mg/kg
Result:	AG-RHO DR-2000 was of very low acute dermal toxicity in rabbits.

9.1.3 Acute Inhalation Toxicity

No study of acute inhalation toxicity was provided by the notifier.

9.1.4.1 Skin Irritation (Toxicol Laboratories Limited, 1987a)

Test substance:	Jaguar C-162
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	6 females
Observation period:	7 days
Method of administration:	A single 4 hour, semi occluded application of 500 mg of test substance, moistened with water, to intact skin.
Test method:	OECD TG 404
Cutaneous reactions:	Very slight erythema (Grade 1) was observed in one animal one hour after the dressings were removed. No other irritation or other effects of treatment were observed for the duration of the study.
24, 48 & 72 hour group mean score:	Erythema/Eschar formulation: 0.0 Oedema: 0.0
Result:	Jaguar C-162 was non irritating to rabbit skin.

9.1.4.2 Skin Irritation (Centre International de Toxicologie, 1997b)

Test substance:	Jaguar C-2000
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	3 days
Method of administration:	A single 4 hour, semi occluded application of 500 mg of test substance, moistened with water, to intact skin.
Test method:	OECD TG 404; EEC TG B4
Cutaneous reactions:	No cutaneous reactions were observed for the duration of the study.
24, 48 & 72 hour individual mean score:	Erythema/Eschar formulation: 0.0 Oedema: 0.0
Result:	Jaguar C-2000 was non irritating to rabbit skin.

9.1.5.1 Eye Irritation (Toxicol Laboratories Limited, 1987b)

Test substance:	Jaguar C-162
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	7 females
Observation period:	7 days
Method of administration:	Preliminary test: A single instillation of 0.1 mL of the neat test substance into the test eye of one rabbit; the contralateral eye served as the control. Main test: As above, using 6 animals.
Test method:	OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation														
Animal #	***1 hour***			***24 hours***			***48 hours***			***72 hours***			***7 days***		
Cornea	*All scores were zero*														
Iris	*All scores were zero*														
Conjunctiva[1]	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1[P]	1	3	1	0	0	0	0	0	0	0	0	0	0	0	0
2	2	4B	0	1	2	0	0	0	0	0	0	0	0	0	0
3	2	2	0	1	0	0	0	0	0	0	0	0	0	0	0
4	1	2	0	0	1	0	0	0	0	0	0	0	0	0	0
5	1	2	0	2	1	0	0	0	0	0	0	0	0	0	0
6	2	3	0	1	0	1	0	0	0	0	0	0	0	0	0
7	2	3	1	2	2	0	1	0	0	0	1	0	0	0	0

[1] See Attachment 1 for Draize scales. r = redness c = chemosis d = discharge.
P – preliminary test. B – blistering of conjunctival membranes.

Ocular response:

Preliminary test:
Moderate conjunctival irritation diminishing within 24 hours.

Main test:
Well defined to severe conjunctival irritation was observed in treated eyes, diminishing within 48 hours.

24, 48 & 72 hour group mean score:

Conjunctival redness: 0.44;
Conjunctival chemosis: 0.39;
Conjunctival discharge: 0.06.

Result:

Jaguar C-162 was a slight irritant to rabbit eye.

9.1.5.2 Eye Irritation (Centre International de Toxicologie, 1997c)

Test substance:

Jaguar C-2000

Species/strain:

Rabbit/New Zealand White

Number/sex of animals:

3 males

Observation period:

3 days

Method of administration:

A single instillation of 100 mg of the neat test substance into the test eye of each rabbit; the contralateral eye served as the control.

Test method:	OECD TG 405; EEC TG B5
Ocular response:	Slight conjunctival reactions were observed in all animals within the first 24 hours: very slight or slight chemosis (grade 1 or 2) was noted in all animals, very slight redness of the conjunctivae (grade 1) was observed in one animal and whitish purulent discharge was recorded in two animals. No ocular reactions persisted on day 2.
24, 48 & 72 hour individual mean score:	Conjunctival chemosis: 0.0; Conjunctival redness: 0.0; Iris lesions: 0.0; Corneal opacity: 0.0.
Result:	Jaguar C-2000 was very slightly irritating to rabbit eye.

9.1.6.1 Skin Sensitisation (Centre International de Toxicologie, 1995b)

Test substance:	Jaguar C-162
Species/strain:	Guinea pig/Dunkin-Hartley
Number of animals:	10 female test animals and 5 female control animals
Induction procedure:	Intradermal Induction: Test animals: Day 1: three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region: • Freund's Complete Adjuvant (FCA) in saline (1:1) v/v; • the test substance, diluted to 1 % p/p in paraffin oil; • the test substance at 1 % p/p in paraffin oil, mixed in a (1:1) v/v mixture of FCA and saline (1:1) p/v. Topical Induction: Day 7 – occlusive application of 0.5 mL sodium lauryl sulphate (10 %) in Vaseline; Day 8 – A 48-hour occluded application of 0.5 mL of test substance, 20 % p/p in paraffin oil, to the treated area. Control Animals: Treated similarly to the test animals omitting the test substance from the intradermal injections and topical application.
Challenge procedure:	Test and Control Animals: Day 22: A 24 hour, occluded application of 20 % p/p of test substance in paraffin oil, to the posterior right flank of each

	animal. Paraffin oil was applied similarly to the posterior left flank of each animal.
Test method:	OECD TG 406 – Magnusson & Kligman Maximisation Method
Cutaneous reaction:	Very slight erythema (grade 1) was observed in one treated animal at the 24 hour observation period. No oedema was observed at the 24 or 48 hour observation period.
Result:	Jaguar C-162 was non sensitising to guinea pig skin.

9.1.6.2 Skin Sensitisation (Centre International de Toxicologie, 1997e)

Test substance:	Jaguar C-2000
Species/strain:	Guinea pig/Dunkin-Hartley
Number of animals:	10/sex (test group), 5/sex (control group)
Induction procedure:	Intradermal Induction: Test animals: Day 1: three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region: • FCA in saline (1:1) v/v; • the test substance, diluted to 5 % w/w in saline; • the test substance at 5 % w/v in a mixture of FCA and saline (1:1) w/w; Topical Induction: Day 7 – occlusive application of 0.5 mL sodium lauryl sulphate (10 % w/w) in Vaseline; Day 8 – A 48-hour, occluded application of 500 mg of neat test substance to the treated area. Control animals: Treated similarly to the test animals omitting the test substance from the intradermal injections and topical application.
Challenge procedure:	Test and Control animals: Day 22: A 24 hour, occluded application of 500 mg of neat test substance, to the posterior right flank of each animal. Saline was applied similarly to the posterior left flank of each animal.
Test method:	OECD TG 406 – Magnusson & Kligman Maximisation

	Method
Cutaneous reaction:	No erythema or oedema was observed at the 24 or 48 hour observation period in test or control animals.
Comment:	Hypoactivity, piloerection and dyspnoea were noted in one male of the treated group on day 22. This animal died later that day. The mortality was not considered attributable to the test substance.
Result:	Jaguar C-2000 was non sensitising to guinea pig skin.

9.2 Repeated Dose Toxicity

No study of repeat dose toxicity of the notified polymer was provided.

9.3 Genotoxicity

9.3.1.1 *Salmonella typhimurium* Reverse Mutation Assay (Centre International de Toxicologie, 1995a)

Test substance:	Jaguar C-162
Strains:	*Salmonella typhimurium:* TA 1535, TA 1537, TA 98, TA 100, TA 102.
Metabolic activation system:	Liver S9 fraction from rats induced with Aroclor 1254.
Concentration range:	0, 312.5, 625, 1 250, 2 500, 5 000 μg/plate. Each concentration was tested in triplicate, with or without metabolic activation, in two independent experiments. Appropriate strain specific positive control reference substances were used.
Test method:	OECD TG 471
Comment:	No precipitation was noted. No toxicity was observed. There were no significant increases in revertant colony numbers at any concentration, in the presence or absence of metabolic activation. Concurrent positive controls used in the test induced marked

	increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.
Result:	Jaguar C-162 was non mutagenic under the conditions of the test.

9.3.1.2 *Salmonella typhimurium* Reverse Mutation Assay (Centre International de Toxicologie, 1997a)

Test substance:	Jaguar C-2000
Strains:	*Salmonella typhimurium*: TA 1535, TA 1537, TA 98, TA 100; *Escherichia coli:* WP2uvrA, WP2pKM101.
Metabolic activation system:	Liver S9 fraction from rats induced with Aroclor 1254.
Concentration range:	0, 62.5, 125, 250, 500, 1 000 μg/plate. Each concentration was tested in triplicate, with or without metabolic activation, in two independent experiments. Appropriate strain specific positive control reference substances were used.
Test method:	OECD TG 471
Comment:	No precipitation was noted. No toxicity was observed. There were no significant increases in revertant colony numbers at any concentration, in the presence or absence of metabolic activation. Concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.
Result:	Jaguar C-2000 was non mutagenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

Jaguar C-2000 was of very low acute oral toxicity (LD50 > 2000 mg/kg) in rats. In an acute oral toxicity study, Jaguar C-162 showed toxic effects, causing 20 % mortality. Nevertheless, the LD50 for this study was determined to be > 2000 mg/kg.

A dermal toxicity study on an analogue substance, AG-RHO DR-2000, indicated an LD50 greater than 2020 mg/kg in rabbits. Given this result and the high molecular weight of the notified polymer, Jaguar C-162 and Jaguar C-2000 are not expected to be acutely toxic via the dermal route. Jaguar C-162 and Jaguar C-2000 were non irritating to rabbit skin. In guinea pigs, there was no evidence of skin sensitisation in an adjuvant type test using Jaguar C-162 at a challenge concentration of 20 % or Jaguar C-2000 at a challenge concentration of 100 %.

Jaguar C-162 caused slight eye irritation (severe to well defined reactions of limited duration) in rabbits. The initial reactions moderated during the first 24 hours and resolved after 3 days. Jaguar C-2000 also caused eye irritation (very slight to slight reactions, resolving after 24 hours), of a lesser degree than those observed for Jaguar C-162.

Jaguar C-162 and Jaguar C-2000 were non mutagenic in bacterial reverse mutation assays.

No study on repeat dose toxicity of the notified polymer was provided; however the notified polymer is not expected to cause significant adverse effects on repeated exposure due to its high molecular weight and consequent low bioavailability, as well as its low acute toxicity.

Hazard Classification
The results of the acute oral studies in rats and eye irritant studies in rabbits do not meet the thresholds for classification as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) (Approved Criteria). Jaguar C-162 and Jaguar C-2000 are therefore not classified as hazardous substances according to the Approved Criteria based on the toxicological endpoints investigated.

10 ASSESSMENT OF ENVIRONMENTAL EFFECTS

10.1 Acute toxicity to aquatic organisms

Summary of the acute toxicity of Jaguar C-162

Test	*Species*	*Results*	*Reference*
Acute toxicity to fish	Rainbow trout *Oncorhynchus mykiss*	96 h LC50 > 100 mg/L NOEC = 100 mg/L	Rhone-Poulenc 1994
Acute immobilisation	Water flea *Daphnia carinata*	48 h EC50 = 282 ± 45 mg/L 48 h NATEC = 128 mg/L	Leeder Consulting 2002
Algal growth inhibition	Unicellular alga *Selenastrum capricornutum*	96 h IC50 > 1000 mg/L LOEC > 1000 mg/L NOEC = 1000 mg/L	Leeder Consulting 2002
Microtox assay	Microtox® bioluminescent bacterium *Vibrio fischeri*	EC50 = 2690 mg/L	Leeder Consulting 2002

- NOEC - No observable effect concentration
- LOEC – Lowest observed effect concentration

- NATEC - No acute toxic effect concentration

10.2 Acute toxicity to Fish (Rhone-Poulenc, 1994, P 102)

Test substance:	Jaguar C-162
Method:	Method published in the "Journal Officiel Des Communautes Europeennes" of December 29 1992 (Limit test in semi-static)
Species:	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period:	96 hours
Auxiliary Solvent:	None
Water Hardness:	160 mg $CaCO_3$/L
Analytical Monitoring:	Not mentioned
Remarks – Method:	The test was limited to a test concentration of 100 ppm (weight/weight). All the fish were transferred into either freshly prepared test solution (treated group) or dilution water (control groups) at 24, 48 and 72 hours. The length of test fish was 6.0 cm ± 2.0 cm whereas the OECD TG 203 recommendation is 5.0 cm ± 1.0 cm. The sensitivity of the batch of fish selected for the study was assessed using a reference substance. The study is reported to have been carried out in accordance with the OECD Principles of Good Laboratory Practices.

Results:

Concentration in ppm (weight/weight) Nominal	***Test tank Number***	***Number of Fish***	***Mortality***			
			24h	***48h***	***72h***	***96h***
Control	1	5	0	0	0	0
Control	2	5	0	0	0	0
100	3	5	0	0	0	0
100	4	5	0	0	0	0

LC50:	> 100 ppm (weight/weight) at 96 hours.
NOEC:	100 ppm
Remarks – Results:	None of the fish exhibited any abnormal behaviour up to 96 hours. The average size and weight of tested fish at 96 hours were 4.4 cm ± 0.3 cm and 0.8 g ± 0.2 g (confidence intervals at 95% with degree of freedom of 19), respectively.
Conclusion:	The results of the acute toxicity test indicate the test substance is not toxic to rainbow trout (Mensink *et al* 1995).

The following three tests assessed the toxicity of Jaguar C-162 to *Daphnia carinata, Selenastrum capricornutum* and Microtox® Bacteria. The exact test methods followed were not specified, but the report indicated that the tests were carried out in accordance with standard test protocols (OECD, USEPA, ASTM). A stock solution of 1 % (weight/volume) of the test substance was made in distilled water and the pH of 8.9 was adjusted to 6.8 with 0.1 N HCl. Test solutions for all three tests were made on a volume/volume basis from this

stock solution. The concentrations used in each test were established by a series of preliminary range finding tests.

10.3 Acute toxicity to aquatic invertebrates (Leeder Consulting, 2002, M220344)

Test substance:	Jaguar C-162
Method:	Daphnia sp. Acute Immobilisation Test – 48 hour static test.
Species:	Water Flea (*Daphnia carinata)*
Exposure Period:	48 hours
Auxiliary Solvent:	None
Water Hardness:	34 mg $CaCO_3$/L
Analytical Monitoring:	Not mentioned
Remarks – Method:	The pH, dissolved oxygen, temperature and conductivity were measured at the commencement and conclusion of the test but not reported.

Results:

Concentration mg/L Nominal	***Number of D. magna***	***% Immobilised 48 h***
0	20	0
100	20	0
180	20	15
320	20	55
560	20	100
1000	20	100

EC50:	282 ± 45 mg/L at 48 hours
NATEC: (No Acute Toxic Effect Concentration)	128 mg/L at 48 hours
Remarks - Results:	The 48 hour EC50 value was calculated by Probit analysis and the NATEC was determined from the polynomial relationship between concentration and response. No immobilisation of daphnia was observed at test concentrations below 100 mg/L.
Conclusion:	The test substance is practically non-toxic to aquatic invertebrates (Mensink *et al* 1995).

10.4 Algal growth inhibition (Leeder Consulting, 2002, M220344)

Test Substance:	Jaguar C-162
Method:	Alga, Growth Inhibition Test.
Species:	Unicellular alga (*Selenastrum capricornutum)*
Exposure period:	96 hours
Concentration range: Nominal	Nine concentrations between 0.1 to 1000 mg/L
Concentration range: Actual	Not reported

Auxiliary solvent:	None
Water hardness:	37 mg $CaCO_3$/L
Analytical monitoring:	Cells were counted at 24, 48, 72 and 96 hours with a haemocytometer.
Remarks – Method:	Standard USEPA test medium without EDTA was used. The conductivity of the test medium ranged from 351 to 403 µS/cm and the pH and dissolved organic carbon were 7.5 and 5 mg/L, respectively. There was significant clumping of cells in the 300 mg/L and 1000 mg/L treatments, which required strong shaking prior to counting. After 96 hours, cells from the 1000 mg/L and control treatments were sub-cultured in fresh diluent and incubated for a further 9 days.

Results:

Effect	***Biomass mg/L***
IC50 values at 24, 48, 72 and 96 hours	> 1000 mg/L
LOEC	> 1000 mg/L
NOEC	1000 mg/L

Remarks - Results:	There was no significant inhibition in cell yield in any treatment. Although there was significant clumping in the 300 mg/L and 1000 mg/L, clumping was not evident in the lower concentrations or the control. Apart from this clumping, cells in the highest concentration were similar in appearance to control cells. There were no algacidal effects in any of the test treatments. The 9 day post test sub-cultures could not be reliably counted in the 1000 mg/L treatment, however, microscopic examination showed normal cell in both the control and 1000 mg/L treatment.
Conclusion:	The test substance is not toxic to algae (Mensink *et al* 1995).

10.5 Microtox assay (Leeder Consulting, 2002, M220344)

Test substance:	Jaguar C-162
Method:	Standard ASTM method
Species:	Microtox® bioluminescent bacterium (*Vibrio fischeri*)
Exposure period:	15 minutes
Remarks – Method:	The study report stated that the assay was carried out in accordance with the Standard ASTM method. Three dilutions of the test substance were tested at four concentrations and a control and the EC50 calculated for each dilution.
Results:	The EC50 and 95 % confidence limits of a 1 % pH adjusted solution was 26.9 % (95 % confidence intervals of 25.1and 28.9). This is equivalent to 2690 mg/L.
Results – Remarks:	The non-toxic concentration was estimated from the

relationship between log Dilution and log Toxic units, the reciprocal of the EC50.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

11.1 Environment –exposure assessment

The notifier has indicated that the estimated import volume will be up to 10000 kg. Apart from about 15 kg that will enter landfill as residues in containers, almost all of the notified polymer will be released into the sewer each year, during manufacturing of the shampoo and skin care products and when the products are washed off the hair in the shower.

The notified polymer is highly water-soluble and hence, in sewage treatment plants, is expected to partition mainly into the water compartment. The partition coefficient indicates the polymer will have little affinity for organic matter in the environment, and hence adsorption onto sewage sludge is not expected. However, due to the presence of the positively charged N ion, the notified polymer can be expected to be partitioned to sludge to some extent. As the polymer does not volatilise, no partitioning into the atmosphere from water is expected.

It is difficult to predict how much of the polymer will be absorbed by the skin and how much will be removed in the shower. A worst-case scenario of predicted environmental concentration (PEC) was calculated for the aquatic environment resulting from release at end use of products. The assumptions used in calculating the PEC are:

- all of the product containing the notified polymer is removed in the shower during bathing, with no skin absorption;
- all of the 10000 kg of polymer (with 90 % purity) imported in one year is released into the sewer over a 365-day period, with no removal of the polymer by adsorption or degradation, giving a daily release of 24.66 kg (24658 g); and
- release to sewage systems occurs on a nationwide basis and is continuous throughout the year, although most releases likely to occur in metropolitan areas.

Based on 18 million people throughout the whole country using water at an average volume of 150 L per day per person, the daily sewer out put is 2700 ML. The nationwide PEC of the notified polymer in the sewer is 9.1×10^{-3} mg/L (9.1 µg/L) per day. This PEC would be further diluted once released into the receiving waters by an amount that will depend on the nature of the receiving waters (eg. ocean, river, flow rate).

The notifier has indicated that approximately 40 % of the product containing the polymer would be sold in the Sydney region. Based on the estimate of import volume of 10000 kg per annum, the amount of polymer entering the Sydney sewerage system will be approximately 3600 kg (9.86 kg per day). As a worst case scenario, a PEC was calculated for the aquatic environment arising from the use of the entire product is within the Sydney region. Assuming a population of 3.5 million people using water at an average of 150 L per day person, the daily sewer out put will be 150 ML. A PEC for the Sydney region arising from the use of the product is 46.97×10^{-3} mg/L (46.97 µg/L).

11.2 Environment –effects assessment

The results of the toxicity tests indicate the test substance is not toxic to fish, daphnia, or algae, with all organisms having LC_{50} values greater than 100 mg/L. The test substance did not inhibit the multiplication of the aquatic bacterium, *Vibrio fischeri*. A predicted no effect concentration (PNEC) calculated using the LC50 of the most sensitive species (> 100 mg/L) and a safety factor of 100 (OECD) would be >1.0 mg/L.

11.3 Environment –risk characterisation

Usage patterns indicate that the most of the notified polymer could eventually be released into the aquatic environment via sewage treatment facilities when the shampoo products are washed off the hair in the shower or during bathing. The notified polymer is highly water-soluble and hence, in sewage treatment plants, is expected to partition mainly into the water compartment. However, being a cationic polymer the polymer is likely to be adsorbed to suspended solids and dissolved organic carbon. The polymer is not readily biodegradable, with only 5% degradation after 28 days, and so is not likely to be eliminated in the sewer prior to its release into the natural environment.

The notified polymer is not toxic to aquatic organisms, with fish, daphnia, and algae all having an LC_{50} greater than 100 mg/L. A worst-case daily PEC calculated, assuming a nationwide use of the products and that all of the yearly import volume is released into the sewer in a diffuse manner, is 9.1×10^{-3} mg/L. The PEC/PNEC ratio is significantly less than one, indicating no immediate concern for the environment.

The PEC/PNEC ratio resulting from the use of the entire product in the Sydney region is also less than one indicating no immediate concern for the environment. As only 40 % of the product is expected to be sold in the Sydney region, the actual PEC will be further diluted. The calculated PEC values would be further reduced once the notified polymer is released into the receiving waters, further reducing aquatic exposure.

The biodegradation tests indicate that the polymer is not readily biodegraded, however, once released into the environment the polymer is not expected to persist, but to undergo eventual degradation by biotic and abiotic processes. The high molecular weight and the water solubility of the notified polymer suggest a low potential to bioaccumulate. Further, due to the very high dilution rates in the release processes, the concentrations of the polymer encountered by aquatic organisms are expected to be very low. Therefore, it is unlikely that the polymer would exist at levels, which could accumulate and pose a threat to aquatic organisms.

Given the above considerations, the notified polymer is not expected to pose any significant hazard to the environment. The low import volumes and the anticipated use patterns (nationwide or 40 % in Sydney region) of the product indicate that the levels of release of the polymer to the environment will be low, and significantly lower than the levels of exposure shown to be toxic to aquatic organisms.

On the basis of the PEC/PNEC ratio and the low environmental exposure, the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment and Classification
Jaguar C-2000 was of very low acute oral toxicity (LD50 > 2000 mg/kg) in rats. In an acute oral toxicity study, Jaguar C-162 was determined to be of very low oral toxicity (LD50 > 2000 mg/kg), though 20 % mortality was observed.

An analogue substance, AG-RHO DR-2000 was determined to be of very low dermal toxicity (LD50 > 2020 mg/kg) in rabbits. Given this result and the high molecular weight of the notified polymer, Jaguar C-162 and Jaguar C-2000 are not expected to be acutely toxic via the dermal route. Jaguar C-162 and Jaguar C-2000 were non irritating to rabbit skin and did not show evidence of skin sensitisation in guineapigs.

Jaguar C-162 caused moderate eye irritation (severe to well defined reactions, resolving after 3 days) in rabbits. Jaguar C-2000 also caused eye irritation (very slight to slight reactions, resolving after 24 hours).

Jaguar C-162 and Jaguar C-2000 were non mutagenic in bacterial reverse mutation assays.

Based on the toxicological data submitted, Jaguar C-162 is not classified as a hazardous substances according to the Approved Criteria.

Occupational Health and Safety
The notified polymer will be imported in 90 % pure form and reformulated in Australia to produce cosmetic products normally containing up to 0.20 % notified polymer. There may be contact with solid notified polymer or with concentrated solutions during the reformulation process and testing of materials. Workers involved in these processes will wear skin and eye protection, and, due to the low acute toxicity of the notified polymer, no significant occupational health and safety risks are expected. Dermal contact with formulated products which are intended for dermal use by consumers is not expected to lead to occupational health and safety risks.

The notifier states that the notified polymer is in use in the USA with no adverse health effects reported. Furthermore, no adverse effects have been reported during its use in Australia under a Commercial Evaluation permit.

Public Health
The notified polymer is present in shampoo and skin care products at a concentration normally up to 0.20 %. 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 shampoo and skin care products and the low toxicity of the polymer suggest that it will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer prior to incorporation in consumer products:
  - impervious gloves, eye protection

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- 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.

Disposal

- The notified polymer should be disposed of by incineration or in landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled by recovering the product by vacuuming/shovelling or sweeping. If necessary, wash with water following recovery. Dispose of at a licensed waste collection point.

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. REQUIREMENTS FOR 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
  - Jaguar C-2000 is to be imported, in which case a full suite of ecotoxicology data

for this grade should be supplied since results of tests on fish indicate much greater toxicity from this polymer grade which contains a higher level of quaternary amine functional group

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.

16. REFERENCES

Centre International de Toxicologie (1995a) Jaguar C162: Reverse Mutation Test on *Salmonella typhimurium* Bacteria, CIT Study No 12112 MMO, Project No. 703/161, Miserey, France. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Centre International de Toxicologie (1995b) Jaguar C162 Cutaneous Sensitization test on Guinea Pigs (Maximisation Method of Magnusson & Kligman) CIT Study No. 12158 TSG, Miserey, France. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Centre International de Toxicologie (1997a) Jaguar C2000: Bacterial Reverse Mutation Test, CIT Study No. 15741 MMT, Project No. 703/161, Miserey, France. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Centre International de Toxicologie (1997b) Jaguar C2000: Acute Dermal Irritation in Rabbits, CIT Study No. 15738 TAL, Miserey, France. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Centre International de Toxicologie (1997c) Jaguar C2000: Acute Eye Irritation in Rabbits, CIT Study No. 15739 TAL, Miserey, France. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Centre International de Toxicologie (1997d) Jaguar C2000: Acute Oral Toxicity in Rats, CIT Study No. 15737 TAR, Miserey, France. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Centre International de Toxicologie (1997e) Jaguar C2000 Cutaneous Sensitization test on Guinea Pigs (Maximisation Method of Magnusson & Kligman) CIT Study No. 15740 TSG, Miserey, France. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Connell DW (1990). General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW (editor). Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA. pp. 47-57.

Institut Fresenius (1993) Study on the Ready Biodegradability of Jaguar C-162 according to Closed Bottle Test (IF-93/15448-01, 20 December 1993). Taunusstein-Neuhof, Germany, Institut Fresenius, Chemische und Biologische Laboratorien GmbH (Unpublished report submitted by Rhodia Australia Pty Ltd).

Leeder Consulting (2002) Assessment of the Toxicity of Jaguar C-162 to *Daphnia carinata, Selenastrum capricornutum* and Microtox® Bacteria (Study No. M220344, June 2002) Fairfield, Victoria, Australia, Leeder Consulting, *aqua*TOX Services, Ecological Testing Services (Unpublished report submitted by Rhodia Australia Pty Ltd).

Mensink, BJWG. Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H. and Linders JBHJ (1995) Manual for summarising and evaluating the environmental aspects of pesticides, National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands. Report No. 679101022.

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.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.

Rhone-Poulenc (1994) Evaluation of the Acute Ecotoxicity After 96 Hours Exposure of Jaguar C 162 in Relation to *Oncorhynchus mykiss* Using the Method Published in the Journal Officiel Des Communautes Europeenes of 29 December 1992 - limited test in semi-static (Study No. P 102, 2 May 1994). Decines Charpieu Cedex, France, Rhone-Poulenc Industrialisation, Centre De Recherche D'Ingenierie, De Technologie –Decines (Unpublished report submitted by Rhodia Australia Pty Ltd).

Rhone-Poulenc (1995) Evaluation in an Aqueous Medium of the Ultimate Potential Aerobe Biodegradability of Jaguar C-162 in Accordance with Regulation 133/99 Published in the Journal Officiel Des Communautes Europeenes of 30 May 1988 – Test of Zahn and Wellens (Study No. BD 86, 16 January 1995). Decines Charpieu Cedex, France, Rhone-Poulenc Industrialisation, Centre De Recherche D'Ingenierie, De Technologie –Decines (Unpublished report submitted by Rhodia Australia Pty Ltd).

Stillmeadow Inc (1995) AG-RHO DR-2000: Acute Dermal Toxicity in Rabbits. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Toxicol Laboratories Limited (1987a) Jaguar C162: Acute Dermal Irritation/Corrosion Study, Study No. A/S/2021, Project No. 703/140, Ledbury, UK. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Toxicol Laboratories Limited (1987b) Jaguar C162: Eye Irritation Study in the Rabbit, Study No. A/E/2022, Ledbury, UK. (Unpublished report submitted by Rhodia Australia Pty Ltd)

Toxicol Laboratories Limited (1987c) Jaguar C162: Single Dose Oral Toxicity in the Rat, Study No. A/O/2023, Project No. 703/138, Ledbury, UK. (Unpublished report submitted by Rhodia Australia Pty Ltd)

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