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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Polyolprepolymer-2

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For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 577-9466 **FAX (61) (02) 577-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in Polyolprepolymer-2

1. APPLICANT

Bronson & Jacobs Pty Ltd of Parkview Drive, Australia Centre HOMEBUSH NSW 2140 has submitted a limited application in support of their application for an assessment certificate for Polymer in Polyolprepolymer-2.

2. IDENTITY OF THE CHEMICAL

Chemical name: poly[oxy(methyl-1,2-ethanediyl)], α-hydro-ω hydroxy polymer with 1,1' methylene-bis-[4, isocyanatocyclohexane]

Chemical Abstracts Service (CAS) Registry No.: 9042-82-4

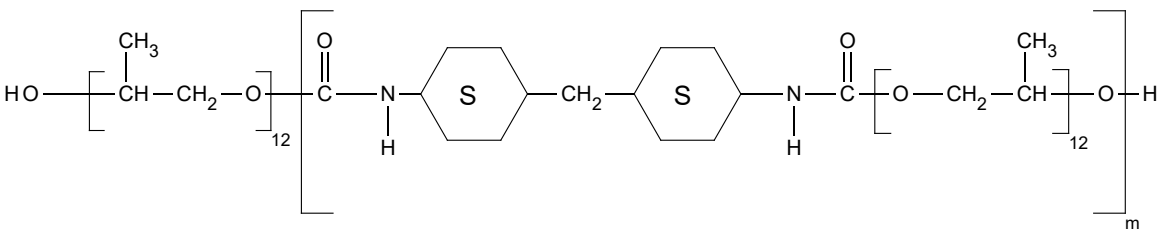
Other names: PPG-12/SMDI Copolymer; PDT 002-002

Trade name: Polyolprepolymer-2 (containing notified polymer and < 20% of the obligatory by-product polypropylene glycol)

Molecular formula: $HO(C_3H_6O)_{12}[C_{15}H_{22}N_2O_2(C_3H_6O_{12}]_mH$

where m = 1-4 predominantly

Structural formula:



where m = 1-4 predominantly

Number-average molecular weight (NAMW): ~ 2000

Weight-average molecular weight: ~ 4000

Method of detection and determination: the chemical can be qualitatively identified by gas permeation chromatography (GPC) and infrared (IR) spectroscopy

Spectral data: IR spectrum

wavenumber (cm^{-1})	*assignment*
3470	ν O-H
3350	ν N-H
2900	ν C-H
1720	ν C=O urethane
1520	ν C-N δ N-H
1450	δ C-H
1375	ω C-H
1100	ν C-O-C

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data were provided for Polyolprepolymer-2.

Appearance at 20°C and 101.3 kPa: non-volatile, clear viscous liquid

Odour: slight and characteristic (claimed in Material Safety Data Sheet (MSDS) to be odourless)

Boiling point: decomposes rather than boiling upon heating above 100°C

Density: 1.06 g/mL at 25°C

Vapour pressure: < 0.133 kPa at 20°C

Water solubility: 100 mg/L (100 ppm)

Partition co-efficient (n-octanol/water): information not provided

Hydrolysis as a function of pH:	expected to be negligible in the pH range 1-9
Adsorption/Desorption:	information not provided
Dissociation constant:	does not dissociate in water
Flash point:	178°C (closed cup)
Flammability limits:	combustible; the chemical decomposes when heated; decomposition products above 100°C are aldehydes or oxides of nitrogen
Autoignition temperature:	not provided
Explosive properties:	none expected
Reactivity/Stability:	stable at ambient temperatures; no known chemical incompatibilities

Comments on Physico-Chemical Properties

Based on standard polyurethane chemistry, hydrolysis in the pH range of 1-9 is expected to be negligible.

The consultant for the notifier argues incorrectly that the partition coefficient can not be measured because the substance does not dissociate in water and has very low water solubility. Neither of these factors would preclude measurement. However, the surface active properties of the substance would preclude measurement of this parameter, and the failure to provide data is therefore acceptable.

The consultant for the notifier argues that the issue of adsorption/desorption is adequately addressed as only 310 mg of the notified substance will enter the aquatic environment annually. This argument is based on the unlikely assumption that only 0.1% of the finished product will be released through bathing and showering, and on an incorrect interpretation of water solubility (a water solubility of 100 ppm means that 100 mg will dissolve in 1 L of water). As a surface active compound, the notified substance would be expected to sorb to soil and other surfaces.

4. PURITY OF THE CHEMICAL

Degree of purity: > 99%

Toxic or hazardous impurities:

Chemical name:	dicyclohexylmethane-4,4'-diisocyanate
Synonyms:	methylenebis(4-cyclohexyl isocyanate) 4,4'-methylenedi(4-cyclohexyl isocyanate)
CAS No.:	5124-30-1
Weight percentage:	0.03%
Toxic properties:	listed on the *List of Designated Hazardous Substances* (1) with a cut-off concentration of 1%

Non-hazardous impurities (> 1% by weight):

Chemical Name	*CAS No.*	*Weight %*
polypropylene glycol*	25322-69-4	< 20%
tin as tin octanoate		< 75 ppm

* Polyolprepolymer-2 contains 20% of an obligatory by-product polypropylene glycol. All other toxic or non-toxic impurities are at less than 1% therefore the notified polymer itself can be considered to be greater than 99% pure

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be imported as the pure reactive product from the USA. It will be imported in 200 L drums in quantities from 500 kg in the first year increasing to 1 tonne in 1999 and 2000.

The product will be reformulated into cosmetic formulations as a 2-3% component. The final cosmetic formulations will be creams or lotions to be packaged in bottles, jars or tubes of up to 500 mL. These cosmetic preparations would be expected to be applied to the skin in the home.

6. OCCUPATIONAL EXPOSURE

Polyolprepolymer-2 will be imported into Australia in sealed epoxy-phenolic-lined 200 L steel drums and transported by road to one formulation plant. Exposure to the chemical during transportation will only be possible in the event of accidental spillage.

At the formulation plant, the imported material will be transferred from the main store to the assembly area and then to the dispensary where the material will be dispensed into steel pails. When required the contents of the steel pails will be mixed with other ingredients in an enclosed system. The resulting cosmetic product

(lotions and/or creams containing 2-3% of the notified chemical) will be sampled and tested. Approved product will be transferred to a filling heads hopper via gravity or monopump and then filled into automatically fed bottles, pots or tubes. The containers will be automatically capped and labelled. Finished product will then be warehoused before sale.

Approximately 3 workers are expected to be involved in the production of cosmetic products at the formulation plant. One handler/formulator will be involved in handling, transporting, storing containers of concentrated chemical and preparing mixtures containing the chemical for 1 hour/day, 4 days/year; 1 tester will sample and test mixtures containing the chemical 4 hour/day, 2 days/year; and 1 packer will dispense and pack the formulated product approximately 4 days/year. Exposure to the notified chemical is expected to occur only during manual operations.

7. PUBLIC EXPOSURE

Polyolprepolymer-2 will be imported in 200 L steel drums and distributed to a manufacturer of cosmetic products. No public exposure is expected to occur during the manufacture, storage or distribution of the notified polymer.

The manufacture of cosmetic products is expected to be conducted in an enclosed system, and as such no public exposure to the notified polymer is expected to occur. Disposal of any waste chemical by landfill is not expected to lead to any public exposure.

Polyolprepolymer-2 will be used in cosmetic products (lotions and creams) that will be applied directly to the skin. The high NAMW (~ 2000) of the notified polymer suggests that dermal absorption is unlikely to occur.

8. ENVIRONMENTAL EXPOSURE

Release

The imported substance will be contained within closed unbreakable containers (epoxy-phenol-lined drums) during storage and closed epoxy-phenol-lined steel drums or steel pails during transportation. Under normal conditions the notified chemical would not be expected to be released during storage and transportation.

The reformulation and packaging will take place in a closed system reducing the likelihood of the chemical being released into the environment during routine mixing of formulations and packing of final products. An estimated 2.5 kg of material will remain in drums after use and another 2.1 kg of material will be lost through cleaning of equipment per annum.

The use of products containing the chemical would be widespread but diffuse as they would be applied in small quantities to the skin. Release to the environment may occur to the sewer or to landfill through the removal of the cosmetic product from the skin by washing or wiping, and the disposal of residual quantities of the

cosmetics within used containers. The notifier claims that due to the chemical's strong affinity with the skin not more than 0.1% of the product will be lost though normal use. However, up to 10% may be a better estimate of the final product lost to the sewer through washing. This would release approx 100 kg of Polyolprepolymer-2 through washing giving a total of 102 kg being released to effluent. This compares with the notifier's estimate that 3.1 kg would be released to effluent from all sources. The quantity released into the environment as residues from the finished product has not been provided by the notifier. Assuming 1% remains in jars etc another 10 kg would be released to the environment through disposal in landfill.

Should a spillage occur a maximum of 200 L of the chemical would be released into the environment and will be recovered either for reprocessing or to be disposed of in landfill. Spillages are to be contained and not released to sewer. Spilled material will be collected using approved absorbents and disposed of in approved landfills.

Fate

The precise fate of the chemical in the environment is not known. Of that which does enter the sewer system part is said to readily biodegrade and the remainder is likely to collect in the solid sludge component owing to its fat solubility and relatively low water solubility. The notifier claims that the quantity of substance released in effluent discharge is likely to be below detection limits. The residue from drums and 'empty' cosmetic containers will go into landfill. According to the notifier, the chemical is expected to break down under anaerobic conditions within the solid phase sludge component, sediment or soil compartment. No evidence has been presented to verify claims of aerobic and anaerobic biodegradability.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicity data are not required according to the Act for chemicals imported in volumes of 1000 kg or less or for polymers with NAMW > 1000. The applicant however supplied the following data for Polyolprepolymer-2 (containing > 80% notified polymer).

9.1 Acute Toxicity

Summary of the Acute Toxicity of Polyolprepolymer-2

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(2,3)
eye irritation	rabbit	non-irritating	(4,5)
skin sensitisation	guinea pig	non-sensitising	(6,7)

9.1.1 Oral Toxicity

Study 1 (2)

Species/strain:	Sprague-Dawley rat
Number/sex of animals:	5 males and 5 females
Observation period:	14 days
Method of administration:	single dose of 5000 mg/kg (undiluted)
Clinical observations:	piloerrection (4 females), scruffy fur (5 males), rapid breathing (5 males) and body tremors (2 females) was noted post-treatment; faecal staining in 1 female at day 1
Mortality:	2 females died on the day of dosing
Morphological findings:	no gross pathological effects in the animals found dead or in surviving animals
Test method:	based on OECD Guidelines for Testing Chemicals (8)
LD_{50}:	> 5000 mg/kg
Result:	low acute oral toxicity in the rat

Study 2 (3)

Species/strain:	Sprague-Dawley rat
Number/sex of animals:	5 males and 5 females
Observation period:	14 days

Method of administration:	single dose of 5000 mg/kg (undiluted)
Clinical observations:	slightly depressed (4 males, 5 females), body tremors (2 females), piloerrection (1 female), urine stains (3 females) and rapid breathing (2 females) was noted post treatment; urine staining (1 female) and scruffy fur (5 males) at day 1
Mortality:	1 female died on the day of dosing
Morphological findings:	no gross pathological effects in the animals found dead or in surviving animals
Test method:	based on OECD Guidelines for Testing Chemicals (8)
LD_{50}:	> 5000 mg/kg
Result:	low acute oral toxicity in the rat

9.1.2 Eye Irritation

Study 1 (4)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	irrigated: 3 males, 3 females non-irrigated: 3 males, 3 females
Observation period:	3 days
Method of administration:	semi-occlusive method using 0.1 mL of 10% Polyolprepolymer-2 in petrolatum; irrigated eyes were flushed with 20 mL tap water for 30 seconds

Draize scores (9) of non-irrigated eyes:

	Time after instillation								
Animal	**1 day**			**2 days**			**3 days**		
Cornea	**o[a]**	**a[b]**		**o[a]**	**a[b]**		**o[a]**	**a[b]**	
1	0	0		0	0		0	0	
2	0	0		0	0		0	0	
3	0	0		0	0		0	0	
4	0	0		0	0		0	0	
5	0	0		0	0		0	0	
6	0	0		0	0		0	0	
Iris									
1	0			0			0		
2	0			0			0		
3	0			0			0		
4	0			0			0		
5	0			0			0		
6	0			0			0		
Conjunctiva	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**
1	1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0
6	1	0	0	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Irrigated eyes: 3 animals showed a Draize score of 1 for conjunctival redness at 24 hours; all other scores were 0

Test method: based on OECD Guidelines for Testing Chemicals (8).

Result: non-irritating to the eyes of rabbits

Study 2 (5)

Species/strain:	New Zealand White rabbit
Number/sex of animals:	irrigated: 3 males and 3 females per dose non-irrigated: 1 male and 2 females per dose
Observation period:	3 days
Method of administration:	semi-occlusive method using 0.1 mL of 10% or 25% Polyolprepolymer-2 in petrolatum; irrigated eyes were flushed with 20 mL tap water for 30 seconds

Draize scores (9) of non-irrigated eyes tested with 25% Polyolprepolymer-2:

	Time after instillation								
Animal	***1 day***			***2 days***			***3 days***		
Cornea	***o[a]***	***a[b]***		***o[a]***	***a[b]***		***o[a]***	***a[b]***	
1	0	0		0	0		0	0	
2	0	0		0	0		0	0	
3	0	0		0	0		0	0	
4	0	0		0	0		0	0	
5	0	0		0	0		0	0	
6	0	0		0	0		0	0	
Iris									
1	0			0			0		
2	0			0			0		
3	0			0			0		
4	0			0			0		
5	0			0			0		
6	0			0			0		
Conjunctiva	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***
1	1	0	0	1	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0
3		0	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0
5		0	0	0	0	0	0	0	0
6		0	0	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Irrigated eyes treated with 25% Polyolprepolymer-2: no Draize scores above 0 were recorded at 24, 48 or 72 hours

Non-irrigated and irrigated eyes tested with 10% Polyolprepolymer-2: no Draize scores above 0 were recorded at 24, 48 or 72 hours

Test Method: based on OECD Guidelines for Testing Chemicals (8)

Result: non-irritating to the rabbit eye

9.1.3 Skin Sensitisation

Study 1 (6)

Species/strain: Hartley guinea pigs

Number of animals: test animals: 5 males and 5 females; positive control animals: 3 males and 3 females (1 female was found dead on day 1; the death was not believed to be treatment-related)

Induction procedure: 0.5 g of undiluted Polyolprepolymer-2 was applied topically to the abraded skin of the test animals on days 0, 2, 4 and 7; test sites were covered with gauze and an occlusive wrap; positive control animals were treated with 25% Isoeugenol in petrolatum

Challenge procedure: on day 21 0.5 g of 10% Polyolprepolymer-2 in petrolatum was applied topically to a virgin site and covered by an occlusive patch on the test animals; positive control animals were treated with 10% Isoeugenol in petrolatum

Challenge outcome:

	Test animals			***Positive control animals***		
Challenge concentration	***24 hrs****	***48 hrs****	***72 hrs***	***24 hrs***	***48 hrs***	***72 hrs***
10%	0/10**	0/10	0/10	5/5	5/5	5/5

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

Test Method: based on the Maguire method (10) using Freund's adjuvant

Result: non-sensitising to guinea pig skin

Study 2 (7)

Species/strain: Hartley guinea pigs

Number of animals: test animals: 6 males and 6 females (1 male died on day 10 and 1 female died on day 11; deaths were not believed to be treatment-related); positive control animals: 3 males and 3 females

Induction procedure: 0.5 g of undiluted Polyolprepolymer-2 was applied topically to the abraded skin of the test animals on days 0, 2, 4 and 7; test sites were covered with gauze and an occlusive wrap; positive control animals were treated with 25% Isoeugenol in petrolatum

Challenge procedure: on day 21 0.5 g of 10% Polyolprepolymer-2 in petrolatum was applied topically to a virgin site and covered by an occlusive patch on the test animals; positive control animals were treated with 10% Isoeugenol in petrolatum

Challenge outcome:

	Test animals			***Positive control animals***		
Challenge concentration	***24 hrs****	***48 hrs****	***72 hrs***	***24 hrs***	***48 hrs***	***72 hrs***
10%	0/10**	0/10	0/10	6/6	6/6	6/6

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

Test Method: based on the Maguire method (10) using Freund's adjuvant

Result: non-sensitising to guinea pig skin

9.2 Repeated Dose Toxicity

21-Day Oral Range Finding Study (11)

Species/strain:	Sprague-Dawley rats
Number/sex of animals:	3/sex/dose
Method of administration:	undiluted Polyolprepolymer-2 was administered by oral gavage
Dose/Study duration::	0 (distilled water), 10, 30, 100, 300 or 1000 mg/kg/day of Polyolprepolymer-2 was given once daily for 21 days
Clinical observations:	in most animals treated with 100 mg/kg/day and above, post-dose salivation was observed in a treatment-related manner
Gross pathology/Organ weights:	no treatment-related effects
Result:	no systemic signs of toxicity were observed in rats when tested with up to 1000 mg/kg/day Polyolprepolymer-2 daily for 21 days

13-Week Dermal Toxicity Study (12)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	7/sex/dose group (3 dose groups including control)
Method of administration:	dermal
Dose/Study duration::	applications of 0.2 or 0.5 mL undiluted Polyolprepolymer-2 (corresponding to 200 and 500 mg/kg) were made to 2 sites/animal (1 abraded and 1 intact) under semi-occluded dressings; control animals received 0.125 mL/kg (equivalent to 125 mg/kg) of polyolprepolymer glycol instead; treatment was carried out 6 hours/day, 5 days/week, for at least 13 weeks
Clinical observations:	1 or 2 animals of each sex showed skin effects (erythema, desquamation, pustules/papules) when tested with either of the doses of Polyolprepolymer-2

Clinical chemistry	no treatment-related effects
Ophthalmic observations;	no treatment-related effects
Gross pathology/Histopathology:	no treatment-related effects
Test method:	based on OECD Guidelines for Testing Chemicals (8)
Result:	Polyolprepolymer-2 resulted in no systemic toxicity when tested topically in rabbits at 500 or 1000 mg/kg/day (total of 2 test sites) 5 days/week for 13 weeks

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (13)

Strains:	TA98, TA100, TA1535, TA1537 and TA1538
Concentration range:	667, 1000, 3333, 6667 and 10000 µg/plate
Metabolic activation:	rat liver S9
Test Method:	plate incorporation method in accordance with OECD Guidelines for Testing Chemicals (8)
Result:	not mutagenic in bacteria in the presence or absence of metabolic activation

9.3.3 L5178Y *Tk*$^{+/-}$ Mouse Lymphoma Mutagenesis Assay (14)

Cell cultures:	*Tk*$^{+/-}$ cells, a subline of the mouse lymphoma cell (L5178Y)
Concentration range:	0.1, 0.8, 1.4, 2.1 and 2.9 µL/mL
Solvent:	dimethylsulfoxide
Positive controls:	ethylmethanesulfonate and 7,12 dimethylbenz(a)anthracene
Metabolic activation:	rat liver S9
Test Method:	based on OECD Guidelines for Testing Chemicals (8)

Result:	not mutagenic in bacteria in the presence or absence of metabolic activation

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (15)

Species/strain:	Swiss Webster mice
Number and sex:	test animals: 10/sex control animals: 10/sex positive control animals: 10 males
Doses:	1250, 2500 or 5000 mg/kg/day for 2 days
Procedure:	animals were treated with Polyolprepolymer-2, vehicle (corn oil) or positive control (benzene) on two consecutive days; animals were sacrificed 24 or 48 hours after the last dose and bone marrow erythrocytes harvested
Test Method:	based on OECD Guidelines for Testing Chemicals (8)
Result:	not clastogenic; no increase in micronuclei in the bone marrow erythrocytes of Swiss Webster mice

9.4 Teratology - Dermal Range-Finding Study (16)

Species/strain:	Sprague-Dawley rats
Number/sex of animals:	6 females per dose group
Method of administration:	non-occlusive topical application; test sites wiped clean after 6 hours
Dose/Study duration:	distilled water or undiluted Polyolprepolymer-2 (1000 or 2000 mg/kg/day) was administered daily from gestation day 6 through to gestation day 15
Clinical observations:	no clinical signs of maternal toxicity
Gross necropsy:	no test article-related changes
Fetal malformations:	there were no external malformations or developmental variations observed in any of the groups

Test method:	based on OECD Guidelines for Testing Chemicals (8), however, the number of animals in each dose group did not meet the requirements of the guidelines (20/dose)
Result:	not teratogenic in rats

9.5 Comedogenicity (17)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	6 males/dose
Method of administration:	topical application to the inner surface of the basal portion of the right ear (left ears served as controls)
Dose/Study duration::	0.2 mL of undiluted Polyolprepolymer-2 or 25% Polyolprepolymer-2 w/v in 95% ethanol was applied once daily, 5 days/week for 3 weeks
Test method:	in accordance with Kligman and Kwong (18)
Result:	not comedogenic in rabbits

9.6 Human Phototoxicity and Photoallergy (19)

Number of volunteers:	27 completed phototoxicity stage: 28 completed photoallergy stage (24 females and 4 males)
Method of administration:	24 hour contact occlusive patches to the paraspinal region of the back
Phototoxicity test procedure	duplicate applications of 0.2 mL Polyolprepolymer-2, distilled water and 3 other test substances were made once to each subject; immediately after patch removal (24 hours later) half the application sites were irradiated with 16-20 Joules/cm^2 of UVA (320-400 nm); test sites were evaluated 1, 24, 48 and 72 hours after irradiation
Photoallergy test procedure:	twice a week for 3 weeks patches were applied to each subject for 24 hours followed by irradiation with twice the minimum

	erythemic dose of UVB (290-320 nm); after a 2 week rest period, a single application of duplicate sets of patches of each test material was made to naive skin sites; after patch removal half the application sites were irradiated with 16-20 Joules/cm^2 of UVA; test sites were evaluated 1, 24, 48 and 72 hours after irradiation
Phototoxicity observations:	mild erythema was observed at both irradiated and non-irradiated sites at the 1 hour observation; irradiated sites resolved by 96 hours, non-irradiated sites resolved by 24 hours
Photoallergy observations:	mild erythema was observed at irradiated sites immediately after the first induction dose and at non-irradiated sites from the 1 hour observation; all sites resolved by 24 hours
Result:	no phototoxicity and no photoallergic potential in humans

9.7 Overall Assessment of Toxicological Data

Polyolprepolymer-2 has low acute oral toxicity in rats (LD_{50} > 5000 mg/kg), is non-irritating to rabbit eyes and non-sensitising to guinea pig skin. No systemic signs of toxicity were observed when the chemical was tested for 21 days in rats at oral doses up to 1000 mg/kg/day or when tested for 13 weeks in rabbits at dermal doses of 500 or 1000 mg/kg/day. The chemical was not mutagenic in bacteria or mouse lymphoma $Tk^{+/-}$ cells in the presence or absence of metabolic activation and was not clastogenic in a mouse micronucleus study. The chemical was found to be non-teratogenic when tested in rats with dermal applications of 1000 or 2000 mg/kg on gestation days 6 to 15. It was also found to be non-comedogenic in rabbits. A human study revealed no phototoxic or photoallergic responses to the notified chemical.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (20).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicological data were not provided, which is acceptable for low volume chemicals (< 1 tonne) according to the Act.

The notified substance is not expected to exhibit toxic characteristics because large polymers of this nature are not readily absorbed by biota. Due its high NAMW (>1000) the polymer is not expected to cross biological membranes.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The hazard posed by the use of the end product appears to be small in that it will be incorporated at a small percentage (2-3%) in a range of cosmetic products the use of which might be expected to be widespread across Australia. The total quantity estimated by the notifier to be released through the sewer system annually Australia wide is 3.1 kg but in the EPA's view a more likely figure may be in the order of 100 kg. Normal use of the end products appear to be unlikely to cause undue load on water and sewage treatment plants that treat and biodegrade effluent.

Taking the worst case assumption that all the chemical to be imported remains suspended and thus is discharged to receiving waters, a predicted environmental concentration (PEC) for the substance in sewage water across Australia can be estimated from the following assumptions: 1 tonne maximum annual use an Australian population of 17 million and a daily per capita waste water discharge (a conservative estimate) of 150 L. This provides a PEC of approximately 1 ppb in sewage water. Assuming only 100 kg is released into effluent the level would be reduced by an order of magnitude.

The notified polymer is unlikely to present a hazard to aquatic organisms due to its very low predicted concentration in surface waters and its low potential to cross biological membranes.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is not classified as hazardous according to Worksafe's *Approved Criteria for Classifying Hazardous Substances* (20). Human and animal experiments using Polyolprepolymer-2 suggest no significant acute or chronic toxicological hazards associated with the chemical. Hazards associated with the chemical's physico-chemical properties should also be low as it has low vapour pressure, is not flammable and is stable at ambient temperatures.

Occupational exposure levels during transport and storage are expected to be negligible unless an accidental spill occurs. In this case exposure will be predominantly dermal. The risks to workers should be low considering the infrequency of exposure, the negligible skin irritancy and low toxicity expected for the chemical.
Significant, though infrequent, exposure (up to 4 times/year) may result during the

handling of the chemical for preparation of mixtures or during quality control sampling. The possible routes of exposure during these operations will be dermal and, to a much lesser extent, oral in the case of splashing and spillages. It is expected that workers will wear safety glasses and gloves at all times while handling the chemical. The use of this protective equipment should minimise the level of exposure.

Workers are not expected to be exposed to significant levels of the chemical during reformulation or packaging as the reformulation will be conducted in enclosed systems and the packaging process will be fully automated.

The overall risk to workers from Polyolprepolymer-2 is considered to be low given the low toxicity of the chemical and the low levels of exposure.

Given that the notified polymer in Polyolprepolymer-2 will be used in cosmetic products, public exposure to the notified polymer is expected to be widespread. However, the toxicological properties of Polyolprepolymer-2 suggest that such use will present negligible risk to public safety.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in Polyolprepolymer-2 the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to a safe level, then the following personal protective equipment which conforms to Australian Standard (AS) or Australian/New Zealand Standard (AS/NZS) should be worn;

  safety goggles should be selected and fitted in accordance to AS 1336 (21) to comply with AS/NZS 1337 (22),

  industrial clothing should conform to the specifications detailed in AS 2919 (23),

  impermeable gloves or mittens conforming to AS 2161 (24),

  all occupational footwear should conform to AS/NZS 2210 (25);

- spillage of the notified chemical should be avoided;

- 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 Polyolprepolymer-2 was provided in accordance with the *National Code of Practice for the Preparation of a Material Safety Data Sheets* (26).

This MSDS was provided by Bronson & Jacobs Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of Bronson & Jacobs Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the polymer in Polyolprepolymer-2 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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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