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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Crepetrol A6115

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in Crepetrol A6115

1. APPLICANT

BetzDearborn Australia Pty Limited of 69-77 Williamson Road, INGLEBURN NSW 2565 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer in Crepetrol A6115.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name: Polymer in Crepetrol A6115 (< 40% notified polymer)

3. PHYSICAL AND CHEMICAL PROPERTIES

The data listed below pertain to the commercial product Crepetrol A6115 which is an aqueous solution containing < 40% (w/w) of the notified polymer.

Appearance at 20°C & 101.3 kPa: Clear amber coloured liquid.

Melting Point: Not stated.

Boiling Point: 100 °C (as for water-see notes below).

Specific Gravity: 1.022 at 21°C.

Vapour Pressure: 2.4 kPa at 25°C (water); insignificant for the notified polymer due to high molecular weight.

Water Solubility: Very high. Commercial product contains < 40% (w/w) of notified polymer in water.

pH: 7.6-8.6; polymer is expected to be stable to hydrolytic degradation in the environmental pH region where

	4<pH<9. See further notes below.
Partition Co-efficient (n-octanol/water):	No data provided, but log K_{ow} is expected to be low due to the high water solubility.
Hydrolysis as a Function of pH:	Under normal conditions the polymer is not expected to undergo hydrolysis.
Adsorption/Desorption:	No data provided - see notes below.
Dissociation Constant:	No data provided, but pKa expected to be approximately 11.
Flash Point:	Not flammable
Flammability Limits:	Not applicable; polymer is combustible
Autoignition Temperature:	Not applicable
Explosive Properties:	The notified polymer is stable and is not explosive
Reactivity/Stability:	The amine functionality in the polymer will be reactive with acids (salt formation) and electrophiles.
Charge Density:	At pH 1.8, 2.85 equiv/1000 g; At pH 8.0, 1.71 equiv/1000 g.

3.1 Comments on Physico-Chemical Properties

The notified polymer is a high molecular weight water soluble polyamine/polyamide which is expected to have high cationic charge density under normal environmental pH conditions due to the basic character of the residual functional groups in the polymer backbones. The stoichiometry of the polymer provided by the company indicates that the Functional Group Equivalent Weight (FGEW) of the cationic groups in the polymer is approximately 347 g/mol.

No partition coefficient data were provided, but the high water solubility indicates that the polymer will have very little affinity for the oil phase.

No data on hydrolytic degradation of the polymer were provided, but the amide linkages are expected to be stable under ambient environmental pH conditions (4<pH<9).

No data on adsorption/desorption from soils were provided. However, the high positive charge density on the polymer indicates that it would have affinity through electrostatic interactions for humic material in soils which contains a high content of (anionic) carboxylic acid residues. However, the high water solubility may indicate that the polymer could be mobile in these media.

4. PURITY OF THE CHEMICAL

Degree of Purity:	99 %
Hazardous Impurities:	Exempt information. At concentration present would not be classified as hazardous under NOHSC.
Non-hazardous Impurities (> 1% by weight):	None.
Additives/Adjuvants:	None indicated.

5. USE, VOLUME AND FORMULATION

Use
The notified polymer will be manufactured at a single plant in Victoria then sold (as a < 40% w/w aqueous solution known as Crepetrol A6115) to a single customer where it will be used as a production aid in the manufacture of soft tissue paper. Specifically, the notified polymer is used to promote adhesion of the wet paper pulp to hot drying rollers during production of the tissue paper. The concentration of notified polymer in tissue products is estimated to be 185 ppm.

Volume
Between 20 and 40 tonnes of the notified polymer will be produced annually, equivalent to 133 and 266 tonnes of Crepetrol A6115.

Manufacture of Crepetrol A6115
The manufacture of Crepetrol A6115 involves a multi-stage reaction which is carried out in batch sizes of 7500 kg. Manufacture occurs in a purpose designed, fully enclosed stainless steel reaction vessel. Raw materials are automatically fed to the vessel via mass flow meters or from tanks fitted with weight measurement equipment. When the polymerisation process is complete, the product receives final adjustment by the addition of water and biocide to a required specification and is left to cool within the reactor vessel. Once cooled, Crepetrol A6115 containing the notified polymer at < 40% is dispensed into 1000 L Intermediate Bulk Containers (IBC).

Paper Manufacture
At the paper manufacturing plant the polymer solution is transferred as required from the IBC to a 1000 L mixing tank where it is further diluted with water prior to being pumped into the process stream and mixed with the dispersion of cellulose fibres in water. The production process uses 114 tonnes of fibre (dispersed in water) daily and around 110 kg of the notified polymer.

99% of the polymer becomes adsorbed to the cellulose fibres, although no data supporting this was submitted. The aqueous fibre dispersion is then fed into the paper making machine where the pulp is subjected to a series of drying and pressing processes (Kent 1992) to produce the finished paper. The notified polymer assists removal of water from the pulp during the processing. Most of the water in the original pulp is removed during the processing and sent to a comprehensive waste water treatment facility before being discharged to Lake Bonney. Waste water from the paper manufacturing process contains around 2.6% of the

original fibre (approximately 3 tonnes per day) together with around 1% of the added Crepetrol polymer, or approximately 1.1 kg/day (i.e. 360 kg each year). These figures are based on the stated fixation for polymer adsorption to the fibres of 99%, however, if this figure were reduced to 90%, then the processes losses would be closer to 10 kg each day or 3.6 tonnes per annum.

6. OCCUPATIONAL EXPOSURE

Category & Number of Workers	*Nature of Work Done*	*Maximum Potential Exposure; Hours/day & days/year*	*Concentration of Notified Polymer*
Polymerisation operators (2)	Control of polymerisation via automated system and cleaning & maintenance	12, 6-7	100%
Technical Staff (1)	Sampling of polymerisation reaction	1, 6-7	100%
Customer Plant Operators (15)	Connection of pump lines and cleaning & maintenance	1-2, 350	< 40%

The manufacture process is an enclosed automated system operated from a control room. Exposure is considered to be limited to occasions where samples for analysis are taken during polymerisation, while dispensing the finished product into IBC and during vessel cleaning and maintenance. Workers will wear protective eyewear, clothing, and gloves when dispensing and for sampling and cleaning will wear breathing canisters in addition. A local exhaust system is attached to the reaction vessel to capture aerosols and fumes.

At the customer site, the spray application process is automated and enclosed and does not require worker intervention. Exposure may occur as workers remove bungs from and connect pump lines to the IBC and during equipment cleaning and maintenance. Workers will wear protective eyewear, clothing, and gloves during these activities.

7. PUBLIC EXPOSURE

The polymer product will be used by industrial end users in the production of tissue/toilet paper and not available to the public. Public exposure through manufacture, processing, waste disposal/discharge or transportation of the notified polymer or product is negligible.

The notifier estimates that the polymer will be present in the paper product at a concentration of 185 ppm. However, since the polymer will be bound to the paper product, which is available to consumers, public exposure will be limited.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier stated that during manufacture of the polymer and its subsequent packing into the 1000 L bulk containers less than 0.5% would be lost, which equates to a maximum annual loss of 200 kg, or assuming 35 production batches each year, a loss of around 6 kg each day of production. It was indicated that these losses would be sent to an on site treatment plant (capacity 90 000 L/day) and then to the sewer. Assuming that none of the polymer is removed or degraded during the treatment process, the plant discharge could contain a maximum of 67 mg/L of the polymer, which would be diluted in the sewer (by a factor of 10) to approximately 6.7 mg/L.

During use of the polymer in paper manufacture the company stated that total losses from spills and tank cleaning activities etc. would be 150 kg/annum (0.43 kg/day) which amounts to around 0.4% of the total use, and this would be sent to the on site effluent treatment plant.

However, it was also estimated that around 1% of the polymer (1.1 kg/day, or annually a maximum of 150 kg) would remain in the process water from the paper manufacturing stages and this would be mixed with other effluent streams and treated at an on site waste water treatment facility before being discharged.

Most of the polymer would become associated with tissue paper with most of this discharged to the domestic sewer (toilet paper) or in the case of facial tissues, placed into landfill. Approximately 2/3 of the paper production is for toilet tissue and 1/3 for facial tissue, and consequently around 26 tonnes of the polymer will be disposed of to sewer each year and 13 tonnes placed into landfill.

8.2 Fate

The polymer has a high density of cationic residues, and consequently is expected to interact strongly with negatively charged colloidal material in the environment. Most natural waters contain colloidal humic material which is negatively charged as a consequence of its high content of carboxylate groups. Therefore, any polymer released to the water compartment will become associated with colloidal material and eventually become assimilated into bottom sediments.

The polymer is not readily biodegradable under aerobic conditions and, in a CO_2 evolution test performed using the protocols of OECD TG 301 B (Wildlife International Ltd 1998c) using the test material at a concentration sufficient to provide 7.4-8 mg/L organic carbon, no evidence for biodegradation was noted, with < 1% of the theoretical CO_2 evolved after 28 days incubation with sewage sludge. In contrast to the test material, a parallel test using sodium benzoate (dissolved organic carbon = 9.6 mg/L) as the reference material produced > 90% of the theoretical CO_2 after 28 days which indicated the viability of the bacterial culture. Further, when the sodium benzoate reference and the test polymer were incubated together with the sewage bacteria, there was no evidence of any CO_2 evolution over the 28 day test period, indicating that the polymer is very toxic to the sewage bacteria at test concentrations equivalent to around 8 mg/L organic carbon.

No data on biodegradation under anaerobic conditions was supplied, and such data would have been useful in assessing the likely persistence of the polymer under these conditions which are usual in landfills and in the bottom sediments of water bodies.

Assuming 99% fixation of the polymer to fibre, approximately 110 kg of the polymer will be lost annually from the paper making process and sent to a water treatment plant prior to discharge. Although the waste treatment plant incorporates a stage of extended aeration in treatment ponds, the very low rate of biodegradation indicates that it is unlikely that much of the polymer would be degraded in this plant. However, it is probable that the polymer would become associated with humic material in solid sludge at the bottom of the aeration lagoons. Waste sludge from this plant is composted with bark and other materials and eventually be applied to land – probably forests.

Most of the polymer will be released to the sewer or to landfill in association with used toilet paper and facial tissues respectively, and would amount to approximately 40 tonnes each year, with approximately 26 tonnes going to sewer and 13-14 tonnes to landfill.

No data on bioaccumulation was included in the notification, but the high water solubility indicates low potential for bioaccumulation (Connell DW 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

The following studies were conducted on Crepetrol A6115 which contains the notified polymer at < 40% in aqueous solution.

9.1 Acute Toxicity

Summary of the acute toxicity

Test	*Species*	*Outcome*
acute oral toxicity	rat	LD50 > 2000 mg/kg bw
skin irritation	rabbit	Slight irritant
eye irritation	rabbit	Slight irritant

9.1.1 Oral Toxicity (Consumer Product Testing 1997a)

Species/strain:	Rat/Wistar albino
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Gavage, 2000 mg/kg bw of test substance as supplied
Test method:	TSCA (40 CFR Part 798.1175) Limit test (similar to OECD TG 401)
Mortality:	Nil
Clinical observations:	No clinical signs of toxicity observed.
Morphological findings:	No abnormalities observed.
LD50:	> 2000 mg/kg bw
Result:	Crepetrol A6115 is of low acute oral toxicity to the rat.

9.1.2 Skin Irritation (Consumer Product Testing 1997b)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	6/sex not stated
Observation times:	1, 3, 7 & 14 days post application
Method of administration:	A single 24-hour occlusive application of 0.5 mL of test substance as supplied to intact and abraded skin.

Test method: Modified Draize

Draize scores for intact skin:

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
1	[a]1	1	1	2	2	1
3	0	0	0	1	1	0
7	-	-	-	0	0	-
14	-	-	-	0	-	-
Oedema						
1	1	0	0	1	1	0
3	0	0	0	0	0	0
7	-	-	-	0	0	-
14	-	-	-	0	-	-

[a] see Attachment 1 for Draize scales

Comment: Well-defined erythema in two animals had resolved by day 7 and very slight oedema observed in three had resolved by day 3.
The Primary Irritation Index (mean scores for 24 and 72 hour gradings) is 0.98. According to the US Federal Hazardous Substances Act Regulations (16 CFR 1500.41) the test substance is not considered a primary dermal irritant. A score of five or more indicates a primary dermal irritant.

Result: Crepetrol A6115 is slightly irritating to rabbit skin.

9.1.3 Eye Irritation (Consumer Product Testing 1997b)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 9/sex not stated

Observation times: 1, 2, 3 days post instillation

Method of administration: A single instillation of 0.1 mL of test substance as supplied into the conjunctival sac of the test eye of nine rabbits. For three rabbits the eye was irrigated with distilled water 30 seconds after treatment. The contralateral eye served as the control.

Test method: Modified Draize

Comment:	Redness of the conjunctivae observed at either day 1 or day 2 had resolved completely by day 3. No other ocular effects were observed.
Result:	Crepetrol A6115 is slightly irritating to rabbit eye.

9.2 Genotoxicity

9.2.1 Bacterial Reverse Mutation Assay (BioReliance 2000a)

Strains:	*Salmonella typhimurium*: TA 1535, TA 1537, TA 98, TA100; *Escherichia coli:* WP2*uvr*A.
Auxillary Metabolic activation system:	S9 fraction from Aroclor 1254 induced rat liver.
Concentration range:	100 – 5000 µg/plate. Vehicle: water
Test method:	OECD TG 471 and 472
Comment:	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:	Crepetrol A6115 was non mutagenic under the conditions of the test

9.2.2 In Vitro Forward Mutation Assay (BioReliance 2000b)

Cells:	Mouse lymphoma L5178Y/TK+/-
Auxiliary Metabolic activation system:	S9 fraction from Aroclor 1254 induced rat liver.
Study design:	A preliminary toxicity study and main study were conducted. In the main study duplicate cell cultures received 4-hour exposure to the test substance as follows: 5, 10, 15, 25, 35, 50 µg/mL in the absence of metabolic activation; 1000, 1500, 2000, 2500, 3000, 4000 µg/mL in the presence of metabolic activation. Vehicle control: distilled water. Positive controls: methyl methanesulfonate (MMS) (without metabolic activation) and 7,12-dimethyl-benz(a)anthracene (with metabolic activation).

Test method: OECD TG 476

Comment:
Preliminary Study
The maximum concentration tested was 5000 μg/mL. With a 4-hour exposure, no visible precipitate was present at any concentration in treatment medium. With a 24 hour exposure, visible precipitate was present at concentrations >= 150 μg/mL in treatment medium; no visible precipitate was present at concentrations <= 50 μg/mL in treatment medium.

Main Study
With metabolic activation: No visible precipitate was observed at any test substance concentration. Toxicity in the cloned cultures was observed at doses of >= 1500 μg/m and at 4000 μg/mL cloning was not possible because of toxicity. No cloned cultures exhibited mutant frequencies that were at least 55 mutants per 10^6 clonable cells over that of the solvent control.
Without metabolic activation: A dose-response trend was observed. Two cloned non-activated cultures exhibited mutant frequencies that were at least 55 mutants per 10^6 clonable cells over that of the solvent control and two exhibited mutant frequencies that were at least 100 mutants per 10^6 clonable cells over that of the solvent control. No cloned activated cultures exhibited mutant frequencies that were at least 55 mutants per 10^6 clonable cells over that of the solvent control. Toxicity in the cloned cultures was observed at doses of >= 15 μg/mL and at 50 μg/mL cloning was not possible because of toxicity.
The trifluorothymidine-resistant colonies for the cloned non-activated cultures and for all positive and solvent control cultures were sized according to diameter over a range from approximately 0.2 to 1.1 mm. The data on colony size distributions showed an increase in the frequency of small to medium-sized colonies when the treated cultures were compared to the solvent control cultures. An increase in the frequency of small colonies is consistent with damage to multiple loci on chromosome 11 in addition to functional loss of the TK locus. The colony sizing for the MMS positive control yielded the expected increase in small colonies, verifying the adequacy of the methods used to detect small colony mutants.

Result: Crepetrol A6115 was positive without activation and negative with activation in the L5178Y/$TK^{+/-}$ mouse lymphoma assay.

9.4 Overall Assessment of Toxicological Data

Crepetrol A6115 is of low acute oral toxicity and is slightly irritating to skin and eyes in laboratory animals. The notified polymer if tested neat may have caused more severe irritancy.

Crepetrol A6115 tested negative in a bacterial reverse mutation assay. In an in vitro mouse lymphoma assay Crepetrol A6115 caused a dose-dependent induction of forward mutations in the absence of metabolic activation. However, this effect was not observed in the presence of metabolic activation. The notifier states that in vivo mutagenic studies have not been conducted. In the absence of further investigations the significance of this finding remains unknown.

For the toxicological endpoints investigated Crepetrol A6115 would not be classified as a

hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided test reports on the toxicity of a < 40% aqueous solution of the polymer to fish, *Daphnia* and algae.

10.1 Summary of Ecotoxicity

Test	*Species*	*Results*
Acute toxicity to fish (OECD TG 203)	Rainbow trout *Oncorhynchus mykiss*	96 h LC_{50} = 7.3 mg/L NOEC = 2.0 mg/L
Acute toxicity to *Daphnia* (OECD TG 202)	*Daphnia magna*	96 h LC_{50} = 54.1 mg/L NOEC = 22.5 mg/L
Algal Growth Inhibition (OECD TG 201)	*Selenastrum capricornutum*	72 h E_bC_{50} = 0.46 mg/L NOEC = 0.1 mg/L
Inhibition of Bacterial Respiration	Sewage bacteria	Toxic, but see notes below.

* NOEC - no observable effect concentration

10.2 Fish (Wildlife International Ltd 1998b)

This static test was conducted over a 96-hour test period at 12±0.5°C using nominal concentrations of the test substance of 0 (control), 13, 25, 50, 100 and 200 mg/L. Each test was performed in duplicate using 10 juvenile fish in each test chamber with the number of dead fish and their general condition monitored every 24 hours. After 24 hours one fish at 50 mg/L died and as exposure increased (i.e. exposure time and concentration) mortality progressively increased till all fish had died after 72 hours to the most concentrated solution. Sublethal effects noted during the course of the test included erratic swimming and immobilisation on the bottom of the tanks with little gill activity. The data were analysed using standard statistical techniques to provide a (nominal) LC_{50} and a (nominal) No Observed Effect Concentration (NOEC). The inferred nominal LC_{50} and NOEC for the polymer are 7.3 mg/L and 2.0 mg/L respectively. These results indicate that the polymer is moderately toxic to this fish species (Mensink B J W G et al 1995).

10.3 Daphnia (Wildlife International Ltd 1998a)

This static test was conducted over a 48-hour test period at 21.7±0.5°C using nominal concentrations of the test substance of 0 (control), 19, 38, 75, 150, 300 and 600 mg/L. Each test was performed in duplicate using 10 *daphnia* in each test chamber with the number of dead (immobilised) animals and their general condition monitored every 24 hours. After 48 hours one daphnid at 150 mg/L was immobile and as exposure increased (i.e. exposure time and concentration) immobilisation progressively increased till all were immobile (dead) after

48 hours exposure to the highest concentration. Sublethal effects such as lethargy were noted during the course of the test. The data were analysed using standard statistical techniques to provide a (nominal) LC_{50} and a (nominal) NOEC. The inferred nominal LC_{50} and NOEC for the polymer are 54.1 mg/L and 22.5 mg/L respectively. These results indicate that the polymer is slightly toxic to this species of cladoceran (Mensink B J W G et al 1995).

10.4 Green Algae (Centre for Advanced Analytical Chemistry Energy Technology 2001)
The test against the green algae *Selenastrum capricornutum* was conducted using a sample of the commercial Australian product Crepetrol A 6115.

The definitive tests were conducted over a 72 hour test period at 24±2 °C using nominal concentrations of the test substance of 0 (control), 0.1, 0.63, 1.25, 2.5, 5 and 10 mg/L. Each test was performed in triplicate and the cell counts in each test vessel determined after 72 hours. The cell count data was analysed using standard statistical techniques to provide a (nominal) E_bC_{50} and a (nominal) NOEC. The inferred nominal E_bC_{50} and NOEC for the polymer are 0.46 mg/L and 0.1 mg/L respectively, and consequently the polymer is regarded as highly toxic to this species of algae (Mensink B J W G et al 1995).

10.5 Bacteria (Wildlife International Ltd 1998c)
No test on the inhibition of bacterial respiration was provided, but it is inferred from the toxic control test performed during the determination of biodegradability that the polymer is very toxic to aerobic bacteria, with concentrations of the polymer equivalent to 8 mg/L of organic carbon completely suppressing bacterial activity.

10.6 Field Studies
The paper making facility discharges its effluent to Lake Bonney after biological treatment in aeration ponds. Because this facility uses a variety of polymers and additives in processing, some of which are known to be toxic to aquatic organisms, toxicity monitoring of the effluent discharged to Lake Bonney is undertaken each quarter. The tests are apparently conducted against rainbow trout and daphnia, and a Microtox bacterial fluorescence test is also a component of this test regime. The company submitted a summary of the effluent toxicity data (four samples) taken between January and December 2000, indicating that the effluent is not toxic[1]. However, since the notified polymer would not have been used during the period of these studies, these data provide no information on potential toxic effects of the polymer

following its introduction.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Approximately 26 tonnes of the polymer will be released to the sewer in association with used toilet paper, and assuming that the tissue is released into sewers throughout Australia

[1] However, it should be noted that prior to 1993 the plant effluent exhibited significant toxicity, and in this year the effluent treatment plant was installed. After 1993 the effluent quality progressively improved till in 1997 the effluent exhibited no toxicity, and this situation has apparently continued.

and that the annual volume of sewage[2] is of the order of 10^{12} L, the global Predicted Environmental Concentration (PEC) of the polymer in sewage is estimated as 0.08 mg/L. However, the polymer would initially be associated with the solid cellulose material in paper and is not in aqueous solution. As the cellulose fibres get broken down through biological action the polymer maybe released but would then become associated with negatively charged humic material and assimilated into sewage sludges. Periodically sludges are removed from the sewage systems by the water authorities and usually placed into landfill.

A further 13 tonnes of polymer will be placed into landfill with used facial tissue. Based on an annual quantity of municipal solid waste of 13 million tonnes, the average concentration of the notified polymer entering landfill from the disposal of facial tissues would be approximately 1 ppm (13 tonnes/year × 1/13 000 000 tonnes/year).

No biodegradation of the polymer was observed in a 28 day CO_2 evolution test, and so it is likely that it would be persistent under aerobic conditions. No data on biodegradation under anaerobic conditions were available and it is not possible to assess the likely persistence of the polymer under these conditions which are usual in landfills and in the bottom sediments of water bodies.

Assuming 99% fixation of the polymer to fibre, approximately 110 kg of the polymer will be lost from the paper making process and sent to a water treatment plant prior to discharge. Although the waste treatment plant incorporates a stage of extended aeration in treatment ponds, the very low rate of biodegradation indicates that it is unlikely that much of the polymer would be degraded in this plant. However, it is probable that the polymer would become associated with humic material in solid sludge at the bottom of the aeration lagoons. The company indicated that waste sludge from this plant is composted with bark and other materials and this would eventually be applied to land – probably forests.

The release of the notified polymer with the greatest potential for environmental impact is the discharge of the waste water from the pulp and paper mill. The notified substance is added during processing of the cellulose fibres and, assuming that only 90% of the polymer becomes adsorbed to the cellulose fibres, up to 4 tonnes of polymer annually could be released to the on site effluent treatment plant. The volume of waste water discharged from the paper plant is approximately 40 megalitres each day, so the maximum concentration of the polymer in the paper plant effluent is expected to be 4 x 10^6/365 grams/40 x 10^6 litres = 0.27 mg/L. If it is assumed that 99% of the polymer is adsorbed to fibres during paper manufacture then the effluent concentration entering the waste treatment plant would be 0.027 mg/L.

The waste treatment plant consists of a primary clarifier and a series of three aerobic degradation ponds, and the residence time in the plant is approximately 10 days. After treatment the effluent then passes into an 11 km drain before discharging into Lake Bonney.

Although biodegradation during the aeration stages is unlikely, it is probable that much of the polymer would adsorb to humic material in the lagoons and would eventually be assimilated into bottom sediments. If it is assumed that (as with the paper fibres) around 90% of this discharged polymer is removed into sediments, the worst case Predicted Environmental

[2] Assuming each person in Australia produces an average of 150 L of sewage each day for 365 days per year and that the Australian population is 19,000,000 the total annual sewage volume is estimated as 10^{12} L.

Concentration (PEC) of the polymer in the effluent discharged to Lake Bonney is estimated as 0.03 mg/L. Various estimates of the PEC in the paper plant effluent and in the drain to Lake Bonney (i.e. from the waste treatment plant) based on various fixation rates of the polymer to fibre and humic material are presented in the table below. All estimates are based on an annual usage of 40 tonnes.

Lake Bonney is dune bound and the water level is managed in such a way as to minimise the need for marine discharge – release to the marine environment has occurred only twice in the last decade (LBMC 1996) - and so it appears that the total volume of water flowing into the lake is roughly in balance with the evaporation rate. Mixing in the lake is not efficient as evidenced by the measurement of faecal coliform levels around the drain (faecal coliforms are also discharged in paper mill effluent). The concentration of bacteria decreases rapidly with distance from the drain (LBMC 1996). Consequently, for the purpose of making some estimate of the polymer concentration in the lake water, a dilution factor of 1:5 will be assumed. The above information has been used to calculate PEC in the effluent stream and in Lake Bonney near to the drain discharge.

Fixation to Paper Making Fibres	*PEC in Paper Plant Effluent*	*Fixation to Humic Material in Treatment Plant*	*PEC in Waste Treatment Plant Effluent (to Lake Bonney)*	*PEC in Lake Bonney near Drain Discharge (Assume 1:5 dilution)*
90%	0.27 mg/L	90% 99%	0.027 mg/L 0.0027 mg/L	0.005 mg/L 0.0005 mg/L
99%	0.027 mg/L	90% 99%	0.0027 mg/L 0.00027 mg/L	0.0005 mg/L 0.00005 mg/L

The notified polymer is highly toxic to green algae (E_bC_{50} = 0.46 mg/L), moderately toxic to fish and slightly toxic to daphnia, but the PEC above indicate that even in the worst case PEC of 0.005 mg/L the safety factor for environmental effects is two orders of magnitude. This safety factor would be further increased due to association of the polymer with colloidal organic matter (humic material) in the lake water.

Once the polymer has entered the Lake Bonney water, although no biodegradation is expected some degradation through direct and indirect photolysis may be possible. However, it is expected that association with humic material would effectively remove the polymer through its incorporation into sediments. The polymer is not expected to bioaccumulate.

Provided the polymer is used as an aid to tissue paper manufacture as described it is not expected to be a hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
Crepetrol A6115 exhibited low acute oral toxicity in rats (LD50 > 200 mg/kg bw), and was slightly irritating to the skin and eyes of rabbits.

In bacteria, Crepetrol A6115 was non-mutagenic. Crepetrol A6115 was found to be non-mutagenic with metabolic activation, and mutagenic without metabolic activation in a mouse lymphoma assay, however this finding is of unknown significance due to the lack of further investigations.

Based on the toxicological data provided, Crepetrol A6115 would not be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999). Moreover, the high molecular weight of the notified polymer would preclude its absorption through biological membranes.

Crepetrol A6115 contains residual monomers which are hazardous substances, however, the monomers are at low concentrations, less than 0.2%, and are not likely to contribute significantly to the toxicity of Crepetrol A6115.

Occupational Health and Safety
The polymer manufacturing process is largely automated. However, dermal and ocular exposure from drips and spills may occur when sampling the polymer reaction mix, while dispensing the finished product into IBC and during vessel cleaning and maintenance. Given the slight skin and eye irritancy of Crepetrol A6115 (which contains < 40% notified polymer) precautions need to be taken to avoid dermal and ocular exposure to the notified polymer. Exposure to the notified polymer at the site of manufacture is limited by wearing personal protective equipment (including safety gloves, glasses and overalls, with breathing canisters also being used when samples are taken from the polymer reaction mix) and through the use of a local exhaust system attached to the reactor vessel. These precautions are expected to substantially reduce the risk of exposure to the notified polymer.

At the customer site, dermal and ocular exposure to drips and spills of the notified polymer at a concentration of < 40% may occur during the removal of bungs from the IBC, while pump lines are connected to the IBC and during cleaning and maintenance of equipment. Exposure to Crepetrol A6115 is limited by wearing personal protective equipment, typically comprising gloves, coveralls and eye protection. Due to the low concentration of notified polymer and low potential for exposure the risk of adverse health effects as a result of this exposure is low.

Conclusion: Due to the low potential for exposure, the notified polymer is of low concern when manufactured and used in the above manner. No additional controls are necessary.

Public Health
Public exposure to the chemical will be limited to the final tissue products, in which the chemical is bound to the paper. The chemical is a slight skin irritant in rabbits but is only present in the tissue products at concentration of 185 ppm. Therefore the risk to public health is not significant.

Based on the above information, it is considered that the notified polymer will not pose a significant threat 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 in the product Crepetrol A6115:

  – Gloves, eye protection, and coveralls.

  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.

Environment

- Quarterly monitoring of the treatment plant effluent which is discharged into Lake Bonney should be continued and if any increase in the toxicity of the effluent is noticed after introduction of the notified polymer, this information be immediately conveyed to the Director of Chemicals Notification and Assessment.

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 if:

(1) Under subsection 64(1) of the Act; any increase in the toxicity of the effluent noticed after introduction of the notified polymer; or

(2) Under subsection 64(2) of the Act: 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 Crepetrol A6115 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

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Wildlife International Ltd (1998c): PTD D-0886: Ready Biodegradability by the Carbon Dioxide Evolution Test Method (Study No. 114E-104, 1 April 1998). Maryland, USA, Wildlife International Ltd. (Unpublished study submitted by BetzDearborn 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

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