File No: NA/560

April 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer B in Basyntan MLB Liquid

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer B in Basyntan MLB Liquid

1. APPLICANT

BASF Australia Ltd of 500 Princes Highway NOBLE PARK VIC 3174 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer B in Basyntan MLB Liquid.

2. IDENTITY OF THE CHEMICAL

Other Names:	Polymer B in Basyntan MLB Liquid
Number-Average Molecular Weight (NAMW):	3 500 - 3 900
Weight-Average Molecular Weight:	8 800 - 9 200
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	7.7%
Molecular Weight < 1 000:	8.6%
Method of Detection and Determination:	gel permeation chromatography (molecular weight only)
Spectral Data:	no spectral data were provided

3. PHYSICAL AND CHEMICAL PROPERTIES

The notiifed polymer is imported as a component of an aqueous solution, Basyntan MLB Liquid, and is never isolated. The physico-chemical properties of Basyntan MLB Liquid are given below.

Appearance at 20°C and 101.3 kPa:	brown liquid

Boiling Point:	approximately 100°C (as for water)
Density:	approximately 1 200 kg/m^3 at 20°C (see notes below)
Vapour Pressure:	approximately 2.3 kPa at 20°C (as for water)
Water Solubility:	> 300 mg/L (see notes below)
Partition Co-efficient (n-octanol/water):	no data provided - see notes below
Hydrolysis as a Function of pH:	no data provided - see notes below
Adsorption/Desorption:	no data provided - see notes below
Dissociation Constant:	no data provided - see notes below
Autoignition Temperature:	> 200°C
Reactivity/Stability:	stated not to degrade, decompose or depolymerise under normal conditions of use

Comments on Physico-Chemical Properties

The new polymer is highly water soluble reflecting the high density of negative ionic charge carried by the sulphonic acid and phenolic groups. The high density of the commercial solution reflects the high solids content resulting from the high water solubility.

No data on hydrolytic degradation was provided. Although the new polymer contains secondary amido linkages which would be susceptible to hydrolysis under extreme pH conditions, hydrolysis is unlikely in the usual pH region (4 to 9). The notifier indicates that polymers with similar chemical constitution have been stored successfully for periods greater than 12 months at pH 4-7 without significant degradation.

No octanol/water partition coefficient data were provided, but the very high water solubility and high density of ionised groups in the new polymer indicate very little affinity for oils or other organic matter. Consequently the partition coefficient will be low, and the notified material would preferentially partition to the aqueous phase.

No quantitative information on adsorption/desorption was provided, but the very high water solubility and relatively low content of hydrocarbon groups indicate little tendency for physical adsorption onto natural organic matter or association with soils and sediments. Most organic colloidal matter carries negative charges, and this would further hinder any association of the (highly negatively charged) polymer molecules with natural organic

material. However, the incorporation of the new material into leather is a chemical reaction - probably under conditions of elevated temperature, and in the presence of additional fixing agents - between the phenolic and sulphonic acid groups with various functional groups within the protein matrix of the leather.

No dissociation data was provided. The polymer is essentially the conjugate base of a strong polyfunctional organic acid. However, in the commercial product Basyntan MLB Liquid, the acid functionality has been neutralised with the strong bases, ammonia (in NA/558) and sodium hydroxide (this notification).

4. PURITY OF THE CHEMICAL

Degree of Purity: > 97.5%

Toxic or Hazardous Impurities: one hazardous impurity at less than 10 ppm

Non-hazardous Impurities (> 1% by weight): none identified

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified polymer is to be used as a retanning agent in the leather industry. It will be imported at less than 500 tonnes per annum in an aqueous solution containing a related polymer (assessed as NA/558) and less than 10% salts and organic acids, known as Basyntan MLB Liquid.

Basyntan MLB Liquid is to be imported in 1 000 L aluminium schutz tanks, or 120 kg polyethylene open head drums when the tanks are not available. The drums or tanks will be transported to the notifier's warehouse and thence to customer tanneries.

At the customer site Basyntan MLB Liquid will be added to retanning vessels containing up to 500 kg of leather and 1 000 L of water in a closed wet system. The retanning vessel consists of a sealed rotating drum. The product is added at not more than 10% of the leather weight. The concentration of the notified polymer will be approximately 2% in the retanning vessel. Addition of the notified polymer will be either by automatic feed or bucket feed. Automatic feed involves pumping the undiluted product from the schutz tank into the retanning vessel. Bucket feed involves adding the product to the retanning vessel through an axel feed line by pouring the product (diluted 1:3) from buckets.

After mixing, the wet skins are transferred to a wringer to remove most of the residual tanning liquour and thence to a conveyor for transport through a drying oven which is controlled for

temperature and humidity.

6. OCCUPATIONAL EXPOSURE

Workers involved in transport and storage would only be exposed to the notified polymer in the event of accidental spillage.

At the customer site, during addition of the polymer formulation to the tanning vessel (2 operators, maximum of 12 times 3 minutes per 24 hour period), some exposure may be expected from drips and spills when disconnecting lines following automatic feed. During bucket feed there is a high probability of exposure due to spillage. During this process, workers will be exposed to a maximum 34% solution of polymer. The total number of workers, including storehouse and maintenance workers as well as those manning the tanning vessel is expected to be 10 per customer site. Ten customer sites are envisaged.

Dermal exposure is possible during the manual transfer of skins to the wringer and from the wringer to the drier. Local exhaust ventilation is employed where general ventilation is considered to be inadequate.

Each batch contains approximately 60 kg of the polymer solution, up to 500 kg of leather and up to 1 000 litres of water. The retanning solution contains approximately 2% polymer. Fixation rate is approximately 72%, after which the polymer is immobile in the leather, although exposure to polymer in the spent solution (0.6% polymer) may occur. The notifier states that local exhaust ventilation is employed in all work areas where natural ventilation is considered inadequate and all personnel minimise their potential exposure to the notified polymer by the use of personal protective equipment such as protective clothing and footwear, gloves and goggles. Residues in the schutz tanks and open head drums are normally removed onsite by washing out in water. The washings are treated onsite as part of normal effluent treatment.

Once the leather is oven-dried, the polymer is fixed and not available for transfer or uptake by anyone handling the leather.

7. PUBLIC EXPOSURE

The use patten indicated by the notifier suggests that public exposure to the notified polymer during transport and industrial processes is very unlikely. The Material Safety Data Sheet (MSDS) specifies that accidental spills are to be contained and soaked up with absorbent material prior to disposal by incineration or landfill. Small spills may be flushed away with water to effluent treatment.

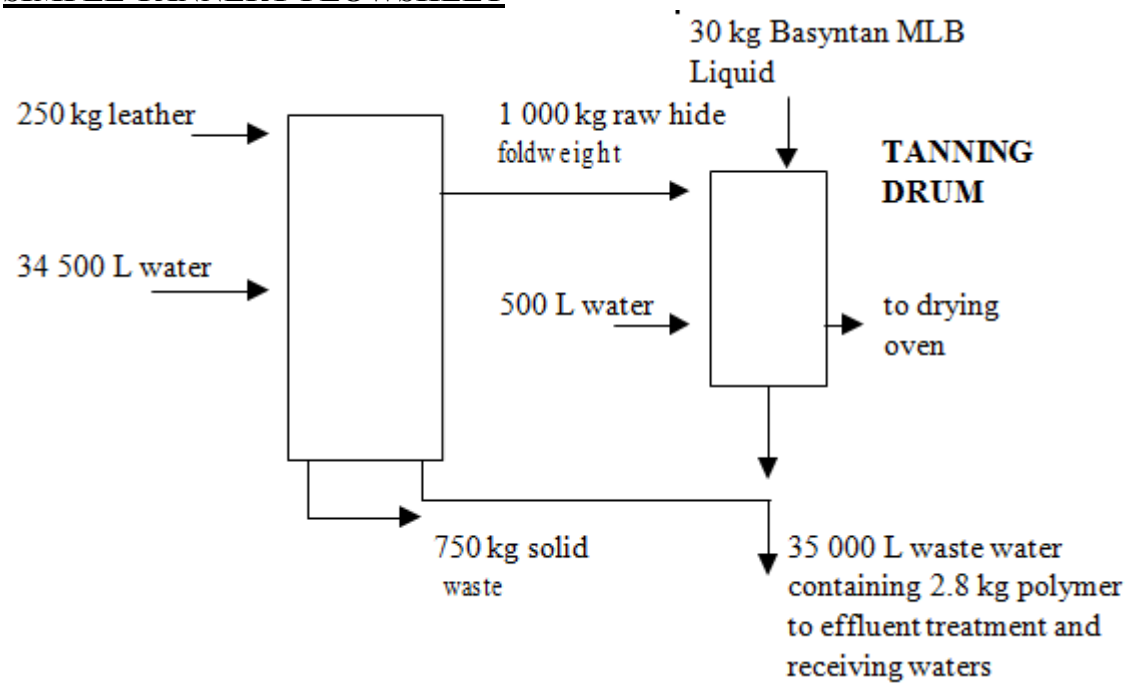
Most of the new polymer will enter the public domain incorporated into finished leather articles. However, by this stage the new polymer will be immobilised on the substrate, minimising its potential for absorption.

8. ENVIRONMENTAL EXPOSURE

Release

Significant release to the water compartment is likely as a consequence of discharge of spent tanning solution from the plant. The notifier indicates that the overall fixation rate for the polymer is expected to be around 72%, which means 28% may be discharged with spent tanning solution. The notifier provided details of a typical mass balance for tannery operations involving the new polymer which is reproduced diagrammatically below.

SIMPLE TANNERY FLOWSHEET



The important features of this mass balance are that each tonne of hides yields approximately 250 kg of leather foldweight which in turn requires the application of 10-12% of Basyntan MLB Liquid (25-30 kg). However, the notifier indicated that approximately 72 % of the polymer becomes fixed to the leather, and the residual will be assimilated into the consolidated plant effluent and discharged to the sewer system, possibly after some treatment to reduce the biological oxygen demand (BOD).

No quantitative details of reduction of polymer levels in the effluent resulting from pre-discharge treatment were provided in the notification, although a figure of 50% reduction was alluded to. However, without further details calculations are based on the worst case scenario where, due to its high solubility, no polymer is removed from the plant effluent during treatment, and consequently the discharged effluent would contain the new polymer at a concentration around 80 mg/L.

The high density of negative charge on the polymer precludes association of the polymer with the natural organic matter present in the sewage - see notes on physico-chemical properties above. However, the tannery effluent contains a high concentration of calcium (typical

concentration of Ca^{2+} is 500 mg/L) and the notifier indicated that this could possibly lead to precipitation of an insoluble calcium salt of the polymer, but no supporting data was presented. However, in the event that such insoluble salts do form, it is likely that these (now substantially neutral) compounds could become incorporated into sewer sediments and the waste sludge from the treatment plant, and placed into landfill or incinerated.

Overall, given the annual import level of new polymer, an annual discharge of less than 10 tonnes per tannery is anticipated. As described above the estimated concentration of the polymer in the discharged effluent could be expected to be around 80 mg/L, but when discharged to sewer (assuming an appropriate dilution ratio of 1:10), this would be reduced to around 8 mg/L.

Since the new polymer is fully miscible with water, any residue remaining in the 1 000 L shulz tanks and in the 120 kg polyethylene drums would be washed out and added to subsequent batches of the tanning mixture. The empty drums would be suitable for appropriate reuse or proper disposal.

Fate

Since the new polymer is firmly fixed to the leather protein, the fate of the majority of the material will be the same as that of the leather articles into which the product is made. At the end of their serviceable life these articles would be disposed of to landfill or incinerated. Similarly any polymer which becomes associated with effluent treatment plant sludge would also be placed into landfill or be incinerated.

No biodegradation data which are specific to the new polymer is available, but in the MSDS supplied by the notifier the decrease in total organic carbon for a polymer of similar chemical composition was found to be less than 20% in an OECD Confirmatory test. The polymer used in the test was Basyntan DLE, which is of similar general chemical composition and structure to the notified polymer but with a NAMW of approximately 1 000 daltons. Assuming this result can be applied to the new polymer, it is apparent that the material is not readily biodegradable, but would probably be slowly degraded through the abiotic and bacteriological processes operative within landfills. The degradation products formed under aerobic conditions would include water, oxides of carbon, nitrogen and sulphur, and under anaerobic conditions, methane, ammonia and hydrogen sulphide.

The high molecular weight and high water solubility preclude bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicological data were provided for the notified polymer. However, data for a related polymer, Basyntan DLE were submitted and are evaluated below. Toxicity data for Basyntan DLE are used as surrogate health hazard information on the Basyntan MLB Liquid MSDS.

9.1.1 Acute Oral Toxicity (Hildebrand & Kirsch, 1989)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	unspecified
LD_{50}*:*	> 2 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Acute Inhalation Toxicity (Gelbke, 1989)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	4-hour exposure, nose-only; particle size: 95% < 29.5 μm; 77% < 8.5μm
Clinical observations:	days one and two: staggering unsteady gait, red eye discharge, accelerated respiration
Mortality:	none
Morphological findings:	none
Test method:	according to OECD guideline TG 403 (Organisation for Economic Co-operation and Development, 1995-1996)
LC_{50}*:*	> 5.2 mg/L

Result: the notified chemical was of very low acute inhalation toxicity in rats

9.1.3 Skin Irritation (Kirsch & Gamer, 1988a)

Species/strain: rabbit/Vienna White

Number/sex of animals: 2 males, 1 female

Observation period: 8 days

Method of administration: 0.5 g of test substance moistened with distilled water under semi-occlusive dressing for 4 hours

Draize scores (Draize, 1959):

Time after treatment	***1***	***2***	***3***
Erythema			
4 h	2[a]	2	2
24 h	2	2	2
48 h	1	1	1
72 h	0	0	1
8 d	0	0	0

Oedema: no scores above zero

[a] see Attachment 1 for Draize scales

Test method: according to OECD guideline TG 404 (Organisation for Economic Co-operation and Development, 1995-1996)

Result: the notified chemical was slight to moderate skin irritant in rabbits

9.1.4 Eye Irritation (Kirsch & Gamer, 1988b)

Species/strain: rabbit/Vienna White

Number/sex of animals: 1 male, 2 females

Observation period: 72 hours

Method of administration: 33 mg of the test substance in the conjunctival sac of one eye

Draize scores (Draize, 1959) of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***24 hours***			***48 hours***			***72 hours***		
Cornea	no scores above zero											
Iris	no scores above zero											
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	0	1	2	1	1	2	0	0	0	0	0
2	2	0	1	2	1	2	2	0	0	0	0	0
3	2	0	1	2	1	1	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Test method: according to OECD guideline TG 405 (Organisation for Economic Co-operation and Development, 1995-1996)

Result: the notified chemical was a slight to moderate eye irritant in rabbits

9.4 Overall Assessment of Toxicological Data

A polymer similar to the notified polymer was of very low acute oral (LD_{50} > 2 000 mg/kg) and inhalation (LC_{50} > 5.2 mg/L) toxicity in rats. It was a slight to moderate skin and a slight to moderate eye irritant in rabbits.

The notified polymer is not determined to be a hazardous substance in accordance with NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) in relation to the submitted toxicological data.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity data are not required by the Act for polymers with NAMW greater than 1 000 g/mol. However, the MSDS supplied with the original notification includes some summary ecotoxicity data for the polymer Basyntan DLE, of similar chemical constitution. The notifier subsequently provided a report detailing the ecotoxicity study on fish.

Test	***Species***	***Results***
Acute Toxicity to Fish DIN 38 412	Ides *Leuciscus idus*	LC_{50} (96 h) = 530 mg/L (interpolated) NOEC = 215 mg/L
Respiration Inhibition (Warburg Test)	Aerobic Waste Water Bacteria	toxicity above 100 mg/L. (see notes below)

The tests on fish were performed over a 96 hour period using a static methodology with nominal concentrations of the polymer of 100, 215, 464 and 1,000 mg/L. Ten fish were used at each test concentration, with a 10 L volume of each test solution. The tests were conducted at 20°C and the dissolved oxygen content was maintained around 8.2 mg/L through air sparging. The pH of the fresh (ie after 1 hour) solutions was dependent on the nominal concentrations, and decreased from 7.0 for the 100 mg/L solution to 4.8 for the 1,000 mg/L solution. The toxicity of the polymer appeared to have some pH dependence (increased toxicity at lower pH), and this is discussed below.

During this series of tests no fish died over the 96 hour test duration when exposed to nominal concentrations of 215 mg/L or less, but after 48 hours exposure to a nominal 464 mg/L one fish had died, and this increased to three after 96 hours. At this, and higher concentrations, the surviving fish exhibited signs of stress including apathy, tumbling and narcosis. All fish had died after only four hours exposure at the highest nominal concentration of 1 000 mg/L.

For solutions with nominal concentrations of 464 mg/L and less, the pH of the test solutions remained at 7.1 ± 0.3 over the 96 hour test duration, but at 1 000 mg/L, the pH of the fresh (1 h) solution was markedly lower at 4.8. In order to discriminate between inherent toxicity of the polymer and that possibly resulting from depressed pH, a parallel study was conducted at 1 000 mg/L where the pH was adjusted to 7.4. In this study some mortality was also observed, although onset of mortality (50%) was not observed till 48 hours of exposure, and there was 90% mortality after 96 hours. This result indicates that low pH may exacerbate the toxic properties of the polymer to fish.

Although toxicity to bacteria was indicated in the MSDS as greater than 100 mg/L, no further details (eg exposure times) were given. The "Warburg" test is said to have been used, however, no supporting test report was provided by the notifier.

The ecotoxicity data provided indicates that the new polymer may exhibit slight toxicity to fish, particularly under low pH conditions (pH < 5). However, the new polymer is unlikely to be released to receiving waters at concentrations sufficient to cause significant environmental toxicity.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified polymer is considered to be low when the material is used in tannery operations as indicated. The new polymer may be slightly toxic to some species of fish, but is unlikely to be released to natural waters in concentrations large enough for manifestation of significant toxic responses.

Although it is likely that about 28% of the imported material (annually up to 57 tonnes) will be released to the sewers, release will be diffuse as it will take place at 10 different sites around Australia. When released to the sewer (at concentrations up to 80 mg/L) the polymer will become appreciably diluted and is also likely to become associated with calcium ions

which will neutralise the substantial negative ionic charge carried by each molecule. Once neutralised in this manner, the material would probably become associated with sediments and sewage treatment plant sludge, and would then be incinerated or placed into landfill. Incineration would destroy the polymer with evolution of water vapour and oxides of carbon, nitrogen and sulphur. The polymer is not expected to be readily biodegradable, but when placed into a landfill, slow degradation processes in an aerobic environment would lead to formation of a similar mix of products to incineration, while in an anaerobic environment reduced hydrides such as methane, ammonia and hydrogen sulphide are the likely products.

Old leather products when discarded are also likely to be incinerated or placed into landfill where the notified polymer would be destroyed or degraded as described.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer has a NAMW greater than 1 000 which is expected to preclude absorption across biological membranes and any potential systemic health effects. Limited toxicological data for a related polymer suggest that the notified polymer would exhibit very low acute oral and inhalation toxicity and would be a slight to moderate skin irritant and a slight to moderate eye irritant. The polymer is not likely to be a hazardous substance, as determined according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a), considering the small amounts of low molecular weight species (NAMW less than 1 000, 8.6%) and residual monomers (2.4%) and accepting the surrogate, limited toxicity data for the related polymer.

The risk of adverse health effects to workers involved in transport, storage, use or disposal of the notified polymer is expected to be minimal given its likely low hazard.

The notified polymer will be imported in an aqueous solution together with another polymer assessed as NA/558 in either large schutz tanks (1 000 L capacity) or 120 kg polyethylene open head drums. Thus, due to the sturdy containers, exposure of workers involved in transport or storage is expected to be low except in the event of an accident. Following transport to tanneries the polymer solution containing 34% polymer is transferred to tanning vessels via line feed (schutz tanks) or bucket feed. In these cases some dermal or ocular exposure may be expected from drips and spills, resulting in skin or eye irritation. The notifier states that industrial clothing, gloves and goggles will be worn and local exhaust ventilation will be provided where general ventilation is considered to be inadequate.

The tanning process is enclosed and the notified polymer is diluted to a low level (maximum of 2%). After tanning, where 72% of polymer is removed via fixation to the leather, the residual solution contains approximately 0.6% of the polymer. Workers may manually transfer wet tanned hides to the wringer and from the wringer to the drier, thereby contacting unfixed polymer at 0.6%.

Given the low concentration of polymer, workers are not likely to experience topical or

systemic effects when handling wet hides. However, personal protection and engineering controls should be used to transfer wet hides where possible.

Once the treated hides are dried, they will not contain polymer in a form available for transfer to skin or absorption.

The public should most likely come in contact with the notified polymer on leather articles. However, exposure and risk of adverse health effects should be negligible due to the polymer's immobilisation on the substrate.

13. MATERIAL SAFETY DATA SHEET

The MSDS for the aqueous solution to be imported containing the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

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.

14. RECOMMENDATIONS

To minimise occupational exposure to the notified polymer the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/ Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillage should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical 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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