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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Bayderm Fix Cin 33107

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in Bayderm Fix Cin 33107

1. APPLICANT

Bayer Australia Limited of 633-647 Springvale Road MULGRAVE NORTH VIC 3170 has submitted a limited notification statement in support of their application for an assessment certificate for **Polymer in Bayderm Fix Cin 33107.**

2. IDENTITY OF THE CHEMICAL

Polymer in Bayderm Fix Cin 33107 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore 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.

Other Names:	Polymer in Bayderm Fix Cin 33107
Trade Name:	Bayderm Fix Cin 33107
Number-Average Molecular Weight:	> 1 000
Method of Detection and Determination:	infrared spectroscopy (IR) and Gel Permeation Chromatography (GPC)

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physical and chemical properties correspond to the product containing the notified polymer.

Appearance and Odour at 20°C and 101.3 kPa:	colourless to yellowish liquid with a weak odour
Boiling Point:	> 225°C

Density:	1160 kg/m^3
Vapour Pressure:	0.7 kPa at 20°C and 2.1 kPa at 50°C
Water Solubility:	not determined
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	> 100°C (closed cup)
Flammability Limits:	not flammable
Autoignition Temperature:	not provided
Explosive Properties:	not explosive
Reactivity/Stability:	reacts strongly with water forming carbon dioxide and a foam-like urea derivative

Comments on Physico-Chemical Properties

The notified polymer contains 15% isocyanate groups which react with water to form carbon dioxide, and polyurea, a firm foam substance. As such, determination of the water solubility of the polymer is difficult. A test was attempted and the report included in the submission, with the reaction outlined above being observed.

Hydrolysis testing was not performed. The free isocyanate groups undergo hydrolysis to form carbon dioxide and an insoluble polyurea foam. Once in the form of a polyurea foam, further hydrolysis within the normal environmental pH range is not expected.

Testing for partition coefficient was attempted, and a report included within the submission. Due to the rapid reaction of the notified substance with water, no value for partition coefficient could be determined.

Adsorption/Desorption has not been determined. This is acceptable given the reactivity of the polymer.

The notified chemical contains no dissociable hydrogens or basic functionalities.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

Toxic or Hazardous Impurities: < 0.07%

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

Maximum Content of Residual Monomers: very low

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified polymer will be fully imported into Australia it will be used as a crosslinking agent for polyurethane and polyacrylate leather finishes. The leather is designed to be used in automotive upholstery.

The anticipated volume is 2 tonnes per annum for the first five years.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported in the product Bayderm Fix Cin 33107 in sealed 50 kg drums. Waterside workers will transfer drums from the ship to trucks. It will be transported by truck to storage in a warehouse until distributed by road to customers. During transport, exposure to the notified polymer is only likely to occur in the unlikely event of an accident.

Following receipt of the notified polymer, the customer unloads and places the drums in a raw materials store. This will be done by one or two persons and as the notified polymer remains in sealed drums exposure is likely to be negligible. The customer essentially mixes the polymer with binders, flow modulators, solvents and pigments to form a “finishing mix” to achieve a final polymer concentration of 2%. This is carried out by pumping (metered dosing) the polymer directly from the drum to a sealed blending tank. The “finishing mix” is then added to the rolling machine manually via a hose using gravity feed and then applied to leather by means of a sealed, slow-speed rolling machine. The blending is conducted by two or more persons for periods of 8 hours per day, 200 days per year. The most likely route of exposure will be dermal during transfer of the notified polymer to the blending equipment and during blending with additives. There is also the potential for exposure to vapours, during these operations, that may have built up in the head space of the drum. Ocular exposure would only be likely to occur in the event of accidental splashing. The blending and application of the noitified polymer is carried out under local exhaust and general ventilation which

will minimise inhalation exposure.

7. PUBLIC EXPOSURE

Public exposure to the the notified polymer during storage and transport is unlikely except in an accident. The treated leather will be used for automotive upholstery.

Dermal contact with car seats will be the primary public exposure to the notified polymer. The notified polymer being a cross linking agent and tightly bound to the leather is not expected to be absorbed by dermal contact with the treated leather. Considering the small import volume, accidental spillage and waste disposal is unlikely to result in significant public exposure.

8. ENVIRONMENTAL EXPOSURE

Release

At the customer's site, the notified polymer is mixed with other chemicals such as binders, flow modulators, solvents and pigments to form the finishing mix which contains a final concentration of the notified polymer of approximately 2%.

Based on previous experience, release of the notified chemical through blending and application is estimated to be a maximum of 1.5%. Based on 2 tonnes import volume per annum, this equates to 30 kg per annum. With leather treatment occurring on 200 days per year (notifier's figures), release through blending and application accounts for a maximum of 150 grams per day.

Any unused finishing mix and wastewater from cleaning of process equipment is treated in the customer's on-site liquid waste treatment plant. Solids, including the notified polymer, would be separated out and disposed of to landfill by a licensed waste contractor. Similarly, empty drums are disposed of to landfill by a licensed waste contractor.

The leather treated with the notified polymer will be used in automotive upholstery, and will be exported. If it were being used within Australia, it is likely the majority of the notified polymer will ultimately be disposed of to landfill, although this will be in a highly diffuse manner.

Fate

Most of the notified polymer is expected to be covalently crosslinked within set adhesive, which will be bound to the leather to which it is applied, with the final environmental fate being incineration or landfill. A small amount will be disposed of to landfill as residues in used adhesive containers. The inert nature of the cured adhesive means that the polymer is not expected to be mobile or to degrade within landfill sites.

The notified product foams quickly with water and solidifies to form a polyurea foam. It is unlikely that any of this will enter the municipal sewer system after going

through the on site liquid waste treatment plant, but rather, will be landfilled with other solid waste.

If moisture enters the containers, pressure build up may occur due to carbon dioxide formation which can cause the rupture of the containers, making proper handling and storage of the polymer essential to reduce spillages. The Material Safety Data Sheet (MSDS) contains adequate instructions to deal with accidental spills.

A manometric respirometry test was performed to determine biodegradation potential of the notified polymer, following EEC guidelines. The polymer was determined to be non biodegradable, with 0% degradation recorded after 28 days.

The notified polymer contains a number-average molecular weight (NAMW) > 1 000 and is unlikely to cross biological membranes, thereby reducing the potential for bioaccumulation. There is relatively high proportion of low molecular weight species less than 1 000 g/mole.

9. EVALUATION OF TOXICOLOGICAL DATA

According to the Act, toxicological data are not required for polymers with a NAMW greater than 1 000, data were submitted and are summarised below.

9.1 Acute Toxicity

Summary of the acute toxicity of Polymer in Bayderm Fix Cin 33107

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(1)

9.1.1 Oral Toxicity (1)

Species/strain:	rat (HanIbm) WIST (SPF)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration (vehicle):	gavage (distilled water)
Dose levels:	2 000 mg/kg
Clinical observations:	no clinical signs noted
Mortality	none
Test Method:	OECD guidelines for testing of chemicals (2)

LD_{50}:	> 2 000 mg/kg
Result:	low oral toxicity in rats

9.2 Overall Assessment of Toxicological Data

The notified polymer was of low acute oral toxicity in rats.

On the basis of limited toxicological data provided for the notified polymer it would not be classified as hazardous according to *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (4) based on the low acute oral toxicity study in rat.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

While no ecotoxicity tests are required under the Act for synthetic polymers with NAMW greater than 1 000, the notifier has submitted a 96 hour acute fish test, conducted with Zebra fish (*Brachydanio rerio*). Stock solutions were prepared by weighing the test substance in water and stirring for two hours. Under the conditions of the study, all ten fish in each group died after 24 hours at the test concentration (≥ 4 mg/L). At a concentration of 8 ppm, 4 fish were observed to be sluggish after 2 hours, while all ten fish were observed to be sluggish after 2 hours at a concentration of 16 ppm.

At tested concentrations of 1 and 2 ppm, no deaths or sub-lethal effects were observed. The LC_{50} lies in the range of 2 to 4 ppm, and the notifier has determined the LC_{50} to be 2.8 ppm.

The notified polymer reacts readily with water and forms a solid polyurea foam. However, this may not be observed at low concentrations in water as the majority of the free isocyanate will rapidly react with the water to form primary amines, thereby making them non available for the further reaction of isocyanate with the amine group to form the polyurea. The primary amines could be expected to exhibit toxicity, and the notified polymer can be considered moderately toxic to fish.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is anticipated that the amount of the notified polymer released to the aquatic environment will be low. Releases through blending and application operations, along with residues from containers, will be removed with other solid wastes after going through the liquid waste treatment plant located at the single site where these operations are performed, with waste waters being sent to sewer. Even if the expected daily release of 150 g did reach receiving waters, it would be diluted to a concentration of 0.6 µg/L (ppb) in 250 ML of sewer output, prior to further dilution in receiving waters.

The inert nature of the polymer when cured on leather means that the polymer is not expected to be mobile or degrade within landfill sites.

The hazard to the environment is restricted by the expected limited release, the low

solubility in water of the polymer and its high molecular weight in the cured film. The environmental hazard posed by the polymer is rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer will be imported at estimated volumes of up to 2 tonnes per annum in the first five years. It will be incorporated into polyurethane and polyacrylate leather finishes as a crosslinking agent to be used in automotive upholstery.

The notified polymer has a high molecular weight which will restrict transfer across biological membranes. The polymer contains a high percentage of low molecular weight species with the potential to cross the skin. Residual monomer, present at a very low percentage, has the potential to cause a range of adverse effects following systemic exposure, including skin and eye irritation and respiratory sensitisation (3). Although the residual monomer is present at a concentration below the level that would require the notified chemical to be classified as hazardous according to the Approved Criteria (4), workers especially atopic individuals should be aware of its hazardous potential.

The main route of exposure is likely to be dermal during blending operations of the notified polymer. The potential for dermal exposure is minimal because of the enclosed nature of these operations. There is also the potential for inhalational exposure to vapours, that may have built up in the headspace of the drum during transport and storage, when workers open drums prior to dispensing the notified polymer. The notifier states that inhalational exposure will be minimised by local exhaust ventilation and that potential inhalational exposure to low molecular weight species and to the hazardous residual monomer will be minimised by its very low vapour pressure. However, workers should be aware that the polymer formulation Bayderm Fix Cin 33107 contains 1,2-propanediol diacetate 10 to 30% and hexamethylene diisocyanate < 1%. The latter has an occupational exposure standard of 0.02 mg/m^3, Time-Weighted Average (TWA) declared by Worksafe Australia (5). Given the concern for exposure to the potentially harmful residual monomer, low molecular weight species and harmful ingredients in the formulation, protection as described in the recommendation section of the report should be employed when there is the potential for exposure to the product containing the notified chemical.

Public exposure to the notified polymer may occur through dermal contact with the leather treated with the notified polymer, however, the notified polymer is tightly bound to the leather and the polymer is not expected to be dermally absorbed. The proposed used is unlikely to result in a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in Bayderm Fix Cin 33107 the following guidelines and precautions should be observed:

- when using the notified polymer containing the formulation the following protective equipment should be worn:

    - Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (6) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (7);

- Industrial clothing should conform to the specifications detailed in AS 2919 (8);

- Impermeable gloves or mittens should conform to AS 2161 (9);

    - All occupational footwear should conform to AS/NZS 2210 (10);

    - Respiratory protection (selected and fitted) according to ANS/NZS 1715 (11) to comply with AS/NZS 1716 (12);

- Spillage of the notified chemical should be avoided, spillages 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; and

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (13).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

1. Cuthbert J.A., *Acute oral toxicity study with UVASIL 299 in rats*. Study No: 242552, project on file, Inveresk Research International (Musselburg, Scotland).

2. Organisation for Economic Co-operation and Development, OECD *Guidelines for Testing of chemicals*, OECD, Paris, France

3. National Occupational Health and Safety Commission 1994, *List of Designated Hazardous Substances* [NOHSC:10005(1994)], Australian Government Publishing Service Publ., Canberra.

4. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service Publ., Canberra.

5. National Occupational Health and Safety Commission 1995, 'Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment', [NOHSC:1003(1995)], in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards*, Australian Government Publishing Service Publ., Canberra.

6. Standards Australia 1994, *Australian Standard 1336-1994*, *Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.

7. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

8. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing,* Standards Association of Australian Publ., Sydney.

9. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves),* Standards Association of Australia Publ., Sydney.

10. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

11. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

12. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

13. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.