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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polyhydroxyaminoether Resin (I)

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Dow Chemical (Australia) Pty Ltd (ABN 72 000 264 979) of Kororoit Creek Rd Altona Vic 3018 has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC) Polyhydroxyaminoether Resin (I).

2. IDENTITY OF THE CHEMICAL

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

Marketing names: Blox Adhesive Resin.

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

Purity (%): High.

Hazardous impurities (other than residual monomers and reactants): None

Non-hazardous impurities at 1% by weight or more: None

Additives/adjuvants: None.

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	Clear solid pellets	
Boiling point		Not determined
Glass transition temperature	60 - 80°C	
Melt temperature	Approximately 200°C	
Density	1200 kg/m^3	
Water solubility	< 0.01 g/L	See notes
Octanol solubility	< 0.05 g/L	See notes
Stability/reactivity	Not reactive	
Hydrolysis as function of pH		Not determined
Partition coefficient	log P_{ow} = - 0.69.	See notes
Adsorption/desorption		Not determined
Dissociation constant		Not determined

5.1 Comments on physical and chemical properties

The solubility in water of a similar polymer to the notified polymer was determined in accordance with OECD TG 120: Solution/Extraction Behaviour of Polymers in Water. This test is a modified version of the Flask Method (TG 105) and is suitable for certain polymers such as emulsion polymers. During the test, the test substance was placed in water and shaken for 24 hours. The sample was then filtered and the concentration of the test substance in the filtrate was determined by size exclusion chromatography using external standard analysis for quantification. The solubility of the test substance was determined to be less than 0.005 g/L (Dow Chemical, 2000a).

The water and n-octanol solubilities of the new polymer were determined by the shake flask method (OECD TG 105). Preliminary studies were conducted to ascertain the solubilities of the test material. This involved adding an aliquot of 0.0996 g of test substance to water to yield volumes of 1.0, 5.0 and 10 mL. The mixture was shaken for 10 minutes at each incremental addition and the solubility determined from visual observation. The material was then added to water to yield volumes of 25, 50 and 100 mL and shaken for 10 minutes at each incremental addition. The solubility was determined from visual observation. The test material was not completely dissolved even after 23 days, and the solubility was deemed to be < 10 ppm. A similar procedure was followed to determine the n-octanol solubility adding n-octanol instead of water, which was deemed to be < 50 ppm (Dow Chemical, 1999).

Following preliminary studies, the concentrations of the test material in water and n-octanol were determined analytically by size exclusion chromatography (Dow Chemical, 1999). The solubility in water was < 0.01 g/L and the solubility in n-octanol was 0.05 g/L, indicating the substance is poorly soluble in both water and n-octanol.

The partition coefficient was calculated by dividing the solubilities in water by the solubility in n-octanol. This gave a Pow of 0.2, indicating the new polymer will have a poor affinity to lipids and hence is not expected to cross biological membrane and bioaccumulate.

6. USE, VOLUME AND FORMULATION

Use: Barrier resin in multi-layer rigid and flexible packaging, hotmelt adhesives, starch-based foams and other applications. The notified polymer may be processed into a number of products using extrusion and/or moulding machinery. In a hot forming process the notified polymer is added alone or with other ingredients to a mixing vessel and formed into the finished shape by extrusion through a die or by injection moulding. Processing temperatures are in the range 150 - 200°C. Finished articles are typically allowed to cool and automatically packed in containers for distribution. The concentration of the notified polymer in the final products ranges from < 5% to 100%. The notified polymer may also be used as a component of powder coatings at a concentration of 1 – 10% for application to articles such as display racks and automotive components.

Manufacture/Import volume: Less than 1000 tonnes per year in the first 5 years.

Formulation details: The notified polymer is imported as clear, solid pellets in 25 kg bags, 500 kg cartons or 1000 kg bags. In addition, powder coatings containing the notified polymer may be imported in 500 kg boxes or 1000 kg bags.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
Formulation		
dermal	The 25 kg bags of the notified polymer will be manually loaded to the mixing vessel but transfer from the larger containers will be via bag cradles or pumps. Once into the mixing vessel, the notified polymer is in a closed system which is typically positively vented with a full extraction system. Typically articles and products are cooled and automatically packaged prior to storage and distribution. During the process small samples will be removed for laboratory analysis and quality control. A conservative estimate of waste generated throughout the life cycle of the notified polymer is 0.02% of the imported volume. Dermal	Quality control testing is performed in a fume cabinet if necessary. Industrial clothing, heat resistant gloves and chemical goggles are made available to workers handling the notified polymer. Dust mask (in dusty environments). Extraction system over mixing vessel.

	exposure is expected to be minimal. At the customers sites it is estimated that, for 300 days per year, workers will be involved in storage (5 workers, 1 hour/day), process (35 workers, 4 hours/day) and sampling for laboratory analysis (5 workers, 4 hours/day).	
End use		
dermal	Some products are used immediately as beverage containers for consumer use. The flexible packaging would be used to package various products where a barrier or extra strength is required. Other products are expected to have industrial uses. Dermal exposure of workers to coated articles will depend on the end use. However, at this stage the notified polymer will be in an impervious coating and would not be bioavailable.	No specific controls required.
Inhalation, dermal	For industrial powder coating use, the potential for inhalation or dermal exposure is dependent on whether an enclosed assembly line or walk-in booths or booths not fully enclosed are employed.	Where enclosed systems are not used, overalls, gloves, goggles, respirator and anti-static and conductive footwear should be worn.
Transport and storage		
dermal	Two workers (4 hours/day, 6 days/year) will unload bags or cartons at the wharf and two workers (4 hours/day, 6 days/year) will deliver the containers to the warehouse. Delivery to customers is accomplished by 6 workers (2 hours/day, 240 days/year). Workers are unlikely to be exposed except in the event of accidental rupture of the packaging.	No particular controls are specified.
Disposal		

dermal	The notified polymer, as part of a spill clean-up or discarded packaging or other products. The notified polymer is firmly adhered to the product and is not expected to be bioavailable.	No particular controls are specified.

8. PUBLIC EXPOSURE

Exposure of the general public as a result of transport, reformulation and disposal of the notified polymer is assessed as being negligible. The notified polymer will not be sold to the public and will be used as a barrier layer in the manufacture of packaging materials and powder coated articles. Packaging materials containing the notified polymer will have a wide variety of uses, including uses as food containers and coated articles. Members of the public will make dermal contact with packaging materials containing the notified polymer and will eat and drink foodstuffs that have been in contact with packaging materials manufactured using the notified polymer. However, exposure is likely to be minimal since the notified polymer chemical is tightly bound to the packaging materials and not likely to be bioavailable. Similar considerations apply to final powder coated articles.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

Minimal release of the notified polymer to the environment is expected. No release is anticipated during importation, transport or storage.

Only minimal release is anticipated during manufacturing of the packaging materials. Release may occur as a result of minor operational spills. The notifier anticipates approximately 20 kg of the notified polymer could be released each year in this way.

The notified polymer may be used in industrial powder coatings. Environmental exposure to the notified polymer resulting from normal use in spray painting workplaces is expected to be low as electrostatic application is an efficient application method. Powder which does not reach the target article (estimated at 2%) will be removed using dust extractors or cured in the original containers before sending to landfill. The notifier anticipates approximately 225 kg of the notified polymer could be released each year in this way.

Extruders and other equipment may need to be emptied before each shut down. No estimates are provided of release through this route. However, the notifier indicated that the moulding process usually operates 24 hours a day, 7 days a week suggesting emptying would be relatively infrequent. It is recommended in the Material Safety Data Sheet that all unused material be collected, placed in properly labelled containers and either recycled, incinerated or disposed of at approved landfill sites.

No release is expected at end use because the notified polymer will be cured, and will be strongly adhered to the end packaging product where it will form an inert barrier against moisture, oxygen, and solvents (White *et al*., 2000).

9.2. Fate

Most of the notified polymer will be incorporated into the end packaging product. Hence the fate of the polymer will follow the fate of the end product to which it is adhered. At the end of their useful life, it is expected that some of these products will be sent to landfill, others may be recycled. Many packaging products have the potential to be recycled. For example, the notifier indicated a high rate of recycling of fibre packaging. Fibre packages includes paper and paperboard containers such as corrugated cardboard boxes used to store fruit in supermarkets. PET bottles and aluminium containers containing the polymer are also able to be recycled. Some of these recycled products may be reused while others may be reformulated into new materials. Incineration is a possible disposal pathway for some packaging materials. If incinerated, the polymer is expected to decompose to produce water and oxides of carbon and nitrogen.

At landfill sites, the fate of the polymer will depend on the type of materials into which it is incorporated. If the polymer is incorporated into packaging materials that are fairly rapidly degraded, the polymer would be expected to enter the soil environment. No biodegradation studies were provided in the dossier, however, the polymer is not expected to be readily biodegradable. Hydrolysis also is not anticipated, given the poor water solubility of the polymer. However, the polymer is expected to eventually degrade through biotic and abiotic processes. If the polymer is incorporated into packaging materials that degrade very slowly, for example PET bottles, the polymer may remain inert for long periods because access by water and microorganisms to chemical substrates which would enable chemical breakdown would be restricted in these materials. A potential pathway for the eventual breakdown of polymer in inert materials is by surface photodegradation upon exposure to sunlight.

No adsorption data were provided in the notification dossier. The polymer is not expected to be mobile or to leach from soils into aquatic compartments because of its low water solubility. The polymer is also not very soluble in fat and hence is not expected to adsorb to organic materials either. In the event that the polymer enters the aquatic environment, it is expected to sink and remain in the sediment or partition in sludge in sewage treatment facilities.

Given the high molecular weight, the notified polymer is not expected to cross biological membranes or to bioaccumulate (Connell, 1990).

10. EVALUATION OF HEALTH EFFECTS DATA

No toxicological data were submitted.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

The notifier provided an acute toxicity to daphnia test report using a similar polymeric substance to the notified polymer. The test substance was added directly to the test water in

the form of 2-4 mm pellets. Immobilisation of the test organisms was not observed at nominal concentrations of up to 100 mg/L. Due to a lack of immobilisation, calculation of the EC50 and NOEC was not attempted (Dow Chemical, 2000b). No mention is made of how or whether the test concentrations in the test media were verified analytically. No observations were included on whether the test substance dissolved in the test water or not.

12. ENVIRONMENTAL RISK ASSSESSMENT

The main environmental exposure of the notified polymer will result from landfill of packaging and other materials containing the polymer at the end of their useful lifetime. At landfill sites, the polymer is expected to be immobile and inert, and to undergo slow degradation along with the packaging materials into which it is incorporated. The main pathways to the breakdown of degradable packaging materials containing the new polymer are expected to be biological and physico-chemical, while the main pathways to the breakdown of poorly degraded materials are expected to be abiotic processes such as photodegradation.

The notified polymer is not soluble in water, and is not expected to enter the aquatic environment under normal use. In the event that the polymer enters the aquatic environment, it is expected to sink and remain in the sediment or partition in sludge in sewage treatment facilities.

Given the high molecular weight of the notified polymer, it is not expected to cross biological membranes or to bioaccumulate (Connell, 1990).

It is unlikely that the notified polymer will present a hazard to the environment when handled and used as instructed in the MSDS or when incorporated into packaging products. Hence, environmental hazard from the proposed use is expected to be low.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

The notified polymer fulfils the criteria for a synthetic polymer of low concern and can be considered not to be a health hazard.

13.2. Occupational health and safety

Transport and storage workers are unlikely to be exposed to the notified polymer except in the event of accidental rupture of the packaging.

The notified polymer is added to the mixing vessel of an extruder or moulder which is essentially a closed system. Little spillage is envisaged and following extrusion and cooling of products the notified polymer will adhere strongly to substrate and will not be bioavailable. It can be concluded that the risk of adverse health effects to quality control personnel, process or warehouse workers will be minimal. Manual addition of pellets may result in dust and an extraction system and respiratory protection is expected to be used.

During end use and disposal of products to which the notified polymer is adhered, the polymer will form an impervious coating and will not be bioavailable.

For powder coating applications, where the powder is sprayed onto metal objects, the potential for dermal and inhalation exposure exists. In the larger establishments a largely enclosed assembly line is used to minimise worker exposure. In the smaller establishments, and particularly where a walk-in booth is used, dermal and inhalation exposure can be high. Normally, workers would employ overalls, gloves, respirator (half-face or in-line air supplied) and anti-static and conductive footwear as personal protective equipment. The risk of adverse health effects is dependent on components of the powder coating other than the notified polymer.

Conclusion

The notified polymer is of low concern to human health and safety and no specific risk reduction measures are necessary.

13.3. Public health

Exposure of the general public as a result of transport, reformulation and disposal of the notified polymer is assessed as being negligible. The notified polymer will not be sold to the public. Packaging materials containing the notified polymer will have a wide variety of uses, including uses as food containers. Members of the public will make dermal contact with packaging materials containing the notified polymer and will eat and drink foodstuffs that have been in contact with packaging materials manufactured using the notified polymer. However, the notified polymer poses minimal risk to public health since public exposure is likely to be minimal because the notified polymer is tightly bound to the packaging materials and not likely to be bioavailable. Similar considerations apply for powder coated articles containing the notified polymer.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

Regulatory controls

- Employers should ensure that the atmospheric level of nuisance dust is maintained below the NOHSC exposure standard of 10 mg/m3 (NOHSC, 1995);

Control Measures

No specific precautions are required to control exposure to the notified polymer. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed:

Occupational Health and Safety

- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly by sweeping or vacuuming and put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer when used in powder coatings:

    - anti-static overalls
    - non-insulating gloves
    - anti-static footwear
    - dust respirators or air fed respiratory equipment

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 containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

15.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if

– the notified polymer is introduced in a chemical form that does not meet the PLC criteria and specifically if it is to be used in the liquid phase.

or

(2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

16. REFERENCES

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