File No: LTD/1443-1446

February 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

LTD 1443: Polymer in HL 9648
LTD 1444: Polymer in HL 9597
LTD 1445: Polymer in HL 9597G
LTD 1446: Polymer in HL 9654B

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
H B Fuller Company Australia Pty Ltd (ABN 37 003 638 435)
16-22 Red Gum Drive, DANDENONG SOUTH, VIC 3175

NOTIFICATION CATEGORY
Limited: Synthetic polymers with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, CAS Number, Molecular Formula, Structural Formula, Polymer Constituents, Molecular Weight, Spectral Data, Concentration and Identity of Impurities and Additives/Adjuvants, Concentration in Product, Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
VARIATION TO THE SCHEDULE OF DATA REQUIREMENTS IS CLAIMED AS FOLLOWS:
Boiling Point, Hydrolysis as a Function of pH, Adsorption/Desorption, Dissociation Constant, Particle Size, Flammability Limits, Autoignition Temperature, Explosive Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
LTD 1443: Polymer in HL 9648
LTD 1444: Polymer in HL 9597
LTD 1445: Polymer in HL 9597G
LTD 1446: Polymer in HL 9654B

ANALYTICAL DATA
Reference IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Benzene, 1,1'-methylenebis[isocyanato- (MDI)		
CAS No.	26447-40-5	*Weight %*	< 5 (LTD1443) < 6 (LTD 1445)

Hazardous Properties	Classification Carc. Cat. 3; R40 Xn; R20-48/20 Xi; R36/37/38; R42/43 Concentration cutoffs Conc≥25%: Xn; R40; R20; R48/20; R36/37/38; R42/43 ≥10%Conc<25%: Xn; R40; R48/20; R36/37/38; R42/43 ≥5%Conc<10%: Xn; R40; R36/37/38; R42/43 ≥1%Conc<5%: Xn; R40; R42/43 ≥0.1%Conc<1%: Xn; R42
Chemical Name	Benzene, 1,1'-methylenebis[4-isocyanato- (MDI)
CAS No.	101-68-8 *Weight %* < 6 (LTD 1444) < 5 (LTD 1446)
Hazardous Properties	Classification Carc. Cat. 3; R40 Xn; R20-48/20 Xi; R36/37/38; R42/43 Concentration cutoffs Conc≥25%: Xn; R40; R20; R48/20; R36/37/38; R42/43 ≥10%Conc<25%: Xn; R40; R48/20; R36/37/38; R42/43 ≥5%Conc<10%: Xn; R40; R36/37/38; R42/43 ≥1%Conc<5%: Xn; R40; R42/43 ≥0.1%Conc<1%: Xn; R42
Chemical Name	Benzene, 1-isocyanato-2-[(4-isocyanatophenyl)methyl]-
CAS No.	5873-54-1 *Weight %* < 0.5 (LTD1443 and 1446)
Hazardous Properties	Classification Carc. Cat. 3; R40 Xn; R20-48/20 Xi; R36/37/38; R42/43 Concentration cutoffs Conc≥25%: Xn; R40; R20; R48/20; R36/37/38; R42/43 ≥10%Conc<25%: Xn; R40; R48/20; R36/37/38; R42/43 ≥5%Conc<10%: Xn; R40; R36/37/38; R42/43 ≥1%Conc<5%: Xn; R40; R42/43 ≥0.1%Conc<1%: Xn; R42

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The notified polymers are reactive hot-melt polyurethane polymers, the linear isocyanate groups of which, when the polymers come into contact with water (liquid or vapour), cure rapidly to produce an unstable carbamic acid. The carbamic acid immediately decomposes to produce carbon dioxide (which is liberated as a by-product) and an amine which further reacts with any isocyanate present to produce the final high molecular weight crosslinked urea product.

DEGRADATION PRODUCTS

Under the normal conditions of use, temperatures up to 135°C, no degradation products are expected. Under fire conditions, pyrolysis combustion products including isocyanate vapours, oxides of carbon and nitrogen, and small amounts of hydrogen cyanide are expected to be produced.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Off-white solid

Property	Value	Data Source/Justification
Melting Point	~70°C	Measured
Boiling Point	Not determined	Notified polymers are solids.
Density	1200 kg/m^3 at 20°C	Measured (ASTM D0792)
Vapour Pressure	0.0066 kPa at 20°C	Due to presence of residual monomers.
Water Solubility	< 0.030 g/L at 20°C	Measured

Hydrolysis as a Function of pH	Not determined	Test not conducted due to the low measured water solubility. The notified polymers contain reactive end functional groups that can readily react with water.
Partition Coefficient (n-octanol/water)	log P_{ow} = 0.40 ± 0.20 at 20°C	Measured
Adsorption/Desorption	Not determined	Predicted to adsorb to soil from water due to its low solubility in water. The notified polymers are also likely to irreversibly combine with soil through chemical reactions that are characteristic of these adhesive polymers.
Dissociation Constant	Not determined	Cannot be evaluated for the notified polymers as they will react with water to form water-insoluble solids.
Particle Size	Not determined	Notified polymers are waxy solids.
Flash Point	196°C at 101.3 kPa	MSDS
Flammability	Not determined	Not expected to be highly flammable based on flash point.
Autoignition Temperature	Not determined	Not expected to autoignite at ambient temperature and during normal use.
Explosive Properties	Not determined	Not expected to be explosive based on absence of explosive functional groups.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
Stable under normal environmental and usage conditions. The notified polymers are designed to react with atmospheric moisture as a part of the curing process.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymers will be introduced as a component (at > 90%) of finished and pre-packaged hot-melt adhesive products.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100-300	100-300	100-300	100-300	100-300

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymers are imported by ship in 20 kg metal pails or 220 kg steel drums. They will be transported from the dock to the notifier and to end-use sites by road.

USE
The notified polymers are components (at > 90%) in ready-to-use polyurethane hot-melt adhesives to bond wood, metal, textiles, leather, polyurethane foams and a wide range of plastics.

OPERATION DESCRIPTION

There will be no reformulation or repackaging in Australia. At the end-use site, drums or pails will be moved from the storage area to the application unit and the seal of the drum/pails will be broken under a vented hood. A plunger from the melter unit will be inserted into the drum and the drum moved into an enclosed melter. The melter will be set to the appropriate temperature to facilitate the delivery of the molten adhesives to the application head, which will then be applied to the substrate in a controlled manner as a molten bead. After 5-25 seconds another substrate will be laid on top of the initial one, sandwiching the adhesives. Complete cure of the adhesives will typically take at least 12 hours depending on the temperature and humidity conditions.

During curing, the articles, including books, magazines, and other substrates made of plastic, polyurethane foam, wood, metal and leather will be stored in ventilated areas of the warehouse.

At the end of the process, the adhesive feed to the application head will be stopped and the remaining adhesive melt allowed to run to the tray below the application head and cured overnight. The applicator roller is coated with cleaning agents and allowed to remain overnight. The cured adhesives are removed for disposal to landfill on the following day.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	100	1	200
Application Operators	100	6	100
Cleaning and Maintenance workers	50	0.5	100
Finished Good Quality Inspector	50	2	40

EXPOSURE DETAILS

Transport and storage workers are not likely to be exposed to the adhesive products containing the notified polymers (> 90%) except in the unlikely event of an accident.

Dermal exposure of the worker to the notified polymers may occur during its transfer to melter. However, such exposure is expected to be minimised by the use of fume extraction system and the use of personal protective equipment (PPE), including nitrile gloves, safety glasses with side shield, and coveralls. Inhalation exposure is not expected to occur at this stage as the adhesives are solid blocks or waxy solid pellets and volatile components are not expected to be released.

Exposure of workers to the notified polymers (> 90%) is not expected during melting and delivery to the application head of the adhesives as it takes place in an enclosed and automated system that is confirmed via a computer monitor that relays information about molten adhesive egress through a bleeder valve at the top of the melter plunger.

Inhalation exposure of workers to the notified polymers during application of the molten adhesives to the substrate is expected to be minimal as the process is automated and takes place under a ventilation hood to remove volatile components of the adhesives. In addition, aerosols are not expected to be formed. Dermal exposure to the notified polymers may occur when workers handle the bonded articles prior to curing. Such exposure is expected be minimised by these workers wearing gloves and overalls. Once cured the adhesives will be inert and not bioavailable.

Cleaning and maintenance workers are expected to wear organic vapour filter masks, goggles, gloves, protective overalls and safety footwear to avoid dermal, ocular and inhalation exposure. If it is determined that a significant amount of the notified polymers and residual monomers remains uncured at this stage, cleaning workers are expected to wear air-line respirators or self-contained breathing apparatus complying with Australian Standard AS 1716.

6.1.2. Public exposure

Since the adhesives are not sold directly to the public, direct exposure to the notified polymers is not expected to occur. Finished articles including books, magazines, and other substrates made of plastic, polyurethane foam, wood, metal and leather bound with the cured adhesives will be sold to the public but the notified polymers will be cured and crosslinked to form an inert matrix and will not be available for exposure.

6.2. Human health effects assessment

The result from an acute oral toxicity study conducted on an analogue polymer is summarised in the table below. Details of the study can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 > 2000 mg/kg bw, low toxicity

The notified polymers are expected to be of low acute toxicity *via* the oral route based on an acute oral toxicity study on an analogue polymer.

In the absence of further toxicological data on the notified polymers, the known general hazards of isocyanates have been considered, in particular, the hazards associated with MDI (benzene, 1,1'-methylenebis[isocyanato- or benzene, 1,1'-methylenebis[4-isocyanato-, a monomer of the notified polymers that is also present at a low concentration as a residual monomer).

The notified polymers are not expected to be absorbed across biological membranes to a significant extent, based on the high molecular weight (Mn > 1000 Da). However, due to the presence of low molecular weight species (5-10% with MW < 1000 Da), some absorption may occur.

Isocyanates are considered highly reactive and are known to be hazardous to human health. The main hazards posed by isocyanates include respiratory sensitisation in the form of asthma, as well as decreased respiratory function with the possibility of interstitial fibrosis and pulmonary oedema (Tillman 2007). Isocyanate exposure is the most common cause of occupational asthma around the world (Mapp et al 1988; Bernstein 1996) and no specific treatment is available for individuals who are sensitised. Individuals with a history of respiratory conditions such as asthma and hay fever may be more likely to develop isocyanate sensitivity (NOHSC 1990). Polymeric isocyanates are less volatile and contain less free isocyanate, and are therefore expected to be less of an inhalation hazard. However, the UK Employment Medical Advisory Service believes polymeric isocyanate aerosols are capable of causing respiratory sensitisation similar to monomer vapours, and reports have shown that inhalation of relatively non-volatile isocyanates in the form of dusts and spray-mists could cause adverse respiratory effects (HSIS, 2008). Isocyanates may also cause respiratory sensitisation by skin contact (US EPA 2002).

Isocyanates may be irritating to the skin and eyes and splashes in the eyes may lead to severe chemical conjunctivitis (NOHSC 1990). In addition isocyanates may cause skin sensitisation from repeated or prolonged exposure (Kirk-Othmer, 1995). Although the potential for these effects is likely to be reduced due to the high molecular weight of the notified polymers, the presence of low molecular weight species means that these effects cannot be ruled out.

Health hazard classification
Based on the presence of the isocyanate functional group in the notified polymers, the notified polymers are classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Xn; R42 May cause sensitisation by inhalation.

The notifier has classified the products containing the notified polymers in the MSDS based on the concentrations of hazardous monomers:

LTD 1443 Polymer in HL 9648 and LTD 1446 Polymer in HL 9654B:
R40 (3) Limited evidence of a carcinogenic effect.
R42/43 May cause sensitisation by inhalation and skin contact.

LTD 1444 Polymer in HL 9597 and LTD 1445 Polymer in HL 9597G:
R40 (3) Limited evidence of a carcinogenic effect.
R42/43 May cause sensitisation by inhalation and skin contact.
R36/37/38 Irritating to eyes, respiratory system and skin.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Workers that are exposed to isocyanates may have a concentration-dependent risk of developing respiratory diseases such as bronchial asthma (Baur et al 1994) and often the only treatment for sensitised individuals is to completely remove the worker from the workplace to avoid exposure (Bernstein 1996). Therefore, measures should be in place to avoid workers from developing sensitisation. The engineering controls in place to reduce the exposure to vapours of the adhesives, such as the enclosed melter, the local exhaust ventilation during the binding process, and the ventilation during curing, are expected to minimise any potential inhalation exposure to the notified polymers. As the cleaning activities will be carried out after leaving the residual adhesives overnight the majority of the residual adhesives is expected to be cured. Cleaners are also expected to wear PPE including an organic vapour filter mask or an appropriately fitted air-line respirator or self-contained breathing apparatus complying with Australian Standard AS 1716 (NOHSC 1990) if significant amounts of the notified polymers or residual monomers remain uncured. Such respiratory protection should also be used as deemed appropriate, during other handing procedures involving the notified polymers. In summary, the risk to workers of developing respiratory sensitisation is not considered unacceptable assuming that the stated engineering controls and proposed PPE are used.

The potential for the notified polymers to cause skin sensitisation, as well as skin and eye irritation can not be ruled out. Dermal and ocular exposure may occur during the opening of the packages containing the solid notified polymers, handling of articles bound with uncured resin, or during the cleaning of equipment. However, this exposure is expected to be minimised by the PPE worn by the workers, including nitrile gloves, coveralls and safety glasses. Therefore, when used under the conditions described the notified polymers are not expected to pose an unacceptable risk to workers.

6.3.2. Public health
The public will not be exposed to the notified polymers or isocyanate monomers; hence the risk to the public is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
Release of the notified polymers from manufacture or reformulation is not expected as the polymers are imported in a ready-to-use form.

RELEASE OF CHEMICAL FROM USE
The application of the hot-melt adhesive is very efficient with little waste being generated. Nearly all the notified polymers released to the environment will be the result of equipment cleaning and container residues. Waste generated from the equipment cleaning could be up to 1% of the total volume of notified polymers imported, which is allowed to cure before disposal of the solid waste to landfill. The residue remaining in drums could be up to 1% and is allowed to moisture cure in the drum before disposal to landfill with the drum.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of the notified polymers will be applied to the surfaces of articles as adhesive and, after curing, will share the fate of the articles. Most of the articles will be sent to landfill, and some may be thermally decomposed during recycling processes.

7.1.2 Environmental fate

No environmental fate data were submitted. In landfill, the notified polymers are not expected to leach and are likely to adhere to organic material, sediment and soil due to their low water solubility, high molecular weights and reactivity with surfaces. Over time, the notified polymers are expected to undergo biotic and abiotic degradation into water and oxides of carbon and nitrogen. The potential for bioaccumulation of the notified polymers is low due to its high molecular weight and low bioavailability.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC has not been calculated since no significant release of the notified polymers to the aquatic compartment is expected to occur.

7.2. Environmental effects assessment

The results from the single ecotoxicological investigation conducted on an analogue of the notified polymers is summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 > 100 mg/L	Not harmful to fish

At the limit of solubility in water, no acute harmful effects were observed on fish exposed to an analogue polymer with similar reactive groups to the notified polymers.

7.3. Environmental risk assessment
The risk of an adverse effect on the environment from the notified polymers is expected to be minimal based on the intended use in hot–melt adhesive products.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the data provided the notified polymers are classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification details are:

Xn; R42 May cause sensitisation by inhalation

The classification of the notified polymers using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Respiratory sensitisation	1	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Based on the concentrations of hazardous monomers present, additional risk phases have been assigned in the MSDS.
Human health risk assessment

Under the conditions of the occupational settings described where sufficient controls are in place to minimise inhalation exposure when necessary, the notified polymers are not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymers are not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the reported use pattern, the notified polymers are not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for products/mixtures containing the notified polymers:
  - Conc ≥ 1%: R42 may cause sensitisation by inhalation

- The following safety phrases should appear on the MSDS and label for the notified polymers:
  - S23 Do not breathe vapour or spray
  - S28 After contact with skin, wash immediately with plenty of water and soap.
  - S36/37 Wear suitable protective clothing and gloves.
  - S38 In case of insufficient ventilation, wear suitable respiratory protection.
  - S45 In case of accident or if you feel unwell seek medical advice immediately (and show the label where possible)

Health Surveillance

- As the notified polymers contain isocyanate functional groups, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a history of isocyanate sensitivity, asthma or other pulmonary condition and who may be adversely affected by isocyanate exposure.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymers:
  - Ventilation system including local exhaust ventilation.
  - Automated processes, where possible.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymers:
  - Keep containers securely sealed and check regularly for spills and leaks.
  - Avoid inhalation of vapours, mists and aerosols.
  - Avoid contact with skin.
  - Wash hands after handling the notified polymers, or containers and equipment containing them.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymers:
  - Isocyanate-resistant gloves
  - Overalls
  - Safety glasses
  - Appropriately fitted air-line respirators or self-contained breathing apparatus complying with Australian Standard AS 1716 for cleaning and maintenance workers

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Atmospheric monitoring should be conducted to measure workplace concentrations of volatile adhesive components during use of the notified polymers.

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

- If products and mixtures containing the notified polymers are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymers should be disposed of to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polymers:
  - Check all containers against leakage and ensure lids and caps are tightly sealed
  - Store in a ventilated and bunded area.
  - Store in a cool dry place away from direct sunlight
  - Store away from acids, alkalis or amines.

Emergency procedures

- Spills or accidental release of the notified polymers should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS 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 polymers have a number-average molecular weight of less than 1000;
  - the polymers are imported in a mixture that can be aerosolised;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemicals has changed from a component (at > 90%) in ready-to-use polyurethane hot-melt adhesive, or is likely to change significantly;
  - the amount of chemicals being introduced has increased from 300 tonne per year, or is likely to increase, significantly;
  - the chemicals have begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemicals on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

The MSDS of the products containing the notified polymers provided by the notifier were reviewed by NICNAS. The polymers have been classified as hazardous according to the concentrations of hazardous monomers. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Vapour Pressure 0.0066 kPa at 20°C.

Remarks Notified polymers are solids. Vapour pressure due to presence of residual monomer.
Test Facility H.B. Fuller (2009)

Water Solubility < 0.030 g/L at 20°C

Method OECD TG 105 Water Solubility
Remarks Flask Method: Shake flask. The water extractability of components of polymer in HL 9648 at pH 1, 7, and 10 was determined gravimetrically over a 9 day period. All tests were performed at a nominal loading level of 10g of polymer in HL 9648 in 250 mL of pH-adjusted water. The mass of the filtered and dried extracts were not significantly different from the solvent blanks in each case, which indicates very low water extractability of polymer in HL 9648. The only significant observation was that the pH of water layers were more acidic after exposure to samples of polymer in HL 9648.
Test Facility H.B. Fuller (2009)

Partition Coefficient (n-octanol/water) $\log P_{ow} = 0.40 \pm 0.20$ at 20°C

Method OECD TG 107 Partition Coefficient (n-octanol/water): Shake Flask Method
Remarks The partitioning of the notified polymers was estimated using 10 g of solid polymer in HL 9648 and various volume ratios of water and octanol (1:2, 1:1, 2:1). The partitioning was calculated based on the masses of material recovered from dried subsamples taken from both phases. The pH of water layers were again more acidic after exposure to samples of polymer in HL 9648.
Test Facility H.B. Fuller (2009)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: TL-0569 (analogue polymer)

METHOD
- Species/Strain: Rat/Sprague Dawley
- Vehicle: None
- Remarks - Method: No deviations from the protocol.

RESULTS

Number and Sex of Animals	*Dose mg/kg bw*	*Mortality*
5 per sex	2000	0

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: No animal displayed signs of toxicity. All animals gained body weight during the study.
- Effects in Organs: A "foreign object" was found in the stomachs of all of the animals. The foreign object was likely to have been test substance that had further polymerised, given the moisture cure properties of the test substance. The presence of the foreign object in the stomachs of the animals did not appear to interfere with digestion and the general well-being of the animals.

CONCLUSION: The test substance is of low toxicity via the oral route.

TEST FACILITY: Nucro-Technics Inc. (2000)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	TL-0569 (analogue polymer)
METHOD	OECD TG 203 Fish, Acute Toxicity Test, 96-hour static limit test
Species	Rainbow trout
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not available
Analytical Monitoring	None
Remarks – Method	The test substance is a polymer with similar reactive end-groups to the notified polymers. Test mixtures of the analogue polymer in dechlorinated tap water were prepared by dispersion of the insoluble liquid test substance with stirring and aeration during a 24-hour pre-mixing period. The test substance formed tendril-like structures linked to globules of the undissolved substance. Fish were introduced directly into these dispersions of the analogue polymer in water.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*				
		1h	*24h*	*48h*	*72h*	*96h*
100	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours
NOEL	100 mg/L at 96 hours
Remarks – Results	No mortality or impairment was observed in any fish of the exposure or control chambers. At the limit of solubility, no acute toxic effects were observed.
CONCLUSION	The analogue polymer is not harmful to fish at the limit of its solubility in water.
TEST FACILITY	Beak International Incorporated (2000)

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