File No: LTD/1871-1872

November 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

LTD/1871: Polymer 1 in EVER®LOCK and SWIFT®LOCK Adhesives
LTD/1872: Polymer 2 in EVER®LOCK and SWIFT®LOCK Adhesives

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

This 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:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1871	H.B. Fuller Company Australia Pty Ltd	Polymer 1 in EVER®LOCK and SWIFT®LOCK Adhesives	Yes	< 300 tonnes per annum	Component of hot melt adhesive
LTD/1872		Polymer 2 in EVER®LOCK and SWIFT®LOCK Adhesives		< 300 tonnes per annum	

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data provided, the notified polymers cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

Based on the available information, the notified polymers are recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R42: May cause sensitisation by inhalation

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings, the notified polymers are not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the reported use pattern, the notified polymers are not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Health Surveillance

- As the notified polymers are potential skin/respiratory sensitisers, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymers as introduced:

- Ventilation systems including local exhaust ventilation during transfer and application, and good general ventilation during curing.
- Enclosed and automated processes, where possible.

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymers as introduced:
  - Avoid inhalation of vapours, mists and aerosols.
  - Avoid contact with skin and eyes.
  - Clean up spills, offcuts and waste promptly
  - Wash hands after handling the products containing the notified polymers, or containers and equipment containing them.

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymers as introduced:
  - Impervious gloves
  - Overalls
  - Safety glasses
  - Respiratory protection if inhalation exposure may occur

  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 isocyanates during use of products containing the notified polymers. Employers should ensure that the exposure standard for isocyanates [NOHSC:1003 (1995)] is not exceeded for all areas where the notified polymer may be handled or present.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymers are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymers in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

- 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 cool, dry, well-ventilated place away from direct sunlight

Emergency procedures

- Spills or accidental release of the notified polymers should be handled by containment, physical 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 polymers are 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 polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymers has changed from component of hot melt adhesive, or is likely to change significantly;
- the amount of polymers being introduced has increased, or is likely to increase, significantly;
- the polymers have begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymers 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.

(Material) Safety Data Sheet
The (M)SDS of the products containing the notified polymers provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

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
LTD/1871 - Limited: Synthetic polymer with Mn ≥ 1,000 Da.
LTD/1872 – Limited (Reduced fee notification): Synthetic polymer with Mn ≥ 1,000 Da. Polymer is being notified at the same time as a similar polymer.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Products containing LTD/1871 include:
EVER®LOCK 2U431-1N
SWIFT®LOCK 2U551-1N, 2U592-1N, 2U597-1N, 9053, 9064, 9079, 9080, 9092, 9096, 9108 and 9113.

Products containing LTD/1872 include:
EVER®LOCK 2U431-1NG,
SWIFT®LOCK 2U551-1NG, 2U592-1NG, 2U597-1NG, 9053G, 9064G, 9079G, 9080G, 9092G, 9096G, 9108G and 9113G,

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) > 1000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

DEGRADATION PRODUCTS
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 cross-linked urea product.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa:
LTD/1871: White resinous solid
LTD/1872: Off-white solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	70 °C approximately	(M)SDS
Boiling Point	> 149 °C at 101.3 kPa	(M)SDS
Density	1100 kg/m3 at 26 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	0.03 ± 0.009 g/L at pH 7 at 20 °C	Analogue chemical
Hydrolysis as a Function of pH	Not determined	Cannot be evaluated for the notified polymers due to low water solubility. The notified polymers contain functionalities that react with water to form inert solids.
Partition Coefficient (n-octanol/water)	log Pow = 0.4 ± 0.2 at 20 °C	Analogue chemical
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on low water solubility. The notified polymers are also expected to irreversibly bind to soil through chemical reactions characteristic of these adhesive polymers.
Dissociation Constant	Not determined	Cannot be evaluated for the notified polymers as they will react with water to form inert solids.
Particle Size	Not determined	Notified polymers are waxy solids.
Flash Point	204°C at 101.3 kPa	(M)SDS
Flammability limits	Not determined	-
Autoignition Temperature	Not determined	Expected to be high based on flash point
Explosive Properties	Not determined	Not expected to be explosive based on absence of explosive functional groups.
Oxidising Properties	Not determined	Not expected to be oxidising based on absence of oxidative functional groups.

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

Reactivity
The notified polymers are expected to be stable under normal conditions of use, however may polymerise at high temperatures. The notified polymers are designed to react with atmospheric moisture as a part of the curing process.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymers are not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymers will not be manufactured, reformulated or repackaged in Australia. They will be imported into Australia as a component of a solid single pack Reactive Hot Melt Polyurethane adhesive at up to 100%.

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

LTD/1871

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

LTD/1872

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

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
H.B. Fuller Company Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in hermetically sealed 200 L steel drums and 20 kg steel pails and transported by road from the wharf to the notifier's warehouse where it will be stored then transported to the end-user sites by road.

USE
The notified polymers, as a component in ready-to-use polyurethane hot-melt adhesives at up to 100% concentration, will be used to bond a wide range of substrates including metals, plastics and woods.

OPERATION DESCRIPTION
There will be no reformulation or repackaging in Australia. At the end-user sites, the liner bag of the adhesive containers containing the notified polymers will be opened under an extraction hood. A plunger from the melter unit will be inserted into the drum or pail, which will be immediately placed into a fully enclosed melter. The melter will be set to the appropriate melting temperature for the adhesive (100-140°C) to be deposited on substrates through rollers or nozzles. A second substrate will be laid onto the substrate, sandwiching the adhesive between the layers. A quality control inspection of the bound substrates is undertaken when the hot-melt is completely cured. A complete cure will depend on temperatures and humidity conditions (usually occurring within 0.5 to 2 days). During curing, the articles will be stored in a ventilated section of the warehouse. Once cured, the adhesive will be inert and not bioavailable.

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

CATEGORY OF WORKERS

Category of Worker	*Number of Workers*	*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
Exposure of transport and storage workers to the notified polymer is not expected to occur except in the event of an accident.

Adhesives applications (End-users)
There will be no reformulation or repackaging in Australia. Dermal, ocular and inhalation exposure of workers to the notified polymers at up to 100% may occur during the different process steps at the end-use sites. Exposure may be to the adhesives in solid form, or to the melted adhesives which would have higher potential for inhalation. Inhalation exposure may also occur when the sealed containers are first opened, and during curing.

During transfer to the melter, exposure is expected to be minimised by a fume extraction system and the use of personal protective equipment (PPE) by workers, including nitrile gloves, safety glasses and coveralls. Similarly, worker exposure is not expected during melting and delivery to the application head of the adhesives as this takes place in an enclosed and automated system.

During application of the molten adhesives to the substrate, the potential for inhalation exposure would be reduced by the automated nature of the process and use of a ventilation hood to remove volatile components of the adhesives. In addition, aerosols are not expected to be formed during this process. Once the adhesive has been applied, 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.

Dermal, ocular or inhalation exposure of workers to the notified polymers during cleaning, maintenance and quality control processes is expected to be minimised by the use of PPE such as wearing of organic vapour filter masks, goggles, gloves, protective overalls and safety footwear.

The possible inhalation exposure of workers to the notified polymer during curing process is expected to be minimised by the use of good general ventilation in the warehouses where the treated substrates will be stored. It is expected that full air replacement will occur every 6 hours.

Once the adhesives are cured, the notified polymers will be reacted into the adhesive polymeric mix and not bioavailable.

6.1.2. Public Exposure
The adhesives containing the notified polymers will not be sold to the general public. Therefore, direct exposure to the notified polymers is not expected to occur. Finished articles including substrates such as plastics, polyurethane foams, woods, metals and leather bound with the cured adhesives containing the notified polymers will be sold to the public. However, the notified polymers will be cured and cross-linked to form an inert matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the analogue polymer is summarised in the following table. For full details of the study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity (Analogue)	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.

No further toxicological data on the notified polymers were provided.

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 a proportion of low molecular weight species with MW < 1000 Da, some absorption may occur.

The notified polymers contain isocyanate functional groups which are of concern for irritation, dermal and respiratory sensitisation and pulmonary toxicity (Barrett 1994, US EPA 2010, Kirk-Othmer 1995).

The USEPA specifies that structures with isocyanate equivalent weights of ≥ 5,000 Da are presumed not to pose a hazard under any conditions. In addition, concerns are generally confined to species with molecular weights < 1,000 Da. The isocyanate functional group equivalent weight of the notified polymer is expected to be < 5,000 Da and although its molecular weight is >1,000 Da, the polymer contains a proportion of low molecular weight species; hence the risks cannot be ruled out.

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). Isocyanates may also cause respiratory sensitisation by skin contact (US EPA 2010).

According to the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004), substances containing isocyanate functional groups should be classified as hazardous unless there is evidence to indicate that the substance does not cause respiratory hypersensitivity. Thus, the following risk phrase should be applied to the notified polymer:

R42: may cause sensitisation by inhalation

Health hazard classification
As no further toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

Based on the presence of the isocyanate functional group in the notified polymers, the notified polymers are recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R42: May cause sensitisation by inhalation.

The notifier has classified the notified polymers with the following risk phrases:

- R40 (category 3): Limited evidence of carcinogenic effect
- R42/43: May cause sensitisation by inhalation and skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymers contain reactive isocyanate functional groups which are of concern for irritation, skin and respiratory system sensitisation and pulmonary toxicity. Dermal, ocular and inhalation worker exposure may occur to adhesives containing the notified polymers at up to 100%, in both solid and molten forms. Potential exposure is highest when the adhesives are being prepared for use, during application and cleaning and during the curing period. Once the adhesives are fully cured, they are expected to be inert and to contain no isocyanate groups. Engineering controls such as exhaust ventilation during transfer and application, closed processes during melting and good general ventilation during the curing process would reduce exposure, as would use of the stated PPE by workers. Adoption of safe work practices to avoid incidental exposure and exposure to partially cured substrates would further reduce exposure and risk.

The adhesives also contain lower molecular weight isocyanate impurities which are classified as hazardous. The controls in place to limit exposure to these chemicals would also reduce exposure to the notified polymers.

Provided that the engineering controls and PPE stated by the notifier are in place as well as safe work practices, the risk to the health of workers from the use of the notified polymers is not considered to be unreasonable.

6.3.2. Public Health

The notified polymers are intended for industrial use only and will not be sold to the public. The public may come into contact with the notified polymers when finished articles (including vehicle and building sub-components and other substrates made of metals, plastics and woods containing the cured adhesive) will be sold

to the public. However, the polymers will be cured and cross-linked to form an inert matrix and will not be available for exposure.

Therefore, the risk to the health of the public from the use of the finished articles containing the notified polymers is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymers will be imported as a component of ready-to-use hot-melt adhesives, and will not be reformulated in Australia. Therefore, no environmental release is expected from manufacture or reformulation in Australia. The release of the notified polymers to the environment during import, storage and transport is also unlikely. Spills or accidental release of the products containing the notified polymers are expected to be allowed to cure, then collected by physical containment and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The products containing the notified polymers will be used for binding wood, metal, textile, leather, polyurethane foams and plastic substrates. Very little waste is expected to be generated from the application of the hot-melt adhesives. Once cured, the notified polymers will be irreversibly bound to the substrate and share the fate of the adhered article. It is estimated by the notifier that up to 2% of the total import volume (or up to 6,000 kg each) of the notified polymers may be released to the environment as a result of equipment cleaning and container residues. These wastes are expected to be allowed to cure before disposal to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymers in adhesives are expected to share the fate of the substrate to which they have been applied, and are predominantly expected to be disposed of to landfill at the end of their useful lives, or undergo thermal decomposition during substrate recycling processes.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymers. The notified polymers react and cure upon contact with moisture, and become irreversibly bound to form part of an inert adhesive matrix. The notified polymers will share the fate of the adhered articles, which will involve eventual disposal to landfill, or undergo thermal decomposition during substrate recycling. In their cured form, the notified polymers are not expected to be bioavailable or biodegradable.

The notified polymers in solid waste disposed of to landfill are not likely to be mobile in the environment and are likely to adhere to organic material, soil and sediment due to their expected low water solubility (based on the measured analogue data), high molecular weight, and reactivity with moisture and surfaces. Bioaccumulation of the uncured notified polymers is unlikely as they are not expected to cross biological membranes due to their high molecular weight and low water solubility. This is supported by the low partition coefficient measured for an analogue (log POW = 0.4 ± 0.2). The notified polymers are expected to eventually degrade by biotic and abiotic processes in landfill, or by thermal decomposition, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

As significant aquatic exposure is not expected at any stage of the notified polymers' life-cycle within Australia, the predicted environmental concentration (PEC) has not been calculated.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymers. However, an ecotoxicological investigation conducted on an acceptable analogue of the notified polymers has been provided for fish, and the results are summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LL50 > 100 mg/L (WAF*)	Not harmful to fish up to limit of water solubility

*Water Accommodated Fraction

Based on the above ecotoxicological endpoint, the analogue, and therefore the notified polymers, are not considered to be harmful to fish up to the limit of their solubility in water. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified polymers are not formally classified for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated since the notified polymers are not considered to be harmful to aquatic organisms up to the limit of their solubility in water (based on the analogue study). Based on their use pattern, no significant release to the aquatic environment is expected.

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) of the notified polymers has not been calculated, due to the low potential for release to the aquatic compartment. The majority of the notified polymers will be irreversibly bound within an inert adhesive matrix during use, and after their useful lives, share the fate of the adhered articles. The notified polymers are not expected to be bioaccumulative based on their high molecular weights, low water solubility and low log POW. Therefore, on the basis of their limited aquatic exposure and assessed use pattern, the notified polymers are not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0.03 ± 0.009 g/L at pH 7 at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Analogue 1. Shake Flask Method.
Test Facility	H.B. Fuller (2009)

Partition Coefficient (n-octanol/water) log Pow = 0.4 ± 0.2 at 20 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water).
Remarks	Analogue 1. Shake Flask Method.
Test Facility	H.B. Fuller (2009)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue 2

METHOD: OECD TG 401 Acute Oral Toxicity – Limit Test.

Species/Strain	Rat/ Sprague Dawley
Vehicle	None
Remarks - Method	No deviations from the protocol. Dosage was chosen on the basis of a preliminary test.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M, 5F	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.
Remarks - Results	

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. Environmental Fate

C.1.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static
Species	Rainbow trout
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	Due to the low aqueous solubility of the test substance, the test substance was prepared as a Water Accommodated Fraction (WAF) of a nominal concentration of 100 mg/L. Samples of the test substance were weighed into aluminium weigh trays and stirred into the test solution with glass rods. Due to the reactivity and adherent nature of the test substance, both the weigh trays and stirring rods were added to the test system to minimise loss of the test substance due to adhesion.

RESULTS

Nominal Concentration mg/L	*Number of Fish*	*Mortality*			
		24 h	*48 h*	*72 h*	*96 h*
100	30	0	0	0	0

LL50	> 100 mg/L (WAF) at 96 hours.
NOEL	100 mg/L (WAF) at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 96 h test period. The 96 h LL50 and NOEC for fish were determined to be > 100 mg/L and 100 mg/L, respectively, based on nominal concentrations.
Conclusion	Under the study conditions the analogue, and hence the notified polymers, are not considered to be harmful to fish up to the limit of their water solubility.
Test Facility	Beak International Incorporated (2000)

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