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November 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Dynasylan® 1146

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 and Energy.

This Public Report is 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:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, 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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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
STD/1683	Evonik Australia Pty Ltd	Dynasylan® 1146	Yes	≤ 30 tonnes per annum	Component of adhesives and sealants

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available physico-chemical properties, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard Classification	*Hazard Statement*
Flammable Liquid (Category 4)	H227 – Combustible liquid

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard Classification	*Hazard Statement*
Acute Aquatic Toxicity (Category 3)	H402 – Harmful to aquatic life

Human Health Risk Assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment
On the basis of the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  – Flammable Liquid (Category 4): H227 – Combustible liquid

  The above should be used for products containing the notified polymer, if applicable, based on the concentration of the notified polymer present.

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 polymer and methanol released during reformulation:
- Enclosed/automated processes
- Local exhaust ventilation

- 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 polymer and methanol released during reformulation:
  - Avoid contact with skin and eyes
  - Avoid breathing in vapours, mists or aerosols

- 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 polymer and methanol release during reformulation and end use:
  - Protective clothing
  - Impervious gloves
  - Safety glasses or goggles
  - Respiratory protection, where vapours, mists or aerosols may be formed

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

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

- If products and mixtures containing the notified polymer 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.

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.

Emergency procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Disposal

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

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 polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer 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 notified polymer is intended to be used in products available to the public;
- the concentration of the notified polymer in end use products is > 1.5%.

or

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

Safety Data Sheet
The SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Evonik Australia Pty Ltd (ABN: 31 145 739 608)
Suite 33, 1 Ricketts Road
MOUNT WAVERLEY VIC 3149

NOTIFICATION CATEGORY
Standard (reduced fee notification): Synthetic polymer with Mn < 1,000 g/mol (more than 1 tonne per year) – Assessed by Comparable Agency (Canada)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, impurities, import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physical and chemical properties except for boiling point, vapour pressure and flash point and for all toxicological endpoints except for skin sensitisation, repeat dose oral toxicity, mutagenicity and genotoxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2002)
USA (PMN, 2003)
South Korea (2009)
Taiwan (2010)
Japan (2016)
Canada (2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dynasylan® 1146

MOLECULAR WEIGHT
Number average molecular weight (Mn) is < 1,000 g/mol

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless to yellowish liquid

Property	*Value*	*Data Source/Justification*
Melting Point/Freezing Point	Not determined	The notified polymer is a liquid

Property	*Value*	*Data Source/Justification*
Boiling Point	Not determined	SDS. The polymer decomposes before boiling at 269 °C at 101.3 kPa
Density	1.06 kg/m^3 at 20 °C	SDS
Vapour Pressure	< 0.1 kPa at 20 °C	SDS
Water Solubility	Not determined	Immiscible. The notified polymer hydrolyses rapidly in water and the products form a large insoluble polymer network
Hydrolysis as a Function of pH	Not determined	Contains readily hydrolysable functionality
Partition Coefficient (n-octanol/water)	Hydrolysed in water and could not be determined	Measured [#]
Adsorption/Desorption	Not determined	Will hydrolyse and based on the structure the hydrolysed product is expected to adsorb to soil and sediments and not expected to be mobile.
Dissociation Constant	Not determined	Does not contain dissociable functionality
Flash Point	> 60.1 – < 93 °C (closed cup method)	SDS
Flammability	Not determined	Combustible liquid based on flash point *
Autoignition Temperature	Not determined	–
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

[#] The study was performed on the two transformation products identified in the biodegradation study, MCMC (2015).
* Based on *Australian Standard AS1940* definitions for combustible liquids.

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer reacts with moisture to release methanol and form a water insoluble polymeric mass.

Physical Hazard Classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

Hazard Classification	*Hazard Statement*
Flammable Liquid (Category 4)	H227 – Combustible liquid

The notified polymer has a flash point of greater than 60 °C and no greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquids, the notified polymer may be considered as a Class C1 combustible liquid.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be imported in neat form for reformulation or as a component of ready to use adhesive and sealant products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 10	≤ 10	≤ 10	≤ 20	≤ 30

PORT OF ENTRY
Major ports of Australia

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in neat form in sealed 25 kg pails, 200 kg drums or 1,000 kg intermediate bulk containers (IBCs) for reformulation into end use products in Australia. It will also be imported as a component of ready to use sealant products (< 500 mL) or sachet packaging in package sizes suitable for professional use (< 1 L). Final products containing the notified polymer will be transported by road to the end use customers.

USE
The notified polymer will be used as a component of adhesive and sealant products for automotive, building and construction at concentrations of ≤ 1.5%. It will be used by industrial and professional workers.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. The notified polymer will be imported in neat form for reformulation and repackaging. It will also be imported as a component of ready to use adhesive and sealant products.

Reformulation
At the reformulation site, the notified polymer will be transferred to the mixing tank by gravity feed or by low pressure pumps and mixed with other additives. The mixing process is enclosed and automated, with local exhaust ventilation in place. Once mixing is complete, sampling for quality assurance purposes will take place and the finished adhesive and sealant products containing the notified polymer at concentrations of ≤ 1.5% will be pumped to filling machines where they will be transferred to a variety of containers (25 kg pails, or 200 kg drums, or 1,000 kg IBCs, or in < 1 L packages suitable for professional use) through gravity feed or low pressure pumps.

End Use
Adhesive and sealant products containing the notified polymer will be used by industrial and professional users for manual application to automotive, building and construction using a caulking gun or by trowel. Excess product and application equipment will be cleaned with rags and the rags will be disposed of properly, preventing environmental exposure.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may come into contact with the notified polymer (at concentrations of ≤ 100%) only in the event of an accident where the containers are breached.

Reformulation
During reformulation operations, dermal and ocular exposure of workers to the notified polymer at concentrations of up to 100% is possible when transferring the notified polymer from imported containers into blending tanks. The blending operation will occur in a closed mixing tank under local exhaust ventilation. The notifier stated that personal protective equipment (PPE), such as coveralls, gloves, and eye protection, will be required when carrying out these activities.

During filling operations, potential exposure of workers to the notified polymer in finished products (at concentrations of ≤ 1.5%) will likely be through dermal or ocular routes. In addition, inhalation exposure to the notified polymer may occur. However, the exposure is expected to be minimal due to the use of automated/enclosed systems and appropriate PPE.

Quality assurance (QA) staff will wear appropriate PPE to minimise exposure to the notified polymer during QA testing.

End Use
Dermal and ocular exposure of workers to the notified polymer at concentrations of ≤ 1.5% may occur during application and cleaning processes. With no spray application proposed, inhalation exposure to the notified polymer under normal use conditions is not expected.

6.1.2. Public Exposure
The products containing the notified polymer will only be used by industrial or professional workers and will not be sold to the public for do-it-yourself (DIY) use. Hence, direct public exposure to the notified polymer is not expected.

Once applied to surfaces, the adhesive and sealant products containing the notified polymer will be cured within 48 hours and the notified polymer is expected to be reacted and bound within the inert matrix. It is not expected to be available for further exposure after curing.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified polymer and an analogue are summarised in the following table (information taken from the Health Canada report).

Endpoint	***Result and Assessment Conclusion***
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity *
Skin sensitisation – guinea pig, Buehler assay	no evidence of sensitisation
Repeat dose oral toxicity – rat, 28 days	NOAEL = 100 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosomal aberration assay	non clastogenic

***** Study data on an analogue chemical

Toxicokinetics, Metabolism and Distribution
No toxicokinetic data on the notified polymer were provided. The notified polymer is of low molecular weight (< 1,000 g/mol) and therefore may have the potential to be absorbed through biomembranes. However, the notified polymer reacts with moisture to form a highly cross-linked, high molecular weight polymer which is not expected to be significantly absorbed by skin or mucous membranes.

Acute Toxicity
No acute toxicity data were provided on the notified polymer. An acute oral toxicity study conducted in rats on an analogue reported the analogue to be of low acute toxicity via the oral route.

Irritation and Sensitisation
No eye or skin irritation toxicity data were submitted for the notified polymer or analogue chemical.

A skin sensitisation study in compliance with OECD TG 406 was conducted on albino guinea pigs using the notified polymer. No evidence of sensitisation resulting from treatment with the undiluted test substance was observed. Twenty test animals were treated with undiluted test substance once every week for three weeks. Fourteen days after the last induction, the challenge was performed by application of 30% of the test substance (in corn oil) to a naïve site. None of the challenged test animals showed any dermal reactions at 24 and 48 hours after challenge. Mild erythema (grade 1) was noted at application site 24 and 48 hours after second and third applications of test substance in some treated animals. The negative and positive control test animals showed proper responses confirming the validity of the test.

Repeated Dose Toxicity
A 28 day repeated dose oral toxicity study with a 14 day recovery period (OECD TG 407) was conducted on Wistar rats. The notified polymer was administered by oral gavage at dosages of 100, 300 and 1,000 mg/kg bw/day prepared in propylene glycol (low, mid and high dose respectively). Five male and five female test animals were used per dose with additional five test animals per sex for control and high dose groups for recovery.

One male test animal in the high dose group was found dead after the first dose. Gasping was observed in the treated animal before death. Necropsy studies revealed microscopic changes including hepatocellular hypertrophy and premature reproductive organs. The dead animal was replaced with another test animal on Day 1. Two male rats in the high dose group and two rats (1 male and 1 female) in the mid dose group were sacrificed due to deteriorating condition between Day 7 and 14. Clinical signs in these four rats prior to sacrifice included salivation, rales, lethargy, abnormal and hunched posture and laboured respiration. Swelling of the abdomen was also noted

in the two animals from the high dose group. Ventro-lateral recumbency, uncoordinated movements, watery discharge of the eyes, piloerection, ptosis and squeaking were noted in animals in the mid dose group. Significant reduction in body weight gain was also noted in the female rat from mid dose and one male rat from high dose. Although microscopic examination indicated possible gavage regurgitation in the sacrificed animals, a possible treatment related connection could not be ruled out due to the number of deaths and the dose related aspects of mortality along with the observed clinical signs.

In functional observations, the grip strength of male forelimbs was higher in the high dose group. Slightly higher motor activity (total movements and ambulations) was also noted in male and female rats in the mid and high dose groups and reached statistical significance in males for ambulations. Although these slight changes occurred in the highest dose group, a treatment related response cannot be excluded. Slightly lower grip strength was also observed in test animals from low and mid dose groups.

There were no significant differences in body weight or food consumption between control and the rest of the treated animals that survived the study. There were toxicologically significant haematological and biochemical changes noted. Significantly lower total protein, albumin, urea and chloride levels and higher bile acid levels were observed in high dose test animals. Significantly lower calcium levels were noted in all treated animals. However, there were no treatment-related macroscopic or microscopic abnormalities detected at necropsy in test animals that survived the study. Slight but significant reduction in absolute testes and epididymides weights were noted in male rats from the high dose group. Reduction in body weight gain was also observed in animals from the high dose group.

Due to the number of deaths and the noted clinical signs in animals in the mid and high dose groups, the no observed adverse effect level (NOAEL) was established as 100 mg/kg bw/day.

Mutagenicity/Genotoxicity
The notified polymer was found to be non mutagenic in a bacterial reverse mutation assay conducted according to OECD TG 471. *Salmonella typhimurium* TA98, TA100, TA 1535, TA 1537 and *Escherichia coli* WPuvrA strains were tested. The test substance was tested at up to 5,000 µg/plate in the presence and absence of metabolic activation.

The notified polymer was found to be non clastogenic in an *in vitro* mammalian chromosome aberration test using human peripheral blood lymphocytes conducted according to OECD TG 473. It was tested at up to 164 µg/mL concentration in the presence and absence of metabolic activation

Other Consideration
The notified polymer contains reactive alkoxysilane functional groups which are of concern for lung toxicity from inhalation of vapours or aerosols. One monomer used for the polymer could be a skin irritant and a severe eye irritant. The degree of concern depends on the relative abundance of lower molecular weight species (US EPA 2010). Exposure to moisture will also result in the notified polymer undergoing further polymerisation and release methanol which is hazardous.

Health Hazard Classification
Based on the limited toxicity data 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.

6.3. Human Health Risk Characterisation
Inhalation toxicity and skin and eye irritation potential of the notified polymer are not provided. The notified polymer contains reactive functional groups known to cause lung toxicity if inhaled. The notified polymer releases methanol during curing.

6.3.1. Occupational Health and Safety

Reformulation
During reformulation of the notified polymer, workers may come into contact with the notified polymer at concentrations of up to 100% through dermal, ocular or inhalation routes. Inhalation exposure to the notified polymer is expected to be limited for workers due to the low vapour pressure of the notified polymer and aerosol generation is unlikely. The use of appropriate personal protective equipment (PPE) including eye protection is expected to minimise the exposure and hence reduce the risk. However, there may be potential for inhalation

exposure to methanol released during the reformulation from reaction of the notified polymer. According to the notifier, the reformulation steps happen in a closed system and any methanol release is extracted out from the closed system. The filling of the drums, pails and other containers of varying size is carried out at dedicated loading stations with built-in fume hoods and good ventilation systems. The use of engineering controls during reformulation (enclosed/automated processes, and local exhaust ventilation), is anticipated to minimise the potential for exposure to the notified polymer and any methanol generation.

Therefore, provided that control measures are in place to minimise exposure to the notified polymer and methanol released during reformulation, the risk to workers from use of the notified polymer is not considered to be unreasonable.

End Use
Workers may come into contact with the notified polymer at concentrations of ≤ 1.5% in ready for use products through the dermal route and accidental ocular route. At this relatively low final use concentration, eye irritation effects are not expected. The use of appropriate PPE including impervious gloves and safety glasses, will reduce the potential for exposure during the operations, and hence reduce the risk of skin and eye irritation effects.

Based on the assessed use patterns, inhalation exposure to the notified polymer is not expected for end use workers due to the low vapour pressure of the notified polymer with no spray applications. The amount of methanol released during the curing of the notified polymer from end use is expected to be negligible. Use of products containing the notified polymer in well ventilated areas may further reduce the risks from potential inhalation exposure and methanol release during the curing process.

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health
Adhesive and sealant products containing the notified polymer will only be used by industrial workers and will not be available to public for DIY use.

Members of the public may come into contact with articles containing the notified polymer. However, the notified polymer is expected to be reacted and trapped within the inert matrix and will not be available for further exposure after curing. General public is not expected to enter treated areas immediately after application of adhesive and sealant products (prior to curing). Considering the low concentration of the notified polymer in end use products (≤ 1.5%), public exposure to methanol release is considered minimal during the curing process.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported into Australia for reformulation into industrial moisture-curable silicone adhesives and sealants as a coupling and crosslinking agent and surface modifier. Environmental release may occur during the transport and storage of the notified polymer. These accidental spills are to be contained and collected using an inert absorbent material and disposed of to landfill in accordance with local government regulations.

The notified polymer is sensitive to water, so reformulation operations are carried out in a fully enclosed system and performed under a nitrogen atmosphere. Release during reformulation is therefore expected to be negligible. Solvent used for equipment washing, containing residues of the notified polymer, is expected to be disposed of via accredited waste disposal contractors. Wastes and spills during reformulation activities are also expected to be contained on-site and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE
The notified polymer in adhesives and sealants will only be used by professionals for industrial applications (e.g. automotive and construction). The notified polymer is an adhesion promoter that will react with other components

in the adhesive or sealant upon exposure to moisture and form crosslinked polymer structures. Once cured, the notified polymer is not expected to be released to the environment.

RELEASE OF CHEMICAL FROM DISPOSAL
The cured notified polymer is expected to share the fate of the substrate (e.g. building materials) to which it has been applied, and is therefore predominantly expected to be disposed of to landfill.

Residues containing the notified polymer on application equipment are expected to be rinsed with solvents into containers, and then allowed to cure before disposal as solid wastes to landfill.

7.1.2. Environmental Fate
The notified polymer is a component of adhesives and sealants which is expected to share the fate of the articles to which it has been applied (e.g. building materials) which will eventually be disposed of to landfill as a part of the cured polymer matrix. The notified polymer is therefore not expected to be mobile, bioavailable or readily biodegradable in this form. Based on the results of a ready biodegradability study, the notified polymer is not readily biodegradable (BOD of 17% in 28 days) (information taken from the Environment Canada report). In landfill, the notified polymer is expected to ultimately degrade via biotic or abiotic processes to form water and oxides of carbon, nitrogen and silicon.

7.1.3. Predicted Environmental Concentration (PEC)
The predicted environmental concentration (PEC) has not been calculated because no significant release of the notified polymer to the aquatic environment is expected based on the reported use pattern.

7.2. Environmental Effects Assessment
The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below (information taken from the Environment Canada report).

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LL50 > 103 mg/L (WAF)	Not harmful to fish up to its limit of water solubility
Daphnia Toxicity	48 h EL50 > 103 mg/L (WSF)	Not harmful to aquatic invertebrates up to the limit of its water solubility
Algal Toxicity	72 h ErL50 = 28.1 mg/L (WSF)	Harmful to algae

WAF: Water Accommodated Fraction
WSF: Water Soluble Fraction

Based on the above ecotoxicological endpoint for the notified polymer, it is expected to be harmful to algae. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009), the notified polymer is formally classified as 'Acute Aquatic Toxicity Category 3; Harmful to aquatic life'.

7.2.1. Predicted No-Effect Concentration
The Predicted No-Effect Concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 100 was used since acute endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ErL50 (Algae)	28.1	mg/L
Assessment Factor	100.0	
Mitigation Factor	1.00	
PNEC	0.281	µg/L

7.3. Environmental Risk Assessment
The Risk Quotient, Q (=PEC/PNEC) has not been calculated as release of the notified polymer to the aquatic environment is not expected based on the assessed use pattern. If accidentally released to waterways as a raw material, the notified polymer is expected to rapidly hydrolyse forming methanol and water-soluble oligomers. However, as a component of a finished product, release to water is not expected because the notified polymer will be contained within the matrix of the sealant and/or adhesive. The low log Pow (< 1) of the transformation products (refer to Appendix A for details) formed by the notified polymer on contact with water, indicate they have a low potential for bioaccumulation.

The majority of the notified polymer will be disposed of to landfill as a cured polymer matrix attached to building materials or completely incinerated during metal reclamation processes at the end of its useful life. In landfill, the cured notified polymer bound to building materials is unlikely to be bioavailable or mobile.

On the basis of the assessed use pattern as an adhesion promoter in adhesives and sealants, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient (n-octanol/water)	Transformation Product 1 log Pow = -0.56 at 20 °C Transformation Product 2 log Pow = 0.39 at 20 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water) – HPLC Method.
Remarks	The test evaluated the bioaccumulation potential of two transformation products detected in the ready biodegradability test (MCMC, 2014) using the aqueous phase of the test suspension.
Test Facility	LSI (2015)

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