File No: LTD/1523

January 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in SpectraLOCK Tile Grout

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 Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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:

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

TABLE OF CONTENTS

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1523	Laticrete Pty Ltd	Polymer in SpectraLOCK Tile Grout	Yes	< 1 tonne per annum	Ingredient in a three part tile grout system at < 2.5%

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] with the following classification:

Xi; R41 Risk of serious damage to eyes
Xi; R43 May cause sensitisation by skin contact

and

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below.

	Hazard category	*Hazard statement*
Skin sensitisation	1	May cause an allergic skin reaction
Serious Eye Damage/Eye Irritation	1	Causes serious eye damage
Environment	Acute category 2 Chronic category 2	Toxic to aquatic life Toxic to aquatic life with long lasting effects

Human health risk assessment
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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified polymer:
  - Xi; R41 Risk of serious damage to eyes
  - Xi; R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified polymer:

  - Concentration ≥ 10%: R41, R43
  - 5% ≤ Concentration < 10%: R36, R43
  - ≥ 1% Concentration < 5%: R43

Health Surveillance

- As the notified polymer presents a skin sensitisation health hazard, 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.

Material Safety Data Sheet

- The MSDS provided by the notifier should be amended as follows:
  - In section 2 of the MSDS that will provided to workers, a full chemical name must be included for the polymer, as well as the classification of R41 and R43, as the polymer is a type I ingredient;

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with skin and eyes
  - Avoid contact with uncured grout
  - Do not inhale vapours/mists
  - Carry out mixing in a well ventilated area

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Gloves
  - Goggles
  - Coveralls
  - Respiratory protection if vapours/mists are generated

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

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

- If products and mixtures containing the notified polymer 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 polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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 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 importation volume exceeds one tonne per annum notified polymer;
- the grout system containing the notified polymer is used by the public;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a part of a three part tile grout system used by professional tilers (< 2.5%), or is likely to change significantly;
- the amount of polymer being introduced has increased from 1 tonne per annum, 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.

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

ASSESSMENT DETAILS

The notifier has submitted with the application an assessment of the chemical by a notification and assessment scheme in an OECD country (Canada). The health and environment hazard assessment of the Canadian reports 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 chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Laticrete Pty Ltd (ABN 57 069 067 992)
29 Telford St, Virginia QLD 4014

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1000 Da (1 tonne or less per year).

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, details of use and site and identity of manufacture.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point, Boiling Point, Density, Vapour Pressure, Hydrolysis as a function of pH, Adsorption/desorption, Dissociation Constant, Particle Size, Flash Point, Autoignition Temperature and Flammability Limits

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2010)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SpectraLOCK Tile Grout (product containing the notified polymer)

ANALYTICAL DATA
Reference GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The polymer is stable under normal conditions of use.

DEGRADATION PRODUCTS
The polymer is not expected to degrade under normal conditions of use. In the event of degradation the typical decomposition products are expected to be oxides of nitrogen and carbon.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: amber liquid (product* MSDS)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-	Not tested
Boiling Point	100°C at 101.3 kPa	Product* MSDS
Density	1090 kg/m^3 at 21°C	Product* MSDS
Vapour Pressure	< 0.67 kPa at 21°C	Product* MSDS
Water Solubility	> 500 g/L at 20°C	Measured, OECD TG 105
Hydrolysis as a Function of pH	Not determined	Hydrolysis of the notified polymer is not expected as it does not contain any environmentally hydrolysable groups.
Partition Coefficient (n-octanol/water)	Log K_{OW} = 1.67	Predicted. The notified polymer is expected to have a low log K_{OW} based on the high water solubility.
Adsorption/Desorption	Not determined	Due to its low molecular weight and high water solubility, the notified polymer is expected not to adsorb significantly to organic carbon, and is therefore expected to be mobile.
Dissociation Constant	Not determined	The notified polymer is a salt and will therefore be ionised in the environmental pH range of 4-9.
Particle Size	Not determined	Liquid (Product* MSDS)
Flash Point	> 100°C (pressure unknown)	Closed cup (Product* MSDS)
Flammability	-	Not tested
Autoignition Temperature	-	Not tested
Explosive Properties	Not expected to be explosive	Based on structural information and the lack of structural alerts.

*Product containing < 70% notified polymer.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer will react with other components of the grout under normal conditions of use.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported at < 30% in Part A of a three part tile grout product.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1	< 1	< 1	< 1	< 1

PORT OF ENTRY

Melbourne, Sydney, Perth and Brisbane

IDENTITY OF RECIPIENTS

Laticrete Pty Ltd

TRANSPORTATION AND PACKAGING

The part A of a three part tile grout product containing the notified polymer is imported in 0.6 kg (approximately 0.5 L) pouches and transported by road.

USE

The notified polymer is used as a part of a three part tile grout system used by professional tilers. The part A of a three part tile grout product contains the notified polymer at < 30% while the final mixed product contains it at < 2.5%. The product will be used for ceramic tiles, glass tiles and stone applications.

OPERATION DESCRIPTION

The notified polymer will not be manufactured or reformulated in Australia.

Grout Preparation

The tile grout kit containing the notified polymer will be available to professional tilers. The kit contains 2 foil pouches, one containing the notified polymer (< 30%), rubber gloves, citric acid and a sponge. The tiler will mix the contents of the two pouches in the 2 L pail. The third component is then added to the pail and mixed to form the grout.

Grout Application

Using a trowel, the tiler will apply the grout (< 2.5% notified polymer) to the tiled area. The cure time is 60 – 80 minutes with a pot life of 30 minutes. The grout is wiped off using a dry sponge and any excess is then wiped away using a sponge and the supplied citric acid.

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	10	1	200
Tiler	1-2 per application	4	220

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the product containing the notified polymer except in the unlikely event of an accident where the packaging becomes breached.

The mixing of the components involves the pouring of the part A (< 30% notified polymer) and the part B into the pail and then mixing with the third component to form the grout. Dermal and ocular exposure is possible during the pouring and the mixing. The product containing the notified polymer will be used at varied indoor and outdoor sites, and only natural ventilation is expected to be available. Gloves and other personal protective equipment including coveralls and eye protection are provided to minimise the exposure during the mixing process.

During the application of the grout (< 2.5% notified polymer), the removal of the excess grout and the cleaning of equipment, dermal exposure is possible. Gloves and other personal protective equipment including coveralls and eye protection are provided to minimise the exposure during the application process.

Once cured the notified polymer is completely reacted into an inert matrix and will not be bioavailable.

6.1.2. Public exposure
The product containing the notified polymer is not available for 'do it yourself' applications. It will only be available to professional tilers. Once cured the notified polymer is completely reacted and therefore although members of the public may come in contact with the grout the notified polymer will be immobilised in the inert matrix.

6.2. Human health effects assessment

6.2.1. Toxicology studies on the notified chemical

The results from toxicological investigations conducted on a product containing 62% notified polymer (unless otherwise indicated) are summarised in the table below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test.	evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay (15%)	evidence of sensitisation

6.2.2. Summaries of the toxicology studies (also see Appendix A)

Acute toxicity:
Five Sprague-Dawley rats per sex were administered a single 2000 mg/kg bw dose of the test substance (in arachis oil) by gavage. One male animal died within four hours of treatment. Clinical observations among all animals included hunched posture, decreased respiratory rate, laboured respiration, lethargy, one case of ataxia, and in the decedent animal, ptosis, coma and pallor of the extremities. Surviving animals had recovered by day 2

of the observation period.

No treatment-related effects on normal bodyweight gain were observed among surviving animals. At the end of the 14-day observation period, gross pathological examination of the surviving animals identified no abnormalities; however, the decedent animal was found to have abnormally red lungs, a dark liver and kidneys and hemorrhaging and sloughing of the epithelial layer of the gastrointestinal mucosa and sloughing of the epithelium of the non-glandular region of the stomach. The notified polymer is considered to have an LD_{50} > 1240 mg/kg bw for acute oral toxicity, after adjustment for the purity of the test substance.

Five Sprague Dawley rats per sex received a single dose of 2000 mg/kg bw test substance (as received) applied to an area of the intact skin approximately equal to 10% of the body surface area for 24 hours under a semi-occlusive dressing. No deaths occurred and there were no clinical signs of systemic toxicity during the 14-day observation period. Very slight to well defined erythema as well as crust formation and desquamation of the treatment site were observed, which resolved within 7-10 days. No treatment-related gross pathological abnormalities were observed upon necropsy. The notified polymer is considered to have an LD_{50} > 1240 mg/kg bw for acute dermal toxicity, after adjustment for the purity of the test substance.

Irritation

The test substance (0.5 mL) was applied to the shaved intact skin of three male New Zealand White rabbits for a period of 4 hours under a semi-occlusive dressing. Very slight erythema was observed at the application site of each rabbit one hour following treatment. Evidence of very slight erythema persisted at the 24 hour observation for one animal. No oedema was observed in any of the animals at any of the observation time points. All evidence of skin irritation had resolved by the 48 hour observation. The test substance caused barely perceptible skin irritation with a PII 0.33 between 1-72 hours.

Application of 0.1 mL of the test substance to the lower conjunctival sac of a single female New Zealand White rabbit produced sloughing of the cornea and corneal opacity, marked conjunctival redness, chemosis and discharge, as well as iridal inflammation. The animal was euthanised after the one hour observation on ethical grounds. The test substance is a severe to very severe eye irritant.

Sensitisation

The potential for the test substance to induce skin sensitisation was determined in a guinea pig maximisation test. Treatment group animals (20 males) received three pairs of 0.1 mL intradermal induction injections to the scapular region, consisting of Freund's complete adjuvant (FCA) 1:1 in distilled water, 0.5% test substance in distilled water, and 0.5% test substance in a 1:1 mixture of FCA and distilled water. One week after intradermal induction, treatment group animals received a topical induction application consisting of 50% test substance in distilled water applied under an occlusive dressing for 48 hours. The negative control group animals (10 males) received the same treatment regimen without the test substance. All animals were challenged with the undiluted test substance (right flank) and 75% test substance (left flank) 14 days after topical induction. Of the 20 treatment group animals, 19 had erythematous dermal reactions indicative of skin sensitisation on both the undiluted and 75% test substance sites, 24 and 48 hours after challenge. Negative control group animals did not show any evidence of skin sensitisation. Based on these observations, the test substance induced dermal sensitisation.

The potential for the test substance to cause skin sensitisation was also determined using the local lymph node assay. For three consecutive days, 25 µL of the test substance was applied to the dorsal surface of both ears of CBA/J mice (5/group) at concentrations of 0% (ethanol), 6.25%, 25% and 50%, along with 25% α-hexacinnamaldehyde as the positive control. Five days after the first application, all mice received a 150 mg/kg intraperitoneal injection of 5-bromo-2-deoxyuridine (BrdU). Five hours later all mice were euthanised and the draining auricular lymph nodes were excised from each animal. The proportion of nuclei staining positive immunohistochemically for BrdU was determined by flow cytometry. No deaths occurred and there was no clinical evidence of systemic toxicity. Slight swelling of the ears was observed among mice in the positive control group, which is consistent with mild to moderate irritation. A positive lymphoproliferative response, consisting of a relative stimulation index exceeding 3, was observed at a concentration of 50%. The EC_3 was 25.3%, suggesting the test substance is a weak dermal sensitiser. Assuming the notified polymer is solely responsible for the sensitising activity of the test substance, at a concentration of 62%, the EC_3 of the notified polymer is adjusted to 15.7%.

6.2.3. Summary of human health effects

Toxicokinetics
No toxicokinetic data was submitted for the notified polymer. Based on the physicochemical properties, percutaneous absorption of the notified polymer is likely. Given the low molecular weight (< 1000 Da) absorption across the GI tract is possible by passive diffusion through the aqueous pores or micellular solubilisation.

Acute toxicity
The notified polymer may have the potential to cause adverse effects via the oral and dermal routes based on studies conducted in rats (LD50 > 1240 mg/kg bw).

Irritation
The notified polymer is expected to be a slight skin irritant and a severe eye irritant based on studies conducted in rabbits.

Skin sensitisation
The notified polymer is expected to be a skin sensitiser based on the results of a guinea pig maximisation test and a Local Lymph Node Assay in mice (EC3 15.7%).

Based on a further Local Lymph Node Assay in mice for Part A of a coating (containing the notified polymer at approximately 15%), Part B of a coating (containing no notified polymer) and a mixture of Part A (2.5 g) and Part B (7.5 g) (containing the notified polymer at approximately 4%), 15% notified polymer in Part A is expected to be a skin sensitiser. However, after mixing with Part B, 4% notified polymer in the mixture was not sensitising (Appendix A). This is consistent with the curing reaction between Part A and B.

Health hazard classification
Based on the eye irritation and skin sensitisation studies, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

Xi; R41 Risk of serious damage to eyes
Xi; R43 May cause sensitisation by skin contact

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Based on the test results, the notified polymer is likely to be slightly irritating to the skin, severely irritating to eyes and sensitising to the skin. The possibility of respiratory sensitisation cannot be ruled out.

The highest risk to workers is likely to occur at end use sites, where Part A of the grout containing the notified polymer (< 30%) is poured and mixed with other components, before being applied by a trowel, and the excess grout is removed and equipment is cleaned. At these sites, PPE such as gloves, coveralls and eye protection is available to reduce exposure. Only natural ventilation is expected to be available at these sites.

After application and once cured and dried, the notified polymer will have reacted with other components and will be trapped in an inert matrix, and will not be bioavailable.

Overall, the risk to workers during blending and application of grout containing the notified polymer at up to 30% is not expected to be unreasonable with the appropriate use of safe work practices and PPE to minimise exposure.

6.3.2. Public health
The grout system will not be available to the public.

Members of the public are unlikely to come into contact with uncured grout containing the notified polymer. After the grout has been applied and dried, the notified polymer will be cured into an inert matrix and will not be available for exposure. Therefore based on low exposure the risk to public health 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 polymer will be imported at < 70% to Australia; it will not be manufactured or reformulated in Australia. Therefore, no release of the notified polymer is expected from manufacturing and reformulation processes.

RELEASE OF CHEMICAL FROM USE
The tile grout containing the notified polymer will be applied by professional tilers to tiled areas with a trowel. The grout will cure within 80 minutes immobilising the notified polymer. Excess grout will be wiped off the tiled area using a dried sponge. It is expected that the excess grout will be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
Excess grout mixture remaining in the mixing pail is expected to cure and the cured grout is expected to be disposed of to landfill. Additionally, there will be some residues of the notified polymer left in the product containers (< 0.1 % of import volume) which are also expected to be disposed of to landfill.
Most of the notified polymer will be applied to tiled areas and will be incorporated in the inert grout matrix after application. At the end of the tiles' life, the notified polymer will share the fate of the associated tiles and is expected to be sent to landfill.

7.1.2 Environmental fate

The majority of the notified polymer will be incorporated into an inert grout matrix in tiled areas.
The notified polymer will be disposed of to landfill as residues, collected spills, collected excess cured grout or with the disposed associated tiles at the end of the tiles' life. Leaching of the notified polymer is not expected, given the polymer is in the cured form. Whilst the uncured polymer was not degradable under the conditions of the test (0% after 5 days, OECD TG 301D), the notified polymer in cured grout matrix is not expected to be bioavailable nor readily biodegradable. The high water solubility indicates a low potential for the uncured notified polymer to bioaccumulate, although no significant release of the uncured polymer to the aquatic compartment is expected. With time, the notified polymer will undergo slow degradation in landfill to form water, oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC has not been calculated since no significant release of the notified polymer to the water environment is expected.

7.2. Environmental effects assessment

The acute toxicity data were provided for daphnids (*Daphnia magna*) using Huntingdon Life Sciences Protocol based on OECD TG 202/EEC-C2 (Study No.: AIP/48/974290). Based on nominal concentrations, the 48-hour EC_{50} was 1.21 mg/L.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity (mg/L)	48 h EC50 = 1.21 24 h EC50 > 10 NOEC = 0.22	Moderately toxic to daphnia

Ecotoxicological endpoints for the notified polymer were calculated based on SAR equations (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by a mitigation factor to account for the anticipated binding of the polymer with organic carbon in surface waters. A mitigation factor of 10 is deemed applicable to account for the high cationic charge density and high oligomer content of the notified polymer.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 2.8 mg/L	Toxic
Daphnia Toxicity	EC50 (48 h) = 1.0 mg/L	Very toxic
Algal Toxicity	EC50 (96 h) = 0.4 mg/L	Very toxic

The notified polymer is potentially toxic or very toxic to aquatic organisms in environmental waters with typical levels of total organic carbon. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2011). However, the notified polymer can be classified as toxic to aquatic life based on the empirically derived endpoint for daphnids. Therefore, based on the toxicity to aquatic biota the notified polymer is formally classified under the GHS as "Acute category 2; Toxic to aquatic life". Based on the acute toxicity and biodegradability data, the notified polymer is formally classified as "Chronic category 2; Toxic to aquatic life with long lasting effects".

7.2.1 Predicted No-Effect Concentration

It was not considered necessary to calculate the PNEC given no significant release of the notified polymer to the aquatic environment is expected from the assessed use pattern.

7.3. Environmental risk assessment

The majority of the notified polymer will be incorporated into an inert grout matrix, and in this form it is not expected to be bioavailable. The notified polymer is toxic to aquatic species; however, the notified polymer is not expected to be present at ecotoxicologically significant concentrations in the environment as, based on the assessed use pattern, release of the uncured notified polymer to the aquatic environment is not expected to occur.

Therefore, based on the assessed use pattern, the notified polymer is not considered to pose any unreasonable risk to the aquatic environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Part A of a coating (containing the notified polymer at approximately 15%) Part B of a coating (containing no notified polymer) Mixture of Part A (2.5 g) and Part B (7.5 g) (containing the notified polymer at approximately 4%)
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/ CBA/J (female)
Vehicle	None
Remarks - Method	No deviations from the protocol.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	18000 ± 7697	-
Part A	72504 ± 24267	4.0
Part B	11091 ± 4012	0.6
Mixture of Part A and Part B	34430 ± 11887	1.9
Vehicle	18806	-
Positive Control (α-hexacinnamaldehyde) (25%)	344944	18.3

Remarks - Results	There were no deaths. No signs of systemic toxicity were noted. Body weight changes were normal. In the screening test, alopecia was observed at the dose site for animals in the dose groups for Part A and Part A + Part B mixture groups. In the definitive study, alopecia was observed at the dose sites for all dose groups. Ear measurements did not result in a greater than 25% increase, indicating that none of the test substances was irritating. In the screening test, there was test substance residue observed on the ears for all dose groups, which may have affected ear thickness measurements. Although there was some test substance residue on the ears in the definitive study for Part A and Part A + Part B mixture groups, it did not appear to interfere with the ear swelling results.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to Part A. There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to Part B or the mixture of Part A and Part B.
TEST FACILITY	MB Research Laboratories (2006)

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