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October 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Intermediate 5800

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:

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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 SUBSTANCE	INTRODUCTION VOLUME	USE
STD/1404	Nuplex Industries (Aust) Pty Limited	Intermediate 5800	Yes	≤ 900 tonnes per annum	A component of high performance composite articles and flooring systems.

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)]. The classification and labelling details are:

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. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Environment	Acute category 3	Harmful to aquatic life
	Chronic category 3	Harmful to aquatic life with long lasting effects
Skin sensitisation	1B	May cause an allergic skin reaction

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: R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - Conc. ≥ 1%: R43

Health Surveillance

- As the notified polymer is a skin sensitiser, 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

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Automated processes when possible
  - Local exhaust ventilation during spray moulding

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced or the partly cured resin:
  - Avoid contact with skin and eyes
  - Avoid generation and inhalation of aerosols

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Protective clothing
  - Safety glasses/goggles
  - Respiratory protection when aerosols or dust may be 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 physical containment, collection and subsequent safe disposal.

Regulatory Obligations

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

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if

- the function or use of the polymer has changed from a component of high performance composite articles and flooring systems, or is likely to change significantly;
- the amount of polymer being introduced has increased from 900 tonnes per annum, or is likely to increase, significantly;
- the method of manufacture of the polymer in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the polymer on occupational health and safety, public health, or the environment;
- 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of 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

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nuplex Industries (Aust) Pty Limited (ABN 25 000 045 572)
49-61 Stephen Road
BOTANY, NSW 2019

NOTIFICATION CATEGORY
Standard: Synthetic Polymer with Mn < 1000 Da (more than 1 tonne per year).

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point, boiling point, vapour pressure, hydrolysis as a function of pH, partition coefficient, adsorption desorption, dissociation constant, flammability, autoignition temperature, oral acute toxicity, eye irritation and repeat dose toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Intermediate 5800
Tires 5800

CAS NUMBER
Not Assigned

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 100%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Not expected to occur under normal conditions of use.

DEGRADATION PRODUCTS
Not expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< 10°C	Estimated.
Boiling Point	Not determined	Undergoes decomposition prior to boiling
Density	1150 kg/m^3 at 22°C	Measured
Vapour Pressure	Not determined	Expected to be low based on the molecular weight and viscosity.
Water Extractability	1.72% (w/w)	Measured
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functional groups that are expected to hydrolyse very slowly in the environmental pH range (4-9)
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to partition from water to octanol based on its hydrophobic structure
Adsorption/Desorption	Not determined	The notified polymer is expected to partition to soil from water based on its hydrophobic structure
Dissociation Constant	Not determined	The notified polymer does not contain dissociable functional groups
Flash Point	75°C	Measured
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use, based on the flash point.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

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

Reactivity
The notified polymer contains allyl ether functional groups that undergo free-radical polymerisation to form the finished composite articles.

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 both manufactured within Australia and imported into Australia. The notified polymer will be manufactured or imported at a concentration of 100%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100-300	300-600	300-600	600-900	600-900

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
When the notified polymer is manufactured within Australia it will be transferred into intermediate bulk containers (IBCs) and when imported it will be packaged in steel drums. Transportation of the notified polymer within Australia is predominantly expected to be by road.

USE
The notified polymer will be used in high performance composite articles and flooring systems. The finished articles are expected to contain between 50-70% notified polymer.

OPERATION DESCRIPTION
Manufacture of the notified polymer
When the notified polymer is manufactured within Australia the reaction will take place within a registered pressure vessel which is jacketed and fitted with internal cooling systems. The liquid reactants will be pumped in the reaction vessel using dedicated lines and any solid reactants will be transferred either manually or with a hoist. Once the manufacture of the notified polymer is complete it is pumped directly from the reaction vessel into IBCs for transfer to the manufacturers of the high performance composite construction and flooring systems that will contain it. Quality control personnel will be required to sample the notified polymer.

Reformulation and manufacture of high performance composite construction and flooring systems
After manufacture or importation the notified polymer is transferred to the manufacturers of the high performance composite construction and flooring systems where it will be charged to mixing tanks and blended with other components to produce finished resins that will contain the notified polymer at a concentration between 50-70%. When the finished resins are used for the manufacture of flooring, specialised levelling systems will be used that automatically dispenses the resin on to the concrete substrate. When the finished resin is used in high performance composite articles, construction will be predominantly carried out using automated injection and spray moulding processes, with local exhaust ventilation expected to be used.

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	1	1	10
Warehouse/store	1-3	8	30
Manufacture/blending	1-3	2	50
QC/testing	1	1	50
Filling	1	1	50
Dispatch	1	1	150
Industrial end users	1	8	200

EXPOSURE DETAILS

It is anticipated that transport and warehouse/store personnel would only be exposed to the notified polymer in the event of an accident.

Manufacture of the notified polymer
There is potential for dermal, ocular and inhalation exposure to the notified polymer (100% concentration) after it has been manufactured, during transfer from the reaction vessel into IBCs for transport to the manufacturers of the high performance composite construction and flooring systems. Quality control personnel will also be exposed to the notified polymer when taking samples. Exposure is expected to be limited by the use of PPE (including face masks, safety glasses, gloves and protective clothing).

Reformulation and manufacture of high performance composite construction and flooring systems
Dermal, ocular and inhalation exposure to the notified polymer (100%) will occur during addition to the mixing tanks. After reformulation into the finished resins dermal, ocular and inhalation exposure to the notified polymer (50-70%) may occur during automated injection and spray moulding processes. Exposure is expected to be limited by the use of PPE (including safety glasses, gloves and protective clothing). When the resins containing the notified polymer are being sprayed there is the potential for the generation of aerosols and the notifier has recommended the use of local exhaust ventilation and full face respirators. Once the resins have been cured to form high performance composite construction and flooring systems, the notified polymer will be incorporated into a polymer matrix and hence will not be bioavailable.

6.1.2. Public Exposure

The notified polymer is intended for industrial use only, and will not be available to the public. Direct exposure would therefore not be expected. Indirect exposure from accidental spills or environmental sources may be possible, but are unlikely for the proposed use.
Members of the public may experience dermal exposure to high performance composite construction and flooring systems containing the notified polymer at a concentration of 50-70%. However, in such products the notified polymer will be bound within a polymer matrix and hence will not be bioavailable.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vivo* mouse micronucleus test	non genotoxic

Toxicokinetics, metabolism and distribution.
Absorption of the notified polymer across biological membranes is likely to be limited, based on the relatively high molecular weight (> 500 Da) and the expected hydrophobicity. However there are significant levels of low molecular weight species and the possibility of absorption cannot be ruled out.

Acute toxicity.
The notified polymer was found to be of low acute dermal toxicity in both an acute dermal toxicity sighting study and limit test. No acute oral or inhalation toxicity studies were available for the notified polymer.

Acute oral toxicity values were reported for a monomer in the notified polymer that contains a functional group of concern (allyl ether). The LD50 values for this monomer were > 2,000 mg/kg bw, and based on this information it is expected that the notified polymer would also display low acute oral toxicity.

Irritation and Sensitisation.
The notified polymer was non-irritating to the skin.
No information was available on the irritant effects of the notified polymer to the eye. An eye irritation study on the monomer in the notified polymer that contains a functional group of concern (allyl ether) was conducted on rabbits with it reported to be non-irritating and based on this information the notified polymer is not expected to be irritating to eyes.

In a local lymph node assay on the notified polymer there was evidence of a proliferative response indicative of skin sensitisation to the notified polymer with a concentration of approximately 24% corresponding to a Stimulation Index (SI) of 3 (also referred to as EC3). This result indicates that the notified polymer is classified as a skin sensitiser.

Repeated Dose Toxicity.
There are no repeated dose toxicity data available for the notified polymer. The notified polymer showed low acute dermal toxicity in an acute dermal toxicity sighting study and limit test and is expected to also have a low acute oral toxicity based on an analogue. Absorption of the notified polymer across biological membranes is likely to be limited but may occur.

Mutagenicity.
The notified polymer was found to not be mutagenic using a bacterial reverse mutation test; however it is noted that appropriate positive controls were not used. The notified polymer was not genotoxic in an *in vivo* mouse micronucleus test however in this study the test substance was not demonstrated to reach the bone marrow.

Health hazard classification
Based on the local lymph node assay the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:
Xi: R43 May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Dermal, ocular and inhalation exposure to the notified polymer, at concentrations up to 100%, by workers may occur during the manufacture of the polymer, reformulation of it into resins and the use of these resins to manufacture articles. Once the notified polymer is reformulated into articles the notified polymer will be incorporated into a polymer matrix and hence will not be bioavailable. Toxicological studies on the notified polymer indicate that it is a skin sensitiser and hence its use at concentrations > 1% is only considered to be reasonable when sufficient engineering controls, safe work practices and personal protective equipment (PPE) are used to greatly reduce the potential for exposure. Dermal exposure is expected to be limited with the use of personal protective equipment (gloves, protective clothing and safety glasses/goggles). Inhalation exposure to the notified polymer is unlikely unless aerosols are generated, and the notifier has recommended local exhaust ventilation and respiratory protection if aerosols containing the notified polymer are present. The details of all likely use scenarios are not known, as the polymer is expected to be used in different industries and workplace settings. Where there may be worker exposure to partly cured resins, precautions to avoid sensitisation should be applied, similar to those for the polymer itself. Once the resin is completely cured, in articles or floors, it is not expected to be bioavailable. Therefore, although the notified polymer is classified as a skin sensitiser, given the use of sufficient workplace controls, it is not expected to pose an unreasonable health risk to workers.

6.3.2. Public Health
The notified polymer will only be available to the public when present in articles, where it will be bound within a polymer matrix and hence will not be bioavailable. Therefore the risk to the public 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 both manufactured and imported into Australia. Equipment used in the production and packaging of the notified polymer will be cleaned by flushing with solvent. The resulting dispersion of solvent and notified polymer will be transferred to settling tanks where the notified polymer precipitates to form a sludge which is collected and dispatched to a trade waste facility for disposal to landfill. Up to 0.5% of the annual introduction volume of notified polymer may be disposed to landfill annually during its manufacture. The notified polymer will be reformulated with other additives to produce finished resins. Equipment used to reformulate the notified polymer will be flushed with solvent as for manufacturing

equipment and up to 0.35% of notified polymer is expected to be disposed of annually to landfill via this route. Accidental spills of notified polymer during manufacture and reformulation (up to 1%) are expected to be absorbed with an inert material such as vermiculite and disposed of according to State/Territory legislation.

RELEASE OF CHEMICAL FROM USE
Composite materials will be fabricated from resins containing notified polymer in an industrial process that will likely utilise injection and spray moulding processes. Such facilities are expected to have extractor fans and filters to prevent release of the notified polymer to the atmosphere by capture on to a filter medium. Any overspray from the moulding process is expected to be captured on an inert material. Filters and waste materials containing the notified polymer are expected to be disposed of to landfill. Direct release of the notified polymer to the environment during floor application is not expected. Up to 0.5% of the notified polymer is expected to be disposed of to landfill due to the cleaning of application equipment.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of the notified polymer will share the fate of end-use composite articles and flooring into which it is incorporated. End-use articles are expected to be disposed of to landfill at the end of their useful life.

7.1.2. Environmental Fate

The majority of the notified polymer will be incorporated into end-use composite articles or cured resin flooring systems. The notified polymer will be irreversibly bound into an inert hardened matrix and, in this form, is not expected to be mobile or bioavailable. Composite articles containing the notified polymer are expected to be disposed of to landfill at the end of their useful life. The notified polymer is not readily biodegradable. However in landfill, the notified polymer will eventually undergo biotic and abiotic degradation to form water and oxides of carbon.

During manufacture and reformulation of the notified polymer, accidental spills and leaks are expected to be physically contained and disposed to landfill. In landfill, the notified polymer is expected to sorb to solid particles and not leach through soil, given its low water solubility and likelihood to partition to soil. The notified polymer contains a significant proportion of low molecular weight species that may bioaccumulate due to the potential for low molecular weight species to cross biological membranes. However, bioaccumulation is not likely as no exposure of the notified polymer to the aquatic environment is anticipated.

For the details of the environmental fate study, refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

The PEC was not calculated as very limited aquatic exposure 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. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LL50 = 19.2 mg/L (WAF)	Harmful to fish
Daphnia Toxicity (48 h)	EL50 > 100 mg/L (WAF)	Not harmful to aquatic invertebrates
Algal Toxicity (72 h)	EL50 > 100 mg/L (WAF)	Not harmful to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified polymer is classified as harmful to fish and not harmful to aquatic invertebrates or algae. Based on the toxicity to aquatic biota the notified polymer is formally classified under the GHS as “Acute category 3; Harmful to aquatic life”. Based on the acute toxicity and biodegradability data, the notified polymer is formally classified as “Chronic category 3; Harmful to aquatic life with long lasting effects”.

7.2.1. Predicted No-Effect Concentration

The lowest endpoint from ecotoxicological studies on the notified polymer was used to calculate the PNEC. An assessment factor of 100 was used as acute toxicity endpoints are available for the effects of the notified polymer on aquatic species from three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LL50 (fish, 96 hr)	19.2	mg/L
Assessment Factor	100	
PNEC:	192	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient, Q (= PEC/PNEC), has not been calculated since a PEC is not available. The notified polymer is harmful to fish and the low molecular weight components of the notified polymer may have the potential to bioaccumulate. However, release of the notified polymer to aquatic ecosystems is not expected from the proposed use pattern. Based on the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Extractability 1.72% (w/w)

Method	Not reported
Remarks	Only a summary of the test was provided. A known weight of test substance was dispersed in water by shaking and then centrifuged at 4000 rpm for 1 hour. Two distinct clear layers were observed. After the top clear water layer was removed and dried, an insoluble residue was obtained. The insoluble residue was weighed and calculated as a percentage of the original sample weight. The reported water extractability was determined from the mean of three tests conducted on the test substance.
Test Facility	Not reported

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	Acute Dermal Toxicity Sighting Study
Species/Strain	Rat/Sprague Dawley
Vehicle	Acetone
Type of dressing	Semi-occlusive.
Remarks - Method	A single dose of the test substance was administered dermally for an exposure period of 24 hours. The animals were observed for 7 days after administration. Body weights were recorded. Macroscopic signs were recorded at necropsy.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
control	1 per sex	0	0/2
low dose	1 per sex	200	0/2
mid dose	1 per sex	1,000	0/2
high dose	1 per sex	2,000	0/2

LD50	2,000 mg/kg bw
Signs of Toxicity - Local	There were no test substance-related dermal reactions.
Signs of Toxicity - Systemic	No clinical signs were observed.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	No significant variations in body weight gains were observed.

CONCLUSION	The notified polymer is of low toxicity via the dermal route.
TEST FACILITY	ICP Firefly (2010a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague Dawley (SD)
Vehicle	Test substance administered as supplied
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. The animals were observed for 15 days after administration. Body weights were recorded on days 1, 8 and 15. Organ weights were determined at necropsy.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	0	0/10
II	5 per sex	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	There were no test substance-related dermal reactions.
Signs of Toxicity - Systemic	No clinical signs were observed.
Effects in Organs	No abnormalities were noted at necroscopy. The weight of the male reproductive organs as a percentage of body weight (but not the absolute weight) was statistically higher for the treated animals than the control.

	This was not considered toxicologically significant by the study authors, however no microscopic examination was made.
Remarks - Results	Body weight gains were as expected.

CONCLUSION The notified polymer is of low toxicity via the dermal route.

TEST FACILITY ICP Firefly (2010b)

B.3. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 female
Vehicle	Test substance administered as supplied
Observation Period	72 Hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	A single 4-hour, semi-occluded application of the test material to the intact skin of the three rabbits produced no adverse skin reactions during the study period (primary irritation index = 0).

CONCLUSION The notified polymer is non-irritating to the skin.

TEST FACILITY ICP Firefly (2010c)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified polymer

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay

Species/Strain	Mouse/(SPF) CBA/CaH
Vehicle	Acetone/olive oil (4:1 v/v)
Remarks - Method	No significant protocol deviations. The positive control used was α-hexylcinnamaldehyde (HCA). The lymph nodes were weighed and dissected.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	396	1
25	1,269	3.2
50	4,326	10.9
100	2,109	5.3
Positive Control		
25% HCA	2,096	5.3

Remarks - Results	There were no obvious signs of toxicity, erythema, oedema and no other findings were observed in the test or control group animals during the study. The animals in the positive control exhibited subdued behaviour for 2 hours after application. The stimulation index (SI) for all three test groups dosed with the notified polymer was above 3 and hence the notified polymer is considered to be a

potential skin sensitiser. The SI value of 3 (also referred to as EC3) of the notified polymer, which is used as the classification cut-off for skin sensitisation, corresponds approximately to 24% concentration (calculated by extrapolating from the 25 and 50% concentration values).

The positive control confirmed the sensitivity of the test system.

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.

TEST FACILITY ICP Firefly (2010d)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Rat liver microsomal enzymes and cofactors, S9 mix. Details of the enzyme-inducing agent were not provided.
Concentration Range in Main Test	a) With metabolic activation: 5 – 500 µg/plate b) Without metabolic activation: 5 – 500 µg/plate
Vehicle	Dimethylsulphoxide
Remarks - Method	Two main tests were conducted, with dosages based on the results of the preliminary study. 2-Aminoanthracene was used as the positive control both in the presence and absence of metabolic activation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 500	> 500	negative
Test 2		> 500	> 500	negative
Present				
Test 1		> 500	> 500	negative
Test 2		> 500	> 500	negative

Remarks - Results Precipitation of the test substance was noted in the preliminary study at concentrations of 1,000, 2,500 and 5,000 µg/plate. Evidence of slight cytotoxicity from the test substance was observed at 2,500 and 5,000 µg/plate in the preliminary test. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of microsomal enzymes prepared from induced rat liver (S9). Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system in the presence of metabolic activation. However, in the absence of metabolic activation the positive control failed to induce a sufficient increase in the mean number of revertants in any of the bacterial strains tested. According to the OECD TG 471 (1997) while 2-aminoanthracene is recommended for assays performed with metabolic activation it is not listed as an appropriate positive control when metabolic activation is not present. Therefore, although there was no evidence that the test substance would be mutagenic to bacteria in the absence of metabolic activation the lack of a suitable positive control means that this part of the assay can not be validated.

CONCLUSION	The notified polymer was not mutagenic to bacteria in the presence and absence of metabolic activation under the conditions of the test, noting the limitations of the methodology.
TEST FACILITY	ICP Firefly (2010e)

B.6. Genotoxicity – in vivo

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/ARC(s) Swiss
Route of Administration	Dermal – semi-occluded
Vehicle	Distilled water
Remarks - Method	The animals were not anaesthetised during application of the test item or vehicle. A preliminary toxicity study was carried out using 2 male and 2 female mice dosed with the test substance at 2000 mg/kg bw. No mortalities were observed.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 per sex	0	24
II (vehicle control)	5 per sex	0	48
III (test substance)	5 per sex	2,000	24
IV (test substance)	5 per sex	2,000	48
V (positive control*)	5 per sex	40	48

* The positive control used was 7,12-dimethylbenz[a]anthracene.

RESULTS	
Doses Producing Toxicity	No clinical abnormalities were observed in the negative control or treated animals during the test period. Animals in the positive control exhibited piloerection on day 2 returning to normal by day 3. In animals treated with the positive control a statistically significant decrease in the proportion of erythrocytes was observed, indicating bone marrow cell toxicity at this dose.
Genotoxic Effects	The test substance induced no statistically significant increases in micronucleated, polychromatic erythrocytes (PCEs) at either sampling time. The positive control caused a significant increase in the frequency of micronucleated immature erythrocytes, demonstrating the sensitivity of the test.
Remarks - Results	No clinical signs of toxicity or reductions in the PCE/NCE ratio (cytotoxicity) were observed with test substance treatment, so it is therefore not known if the test substance reached the bone marrow.
CONCLUSION	The notified polymer was not clastogenic under the conditions of this *in vivo* mouse micronucleus test.
TEST FACILITY	ICP Firefly (2010f)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Aerobic activated sludge from domestic wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	Oxygen consumption determined with a OxiTop Control System
Remarks - Method	No significant deviations from the test guidelines were reported. An abiotic control was run in parallel (containing test substance not inoculated with activated sludge).

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation**	*Day*	*% Degradation***
1	1.7	1	12
11	10.9	4	85
14	11.3	14	96
21	14.8	21	103
28	18.4	28	104

*Based on mean of 2 replicates
**Data was not tabulated in report. Read from graph of results.

Remarks - Results	The reference substance (sodium acetate) was degraded > 60% by the 4th day, indicating a suitable aerobic activated sludge inoculum was used. All validity criteria for the test were satisfied. The test substance did not reach the pass level of 60% degradation for this test and therefore cannot be classified as readily biodegradable.
CONCLUSION	The notified polymer is not readily biodegradable
TEST FACILITY	Ecotox Services International (2011a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	*Danio rerio*
Exposure Period	96 hours
Auxiliary Solvent	None reported
Water Hardness	49 mg $CaCO_3$/L
Analytical Monitoring	TOC
Remarks – Method	Based on the results of a preliminary range-finding test a definitive test was performed. Water accommodated fractions (WAFs) were prepared by adding test substance directly to dilution water and mixing for approximately 6 hours to give loading rates of 5 - 400 mg/L. Following a 1 hour settling period, the aqueous phase of each WAF was drawn off for testing. Test conditions of test and control groups: temperature 23.5 – 24.5°C, pH 7.0 – 7.4, dissolved O_2 72.8 – 103.8% saturation. The median

lethal loading rate (LL50) and 95% confidence limits was determined by Maximum Likelihood regression. The no observed loading rate (NOEL) was determined using Fisher's Exact Binomial Test with Bonferroni Correction.

RESULTS

Concentration mg/L		*Number of Fish*	*Cumulative Mortality*				
Nominal	*Actual**		*2 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	0	7	0	0	0	0	0
5	7	7	0	1	2	2	2
12.5	0	7	0	0	0	1	1
25	1.7	7	1	2	2	2	2
50	12.2	7	3	7	7	7	7
100	26.1	7	3	6	6	7	7
200	36.5	7	6	7	7	7	7
400	73.0	7	6	7	7	7	7

*Measured at 96 h or at time of 100% mortality

LL50	19.2 mg/L at 96 hours (95% C.I. 0.7 – 75.7 mg/L) (based on loading rate, WAF)
NOEL	25.0 mg/L at 96 hours (based on loading rate, WAF)
Remarks – Results	All validity criteria for the test were satisfied and no significant deviations from test guidelines were reported. The LL50 95% C.I. was wide due to a poor fit of the data. The variability in the data may have been due to difficulty in dissolving the test substance and/or a sensitive fish in the 5 mg/L test group. However, the reported LL50 is considered to be a reasonable estimate of toxicity of the test substance to fish based on a qualitative assessment of the mortality data. It is noted that the calculated NOEL is not consistent with the LL50 and is likely to be < 25 mg/L based on a visual inspection of the data. The endpoints are reported based on loading rates due to the multicomponent and insoluble nature of the test substance.

CONCLUSION The notified polymer is harmful to fish

TEST FACILITY Ecotox Services International (2011b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	160 mg $CaCO_3$/L
Analytical Monitoring	TOC
Remarks - Method	Based on the results of a preliminary range-finding test a definitive test was performed. Water accommodated fractions (WAFs) were prepared by adding test substance directly to dilution water and mixing for more than 6 hours to give loading rates of 34.2 – 1100 mg/L. Test conditions of test and control groups: temperature 18.4 – 21.2°C, pH 7.5 – 8.5, dissolved O_2 87.9 – 103.8% saturated. A positive control test was performed by exposing daphnia to potassium dichromate. The median lethal loading rate (LL50) and 95% confidence limits was determined by Maximum Likelihood regression. The no observed loading rate (NOEL) was determined using Fisher's Exact Binomial Test with Bonferroni Correction.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual after 48 h*		*24 h*	*48 h*
Control	0	4 × 5	0	0
34.2	0	4 × 5	0	0
68.6	12	4 × 5	0	0
138	33	4 × 5	0	0
271	90	4 × 5	0	1
557	176	4 × 5	1	8
1100	280	4 × 5	19	20

EL50 562.4 mg/L at 48 hours (95% C.I. 468.2 – 672.2 mg/L) (based on loading rate, WAF)

NOEL 271 mg/L at 48 hours (based on loading rate, WAF)

Remarks - Results All validity criteria for the test were satisfied and no significant deviations from test guidelines were reported. The mean 48 hrs EC50 for the positive control test was 0.60 mg/L which was within the range for the reference material specified in the guideline. The endpoints are reported based on loading rates due to the multicomponent and insoluble nature of the test substance.

CONCLUSION The notified polymer is not harmful to aquatic invertebrates

TEST FACILITY Ecotox Services International (2011c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test

Species *Pseudokirchneriella subcapitata*

Exposure Period 72 hours

Concentration Range Nominal: 35 - 1100 mg/L
Actual: 2 - 162 mg/L (at 72 hours)

Auxiliary Solvent None reported

Water Hardness 0.15 mmol/L (Ca^{2+} and Mg^{2+})

Analytical Monitoring TOC

Remarks - Method Based on a preliminary range-finding test, a definitive test was performed for a period of 72 hrs under constant illumination at a temperature of 25 ± 2°C. Water accommodated fractions (WAFs) were prepared by adding test substance directly to dilution water and mixing for more than 6 hours to give loading rates of 35, 68, 140, 275, 550 and 1100 mg/L. A positive control test was performed by exposing algae to potassium dichromate. Statistical analyses of the results was performed using Dunnett's Test, Shapiro-Wilk's Test and Bartlett's Test.

RESULTS

Biomass		*Growth*	
E_bL50 mg/L at 72 hrs (loading rate WAF)	*NOEL mg/L (loading rate WAF)*	*E_rL50 mg/L at 72 hrs (loading rate WAF)*	*NOEL mg/L (loading rate WAF)*
204.4 (95% C.I. 181.7 – 221.8)	140	605.3 (95% C.I. 545.7 – 722.2)	140

Remarks - Results All validity criteria for the guideline were satisfied and no significant deviations from the guidelines were reported. The EC50 for the positive control test was 0.559 mg/L which was within the acceptable range for the reference material.

CONCLUSION	The notified polymer is not harmful to algae
TEST FACILITY	Ecotox Services International (2011d)

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