File No: LTD/1691

January 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ecosphere

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 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.

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

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1691	ChemColour Industries Australia Pty Ltd	Ecosphere	ND*	< 10,000 tonne/s per annum	Component of adhesives

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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 as introduced:
  - Enclosed, automated processes where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid breathing dusts

- 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 as introduced:
  - Respiratory protection

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

- A copy of the (M)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 for the Classification and Labelling of Chemicals*

(GHS) as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

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

- 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 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 polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of adhesives, 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.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)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)
ChemColour Industries Australia Ltd Pty (ABN: 70 125 602271)
Park 20-22 Gardiner Road
Notting Hill, VIC 3168

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

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

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, flash point, flammability, autoignition temperature, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Ecosphere

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Off white to light beige powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Solid material with no melting point determined.
Boiling Point	Not determined	Solid material not expected to have a boiling point
Density	608-616 kg/m^3	Measured
Vapour Pressure	Not determined	Based on the high molecular weight of the

		polymer, the vapour pressure is expected to be low
Water Solubility	Dispersible	Based on the formation of homogeneous colloidal dispersions
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functionalities that may hydrolyse under acidic conditions
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is not expected to significantly partition to organic phases based on its dispersibility
Adsorption/Desorption	Not determined	The notified polymer is expected to sorb to soil, sediment and sludge based on its high molecular weight
Dissociation Constant	Not determined	Does not contain dissociable functionalities
Particle Size	Inhalable fraction (< 100 μm): < 10% Respirable fraction (< 10 μm): 0%	Measured. Refers to particle size on dispersion.
Flash Point	Not determined	The notified polymer is a solid with an expected high melting point and negligible vapour pressure.
Flammability	Not determined	The notified polymer is explosive under certain conditions
Autoignition Temperature	> 230 °C	Measured
Explosive Properties	Kst 63 bar-m/s	Measured
Oxidising Properties	Not determined	No functional groups that imply oxidative properties

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

Reactivity
The notified polymer is mild to moderately explosive dust and reacts with strong oxidisers.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer may be classified as a weak explosive according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia but as sufficient testing has not been conducted a hazard classification cannot be assigned.

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 the neat form (> 90% concentration) for reformulation into various adhesives at up to 70% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1,000	< 5,000	< 6,000	< 10,000	< 10,000

PORT OF ENTRY
Melbourne, Brisbane and Sydney

TRANSPORTATION AND PACKAGING
The notified polymer will be shipped by sea in 25 kg polyethylene lined bags or 1000 kg supersacks. Within Australia the notified polymer will be transported by road.

USE

The notified polymer will be used in the manufacture of binders/adhesives for paper coatings, carpet backing, fibreglass, and fibreboard.

OPERATION DESCRIPTION

The notified polymer will be imported in the neat form (> 90% concentration). The notified polymer will then be reformulated into various adhesive products at ≤ 70%. The reformulation procedures are expected to all follow the same general methods and will involve the imported supersacks or 25 kg bags containing the neat notified polymer being off loaded into a silo through a powder handling system and conveyed through a hopper to the silo. For supersacks, the sack is suspended above the hopper (funnel) and the material is gravity fed into the powder handling system to the silo. The area above the hopper is typically closed to prevent dust build up in the area around the hopper. From this point on, the dry notified polymer is in a closed system and is fed from the silo to a liquid dispersion system where the material is dispersed and other substances blended in to create the final adhesive product.

Binder in paper coatings

The notified polymer will typically be present at 4-6% concentration in the final coating slurry, which will be pumped directly onto sheets via an automated process. Once the adhesives are dried the notified polymer is expected to be trapped within the coating matrix.

Corrugated solid fibre boxes

The notified polymer will be used for corrugated and solid fibre boxes at > 20%. The dry packaged notified polymer will be added to mixing tanks as described above with hot water and enclosed and heated. The resulting wet adhesive is added to the corrugated and solid fibre boxes and cured by passing over with heated plates to seal the end product.

Carpet adhesives

The notified polymer will be used in carpet adhesives at < 35%. The dry packaged notified polymer will be added to mixing tanks as previously described where it will be blended into the final product. The wet adhesives will then be added by hand with a trowel. Once the adhesives are dried the notified polymer is expected to be trapped within the matrix.

Binder for fibreglass

When used as a binder for fibreglass the notified polymer will be present at up to 70%. The notified polymer is added to mixing tanks as previously described with other products to create the resulting fibreglass adhesive. It is then sprayed directly onto molten glass fibres via a fully automated process. The resulting fibreglass falls onto conveyor belts where it is cooled and cut into the desired sizes. Once the adhesives are dried the notified polymer is expected to be trapped within the matrix.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Binder in paper coatings	4	220
Binder in carpet backing; carpet installers	8	220
Adhesive for corrugated and solid fibre board; glue station	8	15-138
Binder for fibreglass	8	118

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are expected to only be exposed to the notified polymer in the unlikely event of an accident. In this case, dermal and ocular exposure may occur; however, standard clean-up procedures would be in place to minimise worker exposure to the notified polymer.

Formulation of adhesive products/End Use
Workers involved in the formulation of adhesive products may come into contact with the notified polymer at > 90% concentration as a dust when it is being charged into mixing tanks from the bags and supersacks. Dermal, ocular and inhalation exposure are possible at this stage of the reformulation process. Once the polymer is added to mixing tanks minimal to no exposure is anticipated due to engineering controls and enclosed systems. Following the reformulation processes the notified polymer will be in a liquid formulation and inhalation exposure is no longer anticipated. In addition, once the adhesives are dried the notified polymer is expected to be trapped within the adhesive/product matrix and no longer available for exposure.

6.1.2. Public Exposure
The public will not be exposed to the notified polymer except in the unlikely event of an accident or spill.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 10,600 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution.
The notified polymer is a high molecular weight polymer with low water solubility although it is dispersible in water. Inhalation of insoluble respirable particles of polymers with molecular weights > 70,000 Da has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, 2013). The notified polymer is dispersible in water and hence is expected to be rapidly cleared from the lungs with a low potential for lung overloading effects unless large amounts are inhaled.

Due to the high molecular weight of the notified polymer (> 10,000 Da) and low levels of low molecular weight species it is not expected to be absorbed across biological membranes, which is supported by a lack of systemic effects seen in the acute oral toxicity test.

Acute toxicity.
The notified polymer was tested in an acute rat oral study and found to be of low acute oral toxicity with LD_{50} > 10,600 mg/kg bw.

Irritation and sensitisation.
In studies conducted in rabbits, the notified polymer was found to be non-irritating to the eyes and skin. In a guinea pig maximisation test the notified polymer was found to be non-sensitising.

Mutagenicity/Genotoxicity.
The notified polymer did not show signs of mutagenicity in two bacterial reverse mutation assays with and without metabolic activation.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The potential for lung overloading effects may be of specific concern to workers involved in the reformulation of the notified polymer into adhesive products who will routinely be exposed to dusts of the notified polymer (at > 90% concentration). Although reformulation workers will handle the notified polymer frequently, inhalation exposure is expected to be minimised given the proposed use of PPE and largely enclosed, automated processes

used in reformulation facilities. The risk to the health of reformulation workers is therefore not considered to be unreasonable, provided control measures are in place to minimise inhalation exposure (including the use of respiratory protection if ventilation is inadequate).

6.3.2. Public Health

The public are not expected to be exposed to the notified polymer and hence, the risk to the public is not considered to be unreasonable under the proposed use of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be reformulated into different products such as binder in carpet backing, binder in paper coatings, adhesive for corrugated solid fibre board and formaldehyde free binder for fibreglass. The formulation of the notified polymer will take place in industrial settings using efficient automated processes. Waste material containing the notified polymer is expected to be recycled. The main point of release of the notified polymer is in the form of dust generated during the dispersion process. Procedures for mitigation are in place for both in article manufacturing and in subsequent downstream use. Wastes generated from cleaning are expected to be very limited.

Binder in carpet backing

The notified polymer is expected to be used as an ingredient in carpet adhesive. During the reformulation process, less than 1% of the annual import volume of notified polymer is expected to be released in washings from cleaning of the reformulation equipment to wastewater treatment systems. Empty containers are expected to be recycled.

Binder in paper coatings

The notified polymer is expected to be used in a coating agent for papers. During reformulation, less than 1% of the total import volume of notified polymer is expected to be diluted and released to the sewer when the formulation tank is cleaned. At the reformulation site, all the waste products (dry end waste, wet end waste and edge trim) are expected to be recycled.

Adhesive for corrugated and solid fibre board

The notified polymer is expected to be used as adhesive for corrugated and solid fibre board. During the reformulation process, the release of the notified polymer in washings from cleaning of the formulation tank is expected to be less than 1% of the total import volume. The washings are expected to be diluted and released to the sewer. At the reformulation site, all the waste products (dry end waste, wet end waste and edge trim) are expected to be recycled.

Formaldehyde free binder for fibreglass

The notified polymer is expected to be used as formaldehyde free binder for fibreglass. During the process of manufacturing fibreglass insulation, less than 1% of the annual import volume of notified polymer in washings from cleaning of the manufacturing equipment is expected to be released to the sewer. Empty containers are expected to be recycled. At the fibreglass insulation manufacturing site, trimmings from cutting fibreglass into batts are expected to be recycled in the production process.

RELEASE OF CHEMICAL FROM USE

According to the use of the notified polymer stated below, the notified polymer is not expected to be released to the environment during use. The majority of the notified polymer generated as wastes during use is expected to be contained and disposed of to landfill.

Binder in carpet backing

The notified polymer in carpet adhesive is typically applied by a trowel on a floor by commercial carpet installers for carpet installation.

Binder in paper coatings

The notified polymer in the coating slurry is pumped directly to the coating station where it is applied to the paper or paper board.

Adhesive for corrugated and solid fibre board
The notified polymer in the liquid dispersion will be applied to the corrugated and solid fibre board.

Formaldehyde free binder for fibreglass
The fibreglass manufacturing process is almost completely automated due to the high temperature use in the process. Once sprayed onto the fibreglass, the notified polymer is adhered to the fibres.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of the notified polymer will be applied to the surfaces of articles as binder and adhesive, and will share the fate of the articles. At the end of their useful life most of the articles will be sent to landfill. Some of the used papers are likely to be sent to recycling facilities.

Binder in carpet backing
Carpets containing the notified polymer are expected to be disposed of to landfill at the end of their useful life.

Binder in paper coatings
Some of the final packaging material is expected to be repulped into brown grade paper in a paper recycling plant. The recycled papers are then converted into paper liners used in paper boxes. The rest of the packaging material containing the notified polymer is expected to be disposed of to landfill at the end of their useful life.

Adhesive for corrugated and solid fibre board
Some of the final packaging material is expected to be repulped into brown grade paper in a paper recycling plant. The recycled papers are then converted into corrugate liners used in corrugated boards. The rest of the packaging material containing the notified polymer is expected to be disposed of to landfill at the end of their useful life.

Formaldehyde free binder for fibreglass
Fibre glass insulation containing the notified polymer is expected to be eventually disposed of to landfill at the end of their useful life.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be disposed of to landfill as waste from residues in empty import containers, and articles at the end of their useful life. The adhesive containing the notified polymer will form a solid inert resin matrix. Once cured, the notified polymer is physically bound into the resin matrix and is not expected to be mobile or bioavailable.

During paper recycling processes, it is assumed that 50% of the waste paper to which the notified polymer is applied will end up in landfill and the rest will undergo paper recycling processes. During paper recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. The coating containing the notified polymer is expected to partition to sludge due to its high molecular weight, and subsequently be disposed of to landfill.

The release of the notified polymer to the aquatic environment is not expected to be significant based on its assessed use pattern. In the event of release of the notified polymer from equipment washings to sewer, due to its high molecular weight, it is expected that a significant amount of the notified polymer will be removed from wastewaters to the soil/sediment by sorption. Since the backbone of notified polymer is modified natural polymer, it indicates that the notified polymer may be rapidly removed from sewage treatment plant (STP) influent via biodegradation. Only a very small proportion of the notified polymer may be discharged to receiving waters in treated effluent where the notified polymer is expected to disperse and degrade.

The notified polymer has high molecular weight and, as it is not expected to cross biological membranes, it is not likely to bioaccumulate. The notified polymer will eventually degrade biotically or abiotically in landfill and aquatic systems to generate water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The PEC for the notified polymer has not been calculated since no significant release to the environment is expected based on its reported use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified polymer or any acceptable analogue polymer were submitted. High molecular weight non-ionic polymers are a class of substances that are generally assumed to be of low environmental concern.

7.2.1. Predicted No-Effect Concentration

The PNEC has not been calculated since no ecotoxicity data are available for the notified polymer.

7.3. Environmental Risk Assessment

The risk quotient (RQ = PEC/PNEC) for the notified polymer has not been calculated as the notified polymer is unlikely to result in ecotoxicologically significant concentrations in the aquatic environment. The majority of the notified polymer will be disposed of to landfill as cured adhesive or coated articles. The notified polymer in adhesive is physically bound into a solid inert resin matrix, and is unlikely to be bioavailable or leach in this form. On this basis, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility Dispersible

Method In house method.
Remarks Determinations of percent solids were conducted on three separate lots of the test substance (42.08%, 13.73%, and 42.87%), which had been dispersed in water. These dispersions were reported to be homogeneous stable colloidal dispersions. The solids determinations were performed using a Smart System 5 Moisture analyzer (CEM Inc. Charlotte NC) and are accurate to 0.1%.
Test Facility ECOSYNTHETIX (2013)

Particle Size

Method Similar to OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Bin centre (μm)	*Percentile undersize (%)*
10	0.000
30	0.004
50	0.257
70	1.424
90	4.287
110	10.143
130	21.671
370	98.556
650	100.000

Test Facility Nanosight (2013)

Autoignition Temperature > 230°C

Method Similar to EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks At 230°C the test material was observed to expand and harden. At 300°C and above the bottom of the test material was burnt although autoignition was not observed.
Test Facility Kidde Fenwal (2010)

Explosive Properties K_{ST} 63 bar-m/s

Method According to ASTM Standard Test Method E1226 'Pressure and Rate of Pressure Rise for Combustible Dusts'.

Test Facility Kidde Fenwal (2008)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	Non OECD method similar to OECD TG 401 Acute Oral Toxicity – Limit Test. Non-GLP study
Species/Strain	Rat/ Sprague Dawley
Vehicle	Not stated
Remarks - Method	The test article was administered using a feeding needle and syringe. It is unclear whether a gavage procedure was used or how the test substance was prepared.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5M/5F	10,600	0/10

LD50	> 10,600 mg/kg bw
Signs of Toxicity	One female exhibited slight weight loss between 7-14 days following dosing. All other animals displayed normal weight gain.
Effects in Organs	No effects were observed in organs.
Remarks - Results	There were no unscheduled deaths in the study.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	SGS (2001a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	Non OECD test method. Non-GLP study.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	Not stated
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	0.5 g of test material was placed onto clipped abraded and non-abraded skin. An occlusive dressing was then applied for a 24 hour period. At the end of the exposure period the sites were cleaned with water. Observations were made at 24 and 72 hours.
Remarks - Results	No dermal irritation was observed through the 72 hour observation period.
CONCLUSION	The notified polymer is non-irritating to the skin.
TEST FACILITY	SGS (2001a)

B.3. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	Non OECD test method. Non-GLP study.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	72 hours
Remarks - Method	A 0.1 mL volume of test substance was administered into the test eye of

each animal. The lids were held together for one second to minimize sample loss. The animals were returned to their cages for the 24-hour exposure period before the test substance was flushed from the eye. Observations were made at 24, 48 and 72 hours.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.5	1	< 72 hours	0
Conjunctiva: chemosis	0	0	0	0
Conjunctiva: discharge	0	0	0	0
Corneal opacity	0	0	0	0
Iridial inflammation	0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results Five of the six test animals displayed slight conjunctival irritation at the 24-hour observation period. By 72 hours there were no signs of irritation.

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

TEST FACILITY SGS (2001a)

B.4. Skin sensitisation

TEST SUBSTANCE Notified polymer

METHOD Non-OECD test based on the guinea pig Maximisation test. Non-GLP study

Species/Strain Guinea pig/Hartley strain

PRELIMINARY STUDY Not performed

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 20

INDUCTION PHASE Induction Concentration:
Week 1-Topical: 50% (0.5 g)
Week 2-Topical: 50% (0.5 g)

Signs of Irritation Not reported

CHALLENGE PHASE

1st challenge topical: 50%

2nd challenge topical: neat (> 90%)

3rd challenge intradermal: 10%

Remarks - Method The back region of all test and control animals was shaved prior to the first induction. Then, 10% sodium lauryl sulphate was massaged into the shaven area. All test and control animals received duplicate injections of Freunds Complete Adjuvant onto pre-irritated test sites. All animals then received either 0.5 g of the test sample in sesame oil or sodium chloride or 0.5 mL of the vehicle control under occlusive wrap for 48 hours. This was repeated for a second induction in week 2. This was repeated for challenge test except that a new skin site was used and the area was not intentionally irritated and the application was for 24 hours. Re-challenge used neat test article and the second re-challenge used subcutaneous injection.

RESULTS Where 0.9% concentration sodium chloride solution was used as the vehicle

Animal	*Challenge Conc.*	*Number of Animals Showing Skin Reactions after:*					
		1st challenge		*2nd challenge*		*3rd challenge*	
		24 h	*48 h*	*24 h*	*48 h*	*24 h*	*48 h*
Test Group	50%	6/10	0/10		0/10		
	> 90%			1/10	0/10		
	10% (s.c.*)					0/10	1/10

Control Group	50%	4/10	0/10				
	> 90%			1/10	0/10		
	10% (s.c.*)					0/10	0/10

* Where s.c. stands for subcutaneous

Where sesame oil was used as the vehicle

Animal	*Challenge Conc.*	*Number of Animals Showing Skin Reactions after:*					
		1st challenge		*2nd challenge*		*3rd challenge*	
		24 h	*48 h*	*24 h*	*48 h*	*24 h*	*48 h*
Test Group	50%	0/10	0/10		0/10		
	> 90%			2/10	3/10		
	10% (s.c.*)					0/10	0/10
Control Group	50%	2/10	0/10				
	> 90%			1/10	0/10		
	10% (s.c.*)					0/10	0/10

* Where s.c. stands for subcutaneous

Remarks – Results

One hour after the first challenge 8/10 test animals showed slight erythema and 7/10 control animals showed slight erythema (For NaCl vehicle). When sesame oil was used as the vehicle only 3/10 control animals showed slight erythema after 24 hours. All reactions were resolved after 48 hours.
Re-challenge with neat test article resulted in slight erythema in 1/10 test animals and 1/10 control animals in sodium chloride. For sesame oil slight erythema was noted in 3/10 test animals at the 48 hour observation, with no latter observations taking place and only one control animal showing signs of erythema at the 24 hour observation. Although a 30% level of irritation in the test animals compared to the controls seen in the rechallenge where sesame oil was the vehicle could be seen to be a positive indication of sensitisation, the weak effects and lack of effects where sodium chloride solution was used as the vehicle or in the other challenges suggest that on a weight of evidence basis this finding is not relevant.
No dermal irritation was observed during the second re-challenge test in sesame oil and only one test animal showed slight erythema at 48 hours in sodium chloride, which had cleared by the 72 h observation.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY

SGS (2001b)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 471 Bacterial Reverse Mutation Test. Non-GLP study.
Plate incorporation procedure

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System: Rat liver S9 mix
Concentration Range in Main Test: a) With metabolic activation: 5000- 50 µg/plate; b) Without metabolic activation: 5000- 50 µg/plate
Vehicle: Water
Remarks - Method: The negative control was water without S9 mix and with S9 mix the control was test culture and 0.5 mL of S9 fraction. Positive controls were daunomycin, sodium azide, 9-aminoacridine and mitomycin C in the absence of metabolic activation and 2-aminoanthracebe with metabolic

activation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	Not described			
Test 1		Not described	Not described	Negative
Present	Not described			
Test 1		Not described	Not described	Negative

Remarks - Results: No detailed results were provided in the study nor were observations on precipitation or cytotoxicity. The test sample did not produce signs of mutagenicity either with or without S9 mix. The positive controls were reported to have given the expected positive results (Though no data for these was provided) thus validating the test sensitivity.

CONCLUSION: The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: SGS (2012a)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 471 Bacterial Reverse Mutation Test. Non-GLP study.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Rat liver S9 mix
Concentration Range in Main Test	a) With metabolic activation: 5000- 50 µg/plate b) Without metabolic activation: 5000- 50 µg/plate
Vehicle	Water
Remarks - Method	The negative control was water without S9 mix and with S9 mix the control was test culture and 0.5 mL of S9 fraction. Positive controls were daunomycin, sodium azide, 9-aminoacridine and mitomycin C in the absence of metabolic activation and 2-aminoanthracebe with metabolic activation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	Not described			
Test 1		Not described	Not described	Negative
Present	Not described			
Test 1		Not described	Not described	Negative

Remarks - Results: No detailed results were provided in the study nor were observations on precipitation or cytotoxicity. The test sample did not produce signs of mutagenicity either with or without S9 mix. The positive controls were reported to have given the expected positive results (Though no data for these was provided) thus validating the test sensitivity.

CONCLUSION: The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: SGS (2012b)

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