File No: LTD/1355

May 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer (Latemul PD-104 INT) in Emulsion A-200

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 the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kao (Australia) Marketing Pty Ltd (ABN: 59 054 708 299)
Suite 1, 1-5 Commercial Road
Kingsgrove NSW 2208

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 Formula; Structural Formula; Molecular Weight; Spectral Data; Purity; Impurities/Residual Monomers; Additives and Adjuvants; Import volume; Details of use; Identity of Manufacturer/Recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2004)
Canada (2007)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Latemul PD-104 INT
Latemul PD-104 (aqueous solution of the notified polymer at concentrations of 20%)
Emulsion A-200 (imported product containing up to 2% notified polymer)

MOLECULAR WEIGHT
>1000 Da

ANALYTICAL DATA
Reference NMR, IR, GPC, and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None expected under normal conditions of use.

DEGRADATION PRODUCTS
None expected under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Pour Point	1 ± 3 °C	Measured
Melting Point	-10 - 0 °C	MSDS
Density	1.09 x 10^3 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 3.1 x 10^{-6} kPa at 25 °C	Measured
Water Solubility	> 10 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Stable	Measured
Partition Coefficient (n-octanol/water)	Not Determined	See Discussion below.
Adsorption/Desorption	Not Determined	See Discussion below
Dissociation Constant	Not Determined	Strongly acidic and will remain anionic throughout the environmental pH range of 4-9.
Particle Size	Not determined	The notified polymer is a liquid at room temperature.
Flash Point	148 ± 2 °C at 101.325 kPa	Measured
Flammability	Not classified as flammable	Based on the flash point.
Autoignition Temperature	330 ± 5 °C	Measured
Explosive Properties	Not expected to be explosive	Contains no known explosophores.

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

The notified polymer was observed to exhibit surfactant properties. This prevented determination of the partition coefficient and the absorption/desorption properties of the notified polymer.

Reactivity
The notified polymer is expected to be stable in water and air.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of a polymer emulsion formulation (Emulsion A-200) at concentrations of <2%.

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
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Australian subsidiary of the manufacturer of the notified polymer.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 200L lined steel drums. Within Australia it will be transported by truck and/or train. The reformulated paints will be packaged into 200L drums, or 20L, 5L, or 1L cans.

USE
The notified polymer will be used as a polymerisation emulsifier in automotive paints.

OPERATION DESCRIPTION
Reformulation
The imported product containing <2% of the notified polymer will be pumped directly from the import drum

into a closed 10,000L blending vessel following the addition of other ingredients. The formulated paint (<1% notified polymer) will then be pumped to an automatic filling machine and filled into drums or cans under general and local ventilation in a bunded area. The transfer lines and blending vessel will be flushed with water, collected, and reused for subsequent batches.

End use
Spray painters will open the drums/cans containing the finished paint (notified polymer <1%) and may mix it manually with other additives. The mixture will then be manually loaded into the spray equipment. At larger automotive centres, spray application will take place in spray booths. Spray booth filters will be removed by workers for disposal every 2-4 months. At smaller automotive repair centres, spray painting will take place in a well ventilated area where newspaper sheets will be spread on the ground around the area to be painted to collect any waste paint and overspray. In both cases, once spraying is complete, the equipment will be drained and cleaned using solvents and rags. Empty cans will be drained onto absorbent material and subsequently disposed of, and the newspaper sheets will also be disposed of.

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	1	1	4
Warehouse	1	1	4
Reformulation workers	1	2	50
Maintenance	1	1	10
Cleaning workers	1	1	10
End users (including cleaning of equipment)	6	2	100

EXPOSURE DETAILS
Reformulation
Dermal and ocular exposure of workers to the notified polymer (<2%) may occur during reformulation such as from spills and splashes during connection and disconnection of transfer lines and during cleaning processes. However, exposure it is likely to be low due to the short duration of the process, together with the largely automated processes, the enclosed nature of the mixing vessel, the ventilation used in reformulation areas, and the personal protective equipment (PPE) worn by workers.

End use
Dermal and ocular exposure of workers to the notified polymer (<1%) may occur during preparation and loading of the paint formulation and the cleaning/disposal of waste after completion of the spraying. During spray operations, inhalation exposure is an additional possible route of worker exposure. Exposure is expected to be reduced by the use of engineering controls such as spray booths, and the personal protective equipment worn by workers, which is likely to include gloves, boots, eye protection and respiratory protection.

6.1.2. Public exposure
The public may become exposed to automobiles coated with the notified polymer. At this stage the coating will be dried and cured into an inert matrix and is unlikely to be available for exposure. Therefore, public exposure is expected to be negligible.

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 oral toxicity	low oral toxicity LD50 >2000 mg/kg bw
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

The notified polymer may be absorbed dermally/ocularly based on its high water solubility (>10g/L) and surfactant properties.

Upon inhalation of the notified polymer, it is likely to diffuse into the mucus lining the respiratory tract (given that it is a liquid at room temperature). It may then be retained in the mucus and transported out of the respiratory tract (based on its high water solubility) (EC 2003).

The notified polymer was of low acute oral toxicity in rats (LD50 > 2000 mg/kg bw). In addition, it was not shown to cause sensitisation or mutagenic effects.

The notified polymer contains a functional group that is a structural alert for corrosion (Hulzebos 2005). However, the skin sensitisation test suggests that the notified polymer is unlikely to cause corrosion of the skin up to concentrations of 20%. This is based upon the mild irritancy effects that were observed in the preliminary and main studies. However, irritancy effects, including eye irritation at higher concentrations cannot be ruled out.

The notified polymer also contains a functional group that may fall under a USEPA category of concern. Such groups have been associated with a number of health effects, including haemolysis, bone marrow damage, direct and indirect kidney damage, liver damage, immunotoxicity, central nervous system depression, leukopenia of lymphocytes and granulocytes, and developmental and reproductive toxicity. Such concerns may not be relevant for the notified polymer itself given its high molecular weight (>1,000), although the surfactant properties of the notified polymer are likely to enhance its dermal/ocular absorption. In addition, low molecular weight species containing this functional group can be absorbed and cause irritation of skin, eyes and mucous membranes. It should be noted that the gel permeation chromatography (GPC) trace provided by the notifier shows the presence of low molecular weight species, however, these were excluded from the analysis, and as such, the low molecular weight species present in the notified polymer were not quantified (KOPTRI 2005).

Based on the limited data available on the notified polymer, it is concluded that irritancy effects cannot be ruled out based on the structural features of the notified polymer. In addition, further data would be necessary to completely rule out the possibility of the notified polymer causing the systemic effects discussed above.

Classification
Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Workers handling the notified polymer in Australia will only be exposed to concentrations of <2% infrequently and for relatively short time periods. As such, the risk of irritancy effects resulting from dermal and ocular exposure to the notified polymer are unlikely, given that the exposure concentrations will be below the concentration cut off levels for these effects. The risk of skin sensitisation is also unlikely at these concentration levels, given the negative skin sensitisation test provided.

The systemic effects (discussed in Section 6.2) resulting from repeated dermal exposure to the notified polymer cannot be completely ruled out, particularly for any low molecular weight species that may be present in the notified polymer. However, given the likely low exposure, short duration, and the use of automated processes, engineering controls and personal protective equipment, the risk of such effects is considered to be low. However, employers should implement necessary control measures to minimise worker exposure to the notified polymer.

Effects resulting from inhalation exposure of workers to the notified polymer during spray operations are unknown. Again, the likely low exposure, as well as the controls in place during such operations should lower

the risks involved.

The surfactant properties of the notified polymer may result in enhancement of the dermal absorption of other chemicals. Thus consideration should be given as to the other ingredients present within products containing the notified polymer and any health effects that may result from such ingredients upon dermal absorption.

In conclusion, the occupational health and safety risk associated with the notified polymer is considered to be low.

6.3.2. Public health

Members of the public will occasionally come into contact with substrates coated with the notified polymer on which the notified polymer has been cured. As such, the risk to public health is considered to be low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

During paint formulation and packaging, spills are expected to be minimal. When spills occur, they will be contained by bunding, collected with absorbent material and collected by a licensed waste disposal contractor for disposal as landfill. Residual waste from the paint-mixing vessel is anticipated to be 0.5% of imported polymer volume. This waste will be collected when the mixing vessel is cleaned, aqueous residues are dealt with in on-site sewer systems, while solid residues containing the notified polymer are sent to landfill. Drum residual waste is expected to be 1% of imported volume.

RELEASE OF CHEMICAL FROM USE

Under normal use processes, losses of the notified polymer through overspray, cleaning of paint equipment, as well as losses from residues in containers have been estimated to be a maximum 25% of notified polymer. Empty containers that contained the paint will be flushed with water. Residual waste of the notified polymer in paint drums is expected to be 2% of imported volume. Waste from application (paint overspray that does not land on the vehicle) will be trapped in the spray booth water, hardened and disposed of to landfill (estimated to be 20% of imported volume). Waste from cleaning of automatic spray equipment (2% of imported volume) will be collected on rags and disposed of to landfill (a trace amount of the imported polymer).

The remainder of the notified polymer forms a paint film on the vehicle and undergoes a chemical reaction with other polymer components in the paint during the paint baking process, to form the final paint film. It is not available for direct release to the environment. Disposal of the automobile may be through landfill or recycling. For automobiles that are recycled, the notified polymer will be incinerated in the recycling process.

RELEASE OF CHEMICAL FROM DISPOSAL

During formulation, empty drums will be returned to the supplier. Residual waste will either be disposed of via on site sewage systems (aqueous waste) or via landfill (solid waste). End use product will be disposed of to landfill.

7.1.2 Environmental fate

The notified polymer contains no readily hydrolysable groups and is expected to be stable under normal environmental conditions. Due to its high water solubility, the notified polymer is expected to partition to the aqueous phase. However, due to paint collection processes the majority of the waste during the paint formulation and use will be disposed of to landfill and eventually degrade through biotic and abiotic processes. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon and nitrogen.

Based on the above, the notified polymer is not expected to be readily biodegradable or to bioaccumulate.

7.1.3 Predicted Environmental Concentration (PEC)

The release to the aquatic environment of the notified polymer is likely to be low. The following Predicted

Environmental Concentration (PEC) can be estimated as a worst case on using 5% national release to sewer, presuming no removal due to partitioning out of the water column and no degradation:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	50	kg/year
Days per year where release occurs	200	days/year
Daily chemical release:	0.25	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.059	µg/L
PEC - Ocean:	0.006	µg/L

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	EC50 = 75 mg/L	The notified polymer is harmful to fish.
Daphnia Toxicity	EC50 = > 100 mg/L	The notified polymer is not harmful to *Daphnia magna*.
Algal Toxicity	E_bC50 = 29 mg/L	The notified polymer is harmful to algae.
	E_rC50 = 170 mg/L	The notified polymer is not harmful to algae.

7.2.1 Predicted No-Effect Concentration

This has been done using the fish result rather than the algae result (as the algae E_rC50 is a more robust value than the E_bC50, and as such, fish is considered to be the most sensitive trophic level). An assessment factor of 100 was used since results for 3 trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Fish)	75	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	750	µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.059	750	**0.00009**
Q - Ocean	0.006	750	**0.000008**

From the PEC/PNEC (0.059 µg/L÷750 µg/L) ratio, a value of <0.00001 is calculated for the risk quotient for the aquatic environment. The notified polymer is therefore not expected to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) 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*
Acute hazards to the aquatic environment	3	Harmful to aquatic life
Chronic hazards to the aquatic environment	3	Harmful 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 unacceptable risk to the health of workers.

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Good ventilation.
  - Prevent leaks and spills.
  - Use of spray booths whenever possible.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with eyes, skin and clothing.
  - Avoid breathing mists.
  - A shower station should be available.
  - Avoid spills and splashing during use.
  - After exposure, any contaminated PPE should be thoroughly cleaned before re-use.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Chemical resistant gloves, safety glasses, respiratory protection.
  - Chemical resistant clothing which protects the body, arms, legs and feet.

  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.

- Consideration should be given as to the other ingredients present within products containing the notified polymer and any health effects that may result from such ingredients upon dermal absorption.

Environment

- The notified polymer should be disposed of by landfill.

- Small spills should be absorbed with sand, inert absorbent, waste cloth or sawdust. Large spills should be diked and disposed of in a safe area.

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(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000; or
  - if the notified polymer is present in imported products at concentrations >2%;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a polymerisation emulsifier in automotive paints, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 1 tonne per annum, or is likely to increase, significantly;
  - if the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical 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 imported 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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour Point 1 ± 3 °C

Method OECD TG 102 Melting Point/Melting Range.
Test Facility SafePharm (2006a)

Density 1.09 x 10^3 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
Pycnometer method
Test Facility SafePharm (2006a)

Vapour Pressure < 3.1 x 10^{-6} kPa at 25 °C

Method OECD TG 104 Vapour Pressure.
Remarks The given value is the highest estimate, based on readings at 65°C.
Test Facility SafePharm (2006b)

Water Solubility > 10 g/L at 20°C

Remarks Procedure used was Method 120 of the OECD Guidelines for Testing of Chemicals, which is based on Method 105 of the OECD Guidelines for Testing of Chemicals. 100% of the test material extracted into water.

Determination of water solubility was also carried out using OECD Guideline 120 by TOC (total organic carbon) at pH 2, 7 and 9. 100% was dissociated in all cases.
Test Facility Safepharm (2006c)
KOPTRI (2005)

Hydrolysis as a Function of pH Not determined

Remarks Stability test was conducted only at pH 1.2 at 40°C (1-14 days). The molecular weight decreased due to neutralization of the counterion present in the notified polymer.
Test Facility KOPTRI (2005)

Partition Coefficient (n-octanol/water) Not determined

Remarks Could not be determined by Methods 107/117 of the OECD Guidelines as the test material exhibited the properties of a surfactant.
Test Facility Safepharm (2006c)

Adsorption/Desorption – screening test Not determined

Remarks Could not be determined by Method 121 of the OECD Guidelines for Testing of Chemicals as the test material exhibited the properties of a surfactant.
Test Facility SafePharm (2006a)

Dissociation Constant Not determined

Remarks No determination was possible by Method 112 of the OECD Guidelines for Testing of Chemicals as the test material contained dissociation constants outside the range and scope of the method.
Test Facility SafePharm (2006a)

Flash Point 148 ± 2 °C at 101.325 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.

Closed cup equilibrium method
Test Facility SafePharm (2006b)

Autoignition Temperature 330 ± 5 ºC

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility SafePharm (2006b)

Explosive Properties Not predicted to be explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The notified polymer does not contain any known explosophores.
Test Facility SafePharm (2006b)

Oxidizing Properties Not predicted to be oxidising

Method EC Directive 92/69/EEC A.21 Oxidizing Properties (Liquids).
Remarks A statement provided by the testing laboratory indicates that the notified substance does not contain chemical groups that are expected to result in oxidising properties.
Test Facility SafePharm (2006b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (concentration unknown)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 2004/73/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/ Sprague-Dawley CD (Crl: CD (SD) IGS BR)
Vehicle	Arachis oil BP
Remarks - Method	No significant protocol deviations

RESULTS

LD50	>2000 mg/kg bw
Signs of Toxicity	No mortality or signs of toxicity at the dose level of 2000 mg/kg bw.
Effects in Organs	None

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	SafePharm (2006d)

B.2. Skin sensitisation

TEST SUBSTANCE	Notified polymer (20% aqueous solution)
METHOD	Similar to OECD TG 406 Skin Sensitisation – Guinea pig maximisation test
Species/Strain	Guinea pig/ Std:Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 0.06% topical: 3%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 0.6% topical: 20%
Signs of Irritation	Observations were not made following induction.
CHALLENGE PHASE	
1st challenge	topical: 10, 5, 3, 1, 0.5, 0.3%
Remarks - Method	No significant protocol deviations. There was no statement of GLP with the test report.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions After: 1st challenge*	
		24 h	*48 h*
Test Group	10%	6	6
	5%	0	0
	3%	0	0
	1%	0	0
	0.5%	0	0
	0.3%	0	0

Control Group	10%	3	2
	5%	0	0
	3%	0	0
	1%	0	0
	0.5%	0	0
	0.3%	0	0

Remarks - Results: Very slight erythema (grade 1) was observed in 6 out of 10 animals of the test group following challenge with 10% test substance. However, similar effects were observed in 3 out of 5 control animals. These effects were considered to be due to the irritation potential of the notified polymer (refer to Section 6.2). Some of the challenge concentrations used were higher than the highest non-irritant dose (which was 3%). No effects were seen at lower challenge doses (<10%).

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

TEST FACILITY: JBS (2004)

B.3. Genotoxicity – bacteria

TEST SUBSTANCE: Notified polymer (20% aqueous solution)

METHOD: Similar to OECD TG 471 Bacterial Reverse Mutation Test.
Pre incubation procedure

Species/Strain: *S. typhimurium*: TA98, TA100

Metabolic Activation System: S9 mix from Sprague-Dawley rat liver induced with phenobarbital and 5,6-benzoflavone

Concentration Range in Main Test: a) With metabolic activation: 39, 78, 156, 313, 625, 1250, 2500, 5000 µg/plate
b) Without metabolic activation: 78, 156, 313, 625, 1250, 2500, 5000 µg/plate

Vehicle: Distilled water

Remarks - Method: This test does not use the type and number of bacterial strains recommended by the OECD test guideline (at least 5 strains of bacteria should be used, including at least one *E. coli* WP2 strain).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>1250	>2500	>5000	Negative
Test 2		>313	>313	Negative
Present				
Test 1	>313	>625	>5000	Negative
Test 2				

Remarks - Results: No significant increases in the number of revertant colonies were observed during the test.

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

TEST FACILITY: BML (2004)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1 Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – semi-static.
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	Water
Water Hardness	140 mg/L
Analytical Monitoring	The water temperature, pH and dissolved oxygen concentrations were recorded daily throughout the test. The pH and dissolved oxygen concentration were determined using a WTW pH/Oxi 3401 pH and dissolved oxygen meter and the temperature was measured using a Hanna Instruments HI 93510 digital thermometer. Samples were analysed using a spectrophotometer over the range 400 – 800 nm.
Remarks – Method	An amount of the notified polymer (10000 mg) was dissolved reverse osmosis deionised water with the aid of ultrasonication for approximately 15 minutes and the volume adjusted to 5 litres to give a 2000 mg/L stock solution. The pH of the stock solution was adjusted to approximately 7 using 1M sodium hydroxide at 24, 48 and 72 hours. LC50 values were calculated by the trimmed Spearman-Karber method using ToxCalc computer software.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*					
Nominal		*3 h*	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0	0
10	10	0	0	0	0	0	0
18	10	0	0	0	0	0	0
32	10	0	0	0	0	0	0
56	10	0	0	0	0	0	0
100	10	0	0	1	7	9	10

LC50	75 mg/L at 96 hours with 95% confidence limits of 56-100 mg/L
NOEC	56 mg/L at 96 hours
Remarks – Results	Analysis of fresh media at 24, 48, and 72 hours showed measured test concentrations to range from 82% to 119% of nominal with the exception of eight samples which were outside the 80% to 120% acceptance limits. Sub-lethal effects were observed at test concentrations of 100 mg/L and above. These responses were loss of equilibrium and moribund fish.
CONCLUSION	The notified polymer is harmful to Rainbow Trout.
TEST FACILITY	Safepharm (2007a)

C.1.2.Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – 48 h, static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – 48 h, static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Dechlorinated tap water
Water Hardness	130 mg $CaCO_3$/L

Analytical Monitoring	Water temperature, dissolved oxygen concentrations and pH were recorded daily throughout the test. The pH and dissolved oxygen were measured using a WTW pH/Oxi 3401 pH and dissolved oxygen meter and the temperature measured using Hanna Instruments HI 93510 digital thermometer. Samples were analysed using a spectrophotometer over the range 400 – 800 nm.
Remarks - Method	An amount of the notified polymer (200 mg) was dissolved in water and the volume adjusted to 2 Litres to give the 100 mg/L test concentration. Following a specific request by the US EPA, the pH of the 100 mg/L test concentration was adjusted from pH 7.7-7.8 to pH 7.0 using hydrochloric acid prior to introduction of the test organisms.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	10	0	0
0.1	10	0	0
1.0	10	0	0
10	10	0	0
100	10	0	0

LC50	> 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	Analysis of the test preparation at 0 (fresh media), 24 hours (old and fresh media) and 48 hours (old media) showed measured test concentrations to range from 85% to 105% of nominal value and so the results are based on nominal test concentrations only.
CONCLUSION	The notified chemical is not harmful to *Daphnia magna*.
TEST FACILITY	Safepharm (2007b)

C.1.3 Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	Nominal: 10-160 mg/L
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	Samples were analysed using a spectrophotometer over the range 400 – 800 nm. λ max at 653 nm.
Remarks - Method	An amount of the notified polymer (160 mg) was dissolved in culture medium and the volume adjusted to give a 320 mg/L stock solution from which a series of dilution was made to give further stock solutions of 160, 80, 40 and 20 mg/L. An aliquot (250 mL) of each of the stock solutions was separately mixed with algal suspension (250 mL) to give the required test concentrations of 10, 20, 40, 80 and 160 mg/L.

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 96 h	*NOE_bC mg/L*	*E_rC_{50} mg/L at 96 h*	*NOE_rC mg/L*
29 (95% CI: 25 - 33)	9.3	170	10

Remarks - Results	Analysis of the test preparations at 0 hours showed measured test concentrations to range from 99-121% of nominal. Analysis of the test preparations at 96 hours showed slight decline in measured test concentrations in the range of 66-92% of nominal with the lowest test concentrations exhibiting the greatest decline. It was not possible to calculate 95% confidence limits for these E_rC50 values as the data generated did not fit the models available for calculation of confidence limits.
CONCLUSION	The notified chemical is harmful to algae. The No Observed Effect Concentration at 96 hours was 10 mg/L.
TEST FACILITY	Safepharm (2007c)

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