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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer (Piccotac 9095 Hydrocarbon Resin) in H1750G01

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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FULL PUBLIC REPORT**Polymer (Piccotac 9095 Hydrocarbon Resin) in H1750G01****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Eastman Chemical Limited (ABN: 72 001 313 417)
C/- PricewaterhouseCoopers
Level 1 Darling Park, Tower 2
201 Sussex Street
Sydney NSW 2000

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, Other Names, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Purity, Impurities, Additives/Adjuvants, Import Volumes, Identity of Sites, Use Details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Vapour Pressure, Hydrolysis as a Function of pH, Adsorption/Desorption, Dissociation Constant, Particle Size, Flammability, Autoignition Temperature, Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Piccotac 9095 Hydrocarbon Resin (notified polymer)
H1750G01 (containing the notified polymer at concentrations up to 55%)

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellow flakes or pastilles

Property	Value	Data Source/Justification
Softening Point	94.3°C	Measured
Density	970 kg/m ³ at 25°C	Measured
Vapour Pressure	< 1.3x10 ⁻⁹ kPa	Estimated based on molecular weight

Water Solubility	4.87 x 10 ⁻⁵ g/L at pH 6.0 and 20 ± 0.5°C	> 1000 Da (USEPA, 2007). Measured
Hydrolysis as a Function of pH	Not determined	Due to the low water solubility. There are no readily hydrolysable groups present.
Partition Coefficient (n-octanol/water)	log Pow = 4.29 at 20°C	Measured
Adsorption/Desorption	Not determined	Based on the partition coefficient and low water solubility, it is likely to bind strongly to organic matter in soil.
Dissociation Constant	Not determined	No dissociable groups.
Particle Size	Not determined	The notified polymer is in pastille or flake form and is of a size that is visible to the eye.
Flash Point	183.9°C	Measured
Flash Point	270°C	MSDS (Cleveland Open Cup)
Flammability	Not expected to be flammable	Based on the flash point.
Autoignition Temperature	Expected to degrade prior to auto-ignition.	
Explosive Properties	Not expected to be explosive	Contains no explosives

DISCUSSION OF PROPERTIES

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

Reactivity

The notified polymer is not expected to be reactive under normal environmental conditions.

Degradation products

None known

Loss of Monomers, Other Reactants, Additives, Impurities

Residual monomers may be lost to the environment when the polymer or product containing it is in liquid form. Following curing of the adhesive product, the monomers will be trapped within a solid matrix.

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 H1750G01 (finished product) at concentrations up to 55%. In the future (beyond 5 years), it may be imported neat.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	≤100	≤100	≤100	≤100	≤100

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Adhesive manufacturers for construction industry such as tiling, flooring and waterproofing.

TRANSPORTATION AND PACKAGING

The finished product containing the notified polymer will be imported in stick form and packaged within multi-wall paper bags. It will be delivered to a wholesaler's warehouse for storage and then on-sold to customers.

In the future it is envisaged that the notified polymer (neat) will be imported as solid flakes or pastilles in multi-walled paper bags of ~22 kg nett weight and delivered by road to the formulator's warehouse for reformulation. It will then be distributed by road to end users.

USE

The notified polymer will be used as a component of hot-melt adhesives in the construction and packaging industries at concentrations up to 55%.

OPERATION DESCRIPTION

The notified polymer will initially be imported as a component of a finished product (H1750G01), which will not undergo reformulation or repackaging in Australia.

In the future, the notified polymer may be imported in a neat form and will be reformulated in Australia, as detailed below.

Reformulation

The notified polymer (neat) will be weighed and transferred manually to a tumble blender where it will be melted and mixed with other ingredients in a closed batch process, under local ventilation. The molten adhesive formulation containing the notified polymer at < 55% will then be heated and extruded into rod-like shapes. It will then be released from the mould and allowed to cool before being handled for packaging by manual and/or automated means. The final product could also be formed into pellets or ingots. Quality control testing may be performed and appropriate adjustments made accordingly. Cleaning and maintenance of the formulation and filling equipment will be carried out monthly by manually scraping the dried residual adhesive from the mixer and rinsing lines with hot solvent or water/soap mixture.

End-use

The adhesive stick containing the notified polymer will be placed in a hot melt application gun. The gun will extrude the hot melt at a rate of 1 – 2 kg per hour. Less than 30 grams of the hot melt typically will be used per substrate. Typically, a hot melt adhesive bond will achieve 50% of its strength after 1 minute, 75% after 1 hour, and 100% after 1 day. The adhesive product could also be supplied as pellets/ingots to be used in similar melting and processing equipment.

6. HUMAN HEALTH IMPLICATIONS**6.1 Exposure assessment****6.1.1 Occupational exposure****NUMBER AND CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	2	2-3	4
<i>Coating formulation</i>			
Process workers	3	8	4
Quality control workers	1	8	4
Cleaning and maintenance staff	2	8	4
<i>End use</i>			
Construction industry applicators	> 1000	8	30

EXPOSURE DETAILS*Reformulation*

Dermal and ocular exposure to the neat notified polymer and product containing up to 55% of the notified polymer may occur during the transfer of the solid neat notified polymer into mixing vessels, equipment cleaning and maintenance. Engineering controls (automated filling processes, local exhaust ventilation) and personal protective equipment (PPE), such as impervious gloves, safety goggles, coveralls and perhaps dust masks are typically in place to reduce the potential exposure. Inhalation exposure to the solid form of the notified polymer is likely to be low, given that the particle size of the imported product containing the notified polymer is expected to be large (not of inhalable size). In addition, inhalation exposure to vapours of the notified polymer are unlikely as it is expected to be non volatile and the formation of aerosols is not expected.

End-use

There is potential for dermal exposure to the notified polymer when using hot melt application guns. In

addition, there is the possibility that workers may inhale fumes of the notified polymer from the heated molten resin product during bonding as it may become volatile at higher temperatures. Such exposure is expected to be lowered by the use of safety glasses, impervious gloves, overalls and safety boots. After the adhesive bond achieves full strength, exposure is expected to be minimal due to the solid nature of the adhesive resin and its position between layers of material.

6.1.2. Public exposure

Members of the public may make contact with products on which the notified polymer has been applied, such as wood or metals. Exposure to the adhesive resin containing the notified polymer is expected to be negligible as following curing of the adhesive product, it will be trapped within a solid matrix.

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.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	low oral toxicity LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	low toxicity LD50 >2000 mg/kg bw
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation (analogue)	non mutagenic
Genotoxicity – in vivo mouse micronucleus assay	non genotoxic

No information is available on the toxicokinetics of the notified polymer. However, the notified polymer is not expected to be absorbed to a significant extent from the gastrointestinal tract given its high molecular weight and low water solubility. Dermal absorption is likely to be low based on the high molecular weight, low water solubility, and the relatively high partition coefficient of the notified polymer. Inhalation of vapours of the notified polymer is unlikely to result in significant absorption into the respiratory tract given its expected low solubility in blood and relatively high partition coefficient.

The notified polymer was found to be of low toxicity for all tested end points.

No information is available on the effects of the notified polymer following repeated exposure, however, it is expected to be of low toxicity. The basis of this expectation is its low acute toxicity (oral and dermal) and lack of reactive functional groups.

Health hazard classification

Based on the available data the notified polymer is not 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

Dermal and ocular exposure are the main routes of worker exposure to the notified polymer (up to 55% concentration) expected to occur during reformulation and end use processes. The engineering controls and personal protective equipment in place during such processes should limit potential for exposure.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the measured low hazard of the notified polymer.

6.3.2. Public health

Direct contact of members of the public with the notified polymer is expected to be negligible as it will be trapped within a matrix. 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

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks of the bags. Any spilt material will be swept up, washed and dried to be entirely reusable. Empty bags will be disposed of to landfill.

During the future possible reformulation where the notified polymer is blended, it is expected that approximately 100 kg will be released from spills, container residue and equipment cleaning.

RELEASE OF CHEMICAL FROM USE

Limited release to the environment is expected during the end use operation. It is expected that most of the hot melt adhesive containing the notified polymer will be recovered from spills and the cleaning of equipment for re-use. Rinsate collected from the cleaning of equipment will be collected in drums and disposed of to a licensed waste landfill site. It is expected that less than 0.1% of the imported resin volume will be required to be disposed of (< 100 kg per annum) to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty import bags and any residual resin they contain, as well as spills from formulation and use, will be disposed of to landfill.

The adhesive will eventually be disposed of to landfill, depending on what it is used for, for example, wood and metals.

7.1.2 Environmental fate

For details of the environmental fate studies please refer to Appendix C.

The notified polymer is not expected to be released to the aquatic compartment. Once the adhesive has hardened, the notified polymer will be immobilised in the polymer matrix and little release is expected. While many of the applications may be recyclable in the future, it is expected that the low volume in any one application will result in most of the resin being land filled at the end of its functional life.

It is likely that in landfill the polymer matrix and the notified polymer would degrade slowly through biotic and abiotic processes into elemental components.

Due to the low water solubility of the notified polymer and high molecular weight it is likely to bind strongly to organic matter in the soil.

The notified polymer may have the potential to bioaccumulate in the environment. It is not readily biodegradable, has a low aqueous solubility, and a log Pow of 4.29. However, the notified polymer is unlikely to reach the aquatic environment as all wastes generated from application processes are collected and isolated for disposal as prescribed industrial wastes and treated prior to environmental release.

7.1.3 Predicted Environmental Concentration (PEC)

Based on the reported use pattern a predicted environmental concentration (PEC) in water cannot be calculated.

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.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	EC50 > 1 mg/L	Not toxic up to the limit of water solubility
Daphnia Toxicity	EC50 > 1 mg/L	Not toxic up to the limit of water solubility
Algal Toxicity	EC50 > 0.044 mg/L	Not toxic up to the limit of water solubility

7.2.1 Predicted No-Effect Concentration

A predicted no effect concentration (PNEC – aquatic ecosystems) of > 0.44 µg/L has been derived by dividing the end point value of 0.044 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as usable toxicity data are available for three trophic levels).

7.3. Environmental risk assessment

The notified polymer is used in a controlled manner within Australia and only a small release of spilled notified polymer to authorised landfill is expected. Residual chemical from equipment washing will be retained and reused, being maintained in a closed system with no sewer entry points.

Based on the reported use pattern a predicted environmental concentration (PEC) cannot be calculated for Australia. However, the notified polymer is used in a highly controlled manner within Australia and little if any release to the aquatic environment is expected. Consequently, the PEC is expected to be extremely low.

The risk to the aquatic environment is expected to be low due to high molecular weight and very low solubility of the notified polymer in water and virtually no release to the aquatic system of the notified polymer within Australia is expected.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is not 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.

	<i>Hazard category</i>	<i>Hazard statement</i>
Acute hazards to the aquatic environment	Chronic 4	May cause long lasting harmful 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

The notified polymer is not considered to pose a risk to the environment based on its use pattern.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following isolation and engineering controls are in place to minimise occupational exposure to the notified polymer:
 - Automated filling processes.
 - Local ventilation.

- Employers should ensure that the following safe work practices are in place to minimise occupational exposure during handling of the notified polymer in adhesion products:
 - Avoid inhalation of vapours that may be emitted from heated adhesion resin.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Gloves, safety glasses, protective clothing.

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 by landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be collected for disposal. Molten adhesive spills should be allowed to cool and collected for disposal. Prevent the notified polymer from contaminating soil or from entering sewers or waterways.

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 chemical has changed from a component of hot-melt adhesives in the construction and packaging industries, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 100 tonnes 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 notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Softening Point** 94.3°C

Method 'Ring & Ball Softening Point' (internal test method)
Test Facility Eastman (reference details not provided)

Density 970 kg/m³ at 25°C

Method Pycnometer
Test Facility Eastman (reference details not provided)

Water Solubility 4.87 x 10⁻⁵ g/L at 20 ± 0.5 °C (pH 6.0)

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Shake Flask Method with HPLC/UV analysis
Test Facility Springborn (2008a)

Partition Coefficient (n-octanol/water) log Pow = 4.29 at 20°C

Method OECD 107 Partition Coefficient (n-octanol/water): Shake Flask Method with HPLC/UV analysis.
Remarks No deviations from standard protocol.
Test Facility Springborn (2008b)

Flash Point 183.9°C

Method Pensky-Martens closed cup.
Remarks Test report not available.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure
Species/Strain	Rat/Sprague Dawley
Vehicle	0.5% aqueous suspension of carboxymethylcellulose
Remarks - Method	No significant protocol deviations.
RESULTS	
LD50	>2000 mg/kg bw
Remarks - Results	No mortality, signs of toxicity, or adverse effects at necropsy were observed at the dose level of 2000 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Eastman Kodak (2004a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Sprague Dawley
Vehicle	Water
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations.
RESULTS	
LD50	>2000 mg/kg bw
Remarks - Results	No mortality, clinical signs, or adverse necropsy findings were observed at the dose level of 2000 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Eastman Kodak (2004b)

B.3. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/Albino (Hra:(NZW)SPF)
Number of Animals	3
Vehicle	Water
Observation Period	72 hr
Type of Dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	No signs of irritation or lesions were noted during the observation period.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	Eastman Kodak (2003a)

B.4. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/Albino (Hra:(NZW)SPF)
Number of Animals	6
Observation Period	72 hr
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	Slight redness was observed in the eyes of two animals at the one hour observation. There were no other signs of irritation observed.
CONCLUSION	The notified chemical is non-irritating to the eye.
TEST FACILITY	Eastman Kodak (2003b)

B.5. Skin sensitisation

TEST SUBSTANCE	Notified polymer	
METHOD	OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test EC Directive 96/54/EC B.6 Skin Sensitisation - Guinea Pig Maximisation Test.	
Species/Strain	Guinea pig (CrI:(HA)BR VAF/Plus)	
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% topical: 100%	
MAIN STUDY		
Number of Animals	Test Group: 20	Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 100%	
Signs of Irritation	None following intradermal injection. Following application of 10% sodium lauryl sulfate, mild or moderate dermal irritation reactions were observed in all animals (including controls). Following topical induction, mild irritation effects were observed in some animals (8/20), including control animals (4/10).	
CHALLENGE PHASE		
1 st challenge	topical: 100%	
Remarks - Method	The preliminary study only tested a single concentration intradermally (5%), and as such, it is uncertain whether this would be the maximum non-irritant dose. However, sodium lauryl sulfate (10%) was applied prior to topical induction to create a local irritation.	

RESULTS

Remarks - Results	No dermal responses were noted in any of the test or control animals following challenge.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Eastman Kodak (2004c)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Piccotac 8095 Hydrocarbon Resin (analogue of the notified polymer containing the same monomers but in different ratios).
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100, <i>E. coli</i> : WP2uvrA ⁻
Metabolic Activation System	S9 mix from Sprague Dawley rat liver induced with Phenobarbitone and β -naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 50-5000 μ g/plate b) Without metabolic activation: 50-5000 μ g/plate
Vehicle	Tetrahydrofuran
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	The test material caused no visible reduction in the growth of the bacterial background lawn and no significant increase in the frequency of revertant colonies at any dose level in any strain. Precipitation was observed at and above 500 μ g/plate in all tested strains.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (2005)

B.7. Genotoxicity – in vivo

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/Albino Crl:CD-1(ICR)BR
Route of Administration	Intraperitoneal
Vehicle	Arachis oil
Remarks - Method	No significant protocol deviations. A single dose of 2000 mg/kg was tested, with two separate sacrifice times of 24 and 48 hours.

RESULTS

Doses Producing Toxicity	A small but statistically significant decrease in the PCE/NCE ratio was observed in the 24-hour dose group compared to the control. This is suggestive that the test substance reached the bone marrow target tissue.
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Genotoxic Effects	There were no statistically increases in the frequency of micronucleated polychromatic erythrocytes (PCE) compared to the controls.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo mouse micronucleus assay.
TEST FACILITY	SafePharm (2007)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Sodium benzoate
Remarks – Method	There were some temperature deviations beyond that specified by the protocol, however, such deviations did not adversely affect the results of this study.

RESULTS

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
1	-0.30	1	10.73
3	0.67	3	52.89
7	2.32	7	85.21
11	-1.69	11	86.32
14	1.32	14	92.77
19	3.47	19	93.92
23	-0.28	23	88.52
29	-0.02	29	92.27

Remarks – Results	<p>The mean cumulative net CO₂ evolved (amount of biodegradation) from the aqueous medium fortified with the notified polymer at 10 mg C/L was -0.02% of the theoretical amount (based on inorganic carbon measurements). The toxicity control evolved 47.39% of the theoretical carbon available for biodegradation, which indicates that the notified polymer was not inhibitory to the biodegradation of the reference compound.</p> <p>The cumulative net CO₂ evolved from the sodium benzoate procedural control was 86.32% of theoretical by day 11, thus exceeding the "pass" criteria of the test (reaching 60% or greater CO₂ evolution within 28 days and within a 10-day window of reaching 10% biodegradation). This rapid degradation of the reference substance confirmed the presence of an acceptable microbial community and confirmed system integrity.</p>
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CONCLUSION	The notified chemical cannot be classified as ready biodegradable.
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TEST FACILITY	Springborn (2007)
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C.1.2. Bioaccumulation

No test report is available for bioaccumulation. Due to the low water solubility of the notified polymer it is likely to bind strongly to organic matter in the soil and aquatic exposure will be very limited.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static, Limit test
Species	<i>Pimephales promelas</i>
Exposure Period	96 hours
Auxiliary Solvent	N,N-dimethyl formamide (DMF)
Water Hardness	Not given
Analytical Monitoring	None
Remarks – Method	During the study, the test organisms were not inspected after the first 2 to 4 hours. This deviation did not affect the study outcome.

The test solution was prepared at a concentration of 1 mg/L. Test substance exposure solutions appeared clear and colourless with test substance observed on the surface throughout the study.

RESULTS

Concentration mg/L Nominal	Number of Fish	Mortality				
		1h	24h	48h	72h	96h
Dilution water control A	10	0N	0N	0N	0N	0N
Dilution water control B	10	0N	0N	0N	0N	0N
1 A	10	0N	0N	0N	0N	0N
1 B	10	0N	0N	0N	0N	0N

N = Test organism exhibits normal swimming behaviour compared to controls

LC50	> 1 mg/L at 96 hours.
NOEC	1 mg/L at 96 hours.
Remarks – Results	No mortality or behavioural effects were observed in the controls or 1 mg/L exposure solutions during the study. The 24-, 48-, 72- and 96-hour LC50 values were estimated to be > 1 mg/L. The highest tested concentration causing no ($\leq 10\%$) mortality was determined to be 1 mg/L. The lowest tested concentration causing 100% mortality was not determined.

CONCLUSION	The notified polymer is not toxic to <i>Pimephales promelas</i> up to the limit of its water solubility.
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TEST FACILITY	Eastman Kodak (2003c)
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C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static Test
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	N,N-dimethyl formamide (DMF)
Water Hardness	Not given
Analytical Monitoring	None
Remarks – Method	During the study, the test organisms were not inspected after the first 2 to 4 hours. This deviation did not affect the study outcome.

The test solution was prepared at a concentration of 1 mg/L. All solutions were clear and colourless throughout.

RESULTS

Concentration mg/L Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
Dilution water control A	10	0N	0N
Dilution water control B	10	0N	0N
1A	10	0N	0N
1B	10	0N	0N

N = Test organism exhibits normal swimming behaviour compared to controls

LC50 >1 mg/L at 48 hours

NOEC 1 mg/L at 48 hours

Remarks – Results No immobility or behavioural effects were observed in the controls or 1 mg/L test substance exposures during the study. Statistical analysis of the data was not performed due to the lack of observed effects. The 24- and 48-hour EC50 values were estimated to be > 1mg/L. The highest tested concentration causing no immobility was determined to be 1 mg/L. The lowest tested concentration causing 100% immobility was not determined.

CONCLUSION The notified polymer is not toxic to *Daphnia magna* up to the limit of its water solubility.

TEST FACILITY Eastman Kodak (2003d)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species Freshwater Green Alga, *Pseudokirchneriella subcapitata*

Exposure Period 72 hours

Concentration Range Water accommodated fraction of 1400 mg a.i./L (expected to be approximately 0.050 mg a.i./L based on the water solubility of the test substance).

Nominal 0.050 mg/L

Concentration Range

Actual

Water Hardness

Analytical Monitoring

Remarks – Method

Not given

HPLC/UV

There were no deviations from the protocol during this study.

Mixtures of the notified polymer were prepared in sterile AAP medium and following removal of undissolved material, the concentration of the notified polymer in solution was analysed to be approximately 0.050 mg/L, similar to the water solubility limit.

RESULTS

Biomass (cell density)		Growth rate	
Control	Notified polymer	Control	Notified polymer
at 72 h	0.044 mg/L at 72 h	at 72 h	0.044 mg/L at 72 h
126.13	131.96	1.66	1.68

Remarks – Results At test termination (72 hours), cells exposed to the treatment level tested and the control were observed to be normal. The 72-hour cell density in the control averaged 126.13 x 10⁴ cells/mL. Cell density in the 0.044 mg/L treatment level averaged 131.96 x 10⁴ cells/mL, after 72 hours of exposure.

Cell biomass - The 0- to 72-hour yield in the control averaged 125.13 x

10^4 cells/mL. The 0- to 72-hour yield in the 0.044 mg a.i./L treatment level averaged 130.96×10^4 cells/mL. The percent inhibition of 72-hour yield in the 0.044 mg a.i./L solution was -5% relative to the control, indicating an increase in algal density at the termination of the exposure.

The 0- to 72-hour growth rate in the control averaged 1.66 days^{-1} . The 0- to 72-hour growth rate in the 0.044 mg a.i./L treatment level averaged 1.68 days^{-1} . The percent inhibition of 72-hour growth rate in the 0.044 mg a.i./L solution was -1% relative to the control.

Based on these results, the EC50 values for 72-hour yield and average growth rate were empirically estimated to be $>0.044 \text{ mg a.i./L}$, above the solubility limit of the notified polymer in algal growth medium. Since $<20\%$ inhibition was observed for both yield and growth rate, and since the nominal concentration tested, 0.050 mg /L , was established as the water solubility limit of the notified polymer, additional testing to further define the EC50 values was not performed.

The following acceptance criteria were required by the protocol:

Acceptance Criteria for Control	Study Results
Exceed 16×10^4 cells/mL at 72 hours	126.13×10^4 cells/mL
Mean daily growth rate CV* $< 35\%$	21%
0 – 72-hour growth rate CV* $< 7\%$	4.82%

*CV = mean coefficient of variation

CONCLUSION

The notified polymer is not toxic to *Pseudokirchneriella subcapitata* up to the limit of its water solubility.

TEST FACILITY

Springborn (2008c)

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