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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in EPR Resin

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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

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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This notification has been conducted using the cooperative arrangement with the Office of Pollution Prevention and Toxics (OPPT), of the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified polymer as conducted by the US EPA was provided to NICNAS, and where appropriate, has been 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.

Polymer in EPR Resin

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
DuPont (Australia) Ltd (ABN 59 000 716 469)
7 Eden Park Drive
Macquarie Park NSW 2113

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, polymer constituents, residual monomers/impurities, use details, import volume and the identity of the 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, water solubility, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, flash point, flammability limits and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2000) and USA (1999)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
EPR Resin

CAS NUMBER
Not assigned

MOLECULAR WEIGHT
> 1000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Milky aqueous dispersion

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported as a component of an aqueous dispersion.
Boiling Point	Not determined	Imported as a component of an aqueous dispersion.
Density	1010 kg/m^3	MSDS
Vapour Pressure	< 1.3 × 10^{-9} kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007)
Water Solubility	Not determined	Determination of the water solubility of the notified polymer was not technically feasible due to the formation of cloudy, soapy, stable emulsions that could not be cleared by filtration or centrifugation. The notified polymer is expected to be dispersible in water based on the presence of hydrophilic moieties within the chemical structure and the use pattern.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functionality that may slowly hydrolyse in the environmental pH range (4-9)
Partition Coefficient (n-octanol/water)	log K_{ow} < 2.13	Estimated by HPLC method (as stated in the US PMN report).
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to soil, sediment and sludge based on its high molecular weight and the presence of potentially cationic functional groups
Dissociation Constant	Not determined	The notified polymer is a salt and will be ionised in the environmental pH range (4-9).
Particle Size	Not determined	Imported as a component of an aqueous dispersion.
Flash Point	Not determined	Imported as a component of an aqueous dispersion.
Flammability	Not determined	Imported as a component of an aqueous dispersion.
Autoignition Temperature	Not determined	Imported as a component of an aqueous dispersion.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

DISCUSSION OF PROPERTIES

Reactivity

Stable under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured within Australia.

The resin containing the notified polymer (< 5%) will be imported as an aqueous dispersion.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 5	< 10	< 10	< 10	< 10

PORT OF ENTRY
Melbourne and Adelaide.

TRANSPORTATION AND PACKAGING
The notified polymer (< 5% in aqueous dispersion) will be imported in 1,040 L containers and will be transported to the notifiers depot by road. The notified polymer will then be transferred to a 20,000 L road tanker for delivery to the end use site.

USE
The notified polymer will be used as a component of automotive primer paint at concentrations up to 5%.

OPERATION DESCRIPTION
The paint containing the notified polymer (< 5%) will be imported in 1,040 L Shutz boxes before being transferred to a dedicated 20,000 L road tanker for transport to end use site. The application of the paint containing the notified polymer to automotive parts is a closed process. The paint will be pumped from the road tanker into a holding tank before being transferred to an electro-coating bath where the automotive parts are coated before being heated to 163°C to cure the paint and crosslink the notified polymer to other components in the paint. Quality control measurements will be conducted on the electro-coating solution and this solution will also be filtered at various stages of the process. The primer paint containing the notified polymer will be covered by an additional undercoat and then 2-3 topcoats.

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	10	4	40
Storemen	4	1	40
E-coat technicians	4	1	100
Servicing/maintenance	4	1.5	50
Quality Control	2	2	240
Waste treatment/disposal	2	0.5	220

EXPOSURE DETAILS
Transport workers, including those involved in transfer of the notified polymer from import containers to road tankers, are not expected to be exposed to the notified polymer except in the event of an accident. Delivery and container storage areas will be covered and bunded to contain any accidental spills or leakages.

End-use
Exposure to the notified polymer (< 5% concentration) by store workers is not anticipated because of the use of automated pumps and dedicated flexible hose lines for transfer of the solution between the road tanker, holding tank and e-coat bath. Potential dermal and ocular exposure is expected to be further minimised by measures such as container-venting during pumping to reduce the risk of bubbling and spillage and wearing of personal protective equipment (PPE) such as gloves and overalls.

Electro-coating technicians may experience dermal and accidental ocular exposure to < 5% notified polymer due to spills or splashes during the electro-coating process; however the level of exposure is expected to be minimised due to the highly automated coating process whereby the vehicle bodies are moved through the paint and rinse tanks via conveyors. Exposure will be further reduced by workers wearing PPE such as coveralls, face shields or goggles and gloves.

Quality control workers may experience dermal and accidental ocular exposure during testing; however

exposure is likely to be reduced by the use of PPE including gloves and goggles.

Dermal and ocular exposure may occur to workers involved in maintenance, servicing and waste disposal, but the level of exposure is expected to be reduced by the use of PPE (gloves, goggles, coveralls) and dedicated hose lines and valves in the e-coat bath system.

6.1.2. Public exposure

Products containing the notified polymer will not be sold to the public. The notified polymer is a component in primer paint for automobiles which will be covered by additional layers of paint and hence contact with the finished articles to which the paint is applied will not result in any dermal exposure.

6.2. Human health effects assessment

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

The notified polymer is comprised of three components that differ only in the terminal end groups. The analogue polymer is structurally identical to one of the components for the notified polymer. The other two components of the notified polymer differ only by one terminal group from the analogue which is not expected to contribute to toxicity. Therefore, the tested polymer is considered to be an acceptable analogue for the notified polymer.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 400 mg/kg bw

Toxicokinetics, metabolism and distribution.
Based on the high molecular weight (Mn > 1000 Da) absorption across biological membranes is expected to be low. However, systemic toxicity cannot be ruled out given the high percentage (~20%) of low molecular weight species (< 1000 Da).

Acute toxicity.
An LD50 > 2000 mg/kg bw was determined for a 20% aqueous solution of the analogue polymer when tested in rats. Correcting for the concentration, this implies that the analogue polymer, and by inference the notified polymer has an LD50 > 400 mg/kg bw. Given a chemical is of low toxicity if the LD50 > 2000 mg/kg bw, this result is inconclusive. No data was provided on acute dermal or inhalation toxicity of the notified polymer.

Irritation and sensitisation
The notified polymer does not contain any structural alerts for irritation or sensitisation.

Health hazard classification
Based on the limited data provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified polymer is expected to be of low acute oral toxicity and is not expected to have irritating or sensitising potential. The risk of systemic effects cannot be ruled out given the high percentage of low molecular weight species.

Worker exposure to the notified polymer is expected to be low based on the low concentration of the notified polymer (< 5%) in the imported resin combined with the automated and closed processes and the use of PPE. Therefore, the risk to the occupational health and safety of workers is not considered unacceptable, due to the expected low exposure to the notified polymer.

6.3.2. Public health

The notified polymer or products containing it will not be sold to the public. The public may be exposed to automobiles that have the notified polymer as a component in primer paint. However the primer paint will be covered by additional layers of paint and hence contact with the finished articles to which the paint is applied will not result in any dermal exposure to the notified polymer. Therefore the risk to the public from the

notified polymer is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a clear aqueous resin solution for end use as component in primer paint for automobiles. Further transportation of the product containing the notified polymer by road tanker to the end user's site will occur in Australia. Empty import containers containing residues of the notified polymer (estimated to be less than 0.02% of the annual import volume) will be rinsed with water. Any rinsings from the containers and pumping equipment will be placed into the road tanker. Rinsed containers will be sold to a local drum recycler for reuse. The road tanker will be dedicated to carrying the liquid product and will not be washed out between deliveries. No significant release from spillage is expected for these operations, however, in the event of an accidental spill the product containing the notified polymer will be absorbed with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The potential release scenarios of the notified polymer at the car manufacturing plant include:

a) Road tanker delivery to the plant

No significant release of the product containing the notified polymer is expected during transport. In the unlikely event of a spill, the product containing the notified polymer will either be contained and disposed to landfill or will be drained to the internal waste water treatment plant.

b) Electrocoat (e-coat) immersion tank

Automotive bodies and parts are passed through the electrocoat tank by conveyer where the e-coating is deposited on the surface. The e-coat tank is replenished with additional coating from an automated pump, and there is potential for a small amount to overflow. Overflow and excess coating is expected to be recycled or directed to an internal waste water treatment plant (WWTP). Residues collected from filtration of the e-coat tank contents will also be directed to the internal WWTP. It is expected the filters will eventually be dried and disposed to landfill. At no time are the contents of the tank removed for tank cleaning or rinsing. No significant release of the notified polymer is expected at this stage.

c) E-Coat wash water tanks

Rinsing of the automotive metal surfaces after deposition is conducted by a closed loop process, with successive rinses, each feeding back to the previous rinse. Rinse material is obtained from the paint itself by ultrafiltration. The final rinse drainings and filtration residues, containing a very small amount of the notified polymer, are directed to the internal WWTP. In the WWTP, the waste water is treated with sodium hydroxide to aid in the precipitation and coagulation of any suspended or dissolved solids to form a sludge. This sludge is then separated from volatile content through a filtration process and disposed of to landfill.

The notifier indicates that data for the end user's internal waste water treatment plant is not useful for calculation purposes as there are waste streams from other areas of the plant mixed with the e-coat process. Data were therefore used for a large overseas automotive plant in the US PMN documents for this polymer. The overseas data can be assumed to be an estimate of a worst case scenario for the release of notified polymer from use in Australia. Assuming 0.57 kg/day of the notified polymer is released to the internal water treatment processing plant and the e-coat process functions for 340 days per year, the release of the notified polymer to the treatment plant is 193.8 kg per annum (= 0.57 kg/day × 340 days/year). Assuming the coagulation method produces 96% precipitation/coagulation of the notified polymer, the release of the notified polymer with the effluent to the local sewerage treatment plant is 7.75 kg per annum (193.8 kg/year × 4%).

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will coat automobile components and will become irreversibly cross-linked to form part of an inert coating matrix during the heat curing process. The cross-linked notified polymer is expected to share the fate of the coated automobile parts, and at the end of the car's useful life, the coated metal articles will be sent to metal reclamation facilities or be disposed of to landfill.

7.1.2 Environmental fate

Most of the notified polymer will be cured into an inert, cross-linked matrix as part of the e-coating process. The notified polymer will share the fate of the coated automotive parts, which will involve eventual disposal to landfill or thermal decomposition during metal reclamation. In its cross-linked form, the notified polymer is not expected to be bioavailable or mobile in the environment.

Most of the residues of the notified polymer in waste streams generated from the e-coat process will be captured by on-site WWTPs. However, a small amount of the notified polymer may not captured by these systems and could be released to the sewer. In sewage treatment plants, the notified polymer is expected to adsorb to the sludge and sediment based on its cationic characteristics. Sludge from treatment plants may be collected for disposal to landfill or used in soil remediation. The notified polymer is not readily biodegradable, based on studies conducted on an analogue polymer, however, it is not expected to bioaccumulate or leach due to its high molecular weight and charge density. In landfill or in remediated soil, it will undergo slow biotic or abiotic degradation processes. The notified polymer is expected to generate water, oxides of carbon and nitrogen, and inorganic salts during degradation in landfill or by thermal decomposition.

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

7.1.3 Predicted Environmental Concentration (PEC)

Based on data for a large overseas automotive plant, the estimated release of the notified polymer in effluent from the end user's waste water treatment plant to the local sewage treatment plant is a maximum of 7.75 kg/year. Assuming a flow of 85 ML/day for the individual local sewage treatment plant, release on 340 days per annum and no solids removal during sewage treatment, which is the worst case scenario, the PEC can be calculated as 0.27 µg/L (= 7.75 kg/year ÷ 340 days/year ÷ 85 ML/day) for release to a river and 0.027 µg/L (= 0.27 µg/L × 0.1) for release to the ocean.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on an analogue polymer are summarised in the table below. As the tests were conducted on an aqueous solution containing the analogue polymer (20%), the results for the test substance have been corrected to reflect the endpoints of the analogue polymer. The notified polymer is comprised of three components that differ only in the terminal end groups. The analogue polymer is structurally identical to one of the components for the notified polymer. The other two components of the notified polymer differ only by one terminal group from the analogue which is not expected to contribute to toxicity. Therefore, the tested polymer is considered to be an acceptable analogue for the notified polymer. Details of the fish and daphnia studies can be found in Appendix C.

Studies on the effects to algae from the notified polymer, or a suitable analogue, were not provided. The algal endpoint for the notified polymer was calculated with a Structure Activity Relationship (SAR) equation based on the cation charge density of the polymer (Boethling and Nabholz, 1997). The predicted endpoint, which has been modified by a mitigation factor to account for the anticipated binding of the polymer with organic carbon in surface waters, is detailed in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 2.3 mg/L*	Toxic to fish
Daphnia Toxicity	EC50 (48 h) = 6.0 mg/L*	Toxic to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 9.7 mg/L†	Toxic to algae

*Analogue data
†Estimated with a QSAR

The notified polymer is potentially toxic to algae in surface waters with typical levels of total organic carbon. The SAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the notified polymer for acute and long term hazards.

However, under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009) the notified polymer is formally classified as toxic to fish and aquatic invertebrates. Based on this toxicity, the notified polymer is classified as 'Acute Category 2; Toxic to aquatic life'. The notified polymer is not readily biodegradable, and based on its high acute toxicity it is classified as 'Chronic Category

2; Toxic to aquatic life with long lasting effects'.

7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated using the endpoint for the most sensitive trophic level (fish LC50 (96 h) = 2.3 mg/L) and an assessment factor of 500, as although the endpoints for three trophic levels are available, they are derived from the results for an analogue polymer and a SAR estimate based on groupings of broadly related polymers.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish)	2.30	mg/L
Assessment Factor	500	
PNEC:	4.60	µg/L

7.3. Environmental risk assessment

The risk quotient (Q = PEC/PNEC) has been calculated below:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.27	4.6	0.058
Q - Ocean:	0.03	4.6	0.006

As the risk quotient is less than 1, the notified polymer is not expected to pose a risk to the environment when it is introduced at the proposed maximum annual importation volume and used as proposed.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited data provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the analogue 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***
Aquatic environment	Acute Category 2	Toxic to aquatic life
	Chronic Category 2	Toxic to aquatic life with long lasting effects

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an 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 expected 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:
  - Automated and closed systems

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure during handling of the notified polymer:
  - Gloves
  - 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 to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

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

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

(1) Under Section 64(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 a component of automotive paint at concentrations up to 5%, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 10 tonnes, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue polymer (20%) in water (78%) and butanol (2%)

METHOD
- Species/Strain: Rat/Crl:CD(SD)BR
- Vehicle: Test substance administered as supplied.
- Remarks - Method: GLP compliant.
  No significant protocol deviations.

RESULTS

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

- LD50: > 2000 mg/kg bw for the test substance
  > 400 mg/kg bw for analogue polymer
- Signs of Toxicity: There were no deaths.
  No signs of systemic toxicity were noted.
- Effects in Organs: No abnormalities were noted at necroscopy
- Remarks - Results: Body weight gains were as expected in all but three female rats which showed temporary body weight losses of 5, 4 and 3% at various points of the study but otherwise had weight gains similar to the other two female animals over the entire test period.

CONCLUSION: The analogue polymer at 20% is of low toxicity via the oral route. The LD50 derived for the 100% notified polymer (> 400 mg/kg bw) is inconclusive, as it falls within the 'harmful if swallowed' range according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

TEST FACILITY: E. I. du Pont de Nemours and Company (1997a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue polymer (concentration not specified)
METHOD	AEM SOP MI051-P Ready biodegradability: Closed Bottle Test
Inoculum	Wilmington POTW treatment works
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biodegradation was measured as the loss of dissolved oxygen within the closed bottle.
Remarks - Method	Summary provided only. No amendments to the protocol were reported. The theoretical oxygen demand (ThOD) of the test substance was calculated as 2.01 mg O_2 per mg of active substance. The notified polymer is comprised of three components that differ only in the terminal end groups. The analogue polymer is structurally identical to one of the components for the notified polymer. The other two components of the notified polymer differ only by one terminal group from the analogue which is not expected to contribute to toxicity. Therefore, the tested polymer is considered to be an acceptable analogue for the notified polymer.

RESULTS

Test substance		*Sodium Acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	4	7	66
14	11	11	95
21	11	21	-
28	10	28	-

Remarks - Results	The reference substance achieved > 60% degradation within 7 days, thereby validating the test. The test substance achieved a maximum of 11% degradation by day 14, and therefore the test substance is not readily degradable. Additionally, the biodegradability of the counter ion to the analogue polymer may significantly contribute to the limited observed degradation.
CONCLUSION	The test substance and, by inference, the notified polymer are not readily biodegradable.
TEST FACILITY	E. I. du Pont de Nemours and Company (1997b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue polymer (20% in aqueous solution)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static
Species	Fathead Minnows (*Pimephales promelas*)
Exposure Period	96 hours
Auxiliary Solvent	Butanol (<0.01% in total, from the test substance)

Water Hardness	81 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	Following a range-finding test, groups of 5 fish were exposed to the test substance at nominal concentrations of 4, 6, 11, 18 and 30 mg/L (in duplicate). A control was run in parallel. Test conditions were: 20.0 - 21.1°C, pH 7.5 – 7.7, 6.4 – 8.9 mg O_2/L. Statistical analysis was conducted by the moving average method. The analogue polymer contains one monomer constituent less than the notified polymer and hence a proportion of the notified polymer will be equivalent to the analogue polymer. The extra monomer in the notified polymer is not expected to contribute to the toxicity. The tested polymer is therefore considered to be an acceptable analogue for the notified polymer.

RESULTS

Nominal Concentration mg test substance/L	*Number of Fish*	*Cumulative Mortality*			
		24 h	*48 h*	*72 h*	*96 h*
0	2 × 5	0	0	0	0
4	2 × 5	0	0	0	0
6	2 × 5	0	0	0	0
11	2 × 5	1	4	4	4
18	2 × 5	10	10	10	10
30	2 × 5	10	10	10	10

LC50	11.4 mg test substance/L at 96 hours (95% CI: 8.9-13.9 mg/L) 2.3 mg analogue polymer/L at 96 hours
NOEC (or LOEC)	Not reported
Remarks – Results	There was no mortality observed in the control, thereby validating the test. The test was conducted on an aqueous solution containing the analogue polymer (20%), therefore, the results for the test substance have been corrected to reflect the endpoints of the analogue polymer. Solutions were clear at the start of the test, however some test concentrations became slightly cloudy over the duration of the test. Sublethal effects including gasping for air, lethargy and swimming at the surface were observed in the 11 mg/L test solution. In the 18 and 30 mg/L test solutions, in which total mortality was observed, debris had adhered to the fins and gills of the fish.

CONCLUSION	The analogue polymer and, by inference, the notified polymer are toxic to fish.
TEST FACILITY	E. I. du Pont de Nemours and Company (1997c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue polymer (20% in aqueous solution)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test - Static EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Butanol (<0.01% in total, from the test substance)
Water Hardness	85 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	Following a range-finding test, groups of 5 daphnids were exposed to the test substance at concentrations of 4, 6, 11, 18 and 30 mg/L (4 replicates

per concentration). A control was run in parallel. Test conditions were: 19.5 – 19.7°C, pH 7.6 – 8.2, 8.0 - 8.9 mg O_2/L.
The test substance was identical to that used in the fish acute toxicity test.

RESULTS

Nominal Concentration mg test substance/L	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	4 × 5	0	0
4	4 × 5	0	0
6	4 × 5	0	0
11	4 × 5	0	3
18	4 × 5	0	7
30	4 × 5	0	10

LC50	30 mg test substance/L at 48 hours 6 mg analogue polymer/L at 48 hours
NOEC (or LOEC)	Not reported
Remarks - Results	There was no immobility observed in the control, thereby validating the test. The results for the test substance have been corrected to reflect the endpoints of the analogue polymer. No meaningful confidence interval could be calculated for the test substance

CONCLUSION The analogue polymer and, by inference, the notified polymer are toxic to aquatic invertebrates.

TEST FACILITY E. I. du Pont de Nemours and Company (1997d)

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