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

FULL PUBLIC REPORT

Polymer in ZELAN 8719

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 in ZELAN 8719****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 $M_n \geq 1000$ 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, polymer constituents, molecular weight, spectral data, purity, residual monomers, hazardous impurities, percentage of polymer in finished products and reactive groups in the polymer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: melting point/freezing point, vapour pressure, partition coefficient, adsorption/desorption, flammability and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

NOTIFICATION IN OTHER COUNTRIES

USA (2001)
Canada (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

ZELAN 8719 (aqueous product containing up to 30% notified polymer)

OTHER NAME(S)

SR-500 (imported product containing up to 25% notified polymer)

ANALYTICAL DATA

Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Dark brown liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced as an aqueous solution.
Boiling Point	~ 100°C at 101.3 kPa*	MSDS
Density	1100 kg/m ³ *	MSDS
Vapour Pressure	< 1.3 × 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007)
Water Solubility	≤1.76 g/L at 20°C, pH 2	Measured
Hydrolysis as a Function of pH	Not tested	The notified polymer does not contain functional groups that will hydrolyse over the environmental pH range 4–9
Partition Coefficient (n-octanol/water)	Not tested	Expected to have a low log Pow due to the ready water solubility and ionicity of the notified polymer
Adsorption/Desorption	Not tested	The notified polymer is expected to partially partition to soil
Dissociation Constant	pKa = 4.2 and 5.6	Estimated. Expected to be fully dissociated within the environmental pH range 4–9.
Flash Point	> 100°C at 101.3 kPa*	Introduced as an aqueous solution.
Flammability	Not expected to be highly flammable	Introduced as an aqueous solution.
Autoignition Temperature	Not determined	Introduced as an aqueous solution.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosives.

* For SR-500 containing up to 25% notified polymer.

DISCUSSION OF PROPERTIES

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

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 notified polymer will be imported at up to 25% as a component of an aqueous based stain resistant formulation.

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

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

PORT OF ENTRY

Sydney

TRANSPORTATION AND PACKAGING

The notified polymer (at up to 25%) will be imported by sea in 200 L steel drums and transported by road from the wharf to the notifier's warehouse.

USE

The notified polymer will be used as a component of a stain resistant formulation for carpets.

OPERATION DESCRIPTION

At the end-users site, the imported product containing the notified polymer at up to 25% will be poured into a holding tank and diluted with water to give the finished stain resist formulation containing up to 1% of the notified polymer. The diluted stain resist formulation will then be pumped into the spray dunk automated applicator used to treat carpets in an enclosed application area fitted with an exhaust/filter system.

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	~25	0.1-4	1-2
Application to carpet textiles	2-4	1	80
Maintenance	~5	6	4
Quality control	1	0.7	80

EXPOSURE DETAILS

Transport and Storage

Waterfront, transport and warehouse workers will not be exposed to the notified polymer ($\leq 25\%$) except in an accident.

Application

Dermal and ocular exposure to the notified polymer ($\leq 25\%$) by workers will be possible when it is transferred to the holding tank from the imported drums, during equipment maintenance or quality control testing. Exposure is expected to be minimised by the use of PPE including coveralls, goggles and gloves. Inhalation exposure to the notified polymer is likely to be negligible due to the expected low vapour pressure ($< 1.3 \times 10^{-9}$ kPa) of the notified polymer, the use of enclosed systems and exhaust ventilation.

End use

Dermal exposure to notified polymer by workers during the installation or use of carpet is expected. However, the notified polymer is designed to bind to the carpet fibres and hence dermal transfer to workers is expected to be low.

6.1.2. Public exposure

Products containing the notified polymer will not be sold to the public. However, the public will be exposed to the notified polymer through the use of carpet to which it has been applied. The notified polymer is designed to bind to the carpet fibres and hence dermal transfer to the public is expected to be low, with the notifier estimating $< 5\%$ removed from the carpet per annum due to normal use.

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	LD50 > 3300 mg/kg bw; low toxicity
Rabbit, skin irritation (30% notified polymer)	Slightly irritating
Rabbit, eye irritation (30% notified polymer)	Irritating
Rabbit, eye irritation (15-25% notified polymer)	Slightly irritating

Toxicokinetics, metabolism and distribution.

The notified polymer is not expected to be absorbed across biological membranes, based on the high molecular weight ($> 1,000$ Da).

Acute toxicity.

The notified polymer is of low toxicity after oral exposure based on a study conducted in rats.

Irritation

The notified polymer is considered to be slightly irritating to the skin based on a test conducted in rabbits with a 30% aqueous solution of the notified polymer.

The notified polymer was found to be irritating and slightly irritating to the eye when tested at concentrations of 30 and 15-25% respectively. The volume of test substance used in each test (0.01 mL) was 10 times less than that specified in the OECD test guideline. Interestingly, the greatest effects observed were when the eyes were washed 20 seconds after instillation of the test substance. Based on the irritancy effects observed in the study conducted with a 30% aqueous solution of the notified polymer, the notified polymer is classifiable as 'irritating to eyes' (R36) according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Health hazard classification

Based on the eye irritation effects of the notified polymer at 30% concentration, it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

Xi: R36 Irritating to eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified polymer is an eye irritant and is slightly irritating to the skin. Dermal and ocular exposure to the notified polymer ($\leq 25\%$) is expected to be greatest during transfer of the imported product to the holding tank. However, dermal and ocular exposure is expected to be minimised due to the expected use of personal protective equipment by workers. Therefore, the risk of irritation from exposure to the notified polymer by workers is not considered to be unacceptable.

6.3.2. Public health

Dermal exposure to the notified polymer by the public is expected during the use of carpet to which it has been applied. However, the notified polymer is designed to bind to the carpet fibres and hence dermal transfer to the public is expected to be low. Therefore the risk to the public 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 ready-to-use formulation which will undergo further blending at the sites of use. Accidental spills and leaks during transport are expected to be physically contained and disposed of to landfill.

The notified polymer (diluted in water) will be applied to carpet by a combination of enclosed spray and trough dipping systems. After application, the notified polymer is effectively "fixed" to the textile fibres by a high volume, low temperature drying process. The notified polymer is consumed from solution during the application process, thus it is expected that $< 5\%$ of the annual introduction volume of notified polymer may be released from the application facility, as spent solution or from equipment cleaning and maintenance operations. The spent spray/dipping solution containing residual notified polymer is expected to be sent to an on-site facility for flocculation treatment. The solid fraction from the flocculation process is removed, dried, and sent to landfill. Residual notified polymer not captured by the flocculation treatment will be sent to sewer with the aqueous waste and normal operations in sewage treatment plants may remove up to 50% of the notified polymer from influents.

RELEASE OF CHEMICAL FROM USE

It is estimated by the notifier that ~25% of the applied notified polymer may be physically abraded from treated carpet. Of this, the notifier estimates that 60-80% will be collected by routine vacuuming for disposal to landfill as solid waste. The remaining 20-40% of the abraded fraction ($\leq 10\%$ of the overall import quantity) is expected to be collected by steam cleaning or water/shampoo cleaning, and disposed of to sewer. Partial removal of aqueous notified polymer to sludge within sewage treatment plants (STPs) is likely to occur, with eventual disposal of solid waste to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The remaining quantity of notified polymer (~70%) is expected to share the fate of the carpet or article to which it has been applied, and is likely to be disposed of to landfill. In landfill, the notified polymer will ultimately degrade to water, oxides of carbon, and inorganic salts.

7.1.2 Environmental fate

The majority of the notified polymer will be consigned to landfill where the notified polymer will be fixed to coated carpet or treated articles, thus it is not expected to be bioavailable. Residual notified polymer in spent application and shampooing solutions is likely to be disposed of to sewer, where around half will partition to the sludge and be disposed of to landfill. Whilst the notified polymer is not readily biodegradable and does not contain readily hydrolysable functional groups, in water it is not likely to bioaccumulate due to its high molecular weight, ready solubility and expected low partition coefficient. It is expected to ultimately degrade to water, oxides of carbon, and inorganic salts.

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

7.1.3 Predicted Environmental Concentration (PEC)

A worst case PEC might be calculated if it is assumed that 15% of the notified polymer (maximum 750kg) is released to sewer as spent application solutions (~5%) generated from carpet production and solutions used to clean treated articles (~10%). A conservative estimate of 80 days has been used to represent the carpet production scenario, despite carpet cleaning potentially occurring 365 days a year.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	15.000%	
Annual quantity of polymer released to sewer	750	kg/year
Days per year where release occurs	80	days/year
Daily polymer release:	9.38	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:	2.22	$\mu\text{g/L}$
PEC - Ocean:	0.22	$\mu\text{g/L}$

This worst case estimate does not account for partial removal of the notified polymer from the water column by flocculation treatment and STP processes, and assumes that it is released as effluent. STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 2.22 $\mu\text{g/L}$ may potentially result in a soil concentration of approximately 14.8 $\mu\text{g/kg}$. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 73.8 $\mu\text{g/kg}$ and 148 $\mu\text{g/kg}$, respectively.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on an aqueous solution containing 27% of 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	LC50 (96 h) >500 mg/L	Not harmful to fish
Daphnia Toxicity	EC50 (48 h) >500 mg/L	Not harmful to aquatic invertebrates

Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on the alternating carbons of the polymer backbone. This does not apply to the notified polymer.

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified polymer is not harmful to fish and aquatic invertebrates. Details of these studies can be found in Appendix C.

7.2.1 Predicted No-Effect Concentration

The PNEC has been calculated using the fish and daphnia acute toxicity endpoints of LC50 > 500mg/L and EC50 > 500 mg/L respectively, and an assessment factor of 1000, given less than three acute endpoints are available.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>		
E(L)C50	> 500	mg/L
Assessment Factor	1,000	
PNEC:	> 500	µg/L

7.3. Environmental risk assessment

The risk quotients ($Q = \text{PEC}/\text{PNEC}$) are tabulated below.

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	2.22	> 500	< 0.004
Q - Ocean:	0.22	> 500	< 0.001

A calculated risk quotient < 1 indicates that the notified polymer is not expected to pose any unacceptable risk to aquatic life, even under the conservative exposure assumptions outlined above. The PEC overestimates the likely level of exposure, as it reflects a worst case scenario whereby residual notified polymer is removed from spent application solution by flocculation, and that notified polymer sent to the sewer is likely to be partially removed from the water column by STP processes. The notified polymer is not expected to pose a risk to the environment when used as proposed.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the provided data the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The following risk phrase applies to the notified polymer:

- Xi: R36 Irritating to eyes

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>
Eye irritation	Category 2B	Causes eye irritation

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

REGULATORY CONTROLS

Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified polymer:
 - Xi: R36 Irritating to eyes
- Use the following risk phrases for products/mixtures containing the notified polymer:
 - Conc \geq 20%: R36

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer in the product SR-500:
 - Avoid contact with skin and eyes
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during carpet treatment:
 - impervious 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 to landfill.

Emergency procedures

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

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;
 - the concentration of the notified polymer in the finished stain resist formulation exceeds 1%.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of a stain resistant formulations for carpets or is likely to change significantly;
 - the amount of chemical being introduced has increased from 5 tonnes, or is likely to increase significantly;
 - 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.

Material Safety Data Sheet

The MSDS of 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**Water Solubility** ≤ 1.76 g/L at 20°C, pH 2

Method	OECD TG 120; Solution/Extraction Behaviour of Polymers in Water
Remarks	Initial tests revealed that the notified polymer was soluble at pH = 7 and pH = 9, although only the solubility at pH = 2 was determined in this study. Triplicate samples of notified polymer (2.5 g and 0.25 g) in deionised water (250 mL) were adjusted to pH = 2 (with HCl) and shaken for 24 h at 20°C. Aliquots were filtered and the solubilities were determined by total organic carbon (TOC) and gravimetric analysis. The solubility of 2.5 g samples was found to be 1282 ± 58 mg/L, and the solubility of 0.25 g samples was found to be 236 ± 12 mg/L, as determined by TOC. Gravimetrically, the solubilities were found to be calculated as 1,760 mg/L and 334 mg/L for the 2.5 g and 0.25 g samples respectively. Differences between the solubilities as determined by the different analytical methods is reported to be due to a second filtration step prior to the TOC analysis.
Test Facility	DuPont (2009)

Adsorption/Desorption Not tested

Remarks	Anionic polymers typically have a low sorption to soil, although mobility also depends on the size and weight of the polymer. Those with appreciable solubility and a relatively high molecular weight are expected to partially partition to sludge and be removed from sewage treatment plants by approximately 50% (Boethling & Nabholz, 1996).
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Dissociation Constant pKa = 4.2 and 5.6

Remarks	Not tested. The notified polymer contains functional groups with estimated pKas of 4.2 and 5.6, thus the notified polymer is expected to be fully ionised over the environmental pH range 4–9.
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B.1. Acute toxicity – oral

METHOD	Method equivalent to OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Crl: CD [®] BR
Vehicle	Test substance administered as supplied
Remarks - Method	All animals were dosed by gavage.

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose (test substance) mg/kg bw</i>	<i>Dose (notified polymer) mg/kg bw</i>	<i>Mortality</i>
I	1 male	670	201	0
II	1male	2300	690	0
III	1 male	3400	1020	0
IV	1 male	5000	1500	0
V	1 male	7500	2250	0
VI	1male	11000	3300	0

LD50	> 3300 mg/kg bw
Signs of Toxicity	There were no deaths or test substance-related clinical signs during the study period.
Effects in Organs	Pathological examinations of the test animals were not performed.
Remarks - Results	No bodyweight losses were observed in any animal during the course of the study.

TEST FACILITY	Haskell (1995a)
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METHOD	Method equivalent to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 male
Vehicle	Test substance administered as supplied
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	The observation of the test animals was stopped at 72 hours despite signs of irritation still being present. Under OECD TG 404 observation of the test animals should continue for up to 14 days if signs of irritation are still present.

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	1.2	3	> 72 hours	1
<i>Oedema</i>	0	2 (1 hour)	< 24 hours	0

Remarks - Results	A single 4-hour, semi-occluded application of the test material to the intact skin of the 6 rabbits produced mild erythema in 4 animals, moderate
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erythema in 2 animals and mild oedema in 1 animal at the 1 hour observation period. Slight erythema was observed in 2 animals with the remaining 4 displaying moderate erythema after 24 hours. After 48 hours no erythema was observed in 1 animal with 3 animals displaying slight erythema and 2 animals displaying mild erythema. At the 72 hour observation no erythema was observed in 2 animals with 4 animals displaying slight erythema. No oedema was observed at the 24, 48 and 72 hour observations.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Haskell (1995b)

B.3. Irritation – eye

TEST SUBSTANCE Notified polymer at a 30% concentration in an aqueous solution.

METHOD Method equivalent to OECD TG 405 Acute Eye Irritation/Corrosion.
 Species/Strain Rabbit/New Zealand White
 Number of Animals 2 Male
 Observation Period 7 Days
 Remarks - Method The test methods differed from OECD TG 405 in that in 1 of the 2 animals the eyes were washed approximately 20 seconds after the test substance was administered and in the other animal the eyes were not washed. In the test guideline the eyes should only be washed after 24 hours if considered appropriate. Also 0.01 mL of the test substance was administered rather than 0.1 mL.

RESULTS

Lesion	Mean Score*		Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	Animal No. 1	Animal No. 2			
Conjunctiva: redness	0.33	2.7	3	< 7 days	0
Conjunctiva: chemosis	0	2	3	< 7 days	0
Conjunctiva: discharge	0	1	3	< 48 hours	0
Corneal opacity	0	1.3	2	< 72 hours	0
Iridial inflammation	0	0.7	1	< 72 hours	0

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

Remarks - Results In the results above, animal 1 did not have its eyes washed but animal 2 did. Severe conjunctival redness and epithelial sloughing of the cornea was observed up to the 48 hour observation period in the washed rabbit eye. The unwashed and washed rabbit eyes were normal by 2 and 7 days respectively.

CONCLUSION The notified polymer is irritating to the eye.

TEST FACILITY Haskell (1995c)

B.4. Irritation – eye

TEST SUBSTANCE Notified polymer at a 15-25% concentration in an aqueous solution. Two further chemicals were present in the test substance at 3-10% and 2-5% concentration.

METHOD Method equivalent to OECD TG 405 Acute Eye Irritation/Corrosion.
 Species/Strain Rabbit/New Zealand White

Number of Animals 2 Female
 Observation Period 72 hours
 Remarks - Method The test methods differed from OECD TG 405 in that in 1 of the 2 animals the eyes were washed approximately 20 seconds after the test substance was administered and in the other animal the eyes were not washed. In the test guideline the eyes should only be washed after 24 hours if considered appropriate. Also 0.01 mL of the test substance was administered rather than 0.1 mL.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>		<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	<i>Animal No.</i>	<i>Animal No.</i>			
	1	2			
<i>Conjunctiva: redness</i>	0.3	1.3	2	< 72 hours	0
<i>Conjunctiva: chemosis</i>	0.3	0.7	2 (4 hours)	< 72 hours	0
<i>Conjunctiva: discharge</i>	0	0	2 (4 hours)	< 24 hours	0
<i>Corneal opacity</i>	0	0	1 (1 hour)	< 24 hours	0
<i>Iridial inflammation</i>	0	0.3	1	< 48 hours	0

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

Remarks - Results In the results above, animal 1 did not have its eyes washed but animal 2 did. Blistering of the conjunctiva and nictitating membrane was observed in both animals at the 4 hour observation period. All effects were reversible within the 72 hour observation period.

CONCLUSION

The notified polymer is slightly irritating to the eye.

TEST FACILITY

Haskell (1997)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	TLF-8719 (notified polymer in water)
METHOD	AEM SOP MI051-P Ready Biodegradability: Closed Bottle Test.
Inoculum	Publicly owned treatment works (POTW) of Wilmington City
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	None
Remarks - Method	The test substance and reference substance (sodium acetate) were each added to inoculated medium, and the concentrations of dissolved oxygen were measured on days 0, 7, 14, 21 and 28. Test substance concentrations and the conditions of the study were not reported. The summary results provided by the notifier are presented below.

RESULTS

<i>Test substance</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	0.7	7	>60
14	2.1	14	>70
21	5.7	21	Not reported
28	27.1	28	Not reported

Remarks - Results The test substance showed 27% degradation by day 28 and failed to reach 60% degradation within a 14 day window, hence it is not considered readily biodegradable.
The reference substance degraded by >60% in a ten day window, thus validating the test.

CONCLUSION The notified polymer is not readily biodegradable

TEST FACILITY E. I. du Pont de Nemours and Co. (1996)

C.1.2. Bioaccumulation

METHOD	Test not conducted
Remarks - Results	The notified polymer is not expected to bioaccumulate due to its high molecular weight and ready solubility in water

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	TLF-8719 (notified polymer in water)
METHOD	Static, Acute 96-hour Screening Test of H-21821 to Fathead Minnows (Haskell Laboratory for Toxicology and Industrial Medicine Protocol)
Species	<i>Pimephales promelas</i> (Fathead minnow)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None

Remarks – Method

A limit test was conducted on the test substance at nominal concentrations of 0.5 mg/L, 1.0 mg/L, 50 mg/L, 500 mg/L and 5000 mg/L. The test medium was unaerated with pH ranging from 6.7–7.5, and 7.7–8.7 mg O₂/L). The fish were observed for mortality at 96 h.

RESULTS

Concentration mg/L		Number of Fish	Mortality					
Nominal	Actual		1 h	24 h	48 h	72 h	96 h	
0	Not reported	Not reported	0	0	0	0	0	
0.5	Not reported	Not reported	0	0	0	0	0	
1.0	Not reported	Not reported	0	0	0	0	0	
50	Not reported	Not reported	0	0	0	0	0	
500	Not reported	Not reported	0	0	0	0	0	
5000	Not reported	Not reported	Not reported					100

LC50

> 500 mg/L at 96 hours.

NOEC

500 mg/L at 96 hours.

Remarks – Results

All test solutions were clear except for the 500 mg/L solution which was cloudy. At the test end, test material had settled to the bottom of the vessels for the 50 mg/L and 500 mg/L solutions. All other test solutions remained unchanged.

There was no observed mortality of fathead minnow exposed to the test substance at concentrations up to 500 mg/L. In the highest concentration tested, 5000 mg/L, mortality was 100% after 96 h.

There was no mortality observed in the control at 96 h, thus validating the test.

CONCLUSION

The test substance and, by inference, the notified polymer are not harmful to fish.

TEST FACILITY

Haskell (1996a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

TLF-8719 (notified polymer in water)

METHOD

Static, Acute 48-Hour Screening Test of H-21821 to *Daphnia magna* (Haskell Laboratory for Toxicology and Industrial Medicine Protocol)

Species

Daphnia magna

Exposure Period

48 hours

Auxiliary Solvent

None

Water Hardness

Not reported

Analytical Monitoring

None

Remarks - Method

A range finding test was conducted on the test substance at nominal concentrations of 0.5 mg/L, 1.0 mg/L, 50 mg/L, 500 mg/L and 5000 mg/L in duplicate. The test medium was unaerated with pHs ranging 6.7–8.3, and 8.9–9.2 mg O₂/L. The daphnia were observed for immobilisation after 48 h, and daphnia unable to swim after 15 seconds of gentle agitation were considered to be immobile.

RESULTS

<i>Concentration mg/L</i>		<i>Number of D. magna</i>	<i>Number Immobilised</i>	
<i>Nominal</i>	<i>Actual</i>		<i>24 h</i>	<i>48 h</i>
0	Not reported	Not reported	Not reported	0%
0.5	Not reported	Not reported	Not reported	0%
1.0	Not reported	Not reported	Not reported	0%
50	Not reported	Not reported	Not reported	0%
500	Not reported	Not reported	Not reported	10%
5000	Not reported	Not reported	Not reported	100%

EC50

> 500 mg/L at 48 hours

NOEC

50 mg/L at 48 hours

Remarks - Results

All test solutions were clear except for the 500 mg/L solution which was cloudy. At the test end, test material had settled to the bottom of the vessels for the 50 mg/L and 500 mg/L solutions. The 5000 mg/L test solution contained an oil on the surface.

There was no observed immobility of daphnia exposed to the test substance at concentrations up to 50 mg/L. In the two highest concentrations tested, 500 mg/L and 5000 mg/L, immobility after 48 h was 10% and 100%, respectively. It is possible the immobilisations observed in these solutions were due to physical effects.

There was no immobility observed in the control at 48 h, thus validating the test.

CONCLUSION

The test substance and, by inference, the notified polymer are not harmful to aquatic invertebrates.

TEST FACILITY

Haskell Laboratory for Toxicology and Industrial Medicine (1996b)

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