File No: LTD/1326

May 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Polyquart Pro

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 and Water Resources.

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

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Cognis Australia Pty Ltd (ABN 87 006 374 456)
4 Salig na Drive , Tulla mari ne, Victo ria 3043

NOTIFICATION CATEGORY
Limited: Synthetic polymer with NAMW ≥ 1000.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, molecular formula, structural formula, CAS number, polymer constituents, hazardous impurities/residual monomers, specific use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: density, vapour pressure, hydrolysis as a function of pH, flash point, flammability, autoignition temperature, and dissociation constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polyquart Pro (22% aqueous solution of the notified polymer)

MOLECULAR WEIGHT Mn > 10,000

ANALYTICAL DATA
Reference IR and GPC spectra and chemical analysis results were provided.

3. COMPOSITION

DEGREE OF PURITY
>99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities and residual monomers are present at below the relevant cut offs for classification of the notified polymer solution as a hazardous substance.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

ADDITIVES/ADJUVANTS
None

DEGRADATION PRODUCTS
The polymer is expected to be stable, and no degradation products have been identified.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No loss of monomers, reactants or impurities has been identified.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Yellow clear liquid (Polyquart Pro)
Solid (isolated polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 185ºC (decomposition)	Measured (isolated solid)
Boiling Point	> 185ºC at 101.3 kPa (decomposition)	Measured (isolated solid)
Density	990 to 1070 kg/m^3	Value for the product Polyquart Pro, given on Technical Data Sheet.
Vapour Pressure	Not determined	The notified polymer is introduced in an aqueous solution. Based on the high molecular weight and salt form of the polymer it is expected to have a low vapour pressure.
Water Solubility	> 442 g/L at 23ºC	Estimated by the flask method
Hydrolysis as a Function of pH	Not determined	The notified polymer is not susceptible to hydrolysis in the pH range 4-9 at ambient temperature
Partition Coefficient (n-octanol/water)	log P_{ow} = < -3.7 at 23ºC	Estimated by shake flask method
Adsorption/Desorption	Expected to be high	No definitive value obtained from test method.
Dissociation Constant	pK_a = 4.4 at 20°C	Measured by potentiometric titration
Particle Size	Not determined	The notified polymer is introduced in an aqueous solution.
Flash Point	Not determined	The notified polymer is introduced in an aqueous solution. Based on the expected low volatility it is not expected to form a flammable air/vapour mixture.
Flammability	Not determined	The notified polymer is introduced in an aqueous solution. Therefore it is not expected to be flammable under normal conditions of use.
Autoignition Temperature	Not determined	The notified polymer is introduced in an aqueous solution. It is not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	Estimated based on the chemical structure.

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

The notified polymer is stable in aqueous solution.

Dangerous Goods classification

Based on the available physico-chemical properties the notified polymer is not classified as a Dangerous Good according to the Australian Dangerous Goods Code (FORS, 1998).

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported in the product Polyquart Pro (22% aqueous solution) in 150 L plastic drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 2	2-7	4-10	8-12	<15

PORT OF ENTRY

The notified polymer will initially be imported through Melbourne, but import could be via all major Australian ports.

IDENTITY OF MANUFACTURER/RECIPIENTS

Polyquart Pro, the product containing the notified polymer (22%), will initially be stored and distributed from the notifier's site in Melbourne, Victoria. From the notifier's site, Polyquart Pro will be distributed to manufacturers of hard surface cleaners and vehicle washes/shampoos. Such manufacturers may be in all significant industrial centres. From those manufacturers the end-use products will be distributed to major car wash facilities and retail distribution centres.

TRANSPORTATION AND PACKAGING

Polyquart Pro will be imported in 150L high density polyethylene drums. These drums will be transported by road from the wharf to the notifier's site for storage and re-transporting to manufacturers of hard surface cleaners and car wash detergents. The hard surface cleaners and car wash detergents will then be packed into 5L or 20 L high density polyethylene containers. The 5L high density polyethylene containers will be packaged into cardboard cartons, each carton containing 4 bottles. These cartons and 20L cartons will be transported by road to the major car wash facilities. Alternatively the products may be packaged into smaller containers and distributed for sale to the public through retail outlets.

USE

The notified polymer is used as an additive in hard surface cleaners and vehicle washes/shampoos.

OPERATION DESCRIPTION

Formulation

At the formulation sites the liquid Polyquart Pro will be decanted or pumped from the 150 L drums into the mixing vessel and blended with other ingredients. It will be incorporated at less than 1% into hard surface cleaner and car wash formulations. These will be sampled for QC testing and packaged into a range of container sizes for distribution to industrial customers and to the public.

End-use of car wash products

Car wash personnel would put a small amount of the formulated cleaner containing < 1% of the notified polymer into a bucket of water or (more usually) an automatic washing station and apply to the vehicle to be washed. Automatic application is likely to be by rollers or high pressure spray. Approximately 10 g of the product would be used per car. The diluted cleaner would be used to suds up the car, and then rinsed off with water, usually as part of an automatic process.

End-use of other hard surface cleaner products

Manual processes would be used by workers cleaning other surfaces with hard surface cleaners containing < 1% of the notified polymer. Such products may be used without a dilution step or diluted with water before application. Application methods may include spraying. Depending on the type of products, the cleaning product may be rinsed off the surfaces or wiped away.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Store Operator	2/site	0.5 hours/day	24 days/year
Plant Operator	2/site	2 hours/day	48 days/year
Laboratory Technician	1/site	0.5 hours/day	48 days/year
Car Wash Personnel	1/site	2 hours/day	300 days/year

Exposure Details

Transport and storage

Exposure during transport and storage is not expected to occur, except in the case of an accidental breach of the packaging.

Formulation

Plant operators and laboratory technicians may be exposed to solutions containing up to 22% of the notified polymer during formulation and QC sampling processes. Dermal and ocular exposure to the notified polymer may occur, however inhalation exposure is unlikely due to the expected low vapour pressure of the notified polymer and the fact that it is handled only as an aqueous solution.

Dermal and ocular exposure will be limited by the controls commonly applied (including local exhaust ventilation), and the use of standard PPE, especially gloves and protective eyewear.

End-use of car wash products and other hard surface cleaner products

During end-use of the polymer as an ingredient of hard surface cleaners and car wash products at <1%, the major route of exposure is likely to be dermal. Inhalation exposure could also occur if cleaning solutions were sprayed, or applied in such a way that aerosols are formed.

The conditions of use are likely to be variable. Both manual (car-wash and other hard surface cleaners) and automatic (car-wash) cleaning may occur. For the former, PPE (such as impervious gloves) may be worn by workers to minimise dermal exposure. For the latter, isolation of the automatic processes from workers would reduce exposure. Potential exposure during all types of end-use would be reduced by the low concentration of the notified polymer in marketed products and the likely dilution of the products in water.

6.1.2. Public exposure

During transport and storage of Polyquart Pro and products containing the notified polymer, the opportunity for exposure of the general public will be low, occurring only in the case of accidental spillage.

A proportion of the formulated hard surface cleaners and car wash detergents containing up to 1% of the notified polymer will be sold to the public or used by the public at car wash facilities. There may be some dermal or ocular exposure of consumers during routine use of the products. Any such exposure would be reduced by the low concentration of the polymer in the products and the likely dilution of the products in water. Inhalation exposure to products containing the notified polymer could occur if products were applied by spraying or applied in such a way that aerosols are formed.

Secondary dermal exposure of the public to surfaces cleaned with products containing the notified polymer is also possible, although this would be expected to be very low exposure.
Accidental oral exposure to products containing the notified polymer eg by children is also possible, however the concentration of the polymer in the products is low

6.2. Human health effects assessment

No toxicity data was submitted. The MSDS indicates that based on analogy the notified polymer is expected to have a rat oral LD50 > 2000mg/kg, and is not expected to be mutagenic in vitro.

Based on the high molecular weight (Mn > 10,000) and low percentage of low molecular weight species absorption across biological membranes is expected to be very low. Systemic toxicity after exposure to the notified polymer is therefore expected to be low.

The structure of the notified polymer suggests that it could cause skin and eye irritation, as well as skin sensitisation. The possibility of these effects cannot be ruled out, despite a high molecular weight.

As no toxicity data was available the notified polymer can not be classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Transport and storage

The risk to workers involved in the transport and storage of products containing the notified polymer is considered to be low based on the minimal exposure expected.

Formulation

The risk of systemic effects is considered to be low for plant operators and laboratory technicians due to the expected low absorption and low systemic toxicity of the notified polymer, as well as the engineering controls and PPE use at the formulation sites.

While no toxicity data was available on the notified polymer the chemical structure indicated possible irritation and sensitisation effects. Workers involved in formulation processes could potentially be at risk of experiencing these effects due to the concentration of the notified polymer in the imported product (22%). However the use of personal protective equipment during formulation is expected to minimise the exposure, and will therefore reduce the risk of these effects.

End-use of car wash products and other hard surface cleaner products

Workers using car wash products or hard surface cleaners will be exposed to much lower concentrations of the notified polymer (< 1%). Therefore even if personal protective equipment or automatic processes are not used at all sites the risk of these workers experiencing irritation or sensitisation effects is expected to be low.

6.3.2. Public health

While the public will be exposed to products containing the notified polymer through consumer use of car-wash or hard surface cleaners, the low concentration (< 1%) and likely dilution of these products means that the risk of the public experiencing irritation or sensitisation effects is considered to be low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. Local operations will include transport, storage and reformulation. Release to the environment may occur in the unlikely event of an accident during transport or if the packaging (150 L high density polyethylene drums) are damaged during handling and storage. Spills should be physically contained and collected, and subsequently disposed of by incineration or sent to secure landfill. It is expected that losses by this route will account for less than 0.5% (75 kg) of the total import volume per annum.

Reformulation to end-use products is expected to take place at up to 15 separate sites throughout Australia. During reformulation and filling there is potential for release to the environment through spills. However, these should be contained by standard physical engineering means and recycled if not contaminated, or disposed of to the site trade waste treatment plant. In a typical blending process, up to 10 kilograms of Polyquart Pro would be added to a 1000 L vessel to give a concentration of the notified polymer of < 1%. The 150 L drums and buckets will be rinsed and the rinsate will in turn be used in the customers' product. The empty import containers are expected to be either recycled or disposed of to landfill. All equipment, vessels, pipes or minor spills will be flushed with water and become part of the charge for the end-use product. The expected amount of the polymer lost to trade waste treatment plants nationwide in one year during reformulation will be less than 0.5% (75 kg). A substantial portion of this is expected to be adsorbed to solids and disposed of to landfill, where it is not expected to be mobile.

RELEASE OF CHEMICAL FROM USE

The notified polymer has two main uses. It is expected that approximately 80% (12000 kg per annum) will be used in detergents by commercial car wash operators and the general public. These products will be contained in 5 and 20 L high density polyethylene containers. The proportion of notified polymer that is directed to rolling stock and commercial car wash sites will be greater than 80% of this application (9600 kg per annum). It is expected that there will be negligible release to the environment directly from the commercial car wash sites, as all water containing detergent must be recycled and any waste ultimately disposed of by registered disposal firms. However, it is expected that a proportion of the notified polymer used by the general public will not be adsorbed to the hard-surfaces cleaned and may be released to the environment. Polymer released by this route is expected to adsorb to soil where it will slowly degrade, or be released to the sewer and/or stormwater drains.

The second use, accounting for the remaining 20% (3000 kg per annum), will be in commercial hard-surface cleaners. A small proportion of the polymer may be released to stormwater drains and/or the sewer through wash-off of surplus cleaning solutions. However, these losses are not expected to be significant given the low concentration of the polymer used in these applications.

RELEASE OF CHEMICAL FROM DISPOSAL

Containers for commercial end-use products are expected to be recycled, whereas containers for public use are expected to be disposed of as domestic waste to landfill. The losses of notified polymer as residues in these containers are expected to be low (≤ 1%).

7.1.2 Environmental fate

The notified polymer will be used in commercial hard-surface cleaners (20% of imported volume) and domestic and commercial car wash detergents (80% of imported volume). In the former case, the polymer will be exhausted to the hard surfaces cleaned because of its adsorption characteristics, except for some minor losses from wash-off of surplus cleaning solutions. In the latter use, a small proportion of the total quantity used will eventually be released to sewer through the effluent system of the commercial car-wash facilities or from domestic uses. The results of the inherent biodegradability test indicate that in the sewage treatment plant the polymer will be partially eliminated by adsorption to sludge. Polymer bound to sewage sludge will be disposed to landfill where it will not be mobile. It will eventually degrade by abiotic and biotic processes to form simple carbon and nitrogen-based compounds. For the details of the environmental fate study please refer to Appendix B.

7.1.3 Predicted Environmental Concentration (PEC)

The losses to the sewage system from the mixed commercial and domestic uses of the notified polymer cannot be precisely estimated. The predicted environmental concentration has therefore been calculated based on an extreme worst-case scenario in which all of the imported polymer is eventually released to the aquatic environment through the sewer system. It is noted that this scenario is unlikely because of the tendency of this polymer to bind to solids rich in organic carbon and/or minerals such as those found in sewage treatment plants and soils.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	15000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	15000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	41.1	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	10.03	µg/L
PEC - Ocean:	1.00	µg/L

7.2. Environmental effects assessment

The toxic effects of the notified polymer on the fresh water green algae, *Desmodesmus subspicatus*, were tested by means of the OECD TG 201 Alga, Growth Inhibition Test. For the details of this study please refer to Appendix B. The results from this study are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	E_rC50 (72 h) 142 mg/L	Not Acutely Toxic

The notified polymer is not considered to be acutely toxic to algae based on the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations 2003).

7.2.1 Predicted No-Effect Concentration

The Predicted No-Effect Concentration has been calculated from the measured algal toxicity of the notified polymer (growth rate inhibition). As eco-toxicology data are only available for one trophic level, the maximum assessment factor of 1000 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (72 h)	142	mg/L
Assessment Factor	1000	
Mitigation Factor	1.00	
PNEC:	142	µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	10.03	142	**0.07**
Q - Ocean:	1.00	142	**0.01**

The unmitigated Risk Quotients are much less than 1 for both the river and ocean disposal scenarios. Therefore, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment based on the current use pattern and at the maximum permitted import volume.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

As no toxicity data was available the notified polymer could not be classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

8.2. Human health risk assessment

8.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

8.2.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable.

8.3. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

The MSDS of the imported product containing the notified polymer provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS was found to be in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003.

10. RECOMMENDATIONS

REGULATORY CONTROLS
CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Protective gloves
  - Protective clothing
  - Safety glasses

  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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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 incineration or to landfill.

Emergency procedures

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

11. REGULATORY OBLIGATIONS

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 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 chemical has changed from a hard surface cleaner additive, or is likely to change significantly;
- the amount of chemical being introduced has increased from 15 tonnes, 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. call for a secondary notification application) is required.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Melting Point/Freezing Point > 185ºC

METHOD OECD TG 102 Melting Point/Melting Range.
Remarks Exothermal decomposition starts at 185°C. There is no melting point up to the decomposition of the test substance.
TEST FACILITY Bayer Industry Services GmbH (2006b)

Boiling Point > 185ºC at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
Remarks Exothermal decomposition starts at 185°C. There is no boiling point up to the decomposition of the test substance.
TEST FACILITY Bayer Industry Services GmbH (2006b)

Water Solubility > 442 g/L at 23ºC

METHOD OECD TG 105 Water Solubility.
Remarks The water solubility at ambient temperature was estimated from the results of a preliminary test carried out by the flask method. The concentration of the notified polymer in aqueous solution (as total organic carbon) was determined by a combustion method.
TEST FACILITY Bayer Industry Services GmbH (2006a)

Partition Coefficient (n-octanol/water) log Pow < - 3.7 at 23ºC

METHOD OECD TG 107 Partition Coefficient (n-octanol/water): Shake Flask Method
Remarks The oil-water partition coefficient at ambient temperature was estimated from the ratio of the solubilities of the notified polymer in water and 1-octanol. The solubility of the notified polymer in 1-octanol (< 96 mg/L) was estimated by the flask method.
TEST FACILITY Bayer Industry Services GmbH (2006c)

Adsorption/Desorption – screening test No definitive value was determined. Expected to be high.

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using HPLC
Remarks An attempt to determine the soil-water partition coefficient by means of high-performance liquid chromatography did not afford definitive results. However, the chemical structure and intended use of the notified polymer indicate that it will bind strongly to materials rich in organic carbon and/or minerals. It is therefore expected to partition out of the water column onto sediments and sewage sludge.
TEST FACILITY Bayer Industry Services GmbH (2006d)

Dissociation Constant pK_a = 4.4 at 20°C

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks An approximate dissociation constant for the notified polymer in water at 20°C was determined by means of potentiometric titration.
TEST FACILITY Bayer Industry Services GmbH (2007)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Inherent biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 302 B Inherent Biodegradability: Modified Zahn-Wellens Test
Inoculum	Activated sewage sludge bacteria
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Total organic carbon determination
Remarks – Method	The notified polymer and the reference substance (ethylene glycol) were added at nominal levels of 200 mg dissolved organic carbon/L to inoculated mineral salt solution at pH 6.5-8.0. The test solutions were aerated and irradiated with diffuse light for 28 days at 20-25°C.

RESULTS

Notified polymer		*Ethylene glycol*	
Day	*% Elimination*	*Day*	*% Elimination*
3 h	36.2	3 h	-2.2
1	23.2	1	18.5
7	23.5	7	99.3
14	24.7	14	99.7
21	24.5	21	100.4
27	25.2	27	100.3
28	21.9	28	100.2

Remarks – Results	Analysis of the test sample after 3 h showed 36% elimination of the notified polymer, but after 1 day the elimination had *decreased* to 23%. The percentage elimination reached a plateau after 1-day in the range 22-24%. This elimination behaviour is consistent with adsorption of the polymer by the activated sludge. Under the same conditions, the reference substance was essentially eliminated after 7 days. A mixed sample of notified polymer and the reference substance showed a rapid approach to limiting elimination of 66% after 7 days which confirmed that the polymer does not inhibit the biodegradation activity of the sewage microbes under the test conditions.
CONCLUSION	The notified polymer is partially eliminable.
TEST FACILITY	Fraunhofer-Institute for Molecular Biology and Applied Ecology (2005)

B.2. Ecotoxicological Investigations

B.2.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 1.56, 3.13, 6.25, 12.5, 25, 50, 100, and 200 mg/L
Auxiliary Solvent	None
Water Hardness	Nominal: 0.24 mmol (Ca + Mg)/L
Analytical Monitoring	a. Cell density by chlorophyll a fluorescence at 685 nm

b. Notified polymer by Dissolved Organic Carbon (DOC) analysis

Remarks - Method

The notified polymer was added to mineral salt solutions inoculated with a 4-day old pre-culture of the algae (10^3-10^4 cells/mL). The test solutions were irradiated 24 h/day at pH 7.8-8.2 and a nominal temperature of 23°C for a period of 72 hours. The algae were grown for 3 days in fresh untreated media after the test period. The positive control was provided by potassium dichromate (0.1-3.2 mg/L).

RESULTS

Biomass		*Growth*	
Nominal concentration (mg/L)	*Inhibition of biomass (%)*	*Nominal concentration (mg/L)*	*Rate-related inhibition (%)*
200	90.2	200	58.0
100	81.1	100	39.4
50	71.5	50	32.9
25	59.1	25	20.8
12.5	37.6	12.5	9.05
6.25	25.3	6.25	7.95
3.13	6.61	3.13	-0.29
1.56	2.87	1.56	0.56

Remarks - Results

An initial range finding test with the notified polymer demonstrated a 46% inhibition of the specific growth rate at the highest concentration tested (100 mg/L). A definitive test over a wider concentration range was used to determine the following values for the 72 h 50% inhibition of biomass (E_bC50) and 50% inhibition of specific growth rate (E_rC50): E_bC50 = 19.6 mg/L (95% CI 16.1-24.0); E_rC50 = 142 mg/L (95% CI 106-192). Under the same conditions, the E_bC50 and E_rC50 values for the potassium dichromate control were 0.31 mg/L (95% CI 0.28-0.34) and 0.56 mg/L (95% CI 0.50-0.62), respectively. The effect of the notified polymer on the growth of the algae was reversible up to the highest tested concentration (200 mg/L, nominal).

CONCLUSION

The notified polymer is not acutely toxic to algae according to the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations 2003)

TEST FACILITY

Dr. U. Noack-Laboratorien (2005)

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