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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Polyquart Ecoclean

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

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

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

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cognis Australia Pty Ltd (ABN 87 006 374 456)
4 Saligna Drive
TULLAMARINE VIC 3043

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, Spectral Data, Molecular Weight, Purity, Impurities, Import Volume.

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, Hydrolysis as a function of pH, Partition Coefficient, Absorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Autoignition Temperature.

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polyquart Ecoclean (22% notified polymer)

OTHER NAME(S)
Acrylic acid, modified corn starch

MOLECULAR WEIGHT
Mn > 1000 Da

ANALYTICAL DATA
Reference IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Loss of monomers not anticipated.

DEGRADATION PRODUCTS
No significant breakdown of the notified polymer is expected under normal conditions of handling and storage. However, the starch backbone may undergo some degradation.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Yellow-coloured clear aqueous solution (imported product).
The notified polymer is expected to be a solid.

Property	Value	Data Source/Justification
Transition temperature	~ 94°C	Measured
Density	1100 kg/m^3	Imported Product data sheet
Water Solubility	≥ 200 g/L at 20°C	Measured
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight of the notified polymer
Hydrolysis as a Function of pH	Not determined	The notified polymer is not expected to hydrolyse in the pH range 4-9 at ambient temperature
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is an ionic compound and is thus expected to have a low K_{ow}
Adsorption/Desorption	Not determined	The notified polymer has cationic characteristics and is expected to adsorb to soil and sediment
Dissociation Constant	Not determined	The notified polymer contains functional groups that will be ionised in the environmental pH range 4-9
Flash Point	Not determined	Low vapour pressure solid
Flammability	Not determined	Not expected to autoignite under normal conditions of use
Autoignition Temperature	Not determined	Not expected to be flammable in imported mixture
Explosive Properties	Not determined	Does not contain explosophores

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

Reactivity
The notified polymer is expected to be stable under normal environmental conditions.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported at a concentration of 22% in the product Polyquart Ecoclean.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1	2-5	2-7	4-9	6-10

PORT OF ENTRY
Melbourne and potentially other capital cities.

IDENTITY OF RECIPIENTS
Formulators of hard surface cleaning products

TRANSPORTATION AND PACKAGING
The notified polymer will be imported by sea at 22% concentration in 200 L or 30 L plastic drums and transported to the notifier's warehouse and then to customer sites by road for reformulation into hard-surface cleaning products. Plastic containers of 5 L or 20 L capacity (commercial use) and 750 mL containers (domestic use) of finished products containing the notified polymer will be transported by road to retail outlets.

USE

The notified polymer is intended for use as an additive in hard-surface cleaning products at up to 0.3%. It is estimated that products containing the notified polymer will be used by the general public (~85% of import volume) and commercial car wash facilities (~15% of import volume)

OPERATION DESCRIPTION

Reformulation

The notified polymer (22%) is expected to be transferred from the import drum into the blending vessel by automated pumps. Once blended into a hard-surface cleaning product (containing up to 0.3% notified polymer), it will be tested for quality control purposes before being filled into product bottles and distributed for sale.

End-use

The hard-surface cleaning products containing the notified polymer will be applied diluted or undiluted to hard surfaces by spray, mop or cloth by professional cleaners and domestic users.

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)*
Store Operator	2	0.5	12
Plant Operator	2	2	24
Laboratory Technician	1	0.5	24
Cleaners	Many	2	300

EXPOSURE DETAILS

Transport and Storage

Exposure to the notified polymer during transport and storage is not anticipated except in case of an accident leading to release.

Reformulation

Accidental dermal and ocular exposure to drips, spills and splashes of the notified polymer (≤ 22%) may occur during charging of the blending vessel, blending, quality assurance testing and filling of product packaging. Dermal and ocular exposure may also occur during cleaning and washing of equipment used in reformulation. Exposure is expected to be minimised by the anticipated use of local exhaust ventilation (LEV) and personal protective equipment (PPE), such as safety goggles, impervious gloves, protective clothing and safety boots.

Inhalation exposure to aerosols is not expected due to the low speed of the blending process and the use of LEV.

Use of hard surface cleaners

Workers using hard-surface cleaning products containing the notified polymer (≤ 0.3%) are expected to experience extensive dermal exposure during application of the products and rinsing. Accidental ocular and inhalation exposure (during spraying) to hard-surface cleaning product containing the notified polymer is also possible during cleaning. Gloves may be worn when handling the product to minimise exposure to the hands but eye and respiratory protection is unlikely to be used.

6.1.2. Public exposure

Public exposure to the notified chemical is expected to be widespread and frequent through use of hard-surface cleaning products containing the notified polymer at concentrations up to 0.3%. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw low toxicity
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics
Limited data are available to describe the likely toxicokinetic properties of the notified polymer. It has relatively high molecular weight (> 1000 Da.), high water solubility (> 1000 g/L) and estimated low log P_{ow} which indicate absorption across biological membranes is unlikely to be significant. However, some absorption of the low molecular weight species may occur. Inhalation of aerosols of the notified polymer may result in deposition in the airways from which the notified polymer may dissolve into the mucus lining of the respiratory tract and subsequently removed (C. Klaassen, 2008).

Acute toxicity
An aqueous solution containing the notified polymer at a concentration of 20% was found to be of low acute oral toxicity (LD50 > 2000 mg/kg bw/day) in 6 female rats according to the method described by OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (BSL Bioservice Scientific Laboratories GmbH, 2008a). No adverse effects were reported in the study.

No data were provided on the acute toxicity following dermal or inhalation exposure.

Irritation and Sensitisation
The notified polymer contains a functional group that has been associated with irritation/corrosion and sensitisation (Hulzebos et al., 2005, Barratt et al., 1994). The high molecular weight (> 1000 Da.) of the notified polymer is expected to limit its dermal absorption, however, the potential for irritation/corrosion cannot be ruled out, particularly due to the significant proportion of low molecular weight species present.

The potential for skin sensitisation was addressed by a modified local lymph node assay (LLNA). A modified integrated model for the differentiation of skin reactions (IMDS) LLNA was performed on the notified polymer at 20% in aqueous solution at concentrations of 2, 10 and 50%. This procedure has undergone some validation in BALB/c or NMRI mice by ECVAM (Basketter, D., et al., 2008) but has not been validated by the OECD. Instead of using radioactive labelling, lymph node cell counts and weights were measured to indicate sensitising potential. Ear thickness and ear weight measurements were used to indicate irritant potential. There was no statistically significant increase in lymph node cell counts or weights. Nor were there any statistically significant increases in the ear swelling or ear weights in any of the groups of treated animals. Therefore, the notified polymer is considered unlikely to be a sensitiser at concentrations up to 10% (see Appendix B for details).

Mutagenicity
An aqueous solution containing the notified polymer at a concentration of 20% and further diluted with the vehicle: Aqua. dest. was tested according to OECD TG 471 (plate incorporation and pre-incubation methods) in *Salmonella typhimurium* strains: TA 98, TA 100, TA 1535, TA 1537 and TA 102 (BSL Bioservice Scientific Laboratories GmbH, 2008b). No statistically significant increases in revertant colonies were reported at any dose concentrations in any strain with or without metabolic activation. No precipitation or cytotoxic effects were observed at any dose concentration in any strain with or without metabolic activation.

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Dermal and ocular exposure of workers to the notified polymer at concentrations up to 22% may occur during reformulation. At such concentrations the potential for irritation cannot be ruled out. However, the use of LEV and PPE is expected to minimise exposure and reduce the risk of such effects.

Dermal, ocular and inhalation exposure of workers to the notified polymer at up to 0.3% may occur during use of hard surface cleaners. Irritation to the sin, eyes or respiratory tract is not expected to occur at up to 0.3%, and thus the risk associated with such exposure is not considered unacceptable.

Therefore, exposure to the notified polymer (at ≤ 22%) during reformulation and during use of cleaning products (at up to 0.3%) is not expected to pose an unacceptable risk to workers.

6.3.2. Public health

Domestic users of cleaning products containing the notified polymer at up to 0.3% will experience extensive dermal and possibly inhalation and ocular exposure. However, at such low concentrations adverse effects are not expected and thus, the notified polymer is not expected to pose an unreasonable risk to public health during the use of cleaning products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported notified polymer will be reformulated in Australia. The rinsate from import containers and equipment will be used in the end-use product. Residue remaining in the import container (<0.1%) will be disposed to landfill. Major spills (<0.1%) are expected to be contained and sent to landfill.

RELEASE OF CHEMICAL FROM USE

It is estimated that approximately 85% will be used by the general public in hard surface cleaners, and approximately 15% will be used in car wash detergents at commercial car wash sites. Release of the notified polymer to the environment from general use will result from non-adsorbed residue in wash-off, whereby it is completely removed after several washes, and surplus solutions. Notified polymer released by this route is expected to adsorb to soil where it will degrade, or be released to the sewer and/or stormwater drains. From the commercial car wash sites it is expected that the majority of the notified polymer will adsorb to dirt and will be filtered from the water. Any notified polymer remaining in the water will be recycled through the car wash and eventually filtered out. The filters are expected to be disposed by registered disposal companies.

RELEASE OF CHEMICAL FROM DISPOSAL

Containers for commercial end-use products are expected to be recycled and/or disposed of as domestic waste to landfill. The losses of notified polymer as residues in these containers are expected to be low (≤ 0.1%).

7.1.2 Environmental fate

The notified polymer used in commercial hard-surface cleaners will be removed to the hard surfaces cleaned due to its adsorption characteristics. It is anticipated that minor losses will occur from wash-off of surplus cleaning solutions and may be released to sewer through either the effluent system of the commercial car-wash facilities or from domestic use.

The notified polymer was found to be readily biodegradable, potentially generating low molecular weight cationic oligomers (<1000 Dalton) with properties different from the notified polymer. However, it is expected that the oligomers are also readily biodegradable. Both the notified polymer and its oligomer degradation products are expected to adsorb to sewerage sludge. Notified polymer bound to sludge will be disposed to landfill where it is not expected to be persistent as it degrades by biotic and abiotic processes into simple carbon and nitrogen-based compounds.

The notified polymer is not expected to bioaccumulate due to its high water solubility and its expected low

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

7.1.3 Predicted Environmental Concentration (PEC)

The losses to the sewerage 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 a worst-case domestic use scenario in which all of the imported polymer is eventually released to the aquatic environment through the sewerage system via use over 365 days/year.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	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:	6.47	µg/L
PEC - Ocean:	0.65	µg/L

Sewerage treatment plant (STP) effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/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/m^3). Using these assumptions, irrigation with a concentration of 6.47 µg/L may potentially result in a soil concentration of approximately 4.32×10^{-2} mg/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 0.216 mg/kg and 0.432 mg/kg, respectively. However, these calculations are based on a worst case scenario, and have not taken into account the ready biodegradability of the notified polymer.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the formulated end-use product, containing 20% notified polymer in water, and another formulated end-use product, containing 10% of an analogue polymer in water, are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity (analogue polymer)	EC50 (48 h) 341 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity (notified polymer)	E_rC50 (72 h) 24.3 mg/L	Harmful to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations 2003) the notified polymer is considered to be harmful to algae. The notified polymer can be considered as not harmful to aquatic invertebrates, based on studies conducted on an analogue polymer possessing identical side-chains to the notified polymer (the analogue is discussed further in Appendix C.2.1).

The toxicity of ionic polymers depends on the cation to anion ratio (CAR), and polymers that pose a concern for the environment have a net cationic charge. The CAR for this notified polymer is 0.4, indicating that it is anionic overall. Standard hazard testing media usually have low total organic carbon content, which may result in overestimating the aquatic hazard in the laboratory. Surface waters tend to have a higher total organic content, and as such, anionic/cationic polymers have reduced toxicity in the environment (Boethling and Nabholz, 1996).

7.2.1 Predicted No-Effect Concentration

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

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (72h)	24.3	mg/L
Assessment Factor	1000	
PNEC:	24.3	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	6.5	24.3	**0.27**
Q - Ocean	0.65	24.3	**0.027**

The Risk Quotient was derived from a worst case scenario, whereby all the notified polymer was discharged to sewer, and adsorption to sludge was not accounted for. Due to the proposed use pattern and the adsorptive properties of the notified polymer it is expected that not all the imported volume will reach the sewer. Notified polymer that does reach the sewer is expected to biodegrade or adsorb to sludge. The unmitigated Risk Quotients are less than 1 for both the river and ocean worst case disposal scenarios, therefore, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment based on the proposed use pattern and at the maximum proposed import volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided, the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Aquatic Toxicity	Acute Category 3	Harmful to aquatic life

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as imported at a concentration of 22%:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as imported at a concentration of 22%:
  - Avoid contact with eyes and skin.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as imported at a concentration of 22%:
  - Gloves, safety glasses, protective clothing.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical 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.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Disposal

- The notified chemical 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 polymer in products exceeds 3%;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of hard-surface cleaning products, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 10 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 a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Transition temperature ~94ºC

Method	Transition temperature measured using thermogravimetric analysis.
Test Facility	Aqura Analytical Solutions (2008)

Water Solubility >200 g/L at 20ºC

Method	OECD TG 105 Water Solubility
Remarks	Flask test. Approximately 100 mg of the test substance (containing 21% notified polymer) was weighed into a 10 mL vessel, demineralised water (0.1 mL, 0.5 mL, then 1 mL, to a total of 1.6 mL) was added and visually observed for undissolved parts of the test item. The results of the test indicated that a formulation containing 21% of notified polymer was soluble in demineralised water at concentrations ≥1000g/L. It is thus estimated that the neat notified polymer is soluble at concentrations >200 g/L. Miscibility tests were also performed whereby ratios of the test item with demineralised water (1:10, 1:1, 10:1) were agitated for 10 min and checked visually after 72 h (ambient temperature). Clear homogenous solutions were found for each ratio, indicating that the test substance is miscible with demineralised water.
Test Facility	Currenta GmbH & Co (2008)

Hydrolysis as a Function of pH

Method	Test not conducted
Remarks	Hydrolysis of the side-chains or backbone of the notified polymer is not expected to occur in the environmental pH range (4–9). However, under strongly acidic conditions the backbone may be susceptible to breakage.

Partition Coefficient (n-octanol/water)

Method	Test not conducted
Remarks	The log K_{ow} of the notified polymer is expected to be low based on its high water solubility and ionic properties.

Adsorption/Desorption

Method	Test not conducted
Remarks	Given the cationic characteristics of the notified polymer, it is expected to adsorb to soil and sediment (Boethling and Nabholz, 1996), and it is likely to be immobile in soils.

Dissociation Constant

Method	Test not conducted
Remarks	The notified polymer contains functional groups that will be ionised in the environmental pH range (4–9).

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Notified polymer (20%) in aqueous solution

METHOD: Adaptation of OECD TG 429: Skin Sensitisation: Local Lymph Node Assay. The modified assay is known as an Integrated Model for the Differentiation of Skin Reactions (IMDS).

Species/Strain: Female Mouse/Hsd Win:NMRI

Vehicle: Methyl ethyl ketone

Remarks - Method: 25 µL of the test substance in methyl ethyl ketone was applied to the dorsal section of both ears of the animals at concentrations of 2, 10 and 50% each day for 3 consecutive days. Historical positive control data (within 6 months of test) was provided.
Lymph node weights, cell counts, ear swelling and ear weights were measured instead of using radioactive labelling of lymph node cells. The IMDS assay has undergone intralaboratory (Vohr et al., 2000, Ulrich et al., 2001) and interlaboratory (Ehling et al 2005a and 2005b) validation in Europe for the NMRI breed of mice.

RESULTS

Concentration	*Proliferative response*[1]		*Irritant response − Ear swelling ($x10^{-2}$ mm)*[2]			*Irritant response – Ear Weight*	
(% v/v)	*Lymph node weight index*	*Cell count index*	*Day 1*	*Day 4*	*Day 4 Index*	*Ear weight (mg)*[3]	*Ear weight index*[4]
0	1.00	1.00	17.42	17.50	1.00	11.35	1.00
2	1.16	1.05	17.25	17.58	1.00	11.22	0.99
10	0.93	0.93	17.42	17.83	1.02	11.98	1.06
50	1.19	1.12	17.08	17.83	1.02	11.95	1.05

[1] Test/control index calculated from measurements from animals treated with the test substance compared to animals treated with the vehicle control.
[2] Ear swelling was determined by measuring the thickness of both auricles of the animals before first treatment and before sacrifice.
[3] Ear weights were determined by measuring the weight of a 8 mm diameter piece of the ear of the sacrificed animals on Day 4.
[4] Ear weight index was calculated from measurements from animals treated with the test substance compared to animals treated with the vehicle control.

Remarks - Results: There was no statistically significant increase in lymph node weights or cell counts in any of the groups treated with the test substance compared to controls. This indicates that the notified polymer is not likely to cause skin sensitisation at concentrations ≤ 10% (ie. Formulation at 50% concentration containing the notified polymer at 20%).
There was no statistically significant increase in ear swelling or ear weights observed in animals treated with the test substance compared to controls. No deaths or signs of systemic toxicity were noted in the test or control animals during the test.
The study authors cite a test conducted within 6 months of the study confirming the sensitivity of the test system using α-Hexylcinnamaldehyde as a positive control.

CONCLUSION: There was no evidence of reactions that may be indicative of skin sensitisation under the conditions of the test.

TEST FACILITY: Bayer HealthCare AG (2008)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
- Inoculum: Activated sludge from municipal wastewater treatment plant
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring: Total organic carbon determination
- Remarks - Method: The notified polymer (purity 95%) and reference substance (sodium benzoate) were added at nominal levels of 20 mg total organic carbon/L to inoculated mineral medium. The test solutions were aerated and incubated under diffuse light for 28 days. Degradation was determined by measuring the amount of CO_2 produced, corrected with the blank inoculum, and expressed as % of theoretical amount of CO_2 ($ThCO_2$). The results are presented below. The same test performed on nominal levels of 10 mg TOC of notified polymer/L also reached the criterion for ready biodegradation (60% and 10 d window), resulting in 73.8% degradation.

RESULTS

Notified Polymer (20 mg/L TOC)		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
4	52.3	4	82.9
7	60.3	7	89.7
12	63.3	12	94.4
15	66.2	15	98.4
21	66.7	21	101.3
28	68.6	28	103.5

- Remarks - Results: The mean degradation extent was 68.6% over 28 days, based on the above values. The test substance and reference substance degraded by more than 60% each in the 10 day window, thus validating the test.

CONCLUSION: The notified polymer is readily biodegradable

TEST FACILITY: Hydrotox GmbH (2008)

C.1.2. Bioaccumulation

TEST SUBSTANCE

METHOD: Test not conducted
- Remarks - Results: The high water solubility of the notified polymer, as well as its ready biodegradability, indicate that the notified polymer is not expected to partition into membranes, thus it is not expected to bioaccumulate.

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	C-SAT 080043 (10% analogue polymer in water)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – 48 h static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	2.65 mmol Ca & Mg/L
Analytical Monitoring	Test concentrations by Total Organic Carbon (TOC), Total Carbon and Inorganic Carbon analyses.
Remarks - Method	Testing was conducted on an analogous polymer (possessing identical sidechains to the notified polymer) grafted to a polyether backbone. Five concentrations (10, 22, 48.4, 106.5, 234.3 mg/L) of the test substance were prepared. Five replicates of 30 mL for each test concentration, and the M4 medium control were prepared, and each had 5 daphnia added. The daphnia were observed for immobilisation over two days (test conditions: artificial light dark cycle of 16 to 8 hours, 21.8 ± 0.1°C, pH 8.11–8.43). Daphnia unable to swim within 15 seconds of gentle agitation were considered to be immobile. The end-point was extrapolated from statistical evaluation (ToxRat®) of the immobilisation raw data.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual (TOC)*		*24 h*	*48 h*
10	10	25	0	0
22	–	25	0	0
48.4	48.4	25	0	0
106.5	–	25	0	2
234.3	234.3	25	0	8

LC50	341.2 mg/L at 48 hours
NOEC	106.5 mg/L at 48 hours (the immobilisation of 2/25 daphnids was presumably considered not to be significant)
Remarks - Results	The cation to anion ratio for the analogue polymer is higher than that of the notified polymer (2.3 cf. 0.4). Toxicity increases with cationic charge density, hence it is assumed that the toxicity of the analogue represents an over estimate of the toxicity of the notified polymer. There were no immobilised daphnids in the control group, and the DOC in the control and test vessels were ≥3 mg/L, thus validating the test.
CONCLUSION	The analogue polymer and, by inference, the notified polymer are not harmful to daphnids.
TEST FACILITY	Evonik Stockhausen GmbH

C.2.2. Algal growth inhibition test

TEST SUBSTANCE	C-SAT 080066 (20% notified polymer in water)
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 1.0, 3.2, 10, 32, 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Test concentrations by Dissolved Organic Carbon analysis
Remarks - Method	Static test. The test substance was added to mineral salt solutions inoculated with a 3-day old pre-culture of the algae ($2–5 \times 10^3$ cells/mL).

The test solutions were irradiated 24 h/day at pH 7.8–9.4 and a nominal temperature range of 21–24 ± 2°C for a period of 72 hours. The positive control was provided by potassium dichromate (0.28-1.6 mg/L). After 72 h algae were transferred from the upper nominal concentrations (10, 32, and 100 mg/L) and control, to fresh untreated medium and were grown for 4 days to determine whether the effect of the test substance was reversible.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*E_bC10 mg/L*	*E_rC50 mg/L at 72 h*	*E_rC10 mg/L*
4.09 (95% CI: 3.58–4.68)	1.01	24.3 (95% CI: 22.7–26.0)	3.95

Remarks - Results

Under the same conditions as for the test substance, the E_bC50 and E_rC50 values for the control compound were 0.31 (95% CI: 0.30–0.33) and 0.74 (95% CI: 0.70–0.78) respectively. The test substance effect was observed to be reversible for the concentrations tested. Cell growth of the control increased 257-fold after 72h, thus validating the test.

CONCLUSION

The test substance and, by inference, the notified polymer are harmful to algae.

TEST FACILITY

Dr. U. Noack-Laboratorien (2008)

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