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May 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Carbopol Aqua CC

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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Carbopol Aqua CC

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Lubrizol International Inc (ABN 52 073 495 603)
28 River St
Silverwater NSW 2128

Reckitt Benckiser (Australia) Pty Ltd (ABN 17 003 274 655)
44 Wharf Rd
West Ryde NSW 2114

Bronson and Jacobs Pty Ltd (ABN 81 000 063 249)
70 Marple Ave
Villawood NSW 2163

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, CAS number, Molecular formula, Structural formula, Molecular Weight, Spectra Data, Non-hazardous impurities, Polymer constituents and weight percentage, Residual Monomers/Other reactants, Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Vapour pressure, Water Solubility, Absorption/Desorption, Dissociation Constant, Particle Size, Flash Point, Flammability Limits, Autoignition Temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (currently being notified)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Carbopol Aqua CC, Z-86

OTHER NAME(S)
EX-916, EX916, AT 605798, Aqua CC, Polyacrylate-1 Crosspolymer (INCI)

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Pale brown solid

Property	Value	Data Source/Justification

Melting Point/Freezing Point	47.35ºC	Measured
Boiling Point	370- > 400ºC at 102.42 kPa	Measured
Density	1160 kg/m^3 at 25ºC	Measured
Vapour Pressure	Not determined	Notified polymer has a very high molecular weight and is introduced as an emulsion.
Water Solubility	Not determined	The notified polymer is not water-soluble but is manufactured and supplied as a 20% emulsion in water. At low pH values the ionised notified polymer is expected absorb water and act as a thickener (also see dissociation constant).
Hydrolysis as a Function of pH	Not determined	The notified polymer is essentially insoluble in water making the assessment of hydrolytic behaviour impracticable. The notified polymer does, however, contain hydrolysable groups, but these are not expected to undergo hydrolysis in the environmental pH range (4-9).
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is essentially insoluble in water and common organic solvents, making the assessment of Pow impracticable.
Adsorption/Desorption	Not Determined	The notified polymer is essentially insoluble in water and common organic solvents, making the assessment of mobility impracticable. However, the polymer comprises predominantly of hydrophobic functional groups and is likely to adsorb to organic carbon.
Dissociation Constant	pKa = ~9	Contains a potentially cationic functional group, expected to protonate.
Particle Size	Not determined	Notified polymer is introduced as an emulsion in water.
Flash Point	> 101ºC (20% notified polymer)	MSDS
Flammability	Not determined	Notified polymer is introduced as an emulsion in water.
Autoignition Temperature	Not determined	Notified polymer is an emulsion in water.
Explosive Properties	Not determined	Not expected to have explosive properties based on chemical structure.

DISCUSSION OF PROPERTIES

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

Reactivity

The notified polymer is expected to be stable in water and air under normal conditions of temperature and pressure.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a 20% emulsion in water and as a component in finished skincare products (< 2%).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 6	< 6	< 6	< 6	< 6

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturer: The Lubrizol Corporation, 29400 Lakeland Blvd. Wickliffe, Ohio, USA.
Importers: Lubrizol International, Bronson and Jacobs, Reckitt Benckiser (notifiers)

TRANSPORTATION AND PACKAGING
The notified polymer will be shipped into Australia as a 20% emulsion in 208 L plastic drums or 19 L pails. These may be transported directly from the dock to the customers via trucks or taken to another facility for repacking into smaller containers before transportation to customers by road.
The notified polymer may also be imported by shipping containers as a component in finished and individually packaged products (150 ml plastic containers) that are shipped in cardboard boxes.

USE
The notified polymer is used as an ingredient in low pH cosmetic formulations such as hair care products (shampoo, conditioners, styling gels), skin cleansers and body lotions, and acts as a rheology modifier. The polymer will comprise 1-3% of the final product and its role in the formulation is to change the clarity, flow and viscosity of the product to achieve the desired characteristics depending on its use.

OPERATION DESCRIPTION
Repackaging & Reformulation
The notifiers will not reformulate the polymer emulsion but may repack the imported material into other containers. The customers of the notifiers may reformulate the emulsion. Repackaging involves pumping or manually pouring the polymer emulsion (20% of notified polymer) directly from the drums/pails into smaller volume containers that are sealed and then on-sold to other businesses. Reformulation involves pumping the polymer emulsion from drums/pails into the blending tank where it is mixed with other ingredients such as water, dyes, fragrants and cosmetic additives to produce a variety of skin or hair care products (containing 1-3% notified polymer). This is a manual or semi-automatic process in a largely enclosed blending tank. The products are then automatically packaged into plastic bottles for retail sale. Workers will also be involved in testing samples for quality control and cleaning the drums/pails to remove residual products.

Retail
The products containing the notified polymer (1-3%) will be sold through retail outlets such as supermarkets, where workers will be involved in unpacking boxes and shelf-stacking.

End-use
The products containing the notified polymer (1-3%) will be used by the public and may also be used by beauticians and hairdressers.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage workers	2-16	< 9	≤ 200
Laboratory technicians	2	1-2	2-3
Repackaging workers	4	8	10-20
Retail staff	> 10,000	0.5	100
Beauticians/hairdressers	> 1000	1-8	200

EXPOSURE DETAILS

Transport and storage
Workers are unlikely to be exposed to the notified polymer, except in the care of a packaging breach as it will be in sealed drums or containers inside shipping boxes. Workers are trained on safe handling of products.

Laboratory technicians
Dermal exposure may occur during sampling and analysis. This exposure will be reduced by the use of PPE, including laboratory gowns and gloves and the low quantities of the product being handled during testing.

Repackaging and reformulation workers
Dermal and ocular exposure to the notified polymer emulsion (20%) or to the final products (1-3%) is possible due to drips, spills and splashes during transfer and cleaning. This exposure will be minimised by the use of PPE, including safety glasses, gloves, safety shoes, and uniforms that include long trousers and long-sleeved shirts with collars. Inhalation exposure is unlikely due to the expected low vapour pressure of the high molecular weight polymer.

Retail workers
Dermal exposure is unlikely, except in the circumstance of leaks or spills if the packaging was damaged.
No specific controls are expected regarding the notified polymer.

End-use
Dermal and possible ocular exposure to products containing the notified polymer (1-3%) may occur amongst hairdressers and beauticians.

6.1.2. Public exposure
Widespread public exposure is expected as the products containing 1-3% of the notified polymer are intended for the personal skin and hair care market and will be widely available to consumers. Members of the public are likely to experience dermal exposure as a result of using the products, which may be applied to the skin or hair up to twice per day with between 1- 10 g of the product being applied with each use. For some product types, the application will be followed by a rinsing step. In addition, there may be ocular exposure and in minor cases, and some of the products may be unintentionally ingested.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer and an analogue ('310 Polymer') are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Carbopol Aqua CC	Low toxicity, oral LD50 > 2000 mg/kg bw
Rabbit, skin irritation	310 Polymer (20% emulsion)	Slightly irritating
Rabbit, eye irritation	310 Polymer (20% emulsion)	Slightly irritating
Mouse, skin sensitisation – Local lymph node assay	310 Polymer (20% emulsion)	No evidence of sensitisation

Toxicokinetics, metabolism and distribution
Based on the limited physical-chemical data available, the notified polymer is not expected to cross biological membranes and distribute to body compartments, given its high molecular weight (MW > 10,000 Da) and insolubility in water and common organic solvents.

Acute toxicity
The notified polymer has as high oral LD50 (> 2000 mg/kg bw), and therefore accidental oral ingestion of products containing the notified polymer, is unlikely to lead to significant toxic effects.

Irritation and Sensitisation
Based on effects seen in studies on an analogue polymer emulsion (20%), the notified polymer is likely to be only slightly irritating to skin and eyes at the maximum concentration introduced (20%).

Based on the absence of skin sensitisation potential for the analogue polymer, the notified polymer is not expected to cause skin sensitisation.
Classification

Based on the available data the notified chemical cannot be 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

Based on the available information, the notified polymer is expected to exhibit low acute toxicity for workers involved in repackaging and reformulation. The risk of skin irritation for workers exposed to the polymer emulsion (20%) is low but short-term eye irritation is possible if exposure to the polymer emulsion occurs through splashes during handling and reformulation. However, exposure is expected to be mitigated through the use of engineering controls and personal protective equipment.

Therefore, the risk to workers from use of the imported notified polymer emulsion is expected to be acceptable.

The risk for beauticians and hairdressers using the notified polymer in finished hair and skincare products is expected to be low due to its low concentration in the product (< 3%).

6.3.2. Public health

The data available on the health effects of the notified polymer indicate a low hazard. The public will be exposed to the notified polymer on the skin, eye and scalp. However, the notified polymer should not be absorbed due to its high molecular weight. The potential for eye irritation from use of hair products containing the notified polymer should be significantly reduced by the low concentration in use (<3%). Therefore, the risk presented by the notified polymer to the public is considered acceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer is manufactured overseas and is imported as a 20% emulsion. It is then reformulated at customer sites. These sites are expected to be equipped with drip pans and overflow containment facilities and any spills are expected to be contained on site. A small amount (0.1%; < 6 kg per annum) is expected to require disposal to landfill from clean up of spills. Empty import containers are expected to have at most 1% (60 kg per annum) residue. This will be disposed of at a licensed drum recycling facility.

RELEASE OF CHEMICAL FROM USE

The vast majority (~99%) of the notified polymer is expected to be used in its intended manner as a rheology modifier in personal care products. This will be released to sewer during use except for a residual amount (1%; 60 kg per annum), expected to remain in packaging.

RELEASE OF CHEMICAL FROM DISPOSAL

Residue in consumer packaging is expected to be disposed of as domestic waste and landfilled, whilst residue in import containers is expected to be disposed of at licensed drum recycling facilities. The notified polymer released to sewer is expected to be treated at sewage treatment plants (STPs), with the polymer being released to sewage outfall after treatment or adsorbed to sewage sludge. The sewage sludge containing the notified polymer is expected to be landfilled; used as biosolids after treatment; or incinerated.

7.1.2 Environmental fate

The polymer is not readily biodegradable but is expected to slowly degrade by biotic and abiotic processes to oxides of carbon and nitrogen; methane, ammonia; and water vapour. For the details of the environmental fate studies please refer to ‘Appendix C’.

7.1.3 Predicted Environmental Concentration (PEC)

It is expected that the notified polymer will be used throughout Australia on a daily basis. Assuming a worst case scenario where no degradation or adsorption to sewage sludge occur the PEC is calculated as follows.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	6,000	kg/year
Proportion expected to be released to sewer	98 %	
Annual quantity of chemical released to sewer	5880	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	16.1	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:	3.81	µg/L
PEC - Ocean:	0.31	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	ErC50 3.1 mg/L	Toxic

7.2.1 Predicted No-Effect Concentration

Only one trophic level (algae) was tested. Accordingly an assessment (safety factor) of 1000 was applied.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Assessment Factor	1000	
Mitigation Factor	1.00	
PNEC:	3.1	µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	3.81	3.1	**1.23**
Q - Ocean	0.38	3.1	**0.12**

The worst case scenario shows an acceptable risk to ocean sewage outfall but just shows an unacceptable risk to river sewage outfall. However, this scenario does not allow for removal in STPs. Non-ionic, cationic and amphoteric polymers with MW > 1000 are assumed to mainly partition to the solids phase and to be 90% removed relative to the total influent concentration (Boethling & Nabholz 1997). A more realistic scenario, allowing for STP removal of the notified polymer results in a PEC of 0.38 µg/L (3.81 µg/L × 10%) at sewage outfall.

Mitigated for STP removal Risk Quotient

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.38	3.1	**0.12**
Q - Ocean	0.04	3.1	**0.01**

A more realistic scenario allowing for removal of the notified polymer in the STP shows an acceptable risk to the aquatic environment for both ocean and river sewage outfall.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

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

	Hazard category	***Hazard statement***
Aquatic Toxicity	2	Toxic to aquatic life with long lasting effects

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

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

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

Recommendations

REGULATORY CONTROLS

Material Safety Data Sheet and Label

- The MSDS and label provided by the notifier should be amended as follows:
  - Algal Inhibition- 3.1 mg/L based on active constituent;
  - Waste Disposal- Dispose of by authorised landfill or licensed contractor;
  - Spill Procedures- Remove reference to “Do not dispose in landfill”.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid contact with skin and contaminated clothing;
  - Avoid spills and splashing during use

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Eye protection
  - Gloves

  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 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.

Disposal

- The notified chemical should be disposed of by landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment and prevent entry into sewers and waterways. Ventilate area if in confined or poorly ventilated area. Collect free liquid and re-use to the extent practicable or transfer to suitable containers for disposal. Absorb residue with inert material (vermiculite, sand etc) and place in containers for disposal.

Regulatory Obligations

Secondary Notification

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

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

(1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000; or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from an ingredient in low pH cosmetic formulations to act as a rheology modifier, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 6 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. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

The MSDS of 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

Melting Point/Freezing Point 47.36°C

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	Determined using differential scanning calorimetry (DSC).
Test Facility	SafePharm Laboratories (2006a)

Boiling Point 370-> 400°C at 102.42 kPa

Method	OECD TG 103 Boiling Point.
Remarks	Determined using differential scanning calorimetry (DSC). Boiling point can only be approximated, as the rate of decomposition was slow and gradual, although an evident increase was observed at 370°C. Slight gradual decomposition was evident from approximately 130 °C.
Test Facility	SafePharm Laboratories (2006a)

Density 1160 kg/m^3 at 25°C

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Determined using gas comparison pycnometer.
Test Facility	SafePharm Laboratories (2006a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (solid)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Dimethyl sulphoxide
Remarks - Method	No significant protocol deviations. All animals received a single dose of 2000 mg/kg bw.

RESULTS

LD50	> 2000 mg/kg bw
Signs of Toxicity	There were no signs of systemic toxicity in all rats tested.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	There were no deaths and all animals showed expected weight gain over the study period.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	SafePharm Laboratories (2006b)

B.2. Irritation – skin

TEST SUBSTANCE	Analogue - 310 Polymer (20% emulsion)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None. Test substance (20% emulsion in water) administered as supplied.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0.3	0.3	1	< 48 hrs	0
Oedema	0	0	0	0	0	0

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

Remarks - Results	No signs of systemic toxicity were observed and there was no evidence of corrosive effects on the skin. Very slight erythema was observed in 2 animals at the 1-hour and 24-hour observation points.
CONCLUSION	The test substance is slightly irritating to the skin.
TEST FACILITY	Notox B.V. (2003a)

B.3. Irritation – eye

TEST SUBSTANCE	Analogue - 310 Polymer (20% emulsion)

METHOD | OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3
Observation Period: 72 hours
Remarks - Method: No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.0	1.0	1.0	2	< 72 hours	0
Conjunctiva: chemosis	0.3	0.3	0.3	1	< 48 hours	0
Conjunctiva: discharge	0	0.3	0.3	1	< 48 hours	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results: There was no evidence of corneal epithelial damage and no ocular corrosion in any of the animals. No symptoms of systemic toxicity were observed.

CONCLUSION: The test substance is slightly irritating to the eye.

TEST FACILITY: Notox B.V. (2003b)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Analogue - 310 Polymer (20% emulsion)

METHOD

Species/Strain: Mouse/CBA
Vehicle: Acetone/corn oil (4:1 v/v)
Remarks - Method: Twelve animals were used. Body weights were not determined after termination of animals.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	65	-
1	163	2.5
25	89	1.37
100	39	0.59
Positive Control		
10% hexyl cinnamic aldehyde in vehicle	-	6.7

Remarks - Results: Slight erythema was observed in three animals at the site of exposure. All animals showed enlarged lymph nodes compared to normal.

CONCLUSION: There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY: Notox B.V. (2003c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Nominally 20% aqueous emulsion of test substance.
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated Sewage sludge from Cambridge Sewage Treatment Works, treating predominantly domestic waste.
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	Manometer
Remarks - Method	The notified polymer is not considered sufficiently defined to calculate the theoretical oxygen demand (ThOD). Accordingly the chemical oxygen demand (COD) was determined by dichromate reflux. Triplicate 2.50 mL aliquots of a 4.00 g/L solution of notified chemical was mixed with 3.50 mL of 1% Ag_2SO_4 in sulphuric acid and 1.50 mL of $K_2Cr_2O_7$ solution (concentration not recorded, but expected to be saturated; 11.7%). The resulting mixture was refluxed at 180°C for 2 hours. The quantity of reacted dichromate was determined colourimetrically at 600 nm and compared to a previously determined calibration curve. A blank and two check standards were also run. The biological oxygen demand (BOD) was determined by subjecting duplicate tests of notified polymer to activated sludge. Amounts of 11.586 mg (having COD of 100 mg O_2) were used; a blank, reference material (sodium acetate) and toxicity control containing the test material and reference material were also run. The oxygen consumption was measured using a manometer (with CO_2 being captured with NaOH) and compared to the COD. The test temperature was 20.5-22°C.

RESULTS

Test substance		*Sodium Acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	2	7	74
14	5	14	85
28	3	28	88

Remarks - Results	The oxygen uptake of the blank 17.3 mg O_2/L, well below the maximum allowed for the test of 60 mg/L. The toxicity control showed 94% degradation after 28 days and the test substance is not considered inhibitory to the inoculum. The test substance formed a stable emulsion during the test.
CONCLUSION	The notified polymer is not readily biodegradable.
TEST FACILITY	Chemex (2007)

C.1.2. Bioaccumulation

Not tested. Not expected to bioaccumulate as the notified polymer has a high molecular weight and is not expected to cross biological membranes.

C.2. Ecotoxicological Investigations

C.2.1. Algal growth inhibition test

TEST SUBSTANCE	20.04% aqueous emulsion of test substance.
METHOD	OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 1-100 mg/L (based on active constituent) Actual: <1-96 mg/L (based on active constituent)
Auxiliary Solvent	None
Water Hardness	Not recorded
Analytical Monitoring	Haemocytometer and light microscope. A Coulter® Multisizer Particle Counter could not be used due to interference from dispersed test material.
Remarks - Method	A range finding test was conducted by subjecting duplicates of algal cells (~1×10^4/mL) to nominal concentrations of 0.10, 1.0, 10 and 100 mg active constituent/L. All solutions were corrected for a test material content of 20.04%. A control was also run. On the basis of the range finding test a definitive test was run using nominal concentrations of test substance of 1.0, 3.2, 10, 32 and 100 mg/L (active constituent). The initial concentration of algal cells for the definitive test was ~4×10^3 cells/mL, below the standard amount of 1×10^4 cells/mL. However, this did not appear to affect the result of the study. The test concentrations were run in triplicate and six replicates of the blank solution were run. A positive control ($K_2Cr_2O_7$) was also run at concentrations of 0.0625, 0.125, 0.25, 0.50 and 1.0 mg/L. The flasks were incubated at 24±1°C under continuous illumination of approximately 7000 Lux. An analysis of the test material was also performed by total organic carbon (TOC) at the beginning and at the end of the test.

RESULTS

Biomass		*Growth*	
EbC50 *mg/L at 72 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 72 h*	*NOEC* *mg/L*
2.7	1.0	3.1	1.0

Remarks - Results	The test cultures varied from very fine dispersions to white homogenous dispersions, dependent on the concentration. After 72 hours the 1.0 and 3.2 mg/L solutions appeared as pale green dispersions, whilst the higher concentrations remained as white homogenous dispersions (consistent with the test result). The pH increased slightly from 7.4-7.5 to 7.4-7.8 at 72 hours and this is considered within limits of the guidelines. The recovery of the test material at 0 hours was 96% in the highest concentration but lower in the other concentrations. At the end of the test the recovery was 27% and 29% in the 100 and 32 mg/L test solution respectively; with organic carbon below the detection limit (1 mg/L) for the remaining test solutions. The test substance is believed to have adhered to the glass surfaces and possibly algae. The ErC50 was calculated using one way analysis of variance, incorporating Bartlett's test for homogeneity and Dunnett's multiple comparison procedure. The 95% CI was 2.9-3.2 mg/L. All results relate to the nominal concentration of the active constituent.
CONCLUSION	The test substance is toxic to algae.
TEST FACILITY	SafePharm (2007)

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