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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Maxemul 5010

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)
Croda Singapore Pty Ltd Trading as Croda Australia (ABN: 34 088 345 457)
Ground Floor, Suite A1, 44-46 Mandarin Street
Villawood NSW 2163

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Chemical name; Other names; CAS number; Molecular formula; Structural formula; Molecular weight; Spectral data; Methods of detection and determination; Degree of purity; Impurities; Import volume; Confidential details of use; Residual Monomers/Other Reactants; Polymer constituents; Details of analogue chemical.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Boiling point; Vapour pressure; Hydrolysis as a function of pH; Partition coefficient; Adsorption/desorption coefficient; Dissociation constant; Particle size; Flammability limits; Autoignition temperature; Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
United States of America (year unknown)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Maxemul 5010

ANALYTICAL DATA
Reference IR, and GPC spectra were provided.

MOLECULAR WEIGHT
> 1000 Da

3. COMPOSITION

DEGREE OF PURITY > 90%

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White to yellow coloured waxy solid

Property	Value	Data Source/Justification
Pour Point	33°C	MSDS
Boiling Point	Not determined	Estimated to be high, based on molecular weight.
Density	1057 kg/m^3 at 50°C	MSDS
Vapour Pressure	< 10^{-8} kPa	Expected to have a low vapour pressure based on high molecular weight.
Water Solubility	~300 g/L at 20°C	Measured
Viscosity	11.1 x 10^4 Pa.s at 50°C	MSDS
Hydrolysis as a Function of pH	Not determined	Contains functional groups that may be hydrolysed under environmental pH conditions (pH 4-9).
Partition Coefficient (n-octanol/water)	Not determined	Estimated to be low (< 3) based on the measured water solubility.
Adsorption/Desorption	Not determined	Unlikely to adsorb to soil or organic media based on measured water solubility.
Dissociation Constant	Not determined	Contains acid functionality, which should be largely dissociated in environmental pH range of 4-9.
Particle Size	Not determined	Waxy solid at ambient temperatures.
Flash Point	262°C (closed cup)	MSDS
Flammability	Not expected to be highly flammable	Estimated from the measured flash point.
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

DISCUSSION OF PROPERTIES

The notified polymer is highly viscous, highly soluble in water, hydrophilic and non-volatile. It is expected to be a surface-active agent.

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

Reactivity: The notified polymer is predicted to be stable under normal conditions of use, however contact with strong acids or oxidising agents should be avoided.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a pure solid (> 90%) or as a component in finished coatings or adhesive formulations (< 5% concentration).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	10-30	10-30

PORT OF ENTRY

The notified polymer will be introduced through all major Australian sea ports, but especially through Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

None known at this time. The notifier states that it is likely the notified polymer will be supplied to coatings and adhesives manufacturers.

TRANSPORTATION AND PACKAGING
The notified polymer will be transported to the manufacturing or customer site by road or rail. It will be transported either as a solid in sealed 25 kg or 200 kg steel drums, or as a component within finished coating formulations in 4 L or 15 L steel containers.

USE
The notified polymer will be used as a stabiliser in a wide range of emulsion polymerisation products that will subsequently be used as binders in coatings or adhesives (< 5% concentration). Coatings containing the notified polymer will primarily be used for wood protection applications ('clearcoats'), by both professional (≥ 90%) and do-it-yourself (DIY) users (≤ 10%). Adhesives containing the notified polymer will be used in the manufacture of adhesive labels.

OPERATION DESCRIPTION
Imported finished coating or adhesive products will not be reformulated or repackaged in Australia. The imported solid notified polymer will be supplied to customers for blending and use in coatings or adhesive products.

Formulation
The notified polymer will be pumped to the mixing equipment through taps in the drums or by direct lines. It will then be blended with solvents, water, pigments and other additives to produce coatings or adhesive products. All mixing processes will occur under local exhaust ventilation, designed to eliminate volatiles at the point of generation. The finished products will be filled into packaging containers via pipes and transfer lines.

End-use
Coating applications
The majority (90%) of the coating products containing the notified polymer will be sold to commercial applicators for professional application, especially to wood flooring. During application, the product containing the notified polymer will be manually measured, transferred to a mixing vessel and applied to the flooring material by spray (~85% of the applied product), roller (~10%) or brush (~5%). It is expected that up to 10% of the finished coatings may be applied in DIY applications. DIY users will predominantly use rollers and brushes to apply the coatings.

Adhesive applications
At the adhesive manufacturing sites, the adhesive product will be applied to the substrate using an automated process. The adhesive will initially be transferred by pump from the packaging containers to a storage tank, and then as required into the laminating or coating machine trays. The adhesive will then be transferred from these trays to an etched gravure roller that will apply the adhesive to a paper or plastic tape or label stock. The label stock will be heated, dried and fixed to a non-stick backing sheet. The label stocks will then be wound on to rolls or stacked in sheets ready for further printing or die cutting into individual labels.

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)*
Waterside workers	10	4	40
Storage & transport personnel	70	4	50
Formulation workers	50	5	100
Quality control workers	5	4	50
Maintenance workers	10	2	20
Professional applicators	100	6	200

EXPOSURE DETAILS

Transport and storage
Waterside, transport and storage workers will only handle the notified polymer in closed steel containers or drums. No exposure is expected except in extreme circumstances where the containers are damaged and the contents spilt.

Formulation
Formulation workers will experience dermal and ocular exposure to the notified polymer (> 90%) as a result of drips, spills and splashes during transfer into the mixing vessels. Additionally, dermal and ocular exposure to the notified polymer in formulations (< 5% concentration) may occur during the taking and testing of quality control samples, connection and disconnection of filling lines and during maintenance of equipment. Inhalation exposure (to < 5% concentration) due to the formation of aerosols during the blending process is possible, especially during the formulation of products of lower viscosity. As blending will take place in closed vessels, inhalation exposure to aerosols is expected to be minimal except when the vessel is opened for sampling or additions.

Dermal and ocular exposure is expected to be minimised through the use of personal protective equipment (PPE) such as gloves, safety glasses and coveralls. Local exhaust ventilation (LEV) is expected to be available at most workstations, and this is expected to reduce the extent of inhalation exposure. As the notified polymer is unlikely to volatilise given its molecular weight, there will be no vapours to cause inhalation exposure to workers.

End use
Coating application
Professional paint applicators will experience dermal and ocular exposure to the notified polymer during handling and application of the finished coating products (< 5% concentration). Inhalation exposure is likely during spray application of coatings.

Professional applicators will wear coveralls, safety goggles and impervious gloves, and these measures are expected to reduce dermal exposure to the notified polymer. Inhalation exposure may be minimised during spray application of the coatings through the use of appropriate respirators, and for smaller items through the use of spray booths.

Workers are likely to make dermal contact with dried/cured coatings on surfaces that contain the notified polymer. However, in these the notified polymer will be bound within an inert matrix and is not expected to be available to cause further exposure to workers.

Adhesive application
Workers involved in the production of adhesive labels may experience dermal and ocular exposure to adhesive formulations containing the notified polymer (at < 5% concentration). These may occur as a result of drips, spills and splashes during transfer to the laminating or coating trays, connection and disconnection of filling lines and during maintenance of equipment.

These workers are expected to use personal protective equipment such as gloves, safety glasses and coveralls to minimise any potential for dermal and ocular exposure. The notified polymer is unlikely to volatilise given its molecular weight, therefore inhalation exposure to the notified polymer is unlikely, despite the adhesive undergoing heat treatment after application to the label. Nonetheless, LEV is likely to be used at sites where the adhesives will be handled and heated.

It should be that the notified polymer is unlikely to volatilise given its molecular weight, so there will be no vapours to cause exposure to workers.

6.1.2. Public exposure
The exposure of the public to the notified polymer in finished coatings (< 5% concentration) is expected to be identical to that experienced by professional applicators when applying the coating by brush and roller. However, public use of coatings is likely to only be occasional and so the exposure of members of the public is likely to be limited by its duration.

Members of the public are likely to make dermal (and possible oral) contact with dried/cured coatings that contain the notified polymer. However, as the notified polymer will be bound within an inert matrix, this is not expected to cause exposure to members of the public. Given its molecular weight and polarity, it is unlikely to

leach significantly from dried coatings.

Adhesive products containing the notified polymer will only be used by industry, and so public exposure should not occur. The public will make dermal contact with the dried adhesive on adhesive labels. Exposure would be expected to be minimal due to the small amount of adhesive product on the labels and the infrequency of the event.

6.2. Human health effects assessment

No toxicity data were submitted for the notified polymer. However, toxicity data was supplied for an analogue of the notified polymer that was considered acceptable by NICNAS. It should be noted that any toxicity observed for the analogue might be expected to be higher for the notified polymer, as absorption would be expected to be more favourable for the notified polymer based on molecular weight differences and degree of hydrophilicity. The results from toxicological investigations conducted on the analogue are summarised in the table below. Details 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
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating

Absorption
The notified polymer has a high water solubility and an estimated log P_{ow} of < 3. If log P_{ow} is > 1 then some dermal absorption is likely as the notified polymer contains a percentage of low molecular weight species of < 1000 Da.

Inhalation absorption is unlikely given the high molecular weight and hydrophilicity of the notified polymer.

Acute toxicity
The notified polymer is of low toxicity via the oral and dermal routes based on analogue data.

Irritation and Sensitisation
The notified polymer is slightly irritating to the skin and eyes based on analogue data. This may be the result of some surfactant properties (Hulzebos, 2005). Given the differences between the analogue and notified polymer as stated above, the notified polymer may be expected to exhibit stronger irritancy; however, this is not expected to result in its classification.

No sensitisation data was presented for the notified polymer or its analogue. However, the notified polymer does not contain any structural alerts for sensitisation (Barratt et al, 1994).

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
The limited data available on the health effects of an analogue of the notified polymer indicate a low hazard.

The anticipated worker exposure to the notified polymer is expected to be limited, as little direct handling occurs. Exposure is likely during QC sampling and analysis, transfer of the notified polymer into the reaction vessel and cleaning of the reaction vessels and pump lines. Once the polymer has been incorporated in the formulation, exposure would be reduced due to dilution. Exposure during handling and formulation is expected to be mitigated through the use of engineering controls, such as local exhaust ventilation and personal protective equipment.

There is potential for high levels of inhalation exposure during spray application of coating products containing the notified polymer at < 5%. However, it is expected that suitable respiratory protection will be used to reduce potential exposure by the inhalation route. Furthermore, the notifier states that spray application

of coatings containing the notified polymer for smaller items will occur in spray booths.

There is also potential for high levels of dermal and ocular exposure during spray application. However, exposure should be minimised through the use of personal protective equipment such as gloves, safety glasses and coveralls, and good work practices

The notified polymer is not expected to pose an unacceptable risk, provided that workers use engineering controls, good work practices and particularly respiratory protection during spray application.

6.3.2. Public health

The limited data available on the health effects of an analogue of the notified polymer indicate a low hazard.

Dermal and ocular exposure to the notified polymer by the public is likely when using finished coating products at concentrations of < 5%. However, as a consequence of its water solubility, it will be readily removed by washing.

The public will also be exposed to end-use products (i.e. coatings) containing the notified polymer at concentrations of < 5%. However the notified polymer will be bound within a cured polymeric matrix and therefore is not expected to pose a significant risk.

Based on the expected low exposure and expected low hazard, the notified polymer is not expected to pose an unacceptable risk to the public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Release of the notified polymer at the manufacturing site is unlikely to result from storage or transport processes as the polymer is sealed inside durable steel containers.

Release of the notified polymer during blending may be possible but suitable processes will be in place to minimise loss and readily handle any spills that may occur. The formulation processes will take place at the customer manufacturing site and, in the unlikely event that a major spill occurs, the notified polymer will be contained by existing plant bunding and appropriately collected for disposal as landfill. An estimated 1% of the annual introduction quantity of the notified polymer may be lost from spills or leaks and would be collected for appropriate disposal.

Manufacturing equipment washings are likely to account for less than 2% loss of the annual introduction volume of the notified polymer. The washings are collected in holding tanks on-site that will be emptied by licensed contractors on a regular basis, and the notified polymer will be disposed to landfill.

Residues of the notified polymer that remain in the empty storage containers or drums are estimated to be less than 1% of the annual introduction volume of the notified polymer. Drums may be sent straight to landfill or reconditioned by external recycling contractors and reused with the residues being appropriately collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

An estimated less than 1% of the annual introduction volume of the notified polymer will remain as residues in empty coating cans. The cans may be left to dry prior to disposal to landfill.

The losses from overspray during spray application of the finished products are likely to be approximately 10-25% of the applied product and will be captured on kraft paper in spray booths for disposal to landfill or incineration.

Washings resulting from cleaning the application equipment used by professionals (approximately 2% of annual introduction volume) would be isolated and collected for disposal by licensed waste contractors. The washings would then undergo various treatments including deflocculation, thus allowing collection and

disposal of the notified polymer to landfill or incineration.

DIY applications (approximately 10% of total applications) may result in the loss of the notified polymer to the sewers, estimated to be less than 150 kg of annual introduction volumes (assuming less than 5% of the available DIY volume is released to sewers). These releases would result from cleaning the application equipment (i.e. brush or roller) with the residues likely to be washed down the drain. These residues will remain in the water column due to high solubility. Any residues in end-use cans will be disposed in household garbage or will be disposed of at dedicated deposits.

The notified polymer will be bound in the coating matrix once the coating or adhesive has dried and would not be bioavailable to the surrounding environment. Disposal of the substrate material would predominantly be as landfill; the fate of the notified polymer in the coating would be related to the degradability of the substrate material, usually wood. Sanding of timber floors coated with the notified polymer may generate particulate matter, however this would be swept up and landfilled or deposited on the ground.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will predominantly be disposed of by licensed waste contractors. Losses during application by professional applicators and blending processes will be collected and disposed of by licensed waste contractors.

The fate of the notified polymer will depend on the substrate to which it is attached. It is expected that most substrate materials will ultimately end up in landfill.

There will be some loss to the domestic sewer as a result of DIY activities, however, this is estimated to be highly dispersed and highly diluted.

7.1.2 Environmental fate

One test relating to biodegradability was presented. The results indicate that the notified polymer is readily biodegradable. For the details of the environmental fate studies please refer to Appendix C.

In the landfill the notified polymer will slowly degrade to water and oxides of carbon.

7.1.3 Predicted Environmental Concentration (PEC)

In determining the Predicted Environmental Concentration (PEC) for the notified polymer in the aquatic compartment, 10% of the introduction volume has been assumed available for the general public with 5% of this volume likely to be released to sewers. A worst-case scenario of 0.5% loss to the aquatic environment is used to calculate the expected PEC.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	30,000	kg/year
Proportion expected to be released to sewer	0.5%	
Annual quantity of chemical released to sewer	150	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.41	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:	0.1	µg/L
PEC - Ocean:	0.01	µg/L

7.2. Environmental effects assessment

Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. Further, the toxicity to algae is likely

to be reduced due to the presence of calcium ions, which will bind to the functional groups (Nabholz *et al*. 1993).

This is supported by the results from ecotoxicological investigations conducted on the notified polymer, summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	48-hour EC50 87.9 mg/L	Slightly toxic to *Daphnia magna*

7.2.1 Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
	88	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	88	µg/L

Using the available EC50 of 88 mg/L for *Daphnia* toxicity and dividing it by a safety factor of 1000 gives a Predicted No Effect Concentration (PNEC) of 88 µg/L.

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.1	88	0.001
Q - Ocean	0.01	88	0.0001

From PEC/PNEC (0.10 µg/L ÷ 88 µg/L) ratio, a value of 0.001 is the calculated risk quotient (Q) for the aquatic environment. The notified polymer is therefore not expected to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is not 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***
Environment		
Acute	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

REGULATORY CONTROLS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - *Local exhaust ventilation*
  - *Closed mixing vessels*

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - *Use of spray paints containing the notified polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC 1999)*
  - *Avoid contact with eyes.*
  - *Avoid contact with skin*
  - *Avoid inhalation*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - *Respiratory protection where appropriate*

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

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
  - *Store in original containers away from sunlight.*

Emergency procedures

- Spills/release of the notified polymer should be handled by absorption with sand, soil or sawdust and collected into suitable containers for disposal. The spillage area should be washed with water and detergents with all washings collected for adequate disposal. The notified polymer and formulations containing the notified polymer should not be allowed to enter drains, sewers or waterways.

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 a component of coatings and adhesives, or is likely to change significantly;
- the amount of chemical being introduced has increased from 30 tonnes per annum, 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.

Material Safety Data Sheet
The MSDS of the notified chemical 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

Water Solubility ~300 g/L at 20°C

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Determined using a modified shake flask method
Test Facility	Covance Laboratories (2002)

Hydrolysis as a Function of pH Not determined

Remarks	Test not conducted. The hydrolysable functional groups present in the notified polymer typically hydrolyse at pH 5-6

Dissociation Constant Not determined

Remarks	Test not conducted. The polymeric structure has an acidic functional group present that typically exhibits a pKa of 3.75, and would be fully dissociated in the environmental pH range of 4-9.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Acceptable analogue of the notified polymer
METHOD	No test method specified (conducted according to GLP)
Species/Strain	Rat/Wistar Alpk:AP_fSD
Vehicle	Water
Remarks - Method	The duration of the study was 14 days at one dose level of 2000 mg/kg, similar to the OECD TG 401 Acute Oral Toxicity – Limit Test.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5(M)	2000	0/5
II	5(F)	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity	No significant signs of mortality were observed.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	None
CONCLUSION	The notified polymer is expected to be of low toxicity via the oral route based on analogue data.
TEST FACILITY	Central Toxicology Laboratory (1996a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Acceptable analogue of the notified polymer
METHOD	No test method specified (conducted according to GLP)
Species/Strain	Rat/Wistar Alpk:AP_fSD
Vehicle	water
Type of dressing	Unknown/not specified
Remarks - Method	The duration of the study was 14 days at one dose level of 2000 mg/kg, similar to the OECD TG 402 Acute Dermal Toxicity – Limit Test.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5(M)	2000	0/5
II	5(F)	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No significant signs of irritation were observed.
Signs of Toxicity - Systemic	No significant signs of toxicity were observed.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	None
CONCLUSION	The notified polymer is expected to be of low toxicity via the dermal route based on analogue data.
TEST FACILITY	Central Toxicology Laboratory (1996b)

B.3. Irritation – skin

TEST SUBSTANCE	Acceptable analogue of the notified polymer
METHOD	No test method specified (conducted according to GLP)
Species/Strain	Rabbit/strain unknown
Number of Animals	3 females
Vehicle	Not stated
Observation Period	3 days
Type of Dressing	Not specified
Remarks - Method	A group of 3 female rabbits received a single 4-hour application of 500 mg of the analogue and were assessed for up to 3 days for any signs of skin irritation. The dose is equivalent to that stated in OECD TG 404 Acute Dermal Irritation/Corrosion.

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	0.7	1	48 hours	0
Oedema	0	0	0	0	N/A	0

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

Remarks - Results	Slight irritation (redness) was observed in all 3 animals test after 1 hour. The irritation persisted for one of the animals for the full observation period but was resolved in 2 of the animals at the 72 hour observation.
CONCLUSION	The notified polymer is expected to be slightly irritating to the skin based on analogue data.
TEST FACILITY	Central Toxicology Laboratory (1996c)

B.4. Irritation – eye

TEST SUBSTANCE	Acceptable analogue of the notified polymer
METHOD	No test method specified (conducted according to GLP)
Species/Strain	Rabbit/strain unknown
Number of Animals	3 females
Observation Period	4 days
Remarks - Method	100 mg of the analogue was applied into one eye of each of three rabbits and the eyes were examined for up to 4 days to assess the grade of ocular reaction. The dose is equivalent to that stated in OECD TG 405 Acute Eye Irritation/Corrosion.

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	0.7	0.7	1.0	2.0	3 days	0
Conjunctiva: chemosis	0.3	0	0	1.0	1 day	0
Conjunctiva: discharge	0	0	0	2.0	1 hour	0
Corneal opacity	0	0	0	0	N/A	0
Iridial inflammation	0	0	0	0	N/A	0

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

Remarks - Results	No corneal or iridial effects were noted throughout the study. Moderate conjunctiva discharge was observed in all 3 animals in the first hour but this was resolved in all animals at the 24 hour observation. Slight to

	moderate conjunctival irritation was noted in all treated eyes after 1 hour that was resolved in 2 of the animals at the 3 day observation. All signs of irritation had completely regressed by day 4.
CONCLUSION	The notified polymer is expected to be slightly irritating to the eye based on analogue data.
TEST FACILITY	Central Toxicology Laboratory (1996d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	ISO Standard 14593 – "Water quality: evaluation of the ultimate aerobic biodegradability of organic compounds in an aqueous medium – Method by analysis of inorganic carbon in sealed vessels"
Inoculum	Activated sludge obtained locally (Burley Menston sewage treatment works)
Exposure Period	28 days
Auxiliary Solvent	Water
Analytical Monitoring	Total Organic Carbon analyser – Rosemount Dohrmann DC-80
Remarks - Method	The method employed in this study is essentially the same as the US EPA Guideline OPPTS 835.3120 and equivalent to the OECD 301 series ready biodegradability test methods. The method measures the inorganic carbon formed based on the amount of organic carbon initially dosed.

RESULTS

Maxemul 5010		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
28	82	28	89

Remarks - Results	Based on the results of this test, the notified polymer is unlikely to persist and accumulate in the aerobic environment.
CONCLUSION	The notified polymer is deemed to be readily biodegradable based on the conditions of this test.
TEST FACILITY	Covance Laboratories (2000a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Water
Water Hardness	210-212 mg $CaCO_3$/L
Analytical Monitoring	-
Remarks - Method	No significant protocol deviations

RESULTS

Nominal Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	10	0	0
1	10	0	0
10	10	0	0
100	10	0	6

EC50	87.9 mg/L at 48 hours
LOEC	100 mg/L at 48 hours
Remarks - Results	The method of calculation used to determine the EC50 was not described.

CONCLUSION	The notified polymer is slightly toxic to *Daphnia magna*.
TEST FACILITY	Covance Laboratories (2000b)

BIBLIOGRAPHY

Barratt MD, Basketter DA, Chamberlain M, Admans GD and Langowski JJ (1994) An Expert System Rulebase For Identifying Contact Allergens. *Toxic. in vitro*. 8(5):1053-1060.

Central Toxicology Laboratory (1996a) [Analogue chemical]: Acute oral toxicity to the rat. Report No. CTL/L/7545. Central Toxicology Laboratory, Cheshire, UK (unpublished report provided by the notifier).

Central Toxicology Laboratory (1996b) [Analogue chemical]: Acute dermal toxicity to the rat. Report No. CTL/L/7546. Central Toxicology Laboratory, Cheshire, UK (unpublished report provided by the notifier).

Central Toxicology Laboratory (1996c) [Analogue chemical]: Skin irritation to the rabbit. Report No. CTL/L/7548. Central Toxicology Laboratory, Cheshire, UK (unpublished report provided by the notifier).

Central Toxicology Laboratory (1996d) [Analogue chemical]: Eye irritation to the rat. Report No. CTL/L/7547. Central Toxicology Laboratory, Cheshire, UK (unpublished report provided by the notifier).

Covance Laboratories (2000a). Screening test to assess ultimate biodegradability by measurement of inorganic carbon yield. Report number 346/51-D2145. Covance Laboratories Ltd., North Yorkshire, England. (Unpublished report provided by notifier).

Covance (2000b). Screening toxicity test to *Daphnia magna*. Study number 346/50. Ecotoxicology section, Covance Laboratories Ltd, North Yorkshire, England (unpublished report provided by the notifier).

Covance Laboratories (2002). Maxemul 5010: Determination of the water solubility. Report number 346/102-D2149. Covance Laboratories Ltd, North Yorkshire, England (unpublished report provided by the notifier).

Hulzebos E, Walker JD, Gerner I and Schlegel K (2005) Use of Structural Alerts to Develop Rules for Identifying Chemical Substances with Skin Irritation or Skin Corrosion Potential. *QSAR Comb. Sci.* 24, 332-342.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1999) National Guidance Material for Spray Painting. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

PDS (2001). Maxemul 5010 Product Data Sheet. Uniqema, ICI Chemical and Polymers Ltd.

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

Uniqema (2000). GPC analysis of Maxemul 5010. Test report SEP/W000223RL001 dated 28th April 2000. (Unpublished report provided by notifier).

US EPA (2006). Interpretative Guidance Document for Assessment of Polymers. United States Environmental Protection Agency.