File No: STD/1398

October 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

INUTEC SP-1/INUTEC SP-1 T (INCI Name: Inulin Lauryl Carbamate)

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 Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
STD/1398	CEE CHEM AUSTRALIA PTY LTD PROTECTIVE TECHNOLOGY PTY LTD	Inulin dodecyl carbamate INUTEC SP-1/INUTEC SP-1 T (INCI Name: Inulin Lauryl Carbamate)	ND*	≤10 tonnes per annum	Cosmetics, Adhesives, Surface Coatings

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the data provided, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

In addition, the notified polymer is not classified using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

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

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable 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 an unreasonable 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 introduced in powder form:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in powder form:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m^3.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in powder form:
  – Safety glasses

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

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

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

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, collection and subsequent safe 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 polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer 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(2) of the Act; if
  - the function or use of the polymer has changed from component of cosmetic or cleaning products, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 10 tonnes, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer 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 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.

ASSESSMENT DETAILS

The notifier has submitted with the application an assessment of the chemical by a notification and assessment scheme in an OECD country (Canada). The health and environment hazard assessment of the Canadian reports were provided to NICNAS and where appropriate used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
CEE Chem Australia Pty Ltd (ABN 61 081 398 182)
227A Belmore Rd
RIVERWOOD NSW 2210

Protective Technology Pty Ltd (ABN 66 008 269 341)
Suite 1, 208 Whitehorse Rd
BLACKBURN VIC 3130

NOTIFICATION CATEGORY
Standard: Biopolymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point, Density, Vapour Pressure, Water Solubility, Partition Coefficient, Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability, Acute Dermal Toxicity, Acute Inhalation Toxicity, Repeat Dose Toxicity, Induction of Germ Cell Damage, Chromosome Damage.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2008)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
INUTEC SP-1, INUTEC SP-1 T

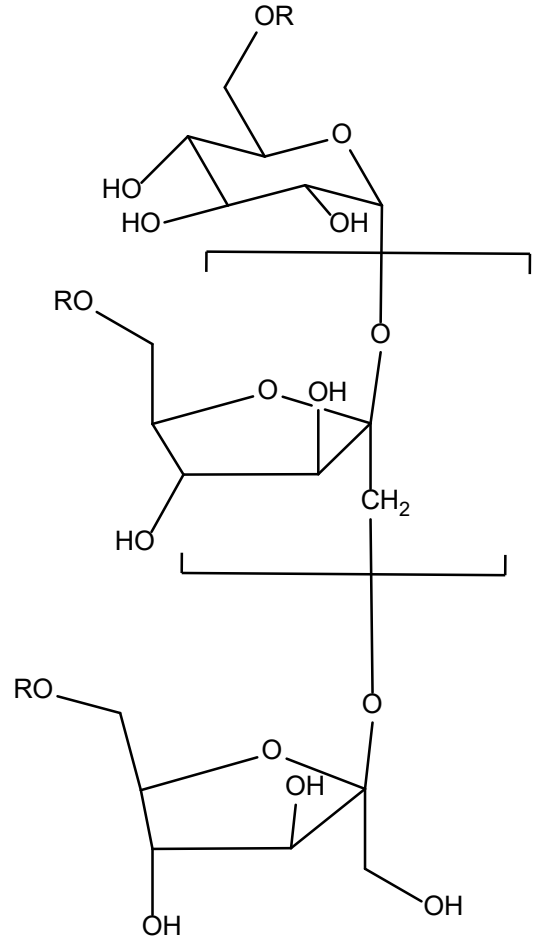
CAS NUMBER
478483-27-1

CHEMICAL NAME
Inulin dodecylcarbamate
Inulin Lauryl Carbamate (INCI Name)

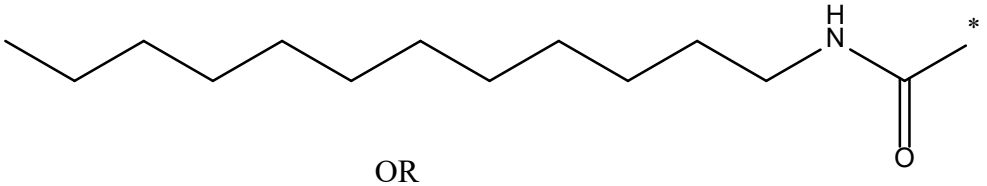
OTHER NAME(S)
Hydrophobised Inulin

MOLECULAR FORMULA
$C_{13}H_{27}NO_2$. xUnspecified

STRUCTURAL FORMULA



where R =



OR

H

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	4,890 Da.
Weight Average Molecular Weight (Mw)	5,093 Da.
Polydispersity Index (Mw/Mn)	1.04
% of Low MW Species < 1000 Da	0.165%
% of Low MW Species < 500 Da	<0.065%

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >96%

POLYMER CONSTITUENTS

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
Inulin	9005-80-5	93	not specified
Dodecane, 1-isocyanato-	4202-38-4	7	not specified

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None

DEGRADATION PRODUCTS
The notified polymer may break down into short chain fatty acids under certain conditions.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: fine white powder

Property	**Value**	**Data Source/Justification**
Melting Point/Freezing Point	174°C	MSDS
Boiling Point	Not determined	Notified polymer is a solid
Density	400 kg/m^3 at 25°C	MSDS
Vapour Pressure	<1x10^{-8} kPa	Estimated based on high molecular weight (US EPA, 2010)
Water Solubility	9.92 g/L at 21°C	Measured
Hydrolysis as a Function of pH	pH 3.5: <20% after 12 months pH 4.0: <10% after 12 months pH 4.5: <5% after 12 months	Measured for an analogue (inulin). The polymer backbone is considered stable at > pH 4.5. Carbamate functionality in the notified polymer may slowly hydrolyse under environmental conditions.
Partition Coefficient (n-octanol/water)	log Pow = -1.8 at 21°C	Measured
Adsorption/Desorption	Not determined	The notified polymer is expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined	The notified polymer is not expected to dissociate in the environmental pH range (4-9).
Particle Size	Inhalable fraction (<100 μm): 46.87% Respirable fraction (<10 μm): 4.37% Ave. particle size = 120-180 μm	Measured
Flash Point	Not determined	Not expected to have a low flash point based on structure
Flammability	Not determined	Not expected to be flammable based on structure
Autoignition Temperature	200°C	MSDS
Explosive Properties	Dust clouds can be ignited by a spark	MSDS

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

Reactivity
Dust clouds of the notified polymer may be explosive.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a fine powder at >96% concentration.

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

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

PORT OF ENTRY
Sydney, Melbourne

IDENTITY OF RECIPIENTS
Cee Chem Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer at >96% concentration will be imported by air or sea in 10 kg fibre drums or 25 kg multiwall paper bags and transported by road to various customers for reformulation. The finished products will be packaged in a variety of packaging formats including tubes, drums or jars from 100 g to 20 kg.

USE
The notified polymer will be used as an emulsifier and dispersant in personal care products, such as creams, lotions, shampoos and bath products, paints, adhesives and household products, such as polishes at concentrations up to 1%.

OPERATION DESCRIPTION
The notified polymer will undergo quality assurance tests prior to being reformulated into personal care, paint, adhesive and household products. The notified polymer will be weighed and manually added to the mixing tank. The mixing facilities are expected to be fully automated, closed systems with local exhaust ventilation. After reformulation, the finished products containing the notified polymer at concentrations up to 1% may undergo further quality assurance tests before being filled into containers for distribution to professionals for end use or retail sale.

The personal care products may be used in the form of a cream, lotion, spray or suspension for application to the skin or hair.

Paints and adhesives may be applied to a variety of substrates by spray, brush or roller.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS
Reformulation
Dermal, ocular and inhalation exposure of workers to the notified polymer at >96% concentration in powder form may occur during handling of the import containers, weighing and charging to the blending vessel, mixing in open vessels (which may occur in some facilities), during cleaning operations, sampling or analysis tasks, and transfer to end-use containers. Exposure to the notified polymer is expected to be lowered by the mainly

automated and enclosed processes used, and the ventilation likely to be in place as well as the personal protective equipment (PPE) expected to be used by workers (dust mask and goggles) during reformulation.

End use
Workers in hair and beauty salons may experience extensive dermal exposure during application of products containing the notified polymer at up to 1% by hand. Such professionals may use some personal protective equipment (such as gloves) to minimise repeated exposure, and good hygiene practices are expected to be in place. Exposure of such workers is expected to be of a similar or higher level than that experienced by consumers using products containing the notified polymer.

Workers using household cleaning products, such as polishes containing the notified polymer at up to 1% concentration are expected to use gloves during application of the product and therefore, exposure to the notified polymer is expected to be low.

Ocular and inhalation exposure may occur during spray application of paints and adhesives containing the notified polymer at up to 1% concentration. Exposure is expected to be lowered if application takes place in a spray booth by trained personnel using PPE such as a fitted respirator, gloves and full length protective clothing. Dermal and ocular exposure may also result from spills, drips and splashes during roller or brush application of paints and adhesives containing the notified polymer at up to 1% concentration. Exposure would be lowered if PPE such as gloves, glasses and full length protective clothing are used.

6.1.2. Public exposure
Public exposure to the notified polymer is expected to be widespread and frequent through daily use of personal care, paint, adhesive and household products containing the notified polymer at concentrations up to 1%. Exposure to the notified polymer will vary depending on individual use patterns. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray. Accidental ingestion from the use of these types of products is also possible from facial application of cosmetic products by spray.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution.
The notified polymer has a high molecular weight (4,890 Da.), low water solubility (<10 g/L) and low partition coefficient (log Pow = -1.8) and therefore is not expected to be absorbed by the dermal, oral or inhalation routes.

Acute toxicity
The notified polymer was tested in a single dose acute oral toxicity study (limited dose toxicity) in rats at 2000 mg/kg bw according to OECD TG 401. No mortalities or signs of toxicity were reported in any of the treated animals (Élevage Scientifique des Dombes (2000a)).

Irritation and Sensitisation
The notified polymer was found to be non-irritating in a dermal irritation test conducted in rabbits according to OECD TG 404. No signs of irritation were reported following application of the notified polymer to intact rabbit skin for 4 hrs (Élevage Scientifique des Dombes (2000b)).

No signs of ocular irritation were observed during an eye irritation test conducted on three New Zealand White male rabbits, according to OECD TG 405. The individual ocular irritation index for each animal was 0. The Total Maximum Ocular Irritation Index for the three rabbits was also 0 (Élevage Scientifique des Dombes (2000c)). The notified polymer is considered to have the potential to cause mechanical eye irritation in powder form.

The notified polymer was found to be non-sensitising in a guinea pig skin sensitisation test (Magnusson and Kligman method) conducted according to OECD TG 406 (see Appendix B for details).

Mutagenicity
The notified polymer was not mutagenic in a bacterial reverse mutation study (Biomatech-NAMSA, 2002).
Carcinogenicity
The notified polymer contains an alkyl carbamate functionality which is a functional group of concern for carcinogenicity according to the Benigni/Bossa rule base for mutagenicity and carcinogenicity (Benigni et al., 2008). However, given the high molecular weight and other unfavourable absorption characteristics, it is not expected to have the potential to cross biological membranes and cause carcinogenicity.

Health hazard classification
Based on the data provided, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is not classified as hazardous and is therefore not expected to cause adverse effects to workers involved in reformulation or workers using cosmetic, paint, adhesive or household products containing the notified polymer at up to 1%.

The notified polymer may cause mechanical eye irritation to workers handling the powder during reformulation. However, the use of safety goggles as stated by the notifier as well as the implementation of good hygiene practices is expected to minimise the potential for ocular exposure for these workers.

Overall, the notified polymer is not expected to pose an unreasonable risk to workers exposed to the notified polymer in powder form at up to 96% concentration or in finished cosmetic, paint, adhesive or household products at concentrations up to 1%.

6.3.2. Public Health
Members of the public are expected to experience widespread exposure to the notified polymer at up to 1% concentration in cosmetic, paint, adhesive and household products. However, given the absence of known health hazards, this exposure is not expected to lead to an unreasonable risk.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
Release of the notified polymer to the environment may occur in an accident during transport or an accidental spill during handling. Spills are expected to be collected and disposed of to landfill. The notified polymer will be formulated into personal care, paints, adhesives and household products in Australia. Equipment washings containing the notified polymer are expected to be treated at a biological water treatment plant prior to release to sewer.

RELEASE OF CHEMICAL FROM USE
The notified polymer is expected to be released to sewer in domestic situations across Australia as a result of its use in personal care and household products. Paints and adhesives containing the notified polymer are expected to be available for both commercial and consumer use. Wastes and equipment washings from application of paint and adhesives to substrates are expected to be predominantly disposed of to landfill, although some release to sewers may occur.

RELEASE OF CHEMICAL FROM DISPOSAL
Notified polymer in paints and adhesives are expected to share the fate of articles to which they have been applied and may be disposed of to landfill or recycled depending on the substrate. Small amounts may be sent to landfill as residues in empty import and end-use consumer containers, or washed to sewer when containers

are rinsed before recycling.

7.1.2. Environmental Fate

The majority of the notified polymer in personal care and household products will enter the sewer system. The provided study indicates that hydrolysis of the polymer backbone will not be significant under environmental conditions, although the carbamate bonds may hydrolyse slowly. Hydrolysis degradation products would be expected to partition to solids and be readily biodegradable. The notified polymer is not readily biodegradable but is inherently biodegradable (56% in 28 days, OECD 301D). Degradation products are not expected to bioaccumulate. The notified polymer is expected to undergo some sorption to sludge, soil and sediment because of its surface activity. If released to surface waters the notified polymer is expected to disperse and degrade. Due to its high molecular weight and low partition coefficient the notified polymer is not expected to bioaccumulate.

Some of notified polymer may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation. Notified polymer residues in landfill, soil and sludge are expected to have low mobility, and are expected to degrade to form water and oxides of carbon and nitrogen.

The majority of the notified polymer used in paints and adhesive are expected to form part of inert polymer matrix adhering to substrates to which it has been applied. In this form, the notified polymer is not expected to be mobile or bioavailable when disposed of to landfill. Depending on the substrate, some of the notified polymer in paints and adhesives may be disposed of to landfill, or thermally decomposed to water and oxides of carbon and nitrogen during metals reclamation.

7.1.3. Predicted Environmental Concentration (PEC)

The worst case scenario for exposure to the aquatic environment is for the entire import volume of notified polymer to be washed to sewer following its use in personal care and household products with no removal of the notified polymer in the sewage treatment plant, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

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)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.06	µg/L
PEC - Ocean:	0.61	µg/L

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 >100 mg/L	Not harmful to fish
Daphnia Toxicity	48 h EC50 >100 mg/L	Not harmful to aquatic invertebrates

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is not harmful to fish and aquatic invertebrates, and is considered not harmful to aquatic life.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the acute fish toxicity of the notified polymer and an assessment factor of 1000. A conservative assessment factor is appropriate as acute ecotoxicological endpoints are only provided for two trophic levels, while no chronic data are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Fish).	>100	mg/L
Assessment Factor	1,000	
PNEC:	>100	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:	6.06	>100	<0.061
Q - Ocean:	0.61	>100	<0.006

The majority of the notified polymer will either be disposed of to sewer, or disposed of to landfill in the form of an inert polymer matrix adhering to articles. The assessment of the worst case scenario, with 100% release to sewer with no mitigation by the partial removal from waste water via biodegradation and sorption to sewage sludge, shows that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in the aquatic environment based on its annual importation quantity and the partial removal from waste water via biodegradation and sorption to sewage sludge. The notified polymer has low potential for bioaccumulation. The risk quotient (PEC/PNEC) is well below 1 for both riverine and oceanic discharge scenarios. Therefore, on the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 9.92 g/L at 21ºC

Method OECD TG 107 Partition Coefficient (n-octanol/water): Shake Flask Method
Remarks See partition coefficient
Test Facility Henkel KGaA (2007)

Hydrolysis as a Function of pH

Method In-house

pH	*T (°C)*	*Hydrolysis after 12 months*
3.5	20	<20%
4	20	<10%
4.5	20	<5%

Remarks The hydrolysis study was conducted on an analogue, the inulin polymer backbone. The analogue is considered hydrolytically stable above pH 4.5.
Test Facility Beneo (2011)

Partition Coefficient (n-octanol/water) log Pow = -1.8 at 21ºC

Method OECD TG 107 Partition Coefficient (n-octanol/water): Shake Flask Method
Remarks The log Pow is calculated from the individual solubilities in water and *n*-octanol for surface-active materials such as the notified polymer. The concentration of the notified polymer in solution was determined by total organic content in water and loss on drying (gravimetric) in *n*-octanol.
Test Facility Henkel KGaA (2007)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin sensitisation

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 406 Skin Sensitisation – Magnusson and Kligman.
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 3.125% topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 3.125% topical: 100%
Signs of Irritation	Signs of irritation were observed immediately following topical application in the negative control group as well as the test group. However, no signs of irritation were observed 24 and 48 hrs following the induction.
CHALLENGE PHASE	
1st challenge	topical: 100%
Remarks - Method	The rest period in this test was 17 days, exceeding the recommended rest period in the OECD TG 406 of 10-14 days. It is uncertain whether this would have any significant effect on the outcome of the study.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*	
		24 h	*48 h*
Test Group	50%	0/10	0/10
	100%	0/10	0/10
Control Group	50%	0/5	0/5
	100%	0/5	0/5

Remarks - Results	No signs of irritation or sensitisation were observed following challenge with the notified polymer at 50% or 100%.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	Phycher Bio développement (2002)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	S9 was prepared from phenobarbital/methylcholanthrene or Aroclor 1254 induced rate liver.
Concentration Range in Main Test	a) With metabolic activation: 25-100% b) Without metabolic activation: 25-100%
Vehicle	0.9% NaCl, Dimethyl sulfoxide (DMSO)
Remarks - Method	The test was conducted to determine whether leachates from the notified polymer were mutagenic. The notified polymer was tested at concentrations of 25% up to 100% in

	0.9% NaCl as well as DMSO. The following positive controls were used: i) without S9: Sodium Azide (TA100, TA1535) ii) 2-Nitrofluorene (TA98) iii) Mitomycin C (TA102) iv) 9-Aminoacridine (TA1537) v) with S9: 2-Anthramine (TA100, TA98, TA102, TA1535, TA1537)
RESULTS	
Remarks - Results	The test report did not include any observations on the growth of the bacterial lawn or precipitation. No statistically or biologically significant increases in the number of revertant colonies were observed in any of the cultures treated with the notified polymer. The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Biomatech-NAMSA (2002)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Activated sludge from oxidation ditch used to treat domestic waste water
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand
Remarks - Method	Summary report provided only. Concentration: 0 and 3.39 mg/L; Temperature: 19.7-20.0°C; pH: 7.1-7.3.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	31	5	78
28	56		

Remarks - Results	Validity criteria for the reference substance and control oxygen depletion were met. The pass levels for ready biodegradability (60% in a 10 day window in the 28 day test) were not met for the notified polymer.
CONCLUSION	The notified polymer is inherently biodegradable
TEST FACILITY	TNO (2000)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Static.
Species	*Brachydanio rerio*
Exposure Period	96 h
Auxiliary Solvent	None reported
Water Hardness	210 mg $CaCO_3$/L
Analytical Monitoring	N/A
Remarks – Method	Summary report provided only. Temperature: 24.4-25.5ºC; pH: 7.8-8.1; oxygen (lowest): 7.4 mg/L; Nominal concentrations: 0, 1.0, 3.2, 10, 32, 100 mg/L.
RESULTS	
LC50	>100 mg/L at 24 hours (survival) >100 mg/L at 96 hours (survival)
NOEC	≥100 mg/L at 96 hours (survival) ≥100 mg/L at 96 hours (condition)
Remarks – Results	Summary provided only.
CONCLUSION	Not harmful to fish
TEST FACILITY	TNO (1999a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for *Daphnia* - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	210 mg $CaCO_3$/L
Analytical Monitoring	N/A
Remarks - Method	Summary report provided only. Temperature: 20.5-20.7ºC; pH: 7.9-8.0; oxygen (lowest): 8.4 mg/L; Nominal concentrations: 0, 1.0, 3.2, 10, 32, 100 mg/L.
RESULTS	
LC50	>100 mg/L at 24 hours (mobility) >100 mg/L at 48 hours (mobility)
NOEC	≥100 mg/L at 48 hours (mobility) ≥100 mg/L at 48 hours (condition)
Remarks - Results	Summary provided only
CONCLUSION	Not harmful to aquatic invertebrates
TEST FACILITY	TNO (1999b)

BIBLIOGRAPHY

Beneo (2010) Molecular Weight Determination – INUTEC SP1. 6 December 2010. Beneo, Leuven-Wijgmaal, Belgium (Unpublished report provided by notifier)

Beneo (2011) Hydrolysis Data as a Function of pH – Hydrolysis of INULIN N25. 19 May 2011. Beneo, Leuven-Wijgmaal, Belgium (Unpublished report provided by notifier)

Benigni, R., Bossa, C., Jeliazkova, N., Netzeva, T., Worth, A. The Benigni/Bossa rulebaase for mutagenicity and carcinogenicity – a module of Toxtree. Joint Research Centre and Institute for Health and Consumer Products (European Commisssion).

Biomatech-NAMSA (2002) Evaluation of the Mutagenicity of Raw Material, Reference Lic 0.1, Batch PC-194: AMES Test. Study No. 9211. 30 August 2002. Biomatech-NAMSA, Chasse-sur-Rhône, France.

Élevage Scientifique des Dombes (2000a) A Single Dose Acute Oral Toxicity Study in Rats (Limited dose toxicity). Study report no. DL 251, 2 June 2000. Élevage Scientifique des Dombes, Chatillon sur Chalaronne, France. (Unpublished report provided by notifier)

Élevage Scientifique des Dombes (2000b) Determination of the Primary Cutaneous Irritation of the Product: LIC 0.1 (pure) on Rabbit Skin. Study report no. IPC 305, 22 May 2000. Élevage Scientifique des Dombes, Chatillon sur Chalaronne, France. (Unpublished report provided by notifier)

Élevage Scientifique des Dombes (2000c) Determination of the Ocular Irritation of the Product: LIC 0.1 (pure) in the Rabbit. Study report no. IO 546, 22 May 2000. Élevage Scientifique des Dombes, Chatillon sur Chalaronne, France. (Unpublished report provided by notifier)

Henkel KGaA (2007) Determination of partition coefficient of Inutec SP1 TMABN7ZBN7 according to OECD 107 test procedure. Registration no. 07-15870, 6 December 2007. Henkel KGaA, Düsseldorf, Germany (Unpublished report provided by notifier)

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 (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.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

Phycher Bio développement (2002) Assessment of Sensitising Properties on Albino Guinea Pig – Maximisation Test (according to Magnussen and Kligman). Final Report: SMK-PH-02/0175, 13 September 2002. Phycher Bio développement, Cestas Cedex, France. (Unpublished report provided by notifier)

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.

US EPA (2010) Interpretive Assistance Document for Assessment of Polymers. US EPA Office of Pollution Prevention and Toxic's Sustainable Futures Assessment Program. Available online [26 July 2011]: www.epa.gov/oppt/sf/pubs/iad_polymers_042010.pdf.