File No: LTD/1755

July 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

1-Propanaminium, N,N,N-trimethyl-3-[(2-methyl-1-oxo-2-propenyl)amino]-, chloride, polymer with N-[3-dimethylamino)propyl]-2-methyl-2-propenamide, 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid and 2-propenamide (INCI: Polyquaternium 43)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

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:

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1755	Reckitt Benckiser (Singapore) Pte Ltd	1-Propanaminium, N,N,N-trimethyl-3-[(2-methyl-1-oxo-2-propenyl)amino]-, chloride, polymer with N-[3-dimethylamino)propyl]-2-methyl-2-propenamide, 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid and 2-propenamide (INCI: Polyquaternium 43)	ND*	≤ 1 tonne per annum	Component of cosmetics

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Toxicity (Category 3)	H402 – Harmful to aquatic life
Chronic Toxicity (Category 3)	H412 – Harmful 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 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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself; however, these should be selected on the basis of all ingredients in the formulation.

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should 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 physical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical/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 cosmetics, or is likely to change significantly;
- the amount of polymer being introduced has increased, 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Reckitt Benckiser (Singapore) Pte Ltd (ABN: 13 557 989 730)
1 Fifth Avenue, 4-6 Guthrie House
SINGAPORE 268802

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

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: all physico-chemical properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAMES
Genamin PQ 43 PB (aqueous solution containing the notified polymer at 14-17%)
INCI Name: Polyquaternium 43

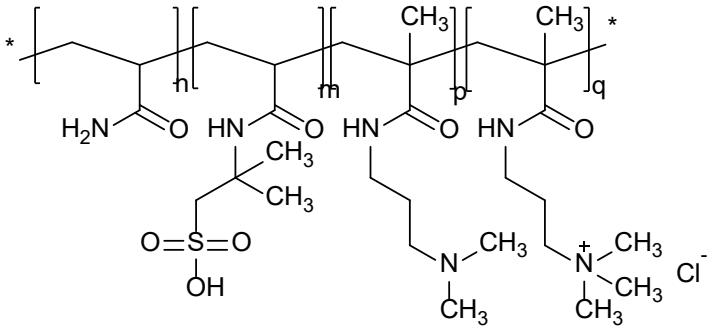
CAS NUMBER
97821-92-6

CHEMICAL NAME
1-Propanaminium, N,N,N-trimethyl-3-[(2-methyl-1-oxo-2-propenyl)amino]-, chloride, polymer with N-[3-(dimethylamino)propyl]-2-methyl-2-propenamide, 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid and 2-propenamide

OTHER NAMES
Acrylamide/Acrylamido propyl trimonium chloride/2-Acrylamidopropyl sulfonate/DMAPA copolymer
Bozequat 4000 (aqueous solution containing the notified polymer at 14-17%)
Genamin PQ43

MOLECULAR FORMULA
$(C_{10}H_{21}N_2O.C_9H_{18}N_2O.C_7H_{13}NO_4S.C_3H_5NO.Cl)x$

STRUCTURAL FORMULA



MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	108,000 Da
Weight Average Molecular Weight (Mw)	509,000 Da
Polydispersity Index (Mw/Mn)	4.69
% of Low MW Species < 1000 Da	< 5%
% of Low MW Species < 500 Da	< 2%

ANALYTICAL DATA

Reference NMR, IR, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 99 % (after removal of water in which it is prepared, at a concentration of 14–17%)

IDENTIFIED HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	2-Propenamide		
CAS No.	79-06-1	*Weight %*	Max. 0.0013
Hazardous Properties	Conc. ≥ 25%: T; R45; R46; R62; R25; R21; R48/25; R48/20/21; R36/38; R43 ≥ 20% Conc. < 25%: T; R45; R46; R62; R22; R48/25; R48/20/21; R36/38; R43 ≥ 10% Conc. < 20%: T; R45; R46; R62; R22; R48/25; R48/20/21; R43 ≥ 5% Conc. < 10%: T; R45; R46; R62; R22; R48/22; R43 ≥ 3% Conc. < 5%: T; R45; R46; R22; R48/22; R43 ≥ 1% Conc. < 3%: T; R45; R46; R48/22; R43 ≥ 0.1% Conc. < 1%: T; R45; R46		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

None

ADITIVES/ADJUVANTS

Chemical Name	2-Phenoxyethanol		
CAS No.	122-99-6	*Weight %*	0.5
Chemical Name	Sodium Benzoate		
CAS No.	532-32-1	*Weight %*	0.3

POLYMER CONSTITUENTS

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
2-Propenamide	79-06-1	75	< 0.0013
1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-	15214-89-8	10	< 0.0010
2-Propenamide, N-[3-(dimethylamino)propyl]-2-methyl-	5205-93-6	10	< 0.0005
1-Propanaminium, N,N,N-trimethyl-3-[(2-methyl-1-oxo-2-propen-1-yl)amino]-, chloride	51410-72-1	5	< 0.0030

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless to opalescent liquid (14–17% notified polymer in water)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	0 °C	(M)SDS*
Boiling Point	100 °C at 101.3 kPa	(M)SDS*
Density	1,050 kg/m^3 at 20 °C	(M)SDS*
Vapour Pressure	Not determined	Expected to be < 10^{-8} mmHg based on the high molecular weight of > 1000 Da
Water Solubility	Not determined	Expected to be readily soluble in water based on the structural information

Hydrolysis as a Function of pH	Not determined	Hydrolysis is not expected to be significant in the environmental pH range (4-9) despite the presence of hydrolysable functional groups
Partition Coefficient (n-octanol/water)	Not determined	Not expected to partition to n-octanol based on the expected ready water solubility
Adsorption/Desorption	Not determined	Expected to adsorb to soil/sediment based on the presence of cationic functional groups
Dissociation Constant	Not determined	Expected to be ionised in the environment given the presence of dissociable functional groups
Flash Point	Not applicable	Introduced as an aqueous dispersion and not isolated
Flammability	Not applicable	Introduced as an aqueous dispersion and not isolated
Autoignition Temperature	Not applicable	Introduced as an aqueous dispersion and not isolated
Explosive Properties	Not explosive	Estimated – no chemical groups associated with explosive properties present in the chemical.
Oxidising Properties	Not oxidising	Estimated – on the basis of its chemical structure, the substance is incapable of reacting exothermally with combustible materials.

*Aqueous solution of the notified polymer (14-17%)

Reactivity
The notified polymer is expected to be stable under normal conditions of use. Thermal decomposition > 250 °C (may produce oxides of carbon, nitrogen or sulphur). No hazardous reactions identified.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported in finished cosmetic skin care products at a maximum concentration of 0.105%.

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

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

PORT OF ENTRY
Sydney via sea

IDENTITY OF RECIPIENTS
Reckitt Benckiser (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component (at ≤ 0.105%) of various cosmetic skin care product formulations, packed in containers suitable for sale direct to consumers. The products will be packed in shippers to protect the containers during transport.

The cosmetic products will be transported in standard containers via sea to Australia and then via road within Australia.

USE
The notified polymer will be imported into Australia in finished cosmetic skin care products at ≤ 0.105% concentration.

OPERATION DESCRIPTION
The notified polymer will not be manufactured, reformulated or repackaged in Australia.

The finished products containing the notified polymer will be used by consumers and professionals (such as workers in beauty salons). Depending on the nature of the product, application could be by hand or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure
The notified polymer will be imported as part of end-use cosmetic skin care products and will not be reformulated or repackaged in Australia. Occupational exposure of transport and storage workers will be only in the event of an accident.

Exposure to the notified polymer (at ≤ 0.105%) in end-use products may occur in professions where the services provided involve the application of skin care cosmetic products to clients (e.g. workers in beauty salons). Such professionals may use some personal protective equipment (PPE) to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure
There will be repeated exposure of the public to the notified polymer (at up to 0.105% concentration) through the use of a wide range of skin care cosmetic products. The principal routes of exposure will be dermal, while ocular and oral (during facial use) exposures are also possible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer (17% aqueous solution) are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution.
No information on the toxicokinetics of the notified polymer was provided. Based on the high molecular weight (> 100,000 Da), the potential for the notified polymer to be absorbed dermally, or for passive diffusion across the gastrointestinal (GI) tract is expected to be limited. However, the notified polymer contains a proportion of low molecular weight species (< 1,000 Da) that may be absorbed.

Acute toxicity.
The notified polymer was found to be of low toxicity under the conditions of an acute oral toxicity study on rats (single test substance concentration of 2,000 mg/kg body weight), with all observed clinical signs no longer apparent by day 2 of the observation period.

Irritation and sensitisation.
The notified polymer (at 17% concentration) was found to be non-irritating to the skin and slightly irritating to the eyes in studies conducted on rabbits (conjunctival effects noted at the 1 hour observation, but no longer evident 24 hours after test substance instillation).

A skin sensitisation study conducted with the notified polymer (17% aqueous solution; Buehler test) on Guinea pigs showed no signs of sensitisation.

Repeated dose toxicity.
No repeated dose toxicity studies were provided on the notified chemical

Mutagenicity/Genotoxicity.
A bacterial reverse mutation study (Ames test) carried out using the notified chemical showed no significant change in mutation rate at highest concentration of the notified chemical tested.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
It is intended that beauty care professionals will handle the notified chemical at ≤ 0.105% concentration, similar to public use. Therefore, the risk for beauty care professionals who regularly use products containing the notified chemical is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis. For details of the public health risk assessment see section 6.3.2.

6.3.2. Public Health
Members of the public may be repeatedly exposed to the notified polymer during the use of skin care cosmetic products containing the notified polymer at the proposed concentration up to 0.105%. At the proposed usage concentration, acute toxicity effects are not expected. The repeated dose toxicity effects of the notified chemical have not been determined. However, systemic exposure is expected to be limited by the low concentration of the notified polymer in end-use products and its limited potential for absorption.

Therefore, the risk associated with use of the notified polymer at ≤ 0.105% in skin care cosmetic products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported as a component of finished skin care cosmetic products and will not be reformulated in Australia. Environmental release during importation, transport and distribution may occur as a result of accidental breakage and spills. In the event of a spill, the notified polymer is expected to be collected and disposed of in accordance with local regulations, which is most likely disposal to landfill.

RELEASE OF CHEMICAL FROM USE
Formulated products containing the notified polymer are expected to be applied to skin. It is expected that the majority of the annual import volume will be washed off the skin and released to the sewer following consumer use.

RELEASE OF CHEMICAL FROM DISPOSAL
A very small amount of the finished cosmetic product containing the notified polymer may remain in the empty containers. The residues are expected to share the fate of the containers and be disposed of to landfill.

7.1.2. Environmental Fate
The notified polymer is not readily biodegradable. For the details of the environmental fate studies please refer to Appendix C. The notified polymer is unlikely to be bioaccumulative given the high molecular weight of > 1000 Da and the presence of cationic functional groups.

The majority of the notified polymer is expected to be disposed of to sewer following its use in cosmetic products. Based on the high molecular weight of > 1000 Da and being an amphoteric polymer, 90% of the notified polymer is expected to be removed from effluent by adsorption to sediment and sludge in sewage treatment plants (STPs; Boethling & Nabholz , 1997)), with the sludge eventually disposed of to landfill or re-used for soil remediation. A small proportion of the notified chemical may be discharged to surface waters in treated effluent. In landfill, soil or water, the notified polymer is expected to degrade biotically and abiotically to form water, oxides of carbon and nitrogen, and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

Since most of the polymer will be washed into the sewer, under a worst case scenario assuming no removal of the notified polymer in the sewage treatment plant (STP), the Predicted Environmental Concentration (PEC) on release of sewage effluent on a nationwide basis has been calculated below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200	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:	0.61	µg/L
PEC - Ocean:	0.06	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.61 µg/L may potentially result in a soil concentration of approximately 4 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 20 µg/kg and 40 µg/kg, respectively.

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 = 26 mg/L	Harmful to fish
Luminescent bacteria	30 min EC50 = 7300 mg/L	Not harmful to luminescent bacteria

The toxicity data to fish in the table above suggests that the notified polymer is harmful to aquatic organisms. No chronic toxicity data is available. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as "Acute Category 3; Harmful to aquatic life" under the GHS. Based on the acute toxicity and biodegradability for the notified polymer, the chronic hazard of the notified polymer has been formally classed as "Chronic Category 3; Harmful to aquatic life with long lasting effects" under the GHS.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) for the notified polymer has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint for fish (LC50 = 26 mg/L). An assessment factor of 1000 has been used as the acute toxicity endpoint is available for one trophic level only.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (fish)	26	mg/L
Assessment Factor	1000	
PNEC:	26	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.61	26	**0.02**
Q - Ocean	0.06	26	**0.002**

The Risk Quotient (RQ = PEC/PNEC) was calculated to be < 1, indicating the notified polymer will not be present at ecotoxicologically significant concentrations in surface waters. The notified polymer is not expected to pose an unreasonable risk to the environment based on the assessed use pattern.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (17% aqueous solution)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Hsd:Sprague Dawley
Vehicle	Water
Remarks - Method	No significant deviations from standard protocol. The test substance was administered by oral gavage.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 male & 3 female	2,000	0

LD50	> 2,000 mg/kg bw
Signs of Toxicity	The animals showed hypoactivity, irregular respiration, drawn in flanks and stilted gait after 1–2 hours of administration of the test substance, with the effects no longer observed by day 2
Effects in Organs	None
Remarks - Results	No deaths occurred during the course of the study and all animals gained body weight.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Aventis (2001a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer (17% aqueous solution)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/Crl:KBL New Zealand White
Number of Animals	3 female
Vehicle	Aqueous solution
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant deviations from standard protocol
RESULTS	
Remarks - Results	No signs of irritation were observed during the study.
CONCLUSION	The notified polymer (at 17% concentration) is non-irritating to the skin.
TEST FACILITY	Aventis (2001b)

B.3. Irritation – eye

TEST SUBSTANCE	Notified polymer (17% aqueous solution)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/Crl:KBL New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	No significant deviations from standard protocol. Prior to the commencement of the study and at 24 and 72 hours after administration, a 0.01% fluorescein solution was instilled into the eyes of

each animal.

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	0	0	1	< 24 hours	0
Conjunctiva: chemosis	0	0	0	0	---	0
Conjunctiva: discharge	0	0	0	2	< 24 hours	0
Corneal opacity	0	0	0	0	---	0
Iridial inflammation	0	0	0	0	---	0

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

Remarks - Results: Conjuctival redness was noted in one animal 1 hour after test substance administration. All the animals exhibited conjuctival discharge 1 hour after test substance administration. The eyes appeared normal 24 hours after substance instillation.

CONCLUSION: The notified polymer (at 17% concentration) is slightly irritating to the eye.

TEST FACILITY: Aventis (2001c)

B.4. Skin sensitisation

TEST SUBSTANCE: Notified polymer (17% aqueous solution)

METHOD: OECD TG 406 Skin Sensitisation – Buehler test.
Species/Strain: Guinea pig/HsdPoc:DH (Harlan)
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 100%
MAIN STUDY
Number of Animals: Test Group: 20 Control Group: 10
INDUCTION PHASE: Induction Concentration:
topical: 100%
Signs of Irritation: None
CHALLENGE PHASE: topical: 100%
Remarks - Method: No deviations from standard protocol.

A concurrent positive control study was not run, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde.

RESULTS
Remarks - Results: Under the study conditions, none of the animals showed a positive skin response after the challenge procedure.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified polymer (at 17% concentration) under the conditions of the test.

TEST FACILITY: Aventis (2001d)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE: Notified polymer (17% aqueous solution)

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA98, TA100, TA102, TA97a
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 50–5,000 µg/plate b) Without metabolic activation: 50–5,000 µg/plate
Vehicle	Double distilled water
Remarks - Method	Vehicle and positive controls were used in parallel with the test material.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 5,000	> 5,000	Negative
Test 2	> 5,000	> 5,000	Negative
Present			
Test 1	> 5,000	> 5,000	Negative
Test 2	> 5,000	> 5,000	Negative

Remarks - Results

No significant increase in the frequency of revertant colonies was recorded for any of the bacterial strains, with any dose material, either with or without metabolic activation.

The positive controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Dr. U. Noack-Laboratorium Für Angewandte Biologie (2001a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (adopted 1992-07-17)
Inoculum	Non adapted activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The biodegradation was determined by titrimetric analyses of the quantity of CO_2 which was produced by the respiration of bacteria.
Remarks - Method	Test conducted in accordance with the test guideline above. No significant deviation from the protocol was reported. Tests were arranged in duplicates. Sodium acetate was used as the reference substance.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
6	2	1	2
21	2	11	65
28	3	28	100

Remarks - Results	The test validity criteria were met. The reference control was found to degrade 100% within 28 days and the 10-day window for ready biodegradability was met. The toxicity control reached 53% degradation, indicating that the notified polymer is not toxic to sludge micro-organisms. The test substance was determined to have ≤ 5% biodegradation in the two repeated tests. Therefore, the notified polymer is not considered to be readily biodegradable according to the test guideline.
CONCLUSION	The notified polymer is not considered to be readily biodegradable.
TEST FACILITY	Dr. Noack-Laboratorium für Angewandte Biologie (2001b)

C.1.2. Biochemical/chemical oxygen demand (BOD/COD)

TEST SUBSTANCE	Notified polymer
METHOD	DIN EN 1484: Water analysis - Guidelines for the determination of total organic carbon (TOC) and dissolved organic carbon (DOC); ISOIDIS 15705: Water quality - Determination of chemical oxygen demand of waste waters (ST-COD) - Sealed tube small-scale method.
Inoculum	Not provided
Exposure Period	Not provided
Auxiliary Solvent	None
Analytical Monitoring	The carbon dioxide formed during the oxidative combustion was measured with IR spectrometry. The amount of dichromate used in the oxidation of the test substance solution was determined by measuring the absorbance of the remaining C_r^{3+} at a wavelength of 600 ± 20 nm.
Remarks – Method	A solution of the test substance in water was prepared so that the expected dissolved organic carbon (DOC) was in the range of 10-200 mg DOC/L. A solution of the test substance in water was prepared so that the expected chemical oxygen demand (COD) was in the range of 10-1000 mg COD/L.

RESULTS

Remarks – Results	The test guidelines are not available. No information regarding test validity criteria were provided. The measured DOC was 91 mg C/g test substance. The measured COD was 218 mg O_2/g test substance. The DOC and COD data are not required for risk assessment purposes.
CONCLUSION	The DOC was 91 mg C/g test substance. The COD was 218 mg O_2/g test substance.
TEST FACILITY	Clariant (2001a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Zebra fish
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	40 – 180 mg $CaCO_3$/L
Analytical Monitoring	DOC content of test solutions (levels of 25, 50 and 100 mg/L) were determined at test start
Remarks – Method	The study was performed following the test guideline and good laboratory practice. Following a range-finding test, a definitive test was performed. The LC50 values and confidence intervals were calculated by probit analysis (Weber, 1986) and standard procedures (Breitig and Tümpling, 1982), respectively.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual**		*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0
6.25	-	7	0	0	0	1
12.5	-	7	0	0	0	0
25	33	7	0	0	1	1
50	44	7	0	7	7	7
100	88	7	0	7	7	7

* Converted from the measured DOC values using the determined 91 mg/g notified polymer (in the previous study) and assuming 0 mg C/L for the control.

LC50	26 mg/L (95% CI 23- 29 mg/L) at 96 hours.
NOEC	12.5 mg/L at 96 hours.
Remarks – Results	The test validity criteria were met. The notified polymer is considered to be harmful to fish based on the test result.
CONCLUSION	The notified polymer is harmful to fish
TEST FACILITY	Dr. Noack-Laboratorium für Angewandte Biologie (2001c)

C.2.2. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
METHOD	DIN EN ISO 11348-2
Inoculum	Luminescent bacteria

Exposure Period	30 minutes
Concentration Range	Nominal: 40, 80, 160, 310, 630, 1,250, 2,500, 5,000, 10,000 mg/L
Remarks – Method	The luminescent was measured after a contact time of 30 minutes and compared to the blank control.
RESULTS	
EC50	7300 mg/L
NOEC	Not determined
Remarks – Results	The test guideline is not available. The test criterion was met according to the study author. The notified polymer is not considered to be harmful to luminescent bacteria based on the test result.
CONCLUSION	The notified polymer is not considered to be harmful to luminescent bacteria
TEST FACILITY	Clariant (2001b)

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