File No: LTD/1698

December 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Aristoflex TAC

(INCI name: Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer)

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 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/1698	Clariant (Australia) Pty. Ltd.	Aristoflex TAC (INCI name: Ammonium Acryloyldimethyltaurate /Carboxyethyl Acrylate Crosspolymer)	ND	< 5 tonne/s per annum	Thickener in personal care products

*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 Category 3	H402: Harmful to aquatic life
Chronic 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

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced for reformulation:
  - Enclosed processes where possible
  - Adequate ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced for reformulation:
  - Avoid contact with skin and eyes

- Avoid breathing powders
- Avoid generation of dust

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced for reformulation:
  - Goggles
  - Coveralls
  - Impervious gloves
  - Respiratory protection such as dust masks

  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 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(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000;
  - the method of manufacture of the notified polymer changes, such that a significant proportion of low molecular weight species (< 1000 Da) will be present;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from thickener in personal care products 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 the notified polymer provided by the notifier was 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)
Clariant (Australia) Pty. Ltd. (ABN: 30 069 435 552)
Brandon Office Park, Building 5, L2
530-540 Springvale Road
Glen Waverley VIC 3150

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: boiling point, vapour pressure, partition coefficient, absorption/desorption, flash point, flammability, auto-ignition temperature, explosive and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Aristoflex TAC

OTHER NAME(S)
Ammonium acryloyldimethyltaurate/carboxyethyl acrylate crosspolymer (INCI name)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
≥90%

ADDITIVES/ADJUVANTS
None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Ammonia may be released under alkaline conditions.

DEGRADATION PRODUCTS
In case of combustion oxides of carbon, nitrogen and/or sulphur may be formed.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White powder.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 250 °C (decomposition)	(M)SDS
Boiling Point	Not determined	-
Density	237 kg/m^3 at 25 °C	(M)SDS
Vapour Pressure	Not determined	Vapour pressure is expected to be low based on the high molecular weight of the notified polymer.
Water Solubility	200 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{½}$ > 1 year at 25 °C (pH 4 – 9)	Measured
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to partition to water due to its high water solubility.
Adsorption/Desorption	Not determined	The notified polymer is expected to sorb to soil sediment and sludge based on its high molecular weight.
Dissociation Constant	Not determined	The notified polymer is a salt and is ionised in this form.
Particle Size	Inhalable fraction (< 100 µm): 90.8% Respirable fraction (< 10 µm): 84.5% Median diameter = 2.8µm	Measured
Solid Flammability	Not determined	-
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties. A dust explosion hazard is possible
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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

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

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 as the technical grade polymer, for reformulation in Australia.

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

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

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 25 kg sealed polyethylene bags inside fibreboard boxes. The boxes will be transported by road to a warehouse for storage before distribution.

USE
As a thickener in aqueous surfactant systems such as shampoos, shower gels and liquid hand soaps (at ≤ 2% concentrations).

OPERATION DESCRIPTION
The notified polymer (neat polymer at > 90% concentration) is not manufactured in Australia. At reformulation sites, the notified polymer will be dispensed into smaller sealable plastic tubs for manual transfer to a mixing/blending vessel. Both dispensing and mixing/blending will be carried out in a closed system or under conditions designed not to create aerosols or generate airborne dust. The final personal care product formulation (containing ≤ 2% of the notified polymer, depending on the final product) will be pumped into a holding tank which will then be moved to the packaging floor using a pallet trolley. A circuit of pipes and pumps will transfer the product from the sealed holding tank to an automated filling line. The end-use products will be packaged in 250 mL, 500 mL, 750 mL, 1L and 5L plastic bottles. The final cosmetic/personal care products will be distributed to retailers for consumer use.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Store personnel (distributor and end-user)	1	26
Quality control	0.5	24
Compounders	2	24
Line setters	0.5	24

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified polymer in the neat form (> 90% purity) or as a component of cosmetic products (≤ 2%) only in the event of accidental rupture of containers.

Formulation of cosmetic products
During formulation of cosmetic products from the neat notified polymer, dermal, ocular and inhalation exposure of workers to the notified polymer in powder form (at > 90% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Dermal and ocular exposure to the formulated products containing ≤ 2% of the notified polymer may also occur during the formulation and packing processes. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves. The use of respiratory protection is also recommended in situations where dust may be generated.

End-use
Exposure to the notified polymer (at ≤ 2%) in end-use products may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. workers in beauty salons). Such professionals may use some 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 polymer.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified polymer (at ≤ 2% concentration) through the use of shampoos, conditioners and hand soaps. The principal route of exposure will be dermal, while accidental ocular exposure is also possible.

6.2. Human Health Effects Assessment

Limited toxicological data was available. The results from toxicological investigations conducted on the notified polymer and an analogue 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 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation –non-adjuvant test (analogue)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution.
The notified polymer is water soluble and its molecular weight is high, characteristics which are expected to limit absorption in the respiratory and GI tracts and across the skin. Its particle size has a respirable fraction (84%) and inhalable fraction (91%). The notified polymer may have water-absorbing characteristics, however as it is water soluble it is expected to be cleared by the lungs if inhaled.

Acute toxicity.
The notified polymer was found to be of low acute oral toxicity (LD_{50} > 2000 mg/kg) in the rat.

Irritation and sensitisation.
The notified polymer (at > 90% concentration) was slightly irritating to the skin and eye of the rabbit. The mild signs of irritation (erythema formation) observed in all animals were no longer evident at day 7 after treatment. The slight to moderate reddening and slight swelling of the conjunctivae in all animals were not observed at 72 hr after treatment.

An analogue polymer was not a skin sensitiser to guinea pigs (at > 90% concentration) in a Buehler test.

Repeated dose toxicity
No data was provided for this endpoint. The notified polymer is of high molecular weight and water soluble, and is expected to have limited potential for absorption.

Mutagenicity/Genotoxicity.
The notified polymer was not mutagenic in a bacterial reverse mutation assay.

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). The notified polymer was slightly irritating to the skin but does not meet the criteria for classification.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Exposure to the notified polymer in powder form (at > 90% concentration) may occur during blending operations. The notified polymer is a slight skin and eye irritant. It is available as respirable (84%) and inhalable (91%) fractions, and may have water-absorbing characteristics; however, it is water soluble, and is thus expected to be cleared by the lungs if inhaled. Inhalation exposure is expected to be further reduced by the use of PPE such as dust masks. Chronic exposure is expected to be low, due to the low absorption characteristics of the polymer.

Provided that control measures are in place to minimise worker exposure, such as automated processes and PPE, the risk to the health of workers from the use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The polymer's high molecular weight and high water solubility indicate that absorption is likely to be low. The potential systemic exposure is also expected to be low, based on the low concentration of the polymer and its use in rinse-off cosmetic products. The notified polymer is slightly irritating to the skin and eyes; however, these effects are expected to be lessened by the low concentration of use. Based on the available information, the risk

to the public associated with the notified polymer in the use of rinse-off cosmetic products (shampoos, hair conditioners and hand soaps) at ≤ 2% 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 reformulated or repackaged in Australia. Approximately 0.005% of the total import volume of the notified polymer, as residues in the empty containers, is expected to be disposed of to landfill. During the reformulation process, it is expected that the notified polymer (up to 5% of the total import volume) in waste waters from washings of equipment will be released to on site wastewater treatment plants (WWTPs). The waste waters treated on site will be discharged to the sewer.

RELEASE OF CHEMICAL FROM USE

During use in cosmetics, almost the entire volume of the notified polymer is expected to be released to sewers. Spills are expected to be cleaned up by washing residues to sewer or by using an appropriate sorbent material and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to be released to sewer. A small amount of the notified polymer is likely to be disposed of to landfill in domestic waste together with empty containers.

7.1.2. Environmental Fate

The notified polymer is not readily biodegradable based on the biodegradation study. For the details of the environmental fate study please refer to Appendix C. The notified polymer is expected to be hydrolytically stable under environmental conditions based on the study provided. The majority of the notified polymer is expected to be released to sewage treatment plants (STPs) via domestic wastewater. Due to its high molecular weight, up to 90% of the notified polymer is expected to be removed due to its expected partitioning to sludge and sediment in STPs (Boethling and Nabholz, 1997). The sludge containing notified polymer residues is expected to be sent to landfill or applied to soils for land remediation. Notified polymer released to surface waters is expected to partition to solids or disperse and eventually degrade. The notified polymer is not expected to bioaccumulate due to its high molecular weight. The notified polymer is expected to ultimately degrade biotically and abiotically to form water and oxides of carbon and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in cosmetic products, it was assumed that 100% of the total volume of notified polymer will be washed to the sewer on a nationwide basis over 365 days per year. It was as conservatively assumed that 0% of the notified polymer partitions to sludge in STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.7	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	3.03	µg/L
PEC - Ocean:	0.30	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 3.0 µg/L may potentially result in a soil concentration of approximately 20.2 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 101.0 µg/kg and 201.9 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer and an analogue are summarised in the table below. Details of the studies can be found in Appendix C. The analogue substance is used as read across to the notified polymer due to their similar molecular structures.

Endpoint	*Result*	*Assessment Conclusion*
Notified polymer		
Fish	EC50 (96 h) = 86.3 mg/L	Harmful to fish
Analogue substance		
Inhibition of Bacterial Respiration	EC50 (3 h) > 3200 mg/L	Not inhibitory to microbial respiration

Based on the endpoint measured for the notified polymer, it is expected to be harmful to fish. 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. Based on the acute toxicity of the notified polymer and lack of ready biodegradability, it has been formally classified under GHS as Chronic Category 3; Harmful to aquatic life with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using the reported toxicity endpoint of the notified polymer and the assessment factor of 1,000. The most conservative assessment factor of 1,000 was used since only one ecotoxicological endpoint for the notified polymer was available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish)	86.3	mg/L
Assessment Factor	1,000	
PNEC	86.3	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	3.03	86.3	0.035
Q - Ocean:	0.3	86.3	0.004

The Risk Quotients (Q = PEC/PNEC) for a worst case discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified polymer is not readily biodegradable nor expected to bioaccumulate in the environment. The notified polymer is not likely to be significantly bioavailable as it is expected to be removed from the water column due to its strong potential to partition from water to solids and sediments. The notified polymer is unlikely to result in ecotoxicologically significant concentrations in aquatic environment for the assessed use pattern. Therefore, the notified polymer is not considered to pose an unreasonable risk to the environment from the assessed use scenario.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Solubility 200 g/L at 20 °C

Method OECD TG 105 Water Solubility
Remarks Preliminary determination by step-wise procedure. The test substance (in different quantities) was mixed with water and shaken for 15 minutes at room temperature. The mixtures were visually checked for any undissolved parts of the test substance or phase separation. The mixture of water and the test substance at concentration up to 200 g/L appeared as homogenous and clear viscous solution. This is an indication that the notified polymer is miscible with water at concentration up to 200 g/L at room temperature. Gel formation takes place in mixtures with higher concentrations, however the notifier advised that adding further quantities of water to a 50% solution produces a lower viscosity solution.
Test Facility Clariant (2013a)

Hydrolysis as a Function of pH $t_{½}$ > 1 year

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	25 °C	> 1 year
7	25 °C	> 1 year
9	25 °C	> 1 year

Remarks In the hydrolysis test the change of the molecular weight of the test substance after 24 hours at 50 °C and pH 1.2 as well as after 5 days at 50 °C and pH 4.0, 7.0 and 9.0 was determined. It was found that the change of the molecular weight of the test substance was less than 10%. It can be concluded that the test substance can be considered as hydrolytically stable under any of the pH conditions i.e., at pH 4.0, 7.0 and 9.0.
Test Facility Clariant (2013b)

Particle Size Volume Median Diameter (d50)= 2.8 µm

Method Laser diffraction method

Range (µm)	*Mass (%)*
<100	90.8
<10	84.5
<5	74
<2	38

Remarks Determined using Malvern Mastersizer 2000 with air as the dispersing fluid.
Test Facility Clariant GmbH (2011)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat / HanRcc:WIST (SPF)
Vehicle	PEG 300
Remarks - Method	The test substance was administered by gavage and formulated in PEG at 0.2 g/mL. This is a limit test.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	2000	0/3
2	3F	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	Approximately 5 hours post-treatment, three animals showed slight ruffled fur. No further clinical signs were observed in the course of the study and no macroscopic findings were observed at necropsy. The body weight of the animals was within the range commonly recorded for this strain and age.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Harlan (2009a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White (1M/2F)
Number of Animals	3
Vehicle	None
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. The polymer was moistened with purified water before application to the skin.

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	1	0.67	1	1	72 hr	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	There were no occurrence of mortality and clinical signs during the course of the study. The body weight of all rabbits was within the normal range of the species and age. No oedema was seen. Slight The mild signs of

irritation (erythema formation) was observed in all animals initially but was no longer evident at day 7 after treatment.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Harlan (2009c)

B.3. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White
Number of Animals 1M/2F
Observation Period 72 hours
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	0	0.7	2	48 hr	0
Conjunctiva: chemosis	0	0	0	0	0	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results No clinical signs were observed. Body weight of all the animals was considered normal for the strain and age. No abnormal findings were observed in the cornea or iris but slight to moderate reddening and slight swelling of the conjunctivae and slight reddening of the sclerae were observed in all animals from 1 hr but were not observed at 72 hr.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY Harlan (2009b)

B.4. Skin sensitisation

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 406 Skin Sensitisation – Buehler Test.
Species/Strain Pirbright-White guinea pig/ HsdPoc:DH
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 25% (w/w)
MAIN STUDY
Number of Animals Test Group: 19 Control Group: 10
INDUCTION PHASE Induction Concentration:
topical: 25% (w/w)
Signs of Irritation
CHALLENGE PHASE
1st challenge topical: 25% (w/w)

Remarks - Method The vehicle used was petrolatum. One treatment animal died before the first induction.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions After: 1st Challenge*	
		24 h	*48 h*
Test Group	25%	0	0
Control Group	0%	0	0

Remarks - Results: None of the nineteen animals in the treatment group showed a positive skin response after the challenge procedure.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY: Hoechst (1996)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE: Notified polymer

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 (Test 1)/Pre incubation procedure (Test 2)

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA

Metabolic Activation System: Phenobarbital/β-Naphthoflavone induced rat liver S9

Concentration Range in Main Test (Test 2):
a) With metabolic activation: 62.5 - 2000 µg/plate
b) Without metabolic activation: 62.5 - 2000 µg/plate

Vehicle: Tetrahydrofuran (THF)

Remarks - Method: The preliminary test was reported as Test 1. The study report did not note whether or not insolubility/precipitation was present during the study, however no precipitation was reported when the solvent was initially evaluated.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>2000		>2000	Negative
Test 2		>2000	>2000	Negative
Present				
Test 1	>2000		>2000	Negative
Test 2		>2000	>2000	Negative

Remarks - Results: Toxicity was not seen up to the maximum dose of 2000 µg/plate.

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

TEST FACILITY: Harlan (2009d)

C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
- Inoculum: Activated sludge
- Exposure Period: 28 days
- Auxiliary Solvent: Not reported
- Analytical Monitoring: Titrimetric analysis
- Remarks - Method: The test was conducted according to the guideline above and good laboratory practice (GLP) principles. No significant deviations from the test guideline were reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
6	1	6	58
14	5	14	76
21	13	21	76
28	17	28	78

- Remarks - Results: All validity criteria for the test were satisfied. The reference control reached the pass level of 60% after 7 days. The toxicity control exceeded 25% biodegradation (required by guideline) showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after the cultivation period was 17%. Therefore, the test substance is not readily biodegradable according to the OECD (301 B) guideline.

CONCLUSION: The notified polymer is not readily biodegradable.

TEST FACILITY: Dr. U. Noack-Laboratorien (2009a)

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 (*Danio rerio*)
- Exposure Period: 96 hours
- Auxiliary Solvent: Not reported
- Water Hardness: 10 – 250 mg $CaCO_3$/L
- Analytical Monitoring: Analysis of organic carbon (DOC, according to DIN EN 1484) at the beginning of the test
- Remarks – Method: The test was conducted according to the guideline above and good laboratory practice (GLP) principles. No significant deviations from the test guideline were reported.

RESULTS

Nominal Concentration (mg/L)	*Number of Fish*	*Mortality (%)*			
		24 h	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0
6.25	7	0	0	0	0
12.5	7	0	0	0	0
25	7	0	0	0	0
50	7	0	0	0	0
100	7	0	0	14	71

LC50	86.3 mg/L at 96 hours.
NOEC	25 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test media were mixed with an ultraturrax (1 min, 17000 rpm). The test item was clearly dissolved in all tested concentrations throughout the exposure period. The LC50 value after 96 hour was calculated by sigmoidal dose-response regression.
CONCLUSION	The notified polymer is harmful to fish.
TEST FACILITY	Dr. U. Noack-Laboratorien (2009b)

C.2.2. Inhibition of microbial activity

TEST SUBSTANCE	Analogue substance
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 320, 580, 1000, 1800, 3200 mg/L
Remarks – Method	The test was conducted according to the guideline above and good laboratory practice (GLP) principles. No significant deviations from the test guideline were reported.
RESULTS	
EC20	3200 mg/L
EC50	> 3200 mg/L
Remarks – Results	All validity criteria for the test were satisfied. The test substance was clearly dissolved up the concentration of 1000 mg/L. The EC20 value was directly determined from the test result. The EC50 was out of the tested concentration range (> 3200 mg/L). Due to the viscosity of the test substance, concentrations greater than 3200 mg/L could not be tested.
CONCLUSION	The analogue and, by inference, the notified polymer is not expected to inhibit microbial respiration.
TEST FACILITY	Dr. U. Noack-Laboratorien (1999)

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