File No: LTD/1977

October 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Genapol™ EC 50

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 and Energy.

This Public Report is 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

TABLE OF CONTENTS

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/1977	Clariant (Australia) Pty Ltd	Genapol™ EC 50	ND*	≤ 50 tonnes per annum	Component of dishwasher tablets

*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 of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

The environmental hazard classification according to the *Globally Harmonised System of 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 2	H401 – Toxic to aquatic life

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

- 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 during reformulation processes
  - Avoid contact with eyes

- No specific engineering controls 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 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 of 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

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of dishwasher tablets, 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.

Safety Data Sheet
The SDS of the notified polymer (provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report 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)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Level 3, Olympus Building
3 Acacia Place
296 – 324 Ferntree Gully Road
NOTTING HILL VIC 3168

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

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints except specific gravity/density, water solubility, flammability limits and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
USA (TSCA)
Canada (DSL)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Genapol™ EC 50

OTHER NAME(S)
Modified alcohol polyglycol ether

MOLECULAR WEIGHT
Value for chemicals > 1,000 Da

ANALYTICAL DATA
Reference IR, ^{1}H-NMR, ^{13}C-NMR, UV-VIS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow to brown wax.

Property	Value	Data Source/Justification
Melting Point	31 °C	Measured
Boiling Point	> 348 °C	Decomposes below the boiling point.
Density	1,062.9 kg/m^3 at 28 °C	Measured
Vapour Pressure	Not determined	Expected to have a low vapour pressure based on the molecular weight.
Water Solubility	0.6 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to significantly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Log Pow = 3.2	Calculated. Expected to partition to phase boundaries based on surface activity
Surface Tension	28.5 mN/m	SDS
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on surface activity
Dissociation Constant	Not determined	Contains no dissociable functionalities
Flash Point	Not determined	Not expected to form flammable vapour
Flammability	Not flammable	Measured
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
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.

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 of 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 not be manufactured in Australia. The notified polymer will be imported into Australia as a component of dishwashing detergents contained in tablets.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10 – 50	10 – 50	10 – 50	10 – 50	10 – 50

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will not be manufactured in Australia. It will be imported as either a waxy solid form (neat concentration) in 180 kg plastic containers for reformulation, or within dishwasher tablet products (at a concentration of < 5%).

USE
The notified chemical will be used at < 5% concentration in automatic dishwasher tablets.

OPERATION DESCRIPTION
Imported products containing the notified chemical (at ≤ 100% concentration) will be stored at the notifier's facilities prior to being transported to customer facilities for reformulation into consumer products or retail sale.

Reformulation
The procedures for incorporating the notified polymer (in neat form) into end-use tablet products vary. In powder form the notified polymer may be manually added to a blending tank. Alternatively, the packaging containing the notified polymer will be heated and the liquefied polymer will be pumped using metered dosing into the blending tank. Under both processes a combination of both automated and manual transfer steps are expected. However, in general it is expected that the reformulation processes will involve blending operations that will be highly automated and use closed systems with adequate ventilation. Tablets (containing the notified polymer at < 5% concentration) will be placed in boxes for retail sale.

End use
The finished dishwasher tablets containing the notified polymer (at < 5% concentration) will be placed into the detergent reservoir in automatic dishwashers. The tablet containing the notified polymer will dissolve in the dishwasher, releasing the contents. The notified polymer will be discharged into the wastewater at the end of the dishwashing cycle.

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)*
Transport and storage workers	1 – 2	24
Reformulation workers	8	200
Retail workers	1000	200

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified polymer in neat form or in end-use products (< 5% concentration), only in the event of an accidental rupture of containers. Retail workers may come into contact with the notified polymer in end-use products (< 5% concentration), only in the event of an accidental rupture of containers

During reformulation of the notified polymer (at neat concentration) into the final consumer products, dermal, ocular and inhalation exposure of workers may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of local and general ventilation and/or enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, safety glasses, face masks and impervious gloves.

Exposure of retail and professional kitchen workers to the notified polymer in end-use products (at < 5% concentration) is expected to be of a similar extent to that experienced by consumers using automatic dishwashing tablets containing the notified polymer (see section 6.1.2).

6.1.2. Public Exposure
The notified polymer will not be sold to the general public except in the form of finished products (containing the notified polymer at < 5% concentration). Incidental dermal and potentially ocular exposure to dishwashing tablets containing the notified polymer is expected when adding the tablet to the dishwashing machine.

Exposure to the notified chemical from washed dishes is expected to be very low as it will be diluted in the wash water, and is expected to be rinsed off from the washed articles prior to drying.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer 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
Skin irritation (in vitro)	non-irritating
Eye irritation (in vitro)	not corrosive or a severe eye irritant
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

Based on the water solubility (0.6 g/L at 20 ºC) and partition coefficient (log P_{ow} = 3.2) of the notified polymer, dermal absorption as well as absorption across the respiratory tract and gastrointestinal (GI) tract may be expected to occur. However, the potential for absorption is expected to be mitigated by the high molecular weight (> 1000 Da) of the notified polymer and the small percentage of low molecular weight species (< 500 Da) present.

Acute toxicity

The notified polymer was found to be of low acute toxicity via the oral route in a study conducted in rats.

Irritation and sensitisation

The notified polymer was determined to be non-irritating in an *in vitro* assay using reconstructed human epidermis. In an eye irritation study in rabbits, slight to moderate conjunctival irritation was observed in all animals. Recovery from the adverse effects was indicated at the 72 hour observation, with all animals exhibiting complete recovery at the end of the observation period (7 days). The severity of the adverse effects did not warrant classification of the chemical as an eye irritant.

The notified chemical was not a skin sensitiser when tested in guinea pigs.

Mutagenicity/Genotoxicity

The notified chemical was found to be non-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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer is expected to be of low toxicity based on the available data, with expected low systemic exposure due to the high molecular weight. The notified polymer may be irritating to the eyes.

Dermal, ocular and inhalation exposure of workers to the notified polymer (at ≤ 100% concentration) may occur during blending operations. Provided that adequate control measures are in place to minimise worker exposure, including the use of automated processes and PPE (impervious gloves, goggles and coveralls), the risk to workers from use of the notified chemical is not considered to be unreasonable.

Transport, storage, retail, and professional kitchen workers exposure to the notified polymer is expected to be very low and limited to accidental spills and splashes. Therefore, the risk to these workers from the use of dishwashing tablets containing the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

Public exposure to the notified polymer from using dishwashing tablets containing it at < 5% is expected to be very low. Given the expected low hazard and exposure, the risk to the public from use of the notified polymer in dishwashing tablets is not considered 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 into Australia either as a component of a product for reformulation into finished automatic dishwashing detergents or within dishwasher tablet products. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the products containing the notified polymer are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer from this process to the environment is not expected. Wastes containing the notified polymer generated during reformulation include equipment wash water, residues in import containers, and spilt materials. Release of the notified polymer could also result from residues remaining in empty import containers. The total release of the notified polymer from these activities is estimated by the notifier to be up to 2% of the import volume of the notified polymer (or up to 600 kg). These will be collected and released to sewers in a worst case scenario, or disposed of to landfill in accordance with local government regulations. Empty import containers are expected to be recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer is expected to be released to sewer across Australia as a result of its use in automatic dishwashing detergents. A small proportion of the notified polymer is expected to be disposed of to landfill as residue in empty end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

Wastes and residue of the notified polymer in empty containers are likely to either share the fate of the container and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

Following its use in automatic dishwashing detergents in Australia, the majority of the notified polymer is expected to enter the sewer system, before potential release to surface waters nationwide. Based on the results of a ready biodegradability study, the notified polymer is considered readily biodegradable (94% in 28 days). For details of the environmental fate studies, please refer to Appendix C. Based on its surfactant properties, release to surface waters is unlikely to occur as partitioning to sludge and sediment is expected under environmental pH. The notified polymer is not expected to be bioaccumulative, due to its surfactant properties, high molecular weight and ready biodegradability. Therefore, in surface waters the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

The majority of the notified polymer will be released to sewer after use. A small proportion of the notified polymer may be applied to land when effluent is used for irrigation, or when sewage sludge is used for soil remediation. The notified polymer may also be applied to land when disposed of to landfill as collected spills and empty container residue. Residues of the notified polymer in landfill, soil and sludge are expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use in automatic dishwashing detergents, it is assumed that 100% of the total import volume of the notified polymer will be released to the sewer. The release is assumed to be nationwide over 365 days per year. Of this, an estimated 87% is predicted to be removed by biodegradation or partitioning to sludge during sewage treatment plant (STP) processes (US EPA, 2013).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	100 %	
Annual quantity of chemical released to sewer	50,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	136.99	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	90%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	2.81	µg/L
PEC - Ocean:	0.28	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 2.81 µg/L may potentially result in a soil concentration of approximately 18.73 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 93.63 µg/kg and 187.3 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*
Daphnia Toxicity	48 h EC50 = 3.86 mg/L	Toxic to aquatic invertebrates

Based on the above acute ecotoxicological endpoints for the notified polymer, it is expected to be toxic to aquatic invertebrates. 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 2; Toxic to aquatic life'.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for aquatic invertebrates. A safety factor of 1000 was used given only one acute endpoint is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (*Daphnia*, 48 h)	3.86	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	3.86	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	2.81	3.86	0.728
Q - Ocean	0.28	3.86	0.073

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified polymer is considered readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio,

maximum annual importation volume and assessed use pattern in automatic dishwashing detergents, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 31 °C

Method	Internal method.
Remarks	Differential Scanning Calorimetry performed in sealed glass vial in air.
Test Facility	Clariant (2013)

Boiling Point > 348 °C at 101.3 kPa

Method	Internal method
Remarks	Differential Scanning Calorimetry performed in sealed glass vial in air. Test substance starts to decompose at 348 °C with a mean energy of 475 J/g
Test Facility	Clariant (2013)

Density 1062.9 kg/m^3 at 28 °C

Method	Internal method.
Remarks	Pycnometer. Average taken over five measurements.
Test Facility	Clariant (2012)

Water Solubility 0.6 g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method
Test Facility	Clariant (2016)

Flammability Not flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks	Test substance did not ignite at room temperature and melted on application of ignition source. When blended with 20% Kieselguhr (form of diatomaceous earth) the test substance showed burning with flame propagation. Pure test substance did not sustain combustion at room temperature.
Test Facility	Consilab (2012)

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/RccHan:WIST (SPF)
Vehicle	Water
Remarks - Method	GLP compliant. No deviations from the protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3 F	2,000	0/3
2	3 F	2,000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	Animals in group 1 exhibited slightly ruffled fur at 1 and 2 hours after exposure on day 1. Recovery from the effect was observed 3 hour after exposure. No signs of toxicity were observed in animals in group 2.
Effects in Organs	None
Remarks - Results	No unscheduled deaths occurred. All animals made the expected body weight gains.

CONCLUSION: The notified polymer is of low toxicity via the oral route.

TEST FACILITY: Harlan (2011a)

B.2. Irritation – skin (in vitro)

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 439 In vitro Skin Irritation: Reconstructed Human *Epidermis* Test Method
EC Council Regulation No 440/2008 B 46.
EpiSkin™ Reconstituted Human Epidermis Model

Vehicle	Water
Remarks - Method	GLP compliant. No deviations from the protocol. Negative (vehicle) and positive controls (5% Sodium lauryl sulfate) were run concurrently.

RESULTS

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	1.062	100	3.7
Test substance	0.978	92.2	8.0
Positive control	0.250	23.6	1.3

OD = optical density; SD = standard deviation

Remarks - Results	Positive and negative controls performed as expected. The test substance recorded a relative mean viability value greater than 50% which is the threshold value for predicting irritancy.

CONCLUSION: The notified polymer was non-irritating to the skin under the conditions of

the test.

TEST FACILITY HCCR (2012)

B.3. Irritation – eye (in vitro)

TEST SUBSTANCE Notified polymer

METHOD OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants
Vehicle Saline solution (0.9% w/v NaCl)
Remarks - Method GLP compliant.
No deviations from the protocol.
Negative (saline solution) and positive controls (10% w/v Benzalkonium chloride in saline solution) were run concurrently.

RESULTS

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	0.667	0.153 (0.031)	2.957 (0.611)
*Test substance**	13.663	-0.065 (0.007)	24.578 (8.566)
*Positive control**	250.997	0.728 (0.615)	251.972 (58.914)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Remarks - Results Positive and negative controls performed as expected.
The test substance recorded an *in vitro* irritation greater than 55.1 which is the threshold value for predicting irritancy.

CONCLUSION The notified polymer was not corrosive or a severe eye irritant under the conditions of the test.

TEST FACILITY HCCR (2011a)

B.4. 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 (Hsdlf:NZW)
Number of Animals 3
Observation Period 7 days
Remarks - Method GLP compliant.
No deviations from the protocol.
Observations were recorded at 1 hour, 1, 2, 3 and 7 days after exposure.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1	1.3	2	2	< 7 d	0
Conjunctiva: chemosis	1	1	1.7	2	< 7 d	0
Conjunctiva: discharge	1	0.7	1.3	2	< 7 d	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 No corneal or iridial effects were observed. Slight ot moderate

conjunctival irritation was observed in all animals. All animals exhibited complete recovery at the 7 day observation.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY Harlan (2011b)

B.5. Skin sensitisation

TEST SUBSTANCE Notified polymer

METHOD OECD TG 406 Skin Sensitisation – Buehler Test.
EC Directive No 440/2008 B.6 Skin Sensitisation – Buehler Test.

Species/Strain Guinea pig/Dunkin Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 75%

MAIN STUDY

Number of Animals Test Group: 20 M Control Group: 10 M

Vehicle Water

Positive control Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using alpha-hexylcinnamaldehyde.

INDUCTION PHASE Induction Concentration:
topical: 75%

Signs of Irritation Discrete or patchy erythema was observed in 2/3 animals at the 24 hour observation, with the effect persisting in one animal at the 48 hour observation. No skin reactions were observed following exposure to 10%, 25% and 50% concentrations of the test substance.

CHALLENGE PHASE

1st challenge topical: 50%

Remarks - Method GLP compliant.
No deviations from the protocol.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	50%	0	0
Control Group	50%	0	0

Remarks - Results All animals made the expected body weight gains. No clinical signs of toxicity were observed. No signs of skin reactions were observed in any of the animals following the induction and challenge phases.

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

TEST FACILITY Harlan (2012)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Commission Regulation (EC) No. 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure and Pre incubation procedure

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

	E. coli: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver.
Concentration Range in Test 1	a) With metabolic activation: 3-5000 µg/plate b) Without metabolic activation: 3-5000 µg/plate
Concentration Range in Test 2	TA1535 and TA1537: a) With metabolic activation: 1-2500 µg/plate b) Without metabolic activation: 1-2500 µg/plate TA98 and TA100: a) With metabolic activation: 3-5000 µg/plate b) Without metabolic activation: 3-5000 µg/plate WP2 uvrA: a) With metabolic activation: 33-5000 µg/plate b) Without metabolic activation: 33-5000 µg/plate
Vehicle	Dimethyl sulphoxide
Remarks - Method	GLP compliant. No deviations from the protocol. The results from the preliminary toxicity test are reported as Experiment 1. Vehicle and positive controls were used in parallel with the test material. Positive controls: without S9: Sodium azide (TA100, TA1535), 4-Nitro-o-phenylene-diamine (TA1537, TA98), Methyl methane sulfonate (WP2uvrA); with S9: 2-aminoanthracene (TA98, TA100, TA1535, TA1537, WP2uvrA).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 333	≥ 2500	negative
Test 2	≥ 333	≥ 1000	negative
Present			
Test 1	≥ 1000	≥ 2500	negative
Test 2	≥ 333	≥ 1000	negative

Remarks - Results

All *Salmonella* strains exhibited a reduction in the bacterial lawn at concentrations ≥ 333 µg/plate in the absence and presence of metabolic activation.

Under the conditions of test 1, cytotoxicity was observed in all *Salmonella* strains at concentrations of ≥ 1000 µg/plate (TA1535, TA1537, TA100) and ≥ 333 µg/plate (TA1535, TA100) in the presence and absence of metabolic activation respectively; and in test 2 at concentrations of ≥ 333 µg/plate (TA1535, TA1537, TA100) and ≥ 333 µg/plate (TA1535, TA100) in the presence and absence of metabolic activation respectively. Cytotoxicity was not observed in the *Escherichia* strain in the presence or absence of metabolic activation in either test 1 or 2.

No biologically relevant increase in the frequency of revertant colonies was observed in any of the bacterial strains tested, in the presence or absence of metabolic activation.

Positive and negative controls performed as expected.

CONCLUSION

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

TEST FACILITY

HCCR (2011b)

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: CO2 Evolution Test.
Inoculum	Activated sewage and surface water sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biological Oxygen Demand (BOD)
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation (mean for 2 replicates)*	*Day*	*% Degradation*
6	3	6	66
14	45	14	84
20	66.5	20	86
28	93.5	28	93

Remarks - Results	All validity criteria for the test were satisfied. The reference item (sodium benzoate) attained 60% biodegradation after 6 days and 93% biodegradation after 28 days thereby confirming the suitability of the inoculums and test conditions. The toxicity control attained 72% degradation after 14 days and 88% biodegradation after 28 days thereby confirming that the test material was not toxic to the sewage treatment micro-organisms used in the study. As the test substance is surface active, the 10-day window is not applicable. The test material attained 93.5% degradation after 28 days. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 B) guideline.
CONCLUSION	The notified polymer is readily biodegradable.
TEST FACILITY	Dr U Noack-Laboratorien (2012)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	262 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. The stock solution (20 mg/L test item) was freshly prepared with dilution water and agitated. Test concentrations of 1.25, 2.4, 5, 10 and 20 mg/L were prepared.

RESULTS

Concentration (mg/L) Nominal	*Number of D. magna*	*Mean Immobilised (%)*	
		24 h	*48 h*
Control	20	0	0
1.25	20	0	0
2.5	20	10	20
5	20	45	70
10	20	75	95
20	20	100	100

EC50	3.86 mg/L (95% CI 3.44 – 4.32 mg/L) at 48 hours
NOEC	1.25 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance were not measured during the 48 h test period. The 48 h EC50 and NOEC for daphnids were determined to be 3.86 mg/L (95% CI 3.44 – 4.32 mg/L) and 1.25 mg/L, respectively, based on nominal concentrations.

CONCLUSION The notified polymer is considered to be toxic to aquatic invertebrates.

TEST FACILITY Dr U Noack-Laboratorien (2011)

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