File No: LTD/2082

December 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Aristocare Smart

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

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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/2082	Clariant (Australia) Pty Ltd	Polymer in Aristocare Smart	ND*	≤ 1.5 tonnes per annum	Component of cleaning products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
As only limited toxicity data were provided, the notified polymer cannot be classified 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*
Chronic (Category 2)	H411 – Toxic 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, 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 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.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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.

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 g/mol;

or

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

Safety Data Sheet
The SDS of a product containing 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

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Level 3, 3 Acacia Place
296-324 Ferntree Gully Road
NOTTING HILL VIC 3168

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for hydrolysis as a function of pH, adsorption/desorption, dissociation constant, flammability, autoignition temperature, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Aristocare Smart (product containing ≤ 15% notified polymer)

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 40%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear, viscous liquid*

Property	*Value*	*Data Source/Justification*
Melting Point/Freezing Point*	-2 °C	Measured
Boiling Point*	101 °C at 101.3 kPa	Measured
Density*	1044.2 kg/m^3 at 20 °C	Measured
Viscosity*	Kinematic viscosity: 30.5 ± 0.3 mm^2/s at 20 °C 13.2 ± 0.3 mm^2/s at 50 °C Dynamic viscosity: 31.9 ± 0.3 mPa.s at 20 °C 13.6 ± 0.3 mPa.s at 50 °C	Measured
Vapour Pressure*^	3.17 kPa at 25 °C	Calculated using MPBPWin v1.43
Water Solubility	> 1000 g/L at 20 °C	Measured

Property	*Value*	*Data Source/Justification*
Hydrolysis as a Function of pH	Not determined	Notified polymer contains hydrolysable functional groups but is not expected to significantly hydrolyse in the environmentally relevant pH range (4-9).
Partition Coefficient (n-octanol/water)	log Pow < -0.7 at 20 °C	Measured
Surface Tension*	60.3 mN/m at 20 °C	Measured
Adsorption/Desorption	Not determined	Notified polymer is surface active and is expected to adsorb to soils and sludge via organic carbon and ionic interactions.
Dissociation Constant	Not determined	The notified polymer is a salt and is expected to ionise under environmental conditions.
Flash Point*	Not detectable due to high content of water	Measured
Flammability	Not determined	Will be imported and used in solution
Autoignition Temperature	Not determined	Will be imported and used in solution
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidising properties

* Property of the notified polymer in aqueous solution at ≤ 15% concentration
^ Vapour pressure of the notified polymer is expected to be low based on its high molecular weight.

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 at ≤ 15% concentration for reformulation into cleaning products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 1.5	≤ 1.5	≤ 1.5	≤ 1.5	≤ 1.5

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
Products containing the notified polymer for reformulation in Australia will be imported in 205 L drums and transported by road. Following reformulation finished cleaning products containing the notified polymer will be packed in 0.3 – 1 L plastic bottles and transported by road.

USE
The notified polymer will be used a component of hard surface cleaning products at a concentration of 0.05 – 0.2%.

OPERATION DESCRIPTION

Reformulation for cleaning products
The imported product containing ≤ 15% notified polymer will typically be transferred by dip pipe or hose and pumped into a closed blending tank under local exhaust ventilation. After blending with other components, the finished cleaning products containing ≤ 0.2% notified polymer will be transferred via automatic filling machines into appropriate containers (typically 0.3 – 1 L plastic bottles with spray pump trigger nozzles) for retail sale.

End-use
Hard surface cleaning products containing the notified polymer will typically be applied to surfaces such as ceramics, glass or stainless steel by spray. The surfaces may then be scrubbed and will generally be rinsed off with water.

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 warehouse	1 – 2	24
Process operators – reformulation	8	200
Retail	≤ 8	200
Professional cleaners	≤ 8	200

EXPOSURE DETAILS
Transport, storage and retail workers may come into contact with the notified polymer only in the event of accidental rupture of packages.

Reformulation
Dermal and ocular exposure of workers to the notified polymer at ≤ 15% concentration may occur during connection and disconnection of transfer lines, quality control processes and cleaning and maintenance of equipment. Exposure is expected to be limited through the use of enclosed systems and personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves, as stated by the notifier. Inhalation exposure is not expected given the estimated low vapour pressure of the notified polymer, and the expected use of closed systems and local exhaust ventilation.

End-use
Exposure of professional cleaners to the notified polymer is expected to be of a similar extent to that experienced by consumers using cleaning products containing the notified polymer (see section 6.1.2).

6.1.2. Public Exposure
Dermal, ocular and inhalation exposure of the public to cleaning products containing the notified polymer at ≤ 0.2% concentration may occur during spray application to and scrubbing of hard surfaces. Exposure from post-application rinsing processes is expected to be low as the notified polymer will be further diluted in the rinsing water.

Dermal exposure to the notified polymer from treated and rinsed surfaces is expected to be low as the amount of residual polymer left on the surfaces is expected to be very low after the rinsing processes are complete.

6.2. Human Health Effects Assessment
The results from some toxicological investigations conducted on the notified polymer (≤ 15% aqueous solution) are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	***Result and Assessment Conclusion***
Skin irritation – *in vitro* reconstructed human epidermis test	non-irritating
Eye irritation – *in vitro* BCOP test	non-irritating
Skin sensitisation – *in vitro* ARE-Nrf2 luciferase test	negative

Endpoint	*Result and Assessment Conclusion*
Skin sensitisation – in vitro human cell line activation test	negative
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, Metabolism and Distribution
Based on the high molecular weight (> 1,000 g/mol), high water solubility (> 1×10^3 g/L at 20 °C) and partition coefficient (log Pow < -0.7), the notified polymer is expected to have limited potential to cross biological membranes.

Irritation
According to the > 50% mean tissue viability observed in an *in vitro* reconstructed human epidermis test, the notified polymer at ≤ 15% concentration in aqueous solution is not classifiable as a skin irritant according to the test guideline. However, mild skin irritation effects cannot be ruled out.

Based on the results of an *in vitro* bovine corneal opacity and permeability (BCOP) test (IVIS ≤ 3), the notified polymer at ≤ 15% concentration in aqueous solution was not considered irritating.

Sensitisation
Two *in vitro* cell based assays were conducted to evaluate the skin sensitisation potential of the notified polymer at ≤ 15% concentration in aqueous solution. The tests are part of Integrated Approach to Testing and Assessment (IATA) which address specific events of the Adverse Outcome Pathway (AOP) leading to development of skin sensitisation (OECD, 2016). The tests are thus considered relevant for assessment of the skin sensitisation potential of the notified polymer, along with other supporting information.

The ARE-Nrf2 luciferase assay aims to address the second key event (keratinocyte activation) of the AOP by measuring the expression of a report luciferase gene under the control of a promoter from the antioxidant response element (ARE), a responding gene known to be upregulated by contact sensitisers. The second in vitro assay was used to evaluate the skin sensitization potential of the notified polymer in the U937 Cell Line Activation Test (U-SENS(tm)) Assay. This assay is used to evaluate the ability of the test item to increase the expression levels of CD86 cell surface marker in the U937 cells.

The notified polymer at ≤ 15% concentration in aqueous solution showed negative responses in two of the three AOP tests (ARE-Nrf2 luciferase assay and U-Sens assay), suggesting no potential for skin sensitisation.

Mutagenicity/Genotoxicity
The notified polymer at ≤ 15% concentration in aqueous solution was negative in a bacterial reverse mutation assay.

Results of a number of mutagenicity studies on acrylate and methacrylate compounds have been evaluated (Johannsen *et al*., 2008). In general, it was found that these compounds were negative in bacterial reverse mutation assays and other *in vitro* mammalian point mutation assays. While some positive results were observed in *in vitro* mammalian clastogenicity assays, the results from *in vivo* assays were all negative. Therefore, based on the available information, the notified polymer is not likely to be genotoxic.

Health Hazard Classification
As only limited toxicity data were provided for the notified polymer at ≤ 15% concentration in aqueous solution, the notified polymer cannot be classified 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
Based on the limited toxicity data, and the high molecular weight of the notified polymer it is expected to be of low hazard.

The notified polymer contains acrylate functional groups which are known to have potential to cause skin and eye irritation, and skin sensitisation (US EPA, 2010). The potential for the notified polymer to cause skin sensitisation may be reduced by the limited potential for the notified polymer to be dermally absorbed due to its high molecular weight. Additionally the notified polymer at ≤ 15% concentration in aqueous solution was determined to be non-irritating to the skin or eyes and non-sensitising through a range of *in vitro* studies.

The repeated dose toxicity effects of the notified polymer has not been determined. However, systemic exposure is expected to be limited by the expected low dermal absorption due to the high molecular weight of the notified polymer.

6.3.1. Occupational Health and Safety

Dermal and ocular exposure of workers to the notified polymer at the imported concentration of ≤ 15% may occur during reformulation of cleaning products. The use of engineering controls (particularly the automation of processes) and personal protective equipment (skin, eye and respiration protection) during the reformulation is expected to minimise exposure.

Dermal, ocular and inhalation exposure of workers to the notified polymer at concentrations of ≤ 0.2% may occur during applications of cleaning products. Unreasonable risk to the health of workers is not expected given the low concentrations.

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

6.3.2. Public Health

Dermal, ocular and inhalation exposure of the public to the notified polymer at concentrations of ≤ 0.2% may occur during application of cleaning products. Unreasonable risk to public health is not expected given the low concentrations.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer is not manufactured in Australia. Release of the notified polymer is expected to be < 1% and will be from accidental spills during transportation or during transfer to the blending tank during reformulation. Accidental spills will be disposed of to the sewer system after treatment at the onsite wastewater treatment plant.

RELEASE OF CHEMICAL FROM USE

Most of the notified polymer is expected to be released into the aquatic environment via the sewer through its use in domestic hard surface cleaning agents.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified polymer may remain in the end use product containers which will be collected for recycling. Wash water from the recycling process containing the notified polymer is expected to be released to surface waterways. Some of the notified polymer is also expected to be disposed of to landfill through the disposal of empty containers.

7.1.2. Environmental Fate

Following its use in surface cleaning agents, the notified polymer is expected to be primarily released into the sewer system and treated at the sewage treatment plants (STP) before release to surface waters nationwide.

A ready biodegradability study was conducted which determined that the notified polymer at ≤ 15% concentration is not readily biodegradable (1% after 28 days). For the details of the environmental fate studies please refer to Appendix C.
The notified polymer is not expected to bioaccumulate due to its high molecular weight (NAMW > 1000 g/mol).

7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) has been calculated based on 100% release rate into the sewer system over 365 days per year. The extent to which the notified polymer is removed from the effluent in

STP processes based on the properties of the notified polymer has not been considered for the worst-case scenario. The resulting PECs in receiving waters is displayed in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,500	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	4.11	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.84	µg/L
PEC - Ocean:	0.08	µg/L

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer at ≤ 15% concentration 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 = 5.79 mg/L	Toxic to aquatic invertebrates

Based on the above ecotoxicological endpoints for the notified polymer, it is expected to be acutely toxic to aquatic life. However, as the notified polymer is not biodegradable, the effects are expected to be long lasting. Therefore, the notified polymer is formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) as Chronic Category 2.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) of the notified polymer was calculated using the only ecotoxicity endpoint provided (48 h daphnia EC50 = 5.79 mg/L). An assessment factor of 1000 was used as there was only one endpoint available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates).	5.79	mg/L
Assessment Factor	1,000	
Mitigation Factor	1	
PNEC:	5.79	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.84	5.79	0.146
Q - Ocean:	0.08	5.79	0.015

The risk quotient (Q = PEC/PNEC) has been calculated based on the assumption of release of 100% of the notified polymer into the sewers. Since the Q value determined was less than 1 for both river and ocean compartments the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on the proposed annual importation and use patterns. Therefore, on the basis of the predicted PEC/PNEC ratio the notified polymer is not expected to pose an unreasonable risk to the aquatic environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -2 °C at 101.3 kPa

Method	OECD TG 102 Melting Point/Melting Range
Remarks	Determined by differential scanning calorimetry
Test Facility	Clariant (2018a)

Boiling Point 101 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point
Remarks	Determined by differential scanning calorimetry
Test Facility	Clariant (2018b)

Density 1,044.2 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids
Remarks	Oscillating density meter method
Test Facility	Clariant (2018c)

Viscosity Kinematic viscosity:
30.5 ± 0.3 mm^2/s at 20 °C
13.2 ± 0.3 mm^2/s at 50 °C
Dynamic viscosity:
31.9 ± 0.3 mPa.s at 20 °C
13.6 ± 0.3 mPa.s at 50 °C

Method	OECD TG 114 Viscosity of Liquids
Remarks	Rotational viscometer method Aqueous solution.
Test Facility	Clariant (2018d)

Water Solubility > 1000 g/L at 20 °C

Method	OECD TG 105 Water Solubility
Remarks	Screening Test
Test Facility	Clariant (2018e)

Partition Coefficient (n-octanol/water) log Pow < -0.7 at 20 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water) Shake Flask Method.
Remarks	Flask Method
Test Facility	Clariant (2018f)

Surface Tension 60.3 ± 0.1 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions
Remarks	Concentration: 5g/L
Test Facility	Clariant (2018g)

Flash Point Not detectable

Method	DIN EN ISO 2719
Remarks	Not detectable due to high content of water
Test Facility	Clariant (2018h)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin Irritation – *In Vitro* Reconstructed Human Epidermis Test

TEST SUBSTANCE: Notified polymer (≤ 15% aqueous solution)

METHOD: OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method
EPISKIN-SM™ Reconstructed Human Epidermis Model

Vehicle: None

Remarks – Method: In a preliminary test the test substance was shown not to directly reduce MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide].

The test substance (25 µL) was applied to the tissues in triplicate. Following exposure periods of 15 ± 0.5 minutes (room temperature), the tissues were rinsed, treated with MTT and then incubated at 37 °C for 42 hours.

Negative and positive controls were run in parallel with the test substance:
- Negative control: phosphate buffered saline (PBS)
- Positive control: 5% sodium dodecyl sulfate in PBS

RESULTS

Test Material	*Mean OD_{570} of Triplicate Tissues*	*Relative Mean Viability (%)*	*SD of Relative Mean Viability*
Negative control	0.974	100	5.7
Test substance	0.833	86	7.5
Positive control	0.314	32	14

OD = optical density; SD = standard deviation

Remarks – Results: The relative mean viability of the tissues treated with the test substance was > 50% (predicted as no GHS classification required).

The positive and negative controls gave satisfactory results, confirming the validities of the test systems.

CONCLUSION: Based on the relative mean tissue viability of > 50%, the test substance is not classified as a skin irritant according to the GHS criteria.

TEST FACILITY: Charles River (2018a)

B.2. Eye Irritation – *In Vitro* Bovine Corneal Opacity and Permeability Test

TEST SUBSTANCE: Notified polymer (≤ 15% aqueous solution)

METHOD: OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage

Vehicle: None

Remarks – Method: No significant protocol deviations. The negative control was physiological saline and the positive control was ethanol.

RESULTS

Test Material	*Mean Opacities of Triplicate Tissues (SD)*	*Mean Permeabilities of Triplicate Tissues (SD)*	*IVIS (SD)*
Vehicle control	2.3	0.003	2.3
*Test substance**	1.2	-0.001	1.2
*Positive control**	20	2.994	64

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

Remarks – Results	The in vitro irritancy score (IVIS) value for the test substance was lower than the cut-off value for GHS no category (≤ 3). The positive and negative controls gave satisfactory results, confirming the validities of the test systems.
CONCLUSION	The test substance was not considered corrosive, a severe eye irritant or irritating under the conditions of the test.
TEST FACILITY	Charles River (2018b)

B.3. Skin Sensitisation – *In Vitro* ARE-Nrf2 Luciferase Test

TEST SUBSTANCE	Notified polymer (≤ 15% aqueous solution)
METHOD	OECD TG 442d *In Vitro* Skin Sensitisation Assays Addressing the AOP Key Event on Keratinocyte Activation (2015) - The ARE-Nrf2 luciferase KeratinoSens™ test method (Appendix IA)
Vehicle	Dimethylsulfoxide
Remarks – Method	No significant deviations from the OECD test guideline. The positive control was ethylene dimethacrylate glycol.

RESULTS

Sample	*EC1.5 (µM)*	*IC30 (µM)*	*IC50 (µM)*	Maximum luciferase activity induction *(I_{max})*
Test substance – Test 1	N/A	4.6	N/A	0.89
Test substance – Test 2	N/A	4.6	14	0.94
Positive Control – Test 1	103	N/A	N/A	2.15
Positive Control – Test 2	83	N/A	N/A	2.13

EC1.5 - concentration for an induction of luciferase activity 50% above vehicle control
IC50 - concentration leading to 50% cell viability compared to vehicle control
I_{max} – maximal induction
N/A – not applicable

Remarks – Results	The test substance showed toxicity (IC30 = 4.6 µg/mL in both experiments, no IC50 in experiment 1 and an IC50 = 14 µg/mL in experiment 2). No biologically relevant induction of the luciferase activity (no EC1.5 value) was measured at any of the test concentrations in both experiments. The maximum luciferase activity induction (Imax) was 0.89-fold and 0.94-fold in experiment 1 and 2, respectively (< 1.5), indicating negative results. The study authors stated that the test conditions were adequate and the test system functioned properly.
CONCLUSION	The test substance was negative under the conditions of the test for the second key event (keratinocytes response) of the adverse outcome pathway (AOP) for skin sensitisation as defined in the test guideline.
TEST FACILITY	Charles River (2018c)

B.4. Skin Sensitisation – *In Vitro* Human Cell Line Activation Test

TEST SUBSTANCE	Notified polymer (≤ 15% aqueous solution)
METHOD	OECD TG 442e *In Vitro* Skin Sensitisation Assays Addressing the Key Event on Activation of Dendritic Cells on the Adverse Outcome Pathway

	for Skin Sensitisation *In Vitro* Skin Sensitisation (2018) - U937 Cell Line Activation Test (U-SENS™)
Vehicle	Complete medium RPMI-1640
Remarks – Method	No significant deviations from the OECD test guideline. A positive control (2,4,6-Trinitrobenzenesulfonic acid, TNBS) and a negative control (lactic acid, LA) were used.

RESULTS

Sample	*% Viability (mean) experiment 1/experiment 2*	*CD86-IgG1 S.I. experiment 1/experiment 2*
Negative Control - LA1	99/99	117/87
Negative Control – LA2	99/100	105/102
Negative Control – LA3	99/99	75/88
Positive Control – TNBS1	99/99	385/375
Positive Control – TNBS2	99/99	491/390
Positive Control – TNBS3	99/99	286/434
Test substance *(µg/mL)*		
1	99/-	96/-
10	99/-	85/-
20	99/99	77/112
50	99/99	85/118
100	99/100	110/113
200	99/100	104/117
Vehicle Control – RPMI	99/99	-
	IgG1 value (%) *experiment 1/experiment 2*	CD86 basal expression (%) *experiment 1/experiment 2*
Vehicle Control – RPMI1	0.6/0.8	8.1/8.5
Vehicle Control – RPMI2	0.7/0.8	10.7/9.1
Vehicle Control – RPMI3	0.4/0.6	7.2/8.5

*S.I. = simulation index

Remarks – Results	The test substance showed no toxicity (no CV70 value, CV70 = theoretical concentration at which the chemical induces 30% cytotoxicity) and no biologically relevant induction of the CD86 activity (no EC150 value, EC150 = theoretical concentration at which the test substance induces a S.I. of 150) was measured at any of the test concentrations in both experiments. The study authors stated that the test conditions were adequate and the test system functioned properly.
CONCLUSION	The test substance was negative under the conditions of the test for the third key event (dendritic cell activation) of the adverse outcome pathway (AOP) for skin sensitisation as defined in the test guideline.
TEST FACILITY	Charles River (2018d)

B.5. Genotoxicity – Bacteria

TEST SUBSTANCE	Notified polymer (≤ 15% aqueous solution)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test Plate incorporation procedure (Test 1)/Pre incubation procedure (Test 2)
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 mix from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 17-5000 µg/plate b) Without metabolic activation: 17-5000 µg/plate
Vehicle	Milli-Q water
Remarks – Method	The dose selection for the main tests was based on the toxicity observed in

a dose-range finding test carried out at 1.7-5000 µg/plate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 5000	> 5000	> 5000	negative
Test 2		≥ 5000	> 5000	negative
Present				
Test 1	≥ 5000	> 5000	> 5000	negative
Test 2		≥ 5000	> 5000	negative

Remarks – Results

No significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

The positive and negative controls gave a satisfactory response confirming the validity of the test system.

CONCLUSION

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

TEST FACILITY

Charles River (2018e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE	Product containing ≤ 15% notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Titration ($Ba(OH)_2$)
Remarks – Method	Test samples were made up such that the carbon content (TOC) in the test vessels was 10.2 mg C/L. A toxicity study was conducted using the test substance with the reference substance.

RESULTS

Test Substance		*Reference (Sodium benzoate)*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0	2	22
10	0	10	80
16	0	16	84
28	1	28	84

Remarks – Results	The toxicity study showed 34% degradation, therefore the test substance is not inhibitory. All validity criteria were met. The inorganic carbon was not determined, however the total CO_2 in the control test was < 70 mg/L.
CONCLUSION	The test substance is not readily biodegradable.
TEST FACILITY	NOACK (2018a)

C.2. Ecotoxicological Investigations

C.2.1. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE	Product containing ≤ 15% notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	291 mg $CaCO_3$/L
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	Test samples were made up using nominal concentrations of the final product containing the notified polymer and not pure samples of the notified polymer. The concentration of the notified polymer was determined using TOC measurements. A reference test ($K_2Cr_2O_7$) was conducted less than 2 months prior to the current study.

RESULTS

Concentration (mg/L)		*Number of D. magna*	*Number Immobilised*	
Nominal (test substance)	*Actual (notified polymer)*		*24 h*	*48 h*
Control	< LOQ	20	0	0

3.88	< LOQ	20	1	1
8.54	2.39	20	1	6
18.8	3.73	20	2	9
41.3	7.01	20	2	13
90.9	16.1	20	2	20

EC50	5.79 mg/L at 48 hours (measured)
NOEC	< 2.00 mg/L at 48 hours (LOQ)
Remarks – Results	The reported EC50 value is calculated based on the measured concentration of the notified polymer. All validity criteria were met. The dissolved oxygen content was maintained above 8 mg/L. The pH was maintained at 7 ± 1 and the temperature was maintained at 20 ± 1 °C. While the water hardness was outside of the recommended range specified in the OECD test guidelines (150 - 250 mg/L), there was no immobilisation in the control group. Therefore, this deviation is not likely to have adversely affected this study. The 24 hour EC50 of the reference test was 2.09 mg/L, within the expected range.
CONCLUSION	The test substance is acutely toxic to aquatic invertebrates.
TEST FACILITY	NOACK (2018b)

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