File No: LTD/2049

September 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in EBECRYL® 4100

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/2049	1. Allnex Australia Pty Ltd 2. Axalta Coating Systems Australia Pty Ltd	Polymer in EBECRYL® 4100	Yes	≤ 1 tonne per annum	Component of industrial and automotive paints and coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is recommended for health hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended health hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Eye irritation (Category 2A)	H319 – Causes serious eye irritation

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 toxicity (Category 2)	H411 – Toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended controls are being adhered to, 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 reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Eye irritation (Category 2A): H319 – Causes serious eye irritation

  The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present.

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:
  - Local exhaust ventilation if formation of mist or aerosol is expected
  - Spray booth during spray application

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling and end use of the notified polymer:
  - Avoid contact with eyes
  - Avoid inhalation of aerosols or sprays

- 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:
  - Chemical resistant gloves
  - Protective clothing
  - Protective eyewear
  - Respiratory protection during spray application

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

- 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.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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 1,000 g/mol;
- the notified polymer is intended to be used in products available to the public;
- the polymer has begun to be reformulated in Australia.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of industrial and automotive paints and coatings, 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.

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 polymer were carried out by NICNAS.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Allnex Australia Pty Ltd (ABN: 24 160 397 768)
49 – 61 Stephen Road
BOTANY NSW 2019

Axalta Coating Systems Australia Pty Ltd (ABN: 53 158 497 655)
15 – 23 Melbourne Road
RIVERSTONE NSW 2765

NOTIFICATION CATEGORY
Limited (Reduced fee notification): Synthetic polymer with Mn ≥ 1,000 g/mol – Approved Foreign Scheme - Canada

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, additives/adjuvants, use details, import volume and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physical and chemical properties except partition coefficient.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2005)
China (2013)
USA (2018)
Taiwan (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME
Polymer in EBECRYL® 4100

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is > 1,000 g/mol

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellowish liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported as a component of a solution
Boiling Point	Not determined	Imported as a component of a solution
Density	1,130 kg/m^3 at 20 °C	SDS
Vapour Pressure	11 kPa at 50 °C	SDS
Water Solubility	Immiscible at 15 °C	SDS
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functionalities but significant hydrolysis is not expected in the environmental pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	log P_{ow} = 2.51 – 3.28	Measured
Adsorption/Desorption	Not determined	Expected to be immobile in soil based on immiscibility in water
Dissociation Constant	Not determined	Contains no dissociable functionalities
Flash Point	> 100 °C	SDS
Flammability	Not determined	Not expected to form flammable vapours based on high molecular weight and flash point. At elevated temperatures the polymer decomposes.
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES
The notified polymer will be imported as a component of finished coatings and will not be isolated.

The notified polymer contains terminal pendant acrylates with a functional group equivalent weight (FGEW) < 5,000. Pendant acrylates are a functional group of high concern.

Reactivity
The notified polymer is expected to be stable under normal conditions of use. Terminal pendant acrylate groups may undergo further polymerisation.

Physical hazard classification
Based on the limited submitted physico-chemical data depicted in the above table, the notified polymer cannot be recommended for physical 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 as a component of finished coatings or paints at concentrations of < 30% and will be used without any local reformulation or repackaging.

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

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

PORT OF ENTRY
Sydney, Melbourne and Brisbane (Sydney will be the primary point of entry).

TRANSPORTATION AND PACKAGING
The notified polymer at concentrations of < 30% in finished coatings/paints will be imported in 20 L cans, 200 L drums or in 1 tonne intermediate bulk containers (ICB).

The finished paint products containing the notified polymer will also be imported in 400 mL aerosol cans or 1 L steel cans.

The finished coating/paint products will be transported by road to end users.

USE
The notified polymer at concentrations of < 30% will be used as a component of transport vehicle and industrial coatings or paints.

OPERATION DESCRIPTION
Manufacture, reformulation and repackaging of the notified polymer or products containing the notified polymer will not occur in Australia.

End Use
The coatings/paints containing the notified polymer will be mainly used at automotive repair shops for aftermarket vehicle body repairs. Other use areas may include equipment manufacture and aviation industries.

The coating system (containing the notified polymer at concentrations of < 30%) will be applied using specialised spray painting equipment for application to vehicles. In a typical use scenario, professional painters will manually pour the coatings containing the notified polymer into the spray equipment. Spray painting applications will be performed in spray booths fitted with ventilation and directional air flow (down draft) to capture and filter mists and overspray.

After the spray operation is completed, the equipment will be cleaned manually. A suitable solvent will be forced through the gun under pressure whilst the trigger unit is maintained in an open position. A clean cloth dampened with an appropriate solvent will be used to remove coating drips and splashes from exterior surfaces. Wastes will be collected for disposal.

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	1 – 2	20
Spray painting	8	300

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may come into dermal contact with the notified polymer at concentrations of < 30% only in the event of an accident where the containers are breached.

End Use
Dermal and ocular exposure of workers to the notified polymer at concentrations of < 30% may occur during opening cans of the coatings and manually pouring the contents into spray equipment. In addition, exposure may occur during connecting and disconnecting transfer hoses. If leakages happen, workers may also be potentially exposed to the notified polymer at < 30% concentrations.

Spray applications will be performed within spray booths. Workers may be exposed to the notified polymer at concentrations of < 30% by inhalation of the aerosolised coatings during spray applications. Inhalation is expected to be minimal as the coatings will be applied in ventilated spray booths and workers are expected to use

appropriate personal protective equipment (PPE), including respiratory protective devices, overalls, chemical resistant gloves and safety boots.

Dermal, ocular and inhalation exposure to the notified polymer at concentrations of < 30% may also occur during the cleaning of the spray equipment. Operators are expected to wear appropriate PPE including overalls, protective eyewear, chemical resistant gloves and breathing protection during the cleaning procedure.

6.1.2. Public Exposure

The products containing the notified polymer will only be used by professional spray painters and will not be sold to the public for do-it-yourself (DIY) use.

Once applied to automobile body parts, the coating containing the notified polymer will be cured and the notified polymer is expected to undergo further polymerisation and to be trapped within the inert coating matrix. It is not expected to be available for exposure after curing.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and an analogue are summarised in the following table. For full details of the bacterial reverse mutation test on the analogue that was not assessed in Canada, refer to Appendix A.

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

* Study on an analogue polymer

Toxicokinetics, metabolism and distribution

The notified polymer is not expected to be readily absorbed across biological membranes, based on the high molecular weight (> 1,000 g/mol) with limited amounts of low molecular weight species (< 2% with molecular weight < 500 g/mol and < 22% with molecular weight < 1,000 g/mol) and low water solubility.

Acute toxicity

The notified polymer was found to have low acute oral toxicity in rats. No acute dermal or acute inhalation toxicity data were submitted for the notified polymer.

Irritation and sensitisation

In a dermal irritation/corrosion study conducted in rabbits, the notified polymer did not produce corrosive or irritating effects under the test conditions.

An eye irritation/corrosion study of the notified polymer in rabbits indicated mild eye irritation. A single ocular application of the notified polymer (undiluted, at a dose of 0.1 mL) produced irritation effects in all animals including corneal opacity (grade 1) with half to complete corneal staining and irritation of the iris (grade 1) in 24 hours. The effects persisted to Day 6 of the observation. Redness and chemosis of the conjunctivae were also observed 1 hour after the application and persisted to Day 5 of the observation. The effects were fully reversible within 7 days of observation. The notified polymer meets the criteria for classification as an eye irritant (Category 2A) according to the GHS.

In a skin sensitisation study conducted in albino guinea pigs, there was no evidence of sensitisation resulting from treatment with undiluted notified polymer.

Mutagenicity

No genotoxicity study was provided for the notified polymer. An *in vitro* bacterial reverse mutation (Ames) test on the analogue polymer indicated that the analogue was not mutagenic to bacteria under the conditions of the test (Appendix A.1).

Other Consideration

The notified polymer contains terminal pendant acrylate groups with a functional group equivalent weight (FGEW) < 5,000. Reactive acrylate groups are known to be associated with a range of adverse health effects

including irritation, sensitisation, genotoxicity and tumorigenicity. These functional groups are expected to be reacted during the end use to form polymerised matrixes and will not be present once the coatings/paints containing the notified polymer are cured.

Health hazard classification
Based on the available information, the notified polymer is recommended for health hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Eye irritation (Category 2A)	H319 – Causes serious eye irritation

6.3. Human Health Risk Characterisation
Based on the toxicological information submitted, the notified polymer is irritating to the eye.

6.3.1. Occupational Health and Safety
Workers may be exposed to the notified polymer at concentrations of < 30% when handling products containing the notified polymer and during spray applications. Workers may also be potentially exposed to the notified chemical at concentrations of < 30% if leakages occur. Systemic absorption of the notified polymer through dermal exposure is unlikely due to the high molecular weight and low water solubility of the notified polymer. The likely exposure routes are expected to be dermal and ocular, with the potential for inhalation during spray. The use of safe work practices, engineering controls and appropriate PPE including protective clothing and eyewear, chemical resistant gloves and safety boots are expected to mitigate the risk of potential adverse health effects to workers from use of the notified polymer.

The inhalation toxicity of the notified polymer has not been fully determined. However, the proposed use of engineering controls including spray booths, local exhaust and general ventilations, and the use of appropriate PPE including respiratory protection devices, will reduce the potential for exposure during the operations, and reduce the risk of possible adverse effects.

Once the coatings and paints containing the notified polymer are cured, the acrylate groups in the notified polymer are expected to be polymerised and the notified polymer will be bound into the inert matrix.

Provided that the work place controls are being adhered to, 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
Products containing the notified polymer will only be used by workers within enclosed systems and in areas which will not be accessible to the general public.

Members of the public may come into contact with articles coated with products containing the notified polymer. However, the notified polymer is expected to be cured and cross-linked to form an inert matrix and will not be available for further exposure.

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 will be imported into Australia as a component of finished coatings; no reformulation or repackaging will occur in Australia. Release of the coatings containing the notified polymer to the environment during import, storage, and transport is expected to be limited to accidental spills or leaks. Spills or accidental release of the coatings containing the notified polymer are expected to be collected with suitable absorbents and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The coatings containing the notified polymer will be mainly used by professional users at automotive repair shops for aftermarket vehicle body repairs. The coatings will be applied using specialised spray painting equipment for application to vehicles. The main release of the notified polymer is likely from overspray during use. The overspray will be collected by spray booth filters before disposal of to landfill in accordance with local government regulations. Waste from application equipment cleaning will be collected by an approved waste management contractor for disposal in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer is expected to share the fate of the article to which it has been applied, either subjected to metal reclamation processes or being disposed of to landfill at the end of their useful lives. Residual notified polymer in empty containers, estimated by the notifier to account for up to 0.5% of the total import volume, is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty containers.

7.1.2. Environmental Fate

A biodegradation test conducted on the notified polymer shows that it is not readily biodegradable (9% degraded over 28 days). As a result of its use pattern, most of the notified polymer is expected to share the fate of the article to which it has been applied, either subjected to metal reclamation processes or being disposed of to landfill at the end of their useful lives. During metal reclamation processes, the notified polymer will thermally decompose to form water vapour and oxides of carbon and nitrogen. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. Therefore, release of the notified polymer to the aquatic environment is expected to be minimal. The notified polymer is not expected to be bioaccumulative based on its high molecular weight. In landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern as a component of industrial and automotive coatings.

7.2. Environmental Effects Assessment

Results from the ecotoxicological investigations conducted on the notified polymer are summarised in the table below. For full details of these tests, refer to Appendix B. As the preparation procedure for the water accommodated fraction (WAF) in the fish test was similar to that of the daphnia and algae tests, it was deduced that the notified polymer was present in the fish study as a WAF. Therefore, the endpoint for the fish study was considered based on a WAF of the nominal concentration.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 = 100 mg WAF/L	Harmful to fish
Daphnia Toxicity	48 h EC50 > 100 mg WAF/L	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	72 h EC50 = 3.9 mg WAF/L	Toxic to alga
Inhibition of Bacterial Respiration	0.5 h EC50 ≥ 10,000 mg/L (nominal concentration)	Does not inhibit microbial activity at STPs

Based on the above ecotoxicological endpoints for the notified polymer, it is expected to be harmful to fish and toxic to alga. Therefore, the notified polymer is formally classified as “Acute Category 2; Toxic to aquatic life” under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS). Based on the acute toxicity and lack of readily biodegradability, the notified polymer is formally classified as “Chronic Category 2; Toxic to aquatic life with long lasting effects” under the GHS (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated based on the most sensitive endpoint for alga as shown in the table below. An assessment factor of 100 was used given the acute endpoint for three trophic levels are available as a general indication of potential toxicity.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
72 h EC50 for alga	3.9	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC	39	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern. Therefore, based on the reported use pattern as a component of industrial and automotive paints and coatings, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue polymer
METHOD	Ames test as described by Ames *et al.* (1973 and 1975) and Maron and Ames (1983) Plate incorporation procedure/Pre-incubation procedure
Species/Strain	*Salmonella typhimurium*: TA1537, TA1535, TA102, TA100 and TA98
Metabolic Activation System	Aroclor 1254 induced rat liver S9 mix
Concentration Range in Main Test	a) With metabolic activation: 16 – 5,000 µg/plate b) Without metabolic activation: 16 – 5,000 µg/plate
Vehicle	Deionised water
Remarks - Method	Concentrations for main test were chosen based on the plate incorporation method conducted on TA100, TA102 and TA1535 (base-pair substitution type) and on TA98 and TA1537 (frameshift type) results. Tests with vehicle control and positive controls were run concurrently. Positive controls were: - With metabolic activation: 2-anthracenamine (TA1537, TA1535, TA102, TA100 and TA98) - Without metabolic activation: sodium azide (TA1535), 2,4-imidazolidinedione, 1-[[(5-nitro-2-furanyl)methylene]amino]- (TA100), 1,2-benzenediamine, 4-nitro- (TA1537 and TA98), hydroperoxide, 1-methyl-1-phenylethyl (TA102) No major deviations from the test protocol were reported.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (plate incorporation)	≥ 1,581	–	> 5,000	negative
Test 2 (pre-incubation)	–	> 5,000	> 5,000	negative
Present				
Test 1 (plate incorporation)	≥ 1,581	–	> 5,000	negative
Test 2 (pre-incubation)	–	> 5,000	> 5,000	negative

Remarks - Results	The test substance did not result in a biological relevant increase of number of revertant colonies in comparison to the negative control. In addition, no dose-related response was observed in any strains of base-pair substitution type or frame-shift type, with or without metabolic activation. The positive and negative controls provided 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	Bayer (1998a)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	EC Council Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static
Species	Zebra fish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	None
Remarks – Method	No significant deviation from the test guidelines was reported. The test item was directly added into the test water and treated at 8,000 rpm for 60 seconds. The dispersion was then stirred for 24 hours and the undissolved particles of the test item were filtered (7 – 12 µm) before testing.

RESULTS

Concentration mg WAF/L*		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Not determined	10	0	0	0	0	0
31.6	Not determined	10	0	0	0	0	0
100	Not determined	10	0	0	1	2	2
316	Not determined	10	0	10	10	10	10

* WAF: Water Accommodated Fraction

LC50	100 mg WAF/L (nominal) at 96 hours (geometric mean of 31.6 mg/L and 316 mg/L)
Remarks – Results	All validity criteria for the test were satisfied. The dissolved oxygen in the test solution during the test was ≥ 80%.
CONCLUSION	The test substance is harmful to fish.
TEST FACILITY	Bayer AG (1998b)

C.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	256 mg $CaCO_3$/L
Analytical Monitoring	Dissolved organic carbon (DOC) by Multi N/C 3000 DOC analyser
Remarks - Method	A limit test was run without significant deviations from the test guidelines. A test concentration of 100 mg/L of test item was prepared and shaken for 24 hours, then the undissolved particles of the test item were removed by centrifugation before testing.

RESULTS

Concentration mg WAF/L*		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
100	Not determined	20	0	0

* WAF: Water Accommodated Fraction

LC50	> 100 mg WAF/L (nominal) at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The dissolved oxygen concentration in the test solution during the test was ≥ 7.63 mg/L at 20 °C (≥ 84%, USGS, 2011).
CONCLUSION	The test substance is not harmful to aquatic invertebrates up to its water solubility limit.
TEST FACILITY	Dr U Noack Laboratorium (2002a)

C.1.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test EC Council Directive 92/69/EEC C.3 Algal Inhibition Test
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 0.31, 0.63, 1.25, 2.5, 5, 10 mg WAF/L
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	DOC by DOC analyser
Remarks - Method	No significant deviation from the test guidelines was reported. A dispersion with the nominal loading of 10 mg/L was prepared and shaken for 24 hours, and then the undissolved particles of the test item were removed by centrifugation before testing. Lower test concentrations were prepared by diluting the 10 mg/L concentration.

RESULTS

Biomass		*Growth*	
EC50	*NOEC*	*EC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
3.9 (95% CI: 3.4 – 4.5)	1.25	9.7 (95% CI: 8.8 – 10.6)	1.25

Remarks - Results	All validity criteria for the test were satisfied. The mean cell density in the control increased by 69 times.
CONCLUSION	The test substance is toxic to alga.
TEST FACILITY	Dr U Noack Laboratorium (2002b)

C.1.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge from a domestic STP
Exposure Period	0.5 hour
Concentration Range	Nominal: 1,000; 1,800; 3,200; 5,600; 10,000 mg/L

Remarks – Method	No significant deviation from the test guidelines was reported. The test substance was directly added into the test vessels.

RESULTS

IC50	≥ 10,000 mg/L
Remarks – Results	All validity criteria for the test were satisfied.

CONCLUSION	The test substance does not inhibit microbial activity at STPs.
TEST FACILITY	Bayer AG (1998c)

BIBLIOGRAPHY

Ames, B.N., Durston, W.E., Yamasaki, E. and Lee, F.D. (1973). Carcinogens are mutagens: A simple test system combining liver homogenates for activation and bacteria for detection, Proc. Nat. Acad. Sci (USA) 70, 2281-2285.

Ames, B.N., McCann, J. and Yamasaki, E. (1975). Methods for Detecting Carcinogens and Mutagens with the Salmonella/Mammalian-Microsome Mutagenicity Test. Mutation Res., 31, 347-364.

Bayer (1998a) [Analogue polymer] Special Study Ames-Test Screening (Study No. T 1059782, July, 1998). Wuppertal, Bayer AG (Unpublished report submitted by the notifier)

Bayer (1998b) Acute Fish Toxicity of [Notified Polymer] (Study No. 81115180, August, 1998). Leverkusen, Germany, Bayer AG, Institute of Environmental Analysis (Unpublished report submitted by the notifier).

Bayer (1998c) Toxicity to bacteria of [Notified Polymer] (Study No. 81115180, June, 1998). Leverkusen, Germany, Bayer AG, Institute of Environmental Analysis (Unpublished report submitted by the notifier).

Dr U Noack Laboratorium (2002a) [Notified Polymer]: Acute Immobilisation Test (48 h) to *Daphnia magna* STRAUS, Limit Test (Study No. DAI858111, June, 2002). Sarstedt, Germany, Dr U Noack Laboratorium Für Angewandte Biologie (Unpublished report submitted by the notifier).

Dr U Noack Laboratorium (2002b) [Notified Polymer]: Alga Growth Inhibition Test with *Scenedesmus subspicatus* 72 h with the Water Accommodated Fraction (Study No. SSO858111, September, 2002). Sarstedt, Germany, Dr U Noack Laboratorium Für Angewandte Biologie (Unpublished report submitted by the notifier).

Maron, D.M. and Ames, B.N. (1983). Revised Methods for the Salmonella Mutagenicity Test. Mutation Res., 113, 173-215.

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-managing-risks-hazardous-chemicals-workplace

SWA (2015) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-spray-painting-and-powder-coating.

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