

File No.: LTD/2156

November 2020

**AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME
(AICIS)**

PUBLIC REPORT

International Polyester LDR

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2156	Akzo Nobel Pty Ltd	International Polyester LDR	ND*	< 65 tonnes per annum	Component of industrial surface coating

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification

Based on the available information, the assessed 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.

Human Health Risk Assessment

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

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

Environmental Risk Assessment

On the basis of the low hazard and reported use pattern, the assessed polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the products containing the assessed polymer during reformulation:
 - Enclosed processes if possible
 - Local exhaust ventilation
 - Adequate general ventilation
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the products containing the assessed polymer during reformulation and end use:
 - Avoid contact with skin and eyes
 - Avoid inhaling spray mist/aerosols
- 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 products containing the assessed polymer during reformulation and end use:
 - Impervious gloves
 - Protective clothing
 - Safety glasses or goggles
 - Respiratory protection

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 assessed 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.

Storage

- The handling and storage of the assessed 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 assessed polymer should be handled by physical containment, collection and subsequent safe disposal.

Disposal

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

Regulatory Obligations

Specific Requirements to Provide Information

This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the polymer based on changes in certain circumstances. Under section 101 of the IC Act the introducer of the assessed polymer has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed polymer is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the polymer has a number-average molecular weight of less than 1000 g/mol;
- the function or use of the polymer has changed from a component of industrial surface coating, 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 human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet

The SDS of the assessed polymer (and products containing the assessed polymer) provided by the applicant was (were) reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT

Akzo Nobel Pty Ltd (ABN: 59 000 119 424)
51 McIntyre Road
SUNSHINE NORTH VIC 3020

APPLICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ g/mol

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)

Data items and details taken to be protected information include: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details, import volume, site of reformulation and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)

Schedule data requirements are not varied.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)

None

APPLICATION IN OTHER COUNTRIES

U.S.A (2012)
Canada (2014)
China (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

International Polyester LDR

OTHER NAME(S)

Polymer in International Polyester LDR - RP4498

MOLECULAR WEIGHT

Number average molecular weight (M_n) is $> 1,000$ g/mol.

ANALYTICAL DATA

Reference NMR, IR, HPLC, GC, GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

$> 75\%$

DEGRADATION PRODUCTS

Oxides of Carbon

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Freezing Point	-28.5 °C	Measured
Boiling Point	Decomposes at > 250 °C at 101.3 kPa	Measured
Density	1.07 kg/m ³ at 20 °C	Measured
Vapour Pressure	0.0003 kPa at 20 °C	Measured

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Water Solubility	Could not be determined	The studies indicate that the assessed polymer is insoluble in water
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality but is not expected to hydrolyse in environmental pH range of 4-9 due to low water solubility
Partition Coefficient (n-octanol/water)	log Pow > 6.5 at 20 °C	Measured
Adsorption/Desorption	Not determined	Based on its low water solubility, the assessed polymer is expected to adsorb strongly to soil, sediment and sludge
Dissociation Constant	Not determined	Does not contain dissociable functionalities
Flash Point	132 °C	Measured
Flammability	Not determined	Not expected to be highly flammable, based on flash point
Autoignition Temperature	415 °C	Measured
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

Reactivity

The assessed 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 assessed 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.

The assessed polymer has a flash point of 132 °C which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the assessed polymer may be considered as a Class C2 combustible liquid if the assessed polymer has a fire point below the boiling point.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS

The assessed polymer will not be manufactured in Australia and will be imported into Australia as a component of various solvent based colourants/tint bases up to 75% concentration.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 65	< 65	< 65	< 65	< 65

PORT OF ENTRY

Melbourne, Sydney, Brisbane, Fremantle and Darwin

TRANSPORTATION AND PACKAGING

The assessed polymer will be imported into Australia as a component of colourants/tint bases up to 75% concentration by sea and transported by road in 5 L containers. Locally reformulated end-use products containing the assessed polymer (at <10% concentration) will be distributed by road, sea and air in containers ranging from 4 L to 200 L.

USE

The assessed polymer (colourants/tint bases) will be used as a component of colourants/tint bases for Akzo Nobel protective topcoat coatings. These colourants/tint bases are to be mixed into a protective coatings base to generate

a formulated colour. Up to 6 tinters can be used to formulate a specific colour. These formulated colour products are used as a topcoat in the professional-use performance coatings market. These products are used to paint structural steel objects such as I-beams used in construction, mining, ships, tanks, externals, bridges, pylons and general infrastructure that requires corrosion and UV protection. These products will not be sold to the consumer or DIY market.

OPERATION DESCRIPTION

The assessed polymer will be imported into Australia as a component of 13 colourants/tint bases (up to 75% concentration) and these colourants/tint bases come in a range of colours. Once an order is placed by a customer, the colourants/tint bases will be used to generate a specific final colour and will be mixed with a respective compatible topcoat base of various Akzo Nobel protective coatings.

Reformulation

Colourants/tint bases containing the assessed polymer will be added to a paint base and mixed until the product is homogeneous, using a tinting machine coupled to an extraction unit. The tinting machine automatically dispenses the exact amount of colourant/tint base into a base container and stirs the contents by using an embedded disperser blade or a paint shaker. Once the tinting process is complete, the formulated product containing the assessed polymer (at < 10% concentration) is specifically re-packaged and labelled as a formulated product. Up to 6 colourants/tint bases can be used to formulate a specific colour. This is a semi-automated process undertaken at the warehouse, with the lids hermetically sealed after the mixing process. The closed drums will be palletised and shipped by licensed transport companies to other warehouses around Australia or directly to customers via road and sea freight.

End-use

The formulated colour products are used as topcoats in the professional-use performance coatings market and are used to paint the substrate (steel structures) either in a workshop as part of a newly constructed item (e.g. ship) or in the field (e.g. bridge) as part of maintenance and repair by professional users. Coatings are applied in a workshop through brush/roller application.

When coatings are applied in the field, application of the coatings is normally by airless spray. The applicator crew consists of the sprayer and a potman. The potman, working at a distance from the sprayer, is responsible for ensuring that the spray equipment is fed with a continual supply of paint, adding thinner when necessary.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Distribution and Warehousing	Nil	Nil
Tinting by Warehouse Employee	2	200
Paint Quality Control and Technicians	1	40
Application process (end-use) - sprayers	6	75
Application process (end-use) - potmen	6	75

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are not expected to be exposed to the assessed polymer except in the unlikely event of a spill or an accident. As there will be no exposure, personal protective equipment (PPE) is not required for these warehouse and transport staff. However, as a general rule, Akzo Nobel warehouse staff must wear safety glasses, protective clothing and safety shoes and highly visible clothing due to forklift activity.

Reformulation

At reformulation sites, dermal or ocular exposure to the assessed polymer (up to 75% concentration) may occur whilst opening containers, connection/disconnection of hoses and quality control testing. Only specifically trained warehouse staff will perform the tinting process. The tinting process (reformulation) is a semi-automated process undertaken at the warehouse, with the lids hermetically sealed after the mixing process. The potential for dermal and ocular exposure will be further minimised by the stated use of PPE (safety glasses, protective clothing, safety shoes) by warehouse workers involved in tinting process. Given the expected low vapour pressure of the assessed polymer, inhalation exposure to the assessed polymer is not expected during blending where aerosols may be generated. However, as all Akzo Nobel tint machines in the warehouses and laboratories are under extraction and use semi-automated processes, inhalation exposure to the assessed polymer and solvents in the tint and bases will be further reduced.

End-use

At end-use sites, dermal or ocular exposure to the assessed polymer may occur during application of the finished coatings containing the assessed polymer. The assessed polymer is used to paint the substrate (steel) either in a workshop as part of a newly constructed item (e.g. ship) or in the field (e.g. bridge) as part of maintenance and repair.

When coatings are applied in a workshop through brush/roller application, exposure of workers will be mitigated through the use of local exhaust ventilation and/or enclosed systems and through the use of PPE (coveralls, apron, rubber boots, safety visor, appropriate respiratory protection, impervious gloves).

When coatings are applied in the field, application of the coatings is normally by airless spray. The applicator crew normally consists of the sprayer and a potman. The latter is responsible for ensuring that the spray equipment is fed with a continual supply of mixed paint. The potman adds any necessary thinner and supplies this to the spray equipment in the original packaging. The potman will work at a distance from the sprayer. This will depend of the length of hose and the working environment.

As the potman will be at a distance from the sprayer, he will not be directly exposed to the assessed polymer. Exposure will be further minimised by the use of specified PPE (long-sleeved overalls, boots, gloves, goggles or face shield and respirator) by all members of the application team.

The applicator crew will clean out the spray equipment using solvent at the end of the spraying operation. This cleaning solvent will be used several times and the used cleaning solvent may be sent for recovery or incineration. All disposal will be in accordance with locally applicable regulations.

The assessed polymer will react as part of the coating curing process on the steel substrate into a coated film. Once cured on a steel substrate, the assessed polymer becomes a part of a complex polymer/pigment network in a cured film bonded to the steel substrate and will not be available for exposure.

6.1.2. Public Exposure

The products containing the assessed polymer will not be sold to the consumer or DIY market. The formulated colour products are used in the professional-use performance coatings market only. Public exposure to the assessed polymer as a result of transportation within Australia will not occur except in the unlikely event of a spill or an accident.

During applications at sites that may experience pedestrian flow (e.g. painting a pedestrian bridge), the work area will be enclosed to ensure that there is no exposure to bystanders. After application, the assessed polymer will be bound within a polymer matrix as part of the paint film as the paint cures. While members of the public may make contact with the painted items after they are dried, the assessed polymer will be bound within a matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the assessed polymer are summarised in the following table. For details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Acute oral toxicity – rat	LD50 > 2000 mg/kg bw; low toxicity
Genotoxicity – bacterial reverse mutation	mutagenic

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Genotoxicity – <i>in vivo</i> mammalian erythrocyte micronucleus test	non-genotoxic

Toxicokinetics

Given its relatively high number average molecular weight (> 1,000 g/mol), low water solubility, and its high partition coefficient (log Pow > 6.5 at 20 °C), limited dermal absorption is expected.

Acute Toxicity

The assessed polymer was of low acute oral toxicity when tested in rats.

Mutagenicity/Genotoxicity

The assessed polymer was mutagenic in a bacterial reverse mutation assay. The mutagenic effects were seen in 2 out of 5 tester strains of *Salmonella typhimurium* at concentrations above 1600 µg/plate. The mutagenicity was confined only to incubations with metabolic activation. Mutagenic effects were not seen in the *Escherichia coli* reverse mutation assay, with or without metabolic activation.

The mutagenicity of the test substance containing the assessed polymer in solution was stated to be due to the high level of a residual monomer, neodecanoic acid, 2-oxiranylmethyl ester (CAS 26761-45-5) (Charles River, 2019a). Therefore, while the assessed polymer is not a mutagenic substance as such, products containing the assessed polymer could be mutagenic substances, as per the concentration of the residual monomer (CAS 26761-45-5).

The assessed polymer was not clastogenic in an *in vivo* mammalian micronucleus test in mice up to gavage doses of 2000 mg/kg body weight. However, this result is not considered conclusive as there was no evidence of bone marrow exposure to the assessed polymer.

Observations on Human Exposure

Akzo Nobel has not reported any effects on the health of workers using the assessed polymer in the development phase. There are also no reported health effects linked to use of the assessed polymer in U.S.A or Europe, where it has been in use since 2012.

Health Hazard Classification

Based on the available information, the assessed 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

The assessed polymer has low acute oral toxicity.

Given its relatively high number average molecular weight (> 1,000 g/mol), low water solubility and high partition coefficient (log Pow > 6.5 at 20 °C), limited dermal absorption is expected. However there are low molecular weight species present in the assessed polymer favouring absorption. Due to low vapour pressure of the assessed polymer, inhalation exposure is not expected, however, exposure to aerosols could be possible during end-use applications.

Although not considered in this risk assessment, AICIS notes that the assessed polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

While the assessed polymer is not classified as a hazardous substance as such, products containing the assessed polymer could be hazardous substances (for irritation, sensitisation & mutagenicity), as per the concentration of the residual monomers in these products. The SDS of the products containing the assessed polymer, therefore, should reflect these risks.

6.3.1. Occupational Health and Safety

Workers may experience dermal, ocular and perhaps inhalation exposure to the assessed polymer at up to 75% concentration during reformulation (tinting process) whilst opening containers, connection/disconnection of hoses and quality control testing. The adoption of control measures including the use of semi-automated tinting processes

with extraction, hermetic sealing of the lids after the mixing process, and use of suitable PPE (safety glasses, protective clothing, safety shoes) would minimise any risk to workers. The risk to workers would be further mitigated as only specifically trained warehouse staff will perform the tinting process.

Professional workers may be exposed to the assessed polymer at < 10% concentration during application and cleaning processes. Control measures such as ventilation and use of PPE (coveralls, apron, rubber boots, safety visor, respiratory protection, impervious gloves) would mitigate any exposure risk to workers. Once the product is cured, the assessed polymer will be bound within an inert solid matrix and will not be available for exposure.

Therefore, provided adequate control measures are in place to minimise worker exposure, including the use of semi-automated processes and the use of PPE, the risk to workers from use of the assessed polymer is not considered to be unreasonable.

6.3.2. Public Health

Products containing the assessed polymer will not be available to the public.

Appropriate precautions will be taken during applications at sites that may experience pedestrian flow (e.g. painting a pedestrian bridge) to ensure that the assessed polymer has no exposure to bystanders. After application, the assessed polymer will be bound within a polymer matrix as part of the paint film as the paint cures. While members of the public may make contact with the painted items after they are dried, the assessed polymer will be bound within a matrix and will not be available for exposure.

When used in the proposed manner, the assessed 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 assessed polymer will be imported into Australia as a component of colourants/tint bases for reformulation into protective coating products. The reformulation process will involve mixing in automated tinting machines and enclosed blending vessels. Release from the reformulation process is limited to accidental spills which are to be collected and disposed of via landfill.

RELEASE OF CHEMICAL FROM USE

Coating products containing the assessed polymer will be used for applications on a variety of steel substrates. Applications will be done by airless spray or brush and roller by professionals under controlled workplace conditions. The overspray is expected to be collected before disposal to landfill. Once the coating is dried, the assessed polymer will be cured and bound into an inert solid matrix and no environmental exposure of the uncured coating product is expected. The solvents used in the cleaning of spray equipment may be sent for recovery or incineration. Solid wastes and residues in empty containers are expected to be collected and disposed of to landfill according to local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the assessed polymer will be chemically cured as part of the protective coatings. The cured coatings are expected to share the fate of the coated substrates to which they have been applied, either subjected to substrate recycling processes, or disposed of to landfill at the end of their useful lives. Exposure of the assessed polymer to the environment is not expected after curing of its coating products. Empty coating product containers containing the assessed polymer are also expected to be recycled or disposed of to landfill.

7.1.2. Environmental Fate

The assessed polymer is not readily biodegradable. For the details of the environmental fate study refer to Appendix C. As a result of its use pattern, most of the assessed polymer is expected to be cured, with insignificant amounts of the assessed polymer remaining in the cured coatings. The cured coatings will share the fate of the substrates to which they have been applied, either subjected to the substrate recycling processes, or disposed of to

landfill at the end of their useful lives. During recycling processes, the cured coatings are expected to thermally decompose. In landfill, the cured coatings are expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

A Predicted Environmental Concentration (PEC) has not been calculated for the assessed polymer, as no significant release to the aquatic compartment is expected from the proposed use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data were provided for the assessed polymer. However, polymers without significant ionic functionality are generally of low concern to the environment.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) could not be calculated as no ecotoxicity data were provided.

Due to the lack of ecotoxicity data, the assessed polymer cannot be classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute and chronic toxicities (United Nations, 2009).

7.3. Environmental Risk Assessment

A risk quotient ($Q = \text{PEC}/\text{PNEC}$) was not calculated as a PNEC was unable to be determined. However, on the basis of the assumed low hazard and assessed use pattern, the assessed polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -28.5°C

Method OECD TG 102 Melting Point/Melting Range
EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks Differential scanning calorimetry (DSC) was used.
Test Facility Charles River (2019)

Boiling Point Decomposes at > 250°C at 101.3 kPa

Method OECD TG 103 Boiling Point
EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks Differential scanning calorimetry (DSC) was used.
Test Facility Charles River (2019)

Density 1.07 x 10³ kg/m³ at 20 °C

Method OECD TG 109 Density of Liquids and Solids
EC Council Regulation No 440/2008 A.3 Relative Density
Remarks The pycnometer method was used.
Test Facility Charles River (2019)

Vapour Pressure 3.3 x 10⁻³ kPa at 25 °C

Method OECD TG 104 Vapour Pressure
EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks The isothermal thermogravimetric effusion method was used.
Test Facility Charles River (2019)

Water Solubility Insoluble in water Both studies indicate that the polymer is insoluble in water.

Method OECD TG 105 Water Solubility
EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks Flask Method. Not determined due to lack of suitable analytical method.
Test Facility Charles River (2020)

Method OECD TG 120 Solution/Extraction Behaviour of Polymers in Water
EC Council Regulation No 440/2008 A.6 Water Solubility and OECD TG 120
Remarks Flask Method. Analysed by total organic carbon (TOC).
Water extractability was determined to be ≤ 0.3 mg/L at the highest tested nominal concentration of 10 g/L.
Test Facility Harlan (2013)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH
EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH
Remarks Not determined due to low solubility in water
Test Facility Harlan (2013)

Partition Coefficient (n-octanol/water) log Pow > 6.5 at 20 °C

Method OECD TG 117 Partition Coefficient (n-octanol/water)
EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks HPLC Method

Test Facility Harlan (2013)

Flash Point 132°C

Method EC Council Regulation No 440/2008 A.9 Flash Point
Remarks The closed cup method was used.
Test Facility Charles River Laboratories (2019)

Autoignition Temperature 415°C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)
EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids
Remarks A commercially available auto-ignition temperature apparatus was used.
Test Facility Charles River Laboratories (2019)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute Oral Toxicity – Rat**

TEST SUBSTANCE	Assessed polymer
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Method (2001) EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed dose method
Species/Strain	Rat/Wistar
Vehicle	Arachis oil
Remarks – Method	No significant protocol deviations.

RESULTS

Group	Number and Sex of Animals	Dose (mg/kg bw)	Mortality
1	1F	300	0
2	1F	2000	0
3	4F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted during the observation period.
Effects in Organs	No abnormalities were recorded at necropsy.
Remarks – Results	No mortality was observed at any dose.

CONCLUSION The assessed polymer is of low acute toxicity via the oral route.

TEST FACILITY Harlan (2012)

B.2. Genotoxicity – Bacteria

TEST SUBSTANCE	Assessed polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test (1997) EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria (2008) Plate incorporation procedure/Pre-incubation procedure
Species/Strain	<i>Salmonella typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>Escherichia coli</i> : WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor 1254-induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 52-5000 µg/plate b) Without metabolic activation: 52-5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks – Method	No significant protocol deviations. Test 1 (Direct plate assay); Test 2 (Pre-incubation Assay) Positive controls: Without metabolic activation: sodium azide (TA1535); ICR-191 (TA1537 (direct plate assay)); 2-nitrofluorene (TA1537 (pre-incubation assay), TA98); methyl methane sulfonate (TA100); 4-nitroquinoline N-oxide (WP2uvrA) With metabolic activation: 2-aminoanthracene

RESULTS

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

Test 2	> 5000	> 5000	≥ 1600	Negative
<i>Present</i>				
Test 1	> 5000	> 5000	≥ 5000	Positive
Test 2	> 5000	> 5000	≥ 1600	Positive

Remarks – Results

The assessed polymer induced increases in the number of revertant colonies in the presence of S9-mix in both the direct plate assay (Test 1) and the pre-incubation assay (Test 2). The increase was observed in the tester strains TA1535 (from 1600 µg/plate) and TA100 (from 5000 µg/plate) but not in the other tester strains.

The increases observed in tester strain TA1535 were above the laboratory historical control data range and up to 3.1- and 6.8-fold the concurrent solvent control in the first and second experiment, respectively. The increases observed in tester strain TA100 were above the laboratory historical control data range in both experiments, but were not greater than two times the concurrent control.

Since dose related increases were observed in two tester strains in the presence of S9-mix and the results were reproducible in the repeat assay, these increases are considered biologically relevant and the test item is mutagenic in the presence of S9-mix.

The negative and positive controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

The assessed polymer was mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Charles River (2019a)

B.3. Genotoxicity – *In Vivo* Mammalian Erythrocyte Micronucleus Test

TEST SUBSTANCE

Assessed polymer

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test (2016)
EC Directive 2000/32/EC B.12 Mutagenicity – Mammalian Erythrocyte Micronucleus Test (2008)

Species/Strain

Mouse/NMRI

Route of Administration

Oral – gavage

Vehicle

Arachide oil

Remarks – Method

No significant protocol deviations. As there were no substantial differences in toxicity between sexes in the dose-range finding study, only males were used in the main study.

Group	Number and Sex of Animals	Dose (mg/kg bw)	Sacrifice Time (hours)
I (vehicle control)	5M	0	48
II (low dose)	5M	500	48
III (mid dose)	5M	1000	48
IV (high dose)	5M	2000	48
V (positive control, CP)	5M	40	48

CP = cyclophosphamide

RESULTS

Doses Producing Toxicity

-

Genotoxic Effects

Negative

Remarks – Results

There was no statistically significant decrease in the ratio of polychromatic to normochromatic erythrocytes (PCE/NCE ratio), indicating that the test substance was not toxic to erythropoiesis. The test substance did not induce a statistically significant increase in the

frequency of micronucleated PCE over the levels observed in the vehicle control. There were no clinical signs of toxicity or evidence of bone marrow exposure to the test substance.

The animals in the groups treated with cyclophosphamide showed an expected decrease in the ratio of PCE/NCE erythrocytes, demonstrating toxic effects on erythropoiesis.

CONCLUSION

The assessed polymer was not clastogenic or aneugenic under the conditions of this *in vivo* mammalian erythrocyte micronucleus test. However, this result was not conclusive as there was no evidence of bone marrow exposure to the test substance.

TEST FACILITY

Charles River (2019b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE	Assessed polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test
Inoculum	Activated sludge
Exposure Period	28 d
Auxiliary Solvent	None
Analytical Monitoring	TOC
Remarks – Method	As per OECD test guidelines, no deviations were noted.

RESULTS

<i>Test Substance</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
14	1	14	73
28	2		

Remarks – Results

All validity criteria for the test were satisfied. Inorganic carbon in the mineral medium at the beginning of the test was < 5% of the total carbon. The CO₂ evolution in the control sample was 24 mg/L (< 40 mg/L). The percentage degradation of the reference compound, sodium acetate surpassed the threshold level of 60% within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the assessed polymer after 28 days was 4%.

CONCLUSION

The test substance is not readily biodegradable.

TEST FACILITY

Charles River (2018)

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