

File No: LTD/1998

November 2017

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME  
(NICNAS)**

**PUBLIC REPORT**

**Polymer in Dispex<sup>®</sup> Ultra PX 4575**

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	<a href="http://www.nicnas.gov.au">www.nicnas.gov.au</a>

**Director  
NICNAS**

## **TABLE OF CONTENTS**

SUMMARY .....	3
CONCLUSIONS AND REGULATORY OBLIGATIONS .....	3
ASSESSMENT DETAILS.....	5
1.    APPLICANT AND NOTIFICATION DETAILS.....	5
2.    IDENTITY OF CHEMICAL.....	5
3.    COMPOSITION .....	5
4.    PHYSICAL AND CHEMICAL PROPERTIES .....	5
5.    INTRODUCTION AND USE INFORMATION.....	6
6.    HUMAN HEALTH IMPLICATIONS .....	7
6.1.    Exposure Assessment.....	7
6.1.1.    Occupational Exposure.....	7
6.1.2.    Public Exposure.....	7
6.2.    Human Health Effects Assessment .....	8
6.3.    Human Health Risk Characterisation .....	8
6.3.1.    Occupational Health and Safety.....	8
6.3.2.    Public Health.....	8
7.    ENVIRONMENTAL IMPLICATIONS.....	9
7.1.    Environmental Exposure & Fate Assessment .....	9
7.1.1.    Environmental Exposure.....	9
7.1.2.    Environmental Fate .....	9
7.1.3.    Predicted Environmental Concentration (PEC).....	9
7.2.    Environmental Effects Assessment.....	10
7.2.1.    Predicted No-Effect Concentration.....	10
7.3.    Environmental Risk Assessment.....	10
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES .....</u>	<u>11</u>
<u>APPENDIX B: TOXICOLOGICAL INVESTIGATIONS.....</u>	<u>12</u>
B.1.    Acute toxicity – oral.....	12
B.2.    Genotoxicity – bacteria .....	12
BIBLIOGRAPHY.....	14

## 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/1998	BASF Australia Ltd	Polymer in Dispex® Ultra PX 4575	ND*	≤ 15 tonnes per annum	Additive in industrial and automotive paints

\*ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Hazard classification**

Based on the limited available information, 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.

### **Human health risk assessment**

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

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

### **Environmental risk assessment**

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

### **Recommendations**

#### **CONTROL MEASURES**

##### **Occupational Health and Safety**

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation:
  - Good general ventilation
  - Enclosed, automated systems where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation:
  - Avoid skin and eye contact
- 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 during reformulation:
  - Impervious gloves
  - Coveralls
  - Eye 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 notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

#### Disposal

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

#### Emergency procedures

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

### Regulatory Obligations

#### *Secondary Notification*

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1,000 g/mol;

or

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

BASF Australia Ltd (ABN: 62 008 437 867)  
Level 12, 28 Freshwater Place  
SOUTHBANK VIC 3006

#### NOTIFICATION CATEGORY

Limited (Reduced fee notification): Synthetic polymer with  $M_n \geq 1,000$  g/mol – Similar to a chemical that has been previously assessed by NICNAS.

#### 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, import volume and site of manufacture/reformulation.

#### VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints except melting point, vapour pressure, water solubility and partition coefficient.

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

#### NOTIFICATION IN OTHER COUNTRIES

Canada, China, Japan, New Zealand, USA

### 2. IDENTITY OF CHEMICAL

#### MARKETING NAME(S)

Dispex® Ultra PX 4575 (product containing the notified polymer at < 20% concentration)

#### MOLECULAR WEIGHT

Number Average Molecular Weight ( $M_n$ ) is > 1,000 g/mol.

#### ANALYTICAL DATA

Reference IR and GPC spectra were provided.

### 3. COMPOSITION

#### DEGREE OF PURITY

> 95%

### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow liquid with product specific odour\*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-10–15 °C with peak maximum of $8.4 \pm 0.2$ °C	Measured <sup>†</sup>
Boiling Point	> 100 °C at 101.3 kPa	SDS*
Density	1070 kg/m <sup>3</sup> at 20 °C	SDS*
Vapour Pressure	could not be determined	Measured <sup>†</sup> . Based on the high molecular weight of the notified polymer, the vapour pressure is expected to be low.
Water Solubility	Miscible	Measured <sup>†</sup>

Property	Value	Data Source/Justification
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functional groups. However, significant hydrolysis is not expected in the environmental pH range of 4–9.
Partition Coefficient (n-octanol/water)	Could not be determined	Measured <sup>†</sup> . The notified polymer has a structure characteristic of a surfactant. Therefore, it may partition to the n-octanol/water phase boundary.
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to soil and sediment through hydrophobic and ion exchange mechanisms.
Dissociation Constant	Not determined	The notified polymer contains anionic functionalities with a typical pKa ~ 4. It is expected to be ionised in the environmental pH range (4–9).
Flash Point	> 100 °C	SDS*
Flammability	Not determined	-
Autoignition Temperature	Not determined	The polymer is expected to decompose prior to ignition
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

\* SDS of product containing the notified polymer

<sup>†</sup> Mixture containing 50% of the notified polymer

#### 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. It will be imported as a component of paint formulation Dispex<sup>®</sup> Ultra PX 4575 at ≤ 20% concentration and in end-use industrial and automotive paints at ≤ 2% concentration.

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

Year	1	2	3	4	5
Tonnes	5–15	5–15	5–15	5–15	5–15

#### PORT OF ENTRY

Throughout Australia

#### TRANSPORTATION AND PACKAGING

The notified polymer will be imported in containers of various sizes including 20 L open head steel pails, 190 kg open head steel drums and 1,000 L intermediate bulk containers. The packages will be transported by road from the port of entry to the storage site and/or industrial customers.

**USE**

The formulation containing the notified polymer will be used as an additive in water based industrial and automotive paints. The notified polymer functions as a pigment dispersant.

**OPERATION DESCRIPTION**

The notified polymer will be imported in formulations and end-use paints. The formulations will be used to formulate paints at the notifier's industrial customers. At the paint formulation facility, the formulation containing the notified polymer will be transferred to an explosion proof mixing container using gravity or low pressure pump transfer method and mixed with other ingredients. Samples will be collected at various stages for quality control. The finished paints will be transferred to containers by gravity feed or low pressure pumps and stored or distributed to end-users. After the process, the mixing equipment will be cleaned with water and the water reused for paint manufacture or disposed of in accordance with environment regulations. The process will be carried out in a well ventilated area.

The paints will be applied by spray (about half of applications), roller and brush. The paints will be primarily used by professionals in automotive repair shops, industrial and protective paint application facilities in purpose built spray facilities, and in coating large fibreglass mouldings such as boats and pools.

**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>
Transport and storage	1	4
Warehouse	1	4
Process operator	2.5	40
Quality control	0.5	40
Packaging	2	40
End use	1	60

**EXPOSURE DETAILS***Transport and storage*

Transport and storage workers are unlikely to be exposed to the notified polymer except in the unlikely event of an accident. The workers may experience dermal and accidental ocular exposure during clean-up of spills and leaks.

*Reformulation*

Reformulation, maintenance and quality control workers may experience dermal and accidental ocular exposure during the addition of the formulation containing the notified polymer ( $\leq 20\%$  concentration) to the blending equipment, sample collection for quality testing and cleaning and maintenance of the blending equipment. The blending process is expected to be automated and carried out in an enclosed system with good ventilation, therefore, no inhalation exposure is expected. Packaging workers may experience dermal and accidental ocular exposure during transfer of end-use paint to small packages containing up to 2% of the notified polymer. According to the notifier, standard operating procedures will be followed and appropriate personal protective equipment (PPE) will be used to reduce exposure.

*End-use*

Professional painters may experience dermal and ocular exposure to the notified polymer at up to 2% concentration during application of paint. The paints will be applied by spray, brush or roller. For spray applications, the process is expected to be performed in spray booths with exhaust ventilation. According to the notifier, PPE such as coveralls, impervious gloves, boots and air fed respirators will be used to reduce exposure during spray paint application.

**6.1.2. Public Exposure**

Paints containing the notified polymer (at  $< 2\%$  concentration) are predominantly intended for industrial use and significant do-it-yourself (DIY) use is not expected ( $< 1\%$  of the market). Paint use is expected to be on a less

frequent basis than for professional users, although PPE may not be worn. The paints are expected to be applied using brush and rollers. Dermal and accidental ocular exposure to the notified polymer may occur during application of paints. Once the paint has dried, the notified polymer will be bound within the polymer matrix and will not be available for exposure.

## 6.2. Human Health Effects Assessment

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

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic

### *Toxicokinetics, metabolism and distribution*

No information on the toxicokinetics, metabolism and distribution was provided. Based on the molecular weight of the notified polymer ( $M_n > 1,000$  g/mol) it is not expected to cross biological membranes.

### *Acute toxicity*

A mixture containing 50% of the notified polymer was found to be of low acute toxicity when administered by the oral route.

### *Irritation and sensitisation*

No information on the irritation and sensitisation potential of the notified polymer was provided. The notified polymer contains a functional group which is a structural alert for irritation and sensitisation. However, the potential for causing these effects may be limited by the high molecular weight of the notified polymer.

### *Repeated dose toxicity*

No information on the repeated dose toxicity potential of the notified polymer was provided.

### *Mutagenicity/Genotoxicity*

A mixture containing 50% of the notified polymer was not mutagenic when tested in a bacterial reverse mutation test.

### **Health hazard classification**

Based on the limited available information, 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

The notified polymer contains functional group with structural alerts for irritation and sensitisation. These effects may be limited due to the high molecular weight of the notified polymer. However, the potential for these effects cannot be ruled out.

### 6.3.1. Occupational Health and Safety

Workers involved in reformulation of the notified polymer into paints may experience dermal and accidental ocular exposure at up to 20% concentration. The reformulation process will be carried out in a closed system with explosion proof blenders and most of it will be automated with very little human intervention which will limit exposure. In addition the workers are expected to wear PPE such as coveralls, impervious gloves and eye protection to further reduce exposure.

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

The public may experience dermal and accidental ocular exposure to paint products containing the notified polymer at < 2% concentration. Inhalation exposure is not expected due to the method of application which would not result in formation of aerosols. The public may also come into contact with the coatings containing the notified polymer; however, in such cases the notified polymer will be bound within the polymer matrix and will not be available for exposure.



Given the low end use concentration and high molecular weight, the potential risk of irritation and sensitisation effects is expected to be low. Therefore, 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 either in end-use paints, or in formulations for reformulation into the end-use paints. The reformulation process will involve transferring the formulations containing the notified polymer to an explosion proof mixing container using gravity or low pressure pumps, where it will be blended with other ingredients. The finished paints will then be filled into end-use containers. Liquid waste from cleaning of the reformulation equipment will either be reused or disposed of through an approved waste management facility. Release of the notified polymer to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. Empty import containers containing the notified polymer will either be recycled or disposed of through an approved waste management facility.

##### **RELEASE OF CHEMICAL FROM USE**

The finished paints containing the notified polymer will be used primarily by professionals in automotive repair shops, industrial and protective paint application facilities, with a small fraction being used by Do It Yourself (DIY) users. During use, the paints will be applied primarily by spray and also by brush and roller. The main release of the notified polymer is likely from overspray during use. The overspray is expected to be collected using standard engineering controls such as spray booths before disposal to landfill. The solvent waste from cleaning of the application equipment is expected to be collected by a licensed waste contractor, and be disposed of in accordance with local government regulations. During use, the notified polymer may also be released to the environment as accidental spills. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

##### **RELEASE OF CHEMICAL FROM DISPOSAL**

Most of the notified polymer is expected to share the fate of the substrate to which it has been applied, to be either disposed of to landfill or recycled for metal reclamation. Residual notified polymer in empty end-use containers is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty containers.

As the worst case scenario, it is assumed that up to 5% of the paints containing the notified polymer used by DIY users may be incorrectly disposed of to sewers, drains, or ground from waste and washing of application equipment.

#### **7.1.2. Environmental Fate**

No environmental fate data were submitted. As a result of its use pattern, most of the notified polymer is expected to share the fate of the substrate to which it has been applied, to be either recycled for metal reclamation or disposed of to landfill. During metal reclamation, 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. A small proportion of the paints used by DIY users may be incorrectly disposed of to sewers, and is expected to be moderately removed through adsorption to sludge at sewage treatment plants (Boethling and Nabholz, 1997). Sludge containing the notified polymer will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil or sludge through hydrophobic and ion exchange mechanisms and is not expected to be mobile in the environment. The notified polymer is not expected to bioaccumulate given its high molecular weight. In landfill, soil, sludge and water, the notified polymer is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon and nitrogen.

#### **7.1.3. Predicted Environmental Concentration (PEC)**

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the reported use in paints for professional and DIY-users, a conservative release of 5% of the annual import

volume to sewers on a nationwide basis over 365 days per year is used for the notified polymer. It is also assumed under the worst-case scenario that there is no removal of the notified polymer during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	15,000	kg/year
Proportion expected to be released to sewer	5	%
Annual quantity of chemical released to sewer	750	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2	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:	0.42	µg/L
PEC - Ocean:	0.04	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m<sup>2</sup>/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m<sup>3</sup>). Using these assumptions, irrigation with a concentration of 0.42 µg/L may potentially result in a soil concentration of approximately 2.8 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 14 µg/kg and 28 µg/kg, respectively.

## 7.2. Environmental Effects Assessment

No ecotoxicological data for the notified polymer were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they can be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone (Boethling and Nabholz, 1997). However, this does not apply to the notified polymer and it is not considered to be an over-chelation hazard to algae.

### 7.2.1. Predicted No-Effect Concentration

The most toxic anionic polymers to algae known, have EC50 values of > 1 mg/L (Boethling and Nabholz, 1997). As this is likely to be the most sensitive species an assessment factor of 100 is used to estimate the Predicted No-Effect Concentration (PNEC). Therefore the estimated PNEC is likely to be > 10 µg/L.

## 7.3. Environmental Risk Assessment

The PEC from the maximum annual importation volume, and the assessed use pattern as a pigment dispersant in automotive and industrial paints is well below the estimated PNEC. Therefore, 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** -10–15 °C with peak maximum of  $8.4 \pm 0.2$  °C

Method OECD TG 102 Melting Point/Melting Range  
Remarks Differential scanning calorimetric method. A discrete melting point could not be determined.  
Test Facility Institut Kuhlmann GmbH (2014a)

**Vapour Pressure** Could not be determined

Method OECD TG 104 Vapour Pressure  
Remarks A discrete vapour pressure could not be determined because of the complex mixture of the test substance.  
Test Facility Institut Kuhlmann GmbH (2014b)

**Water Solubility** Miscible at 20 °C

Method OECD TG 105 Water Solubility  
Remarks Flask Method  
Test Facility Institut Kuhlmann GmbH (2014c)

**Partition Coefficient (n-octanol/water)** Could not be determined

Method OECD TG 107/117 Partition Coefficient (n-octanol/water).  
Remarks HPLC Method. The test substance was miscible in all ratios in 1-octanol and water; thus the partition coefficient could not be determined.  
Test Facility Institut Kuhlmann GmbH (2014d)

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

### B.1. Acute toxicity – oral

TEST SUBSTANCE	Mixture containing 50 % notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/Wistar/Crl:WI (Han) SPF
Vehicle	Deionized water
Remarks - Method	No significant deviations from the OECD test guideline. 2 groups of female rats consisting of 3 rats each were tested. The test substance contained 50% of the notified polymer and thus was administered at a dose of 4,000 mg/kg bw to get an actual dose of 2,000 mg/kg bw for the notified polymer.

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw*</i>	<i>Mortality</i>
1	3 F	4,000	0/3
2	3 F	4,000	0/3

\* the test substance administered contained 50% of notified polymer

LD50 > 2,000 mg/kg bw

Signs of Toxicity No clinical signs were observed in group 1 rats. Impaired general state and piloerection was observed in all rats from 2 h until 5 h from test group 2 and cowering position was noted in two test animals.

Effects in Organs None reported

Remarks - Results All the test animals survived the study period of 14 days. The body weight gains were within the normal range throughout the study period.

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

TEST FACILITY Bioassay (2015)

### B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Mixture containing 50 % notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test
Species/Strain	Plate incorporation procedure and Pre incubation procedure <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33–10,000 µg/plate b) Without metabolic activation: 33–10,000 µg/plate
Vehicle	Water
Remarks - Method	No significant deviations from the OECD test guideline. No preliminary test was conducted to assess cytotoxicity. The maximum test substance concentration was increased to 10,000 µg/plate to account for the dilution.

#### RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>		
	<i>Cytotoxicity</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>			
Test 1	> 10,000	> 10,000	Negative
Test 2	> 10,000	> 10,000	Negative
<i>Present</i>			
Test 1	> 10,000	> 10,000	Negative
Test 2	> 10,000	> 10,000	Negative

Remarks - Results	<p>A weak bacteriotoxic effect was observed occasionally in the plate incorporation assay from about 1,000 µg/plate onward. No bacteriotoxicity was observed.</p> <p>The positive controls produced satisfactory responses, thus confirming the activity of S9 mix and the sensitivity of the bacterial strains.</p>
CONCLUSION	<p>The notified polymer was not mutagenic to bacteria under the conditions of the test.</p>
TEST FACILITY	<p>BASF (2015)</p>

## **BIBLIOGRAPHY**

- BASF (2015) [Notified polymer] Salmonella typhimurium / Escherichia coli Reverse Mutation Assay (Study No. 40M0235/15M050, July, 2015). Ludwigshafen, Germany, BASF SE (Unpublished report submitted by the notifier)
- Bioassay (2015) [notified polymer] Acute Oral Toxicity Study in Rats (Study No. 15-BF-OT057, July, 2015). Heidelberg, Germany, Bioassay Labor für biologische Analytik GmbH (Unpublished report submitted by the notifier)
- Boethling, RS & Nabholz VJ (1997) Chapter 10 Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.
- Institut Kuhlmann GmbH (2014a) [Notified polymer] Determination of the Melting Point (Study No. 3673/14-a, September, 2014). Ludwigshafen, Germany, Institut Kuhlmann GmbH (Unpublished report submitted by the notifier)
- Institut Kuhlmann GmbH (2014b) [Notified polymer] Determination of the Vapour Pressure (Study No. 3673/14-b, September, 2014). Ludwigshafen, Germany, Institut Kuhlmann GmbH (Unpublished report submitted by the notifier)
- Institut Kuhlmann GmbH (2014c) [Notified polymer] Determination of the Solubility in Water (Study No. 3673/14-d, September, 2014). Ludwigshafen, Germany, Institut Kuhlmann GmbH (Unpublished report submitted by the notifier)
- Institut Kuhlmann GmbH (2014d) [Notified polymer] Determination of the  $\log P_{ow}$  (Study No. 3673/14-c, September, 2014). Ludwigshafen, Germany, Institut Kuhlmann GmbH (Unpublished report submitted by the notifier)
- 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>.