File No: LTD/2054

December 2018

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

## **PUBLIC REPORT**

## Polymer in EFKA® PX 4780

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: www.nicnas.gov.au

**Director NICNAS** 

## TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	
1. APPLICANT AND NOTIFICATION DETAILS	5
2. IDENTITY OF CHEMICAL	5
3. COMPOSITION	
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	7
6.3. Human Health Risk Characterisation	8
6.3.1. Occupational Health and Safety	8
6.3.2. Public Health	8
7. ENVIRONMENTAL IMPLICATIONS	8
7.1. Environmental Exposure & Fate Assessment	8
7.1.1. Environmental Exposure	8
7.1.2. Environmental Fate	
7.1.3. Predicted Environmental Concentration (PEC)	9
7.2. Environmental Effects Assessment	9
7.2.1. Predicted No-Effect Concentration (PNEC)	9
7.3. Environmental Risk Assessment	9
APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES	10
BIBLIOGRAPHY	11

#### **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/2054	BASF Australia Ltd	Polymer in EFKA® PX 4780	No	< 60 tonnes per annum	Component of industrial and automotive coatings

#### CONCLUSIONS AND REGULATORY OBLIGATIONS

#### **Hazard classification**

Based on the available information, the notified polymer is not recommended for classification according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), as adopted for industrial chemicals in Australia.

#### Human health risk assessment

Based on the assumed low hazard and 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

CONTROL MEASURES

Occupational Health and Safety

• No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

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

- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

#### Disposal

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

#### Emergency procedures

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

#### **Regulatory Obligations**

#### Secondary Notification

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

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

- (1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000 g/mol;

or

- (2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of industrial and automotive 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 products containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

## **ASSESSMENT DETAILS**

#### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

BASF Australia Pty Ltd (ABN: 62 008 437 867)

Level 12

28 Freshwater Place SOUTHBANK VIC 3006

NOTIFICATION CATEGORY

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

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, spectral data, degree of purity, polymer constituents, residual monomers, impurities, import volume, and site of reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Schedule data requirements are varied for all physico-chemical endpoints except water solubility.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES China (2017)

#### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

EFKA® PX 4780 (product containing the notified polymer at > 95% concentration)

OTHER NAME(S)

Polymer based on polyethyleneimine-polyester-fatty acid

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn) is > 10,000 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-brown liquid

Property	Value	Data Source/Justification
Freezing Point*	Not determined	SDS
Boiling Point*	> 100 °C at 101.3 kPa	SDS
Density*	$1,097.1 \text{ kg/m}^3 \text{ at } 20 ^{\circ}\text{C}$	SDS
Vapour Pressure*	< 20 mbar at 20 °C	SDS
Water Solubility	$9.49 \times 10^{-3}$ g/L at 20 °C for test with 0.5 g/L	Measured
	$55.1 \times 10^{-3}$ g/L at 20 °C for test with 5 g/L	
Hydrolysis as a	Not determined	Contains hydrolysable functionalities
Function of pH		but significant hydrolysis is not
		expected in the environmental pH

		range of 4-9
Partition Coefficient	Not determined	Contains both hydrophobic and
(n-octanol/water)		hydrophilic functionalities and may
		partition to n-octanol/water interface.
Adsorption/Desorption	Not determined	Expected to adsorb to soil and
		sediment through hydrophobic and
		ion exchange mechanisms
Dissociation Constant	Not determined	Contains potential cationic
		functionalities which are likely to be
		ionised in the environmental pH
		range of 4-9
Flash Point*	201.5 °C	SDS
Autoignition	422 °C	SDS
Temperature*		
Explosive Properties	Not determined	Contains no functional groups that
		imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that
		imply oxidative properties

<sup>\*</sup> Properties of the product EFKA® PX 4780 that contains the notified polymer (at > 95% concentration) in solvent.

#### 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 into Australia in the product EFKA® PX 4780 at > 95% concentration, and reformulated into industrial and automotive coatings (containing the notified polymer at  $\le 5\%$  concentration).

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

Year	1	2	3	4	5
Tonnes	< 60	< 60	< 60	< 60	< 60

## PORT OF ENTRY

Melbourne

#### TRANSPORTATION AND PACKAGING

The product EFKA® PX 4780 (containing the notified polymer at > 95% concentration) will be imported by sea in 20 kg or 200 kg steel drums. These containers will be transported by road to warehouses for storage, and then delivered to the reformulation sites.

#### Use

The notified polymer will be used as a component of industrial and automotive coatings at < 5% concentration.

#### **OPERATION DESCRIPTION**

#### Reformulation

At the reformulation site, EFKA PX® 4780 (containing the notified polymer at > 95% concentration) will typically be pumped (using a mix of manual and closed, automated processes) into paint mixers, to which other

ingredients (such as pigments) will be added. The coating mixture will be mixed at high speed under exhaust ventilation. The reformulated product (containing the notified polymer at < 5% concentration) will then be pumped into steel containers using closed and automated processes. Quality control (QC) workers will sample the final reformulated product containing the notified polymer.

#### End Use

The notified polymer is a component of industrial and automotive coating products (containing the notified polymer at < 5% concentration) and will be used in industrial settings. The coating products will be predominantly applied by spray, but brushes and rollers may also be used.

#### 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	5 – 10
Warehouse	1	5 - 10
Process operator	2-3	30 - 50
Packaging	2	30 - 50
End use	1 - 2	30 - 50

#### EXPOSURE DETAILS

#### Transport and Storage

Transport and storage workers may come into contact with the notified polymer at > 95% concentration (as imported) or < 5% concentration (in end-use products) only in the unlikely event of accidental breaching of containers.

#### Reformulation

At reformulation sites, dermal and ocular exposure to the notified polymer at up to > 95% concentration may occur when weighing and transferring the notified polymer to the mixing tank or during equipment cleaning and maintenance. Given the low vapour pressure of the notified polymer, inhalation exposure is not expected unless aerosols are formed during the mixing process. Exposure to the notified polymer during reformulation is expected to be minimised through the use of enclosed and automated systems, local exhaust ventilation and personal protective equipment (PPE), including gloves, safety goggles, coveralls and respiratory protection (if aerosols are expected).

#### End use

At end use sites, dermal, ocular and inhalation exposure to coatings containing the notified polymer at < 5% concentration may occur during transfer, application and cleaning processes. The potential for exposure should be minimised through the use of engineering controls such as spray booths and PPE, including coveralls, gloves and goggles, as well as appropriate respiratory protection where ventilation is inadequate. Once dried and cured, the notified polymer will be bound within a polymer matrix and is not expected to be available for exposure.

## **6.1.2.** Public Exposure

Products containing the notified polymer are for industrial use only and will not be available to the general public. The public may come into contact with coated articles containing the notified polymer. However, once the notified polymer is dried and cured, it will be bound within the polymer matrix and will not be available for exposure.

#### **6.2.** Human Health Effects Assessment

No toxicological data were submitted. The notified polymer meets the polymer of low concern (PLC) criteria for human health and can therefore be considered to be of low hazard.

#### Health hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), as adopted for industrial chemicals in Australia.

#### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety

The notified polymer meets the PLC criteria for human health and is therefore considered to be of low hazard.

#### Reformulation

During reformulation workers may come into contact with the notified polymer at > 95% concentration during transfer, maintenance, and cleaning operations. Control measures including the use of engineering controls (enclosed/automated processes and local exhaust ventilation) and suitable PPE (impervious gloves, goggles, coveralls and respiratory protection (if aerosols are expected)) is expected to minimise worker exposure.

#### End-use

During end-use, professional workers may come into contact with the notified polymer at  $\leq 5\%$  concentration during transfer, application and cleaning processes. The use of control measures including engineering controls (such as spray booths) and PPE (impervious gloves, goggles, coveralls and respirators where ventilation is inadequate) is expected to minimise exposure to the notified polymer.

Overall, based on the assumed low hazard and 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 not be available to the public. Members of the public may come into contact with articles coated with finished coating products containing the notified polymer at  $\leq 5\%$  concentration. However, the notified polymer in cured coatings is expected to be bound with the inert matrix and will not be available for 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 imported products containing the notified polymer will be reformulated into industrial and automotive coatings. The reformulation processes involve blending operations in an enclosed environment, followed by filling of the finished products into end-use containers. Solvent waste from reformulation equipment cleaning is expected to be disposed of by approved waste management facilities. In the event of accidental spills or leaks during reformulation, storage and transport, products containing the notified polymer are expected to be absorbed on suitable materials before disposal, in accordance with local government regulations. Empty import containers containing residual notified polymer are expected to be disposed of by approved waste management facilities.

#### RELEASE OF CHEMICAL FROM USE

The coatings containing the notified polymer will be applied in industrial settings mainly by spray, but brushes and rollers may also be used. The main release of the notified polymer is likely to be from overspray during use, estimated by the notifier to account for up to 30% of the total annual import volume. The overspray will be trapped onto spray booth filters before disposal to landfill in accordance with local government regulations. As estimated by the notifier, the liquid waste from cleaning of application equipment contains up to 5% of import volume of the notified polymer, which will be collected for disposal, in accordance with local government regulations. During use, the notified polymer may also be released as accidental spills. These releases are also expected to be collected 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 articles to which it has been applied, to either enter metal recycling or be disposed of to landfill at the end of their useful lives. Used plastic material containing the notified polymer may enter recycling streams, but they will ultimately end up in landfill. Residual notified polymer in empty end-use containers, estimated by the notifier to account for up to 2.5% 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

As a result of its use pattern, most of the notified polymer is expected to share the fate of the articles to which it has been applied, either subjected to metal reclamation or being disposed of to landfill at the end of their useful lives. 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. The notified polymer is not expected to be bioaccumulative due to 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

No ecotoxicological data were submitted for the notified polymer. The notified polymer contains potentially cationic functionalities with Functional Group Equivalent Weight (FGEW) < 5,000 and therefore is potentially harmful to aquatic organisms in environmental waters.

#### 7.2.1. Predicted No-Effect Concentration (PNEC)

The Predicted No-Effect Concentration (PNEC) has not been calculated since no ecotoxicological data are available.

### 7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) for the aquatic compartment has not been calculated as no ecotoxicological data are available and release of the notified polymer to the aquatic environment will be limited based on its reported use pattern. On the basis of the reported use pattern as a component of industrial and automotive coatings, the notified polymer is not considered to pose an unreasonable risk to the environment.

## **APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**

Water Solubility 9.49  $\times$  10<sup>-3</sup> g/L at 20 °C for test with 0.5 g/L 55.1  $\times$  10<sup>-3</sup> g/L at 20 °C for test with 5 g/L

Method OECD TG 105 Water Solubility

Remarks Flask Method; the solubility in water increases with the mass of test item applied in the

experiment.

Test Facility BASF (2018)

## **BIBLIOGRAPHY**

BASF (2018) Water Solubility of [Notified Polymer] (Study no. 17Y44787, January, 2018). Ludwigshafen, Germany, BASF Competence Center Analytics.

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 .