File No: LTD/2009

January 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in EFKA® PX4300

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/2009	BASF Australia Ltd	Polymer in EFKA® PX 4300	ND*	≤ 10 tonnes per annum	Component of industrial coatings

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

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 limited aquatic exposure and assessed use pattern, the notified polymer is not expected 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 spray painting:
  - Spray booths

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of products containing the notified polymer:
  - 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:
  - Gloves, goggles, protective clothing
  - Respiratory equipment if inhalation exposure may occur.

  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 1000 g/mol;

or

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia 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, degree of purity, polymer constituents, residual monomers, impurities, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: boiling point, specific gravity/density, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, particle size, flash point, autoignition temperature, explosive properties and oxidising properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2012), Korea (2013), New Zealand (2012), USA (2012)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
EFKA® PX 4300 (containing < 70% notified polymer)

OTHER NAME(S)
Modified polyacrylate (generic name)

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

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No losses by volatilisation, exudation or leaching are expected from the polymer.

DEGRADATION PRODUCTS
No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use. Thermal decomposition may release toxic fumes containing products of combustion such as oxides of carbon and nitrogen.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: reported to be a viscous liquid at room temperature

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Measured	No melting temperature was found between -100 °C and 100 °C. A broad glass transition was found between about -80 °C and -40 °C.
Boiling Point	Not determined	Decomposed without boiling at approximately 300 °C
Density	1,005 kg/m^3 at 20 °C*	SDS
Vapour Pressure	< 1 × 10^{-7} kPa (at 20 °C, 25 °C and 50 °C)	Measured
Water Solubility	0.026 – 0.146 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains functionality that is expected to hydrolyse slowly under environmental conditions (pH 4-9, 25 °C)
Partition Coefficient	log Pow ≥ 4 at 20 °C	The notified chemical is surface active. The partition coefficient was estimated from the single solubilities in n-octanol and in water.
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined	The notified polymer is expected to ionise in the environmental pH (4-9).
Particle Size	Not determined	The notified polymer will be imported in solution.
Flash Point	Not determined	The notified polymer will be imported in a flammable solvent solution.
Autoignition Temperature	Not determined	The notified polymer will be imported in a flammable solvent solution.
Explosive Properties	Not determined	The structure does not indicate explosive properties.
Oxidising Properties	Not determined	The structure does not indicate oxidising properties.

* Value for the imported product that contains < 70% 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. Incompatible substances are likely to be strong oxidising agents, strong acids and strong bases. The decomposition products are not known but are likely to be oxides of carbon and some oxides of nitrogen.

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 be imported in Australia by sea as a component of Efka® PX 4300 at a concentration of < 70%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-10	1-10	1-10	1-10	1-10

PORT OF ENTRY
Melbourne

IDENTITY OF RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported by sea as a component (< 70%) of Efka® PX 4300 in 20 kg and 200 kg UN approved steel drums. These steel drums will be packed on wooden pallets and bound with a plastic shrink wrap. The plastic shrink wrapped pallets holding the containers of the imported product will be transported by road to the third party warehouse for storage and to reformulation sites.

The finished paints containing the notified polymer will be stored and transported in 1 L, 4 L and 10 L steel paint cans and 210 kg steel drums.

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

OPERATION DESCRIPTION
At the reformulation site, Efka® PX 4300, which contains the notified polymer at a concentration of < 70%, will be mixed with a range of inorganic and organic pigments as a dispersant. Efka® PX 4300 will be added to other components in a mill using a gravity or low pressure pump transfer. Once incorporated, the mixture will pass through a bead mill. Reformulation processes to produce either a pigment slurry or finished paint will occur under exhaust ventilation. The formulation of the final paint product, which contains the notified polymer at < 5%, may take up to 24 hours. The paint or pigment slurry will be sold and distributed, after QC testing, in steel containers.

The end-use paint products containing the notified polymer at < 5% will be used in facilities for applying protective and industrial coatings, predominantly by spray painting. Application will be conducted under ventilation in engineered facilities. The painting may also be conducted by roller or brush.

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	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
It is anticipated that transport and warehouse/store personnel would only be exposed to the notified polymer in the event of an accident.

Reformulation
During reformulation, dermal and ocular exposure of workers to the product containing the notified polymer (at < 70%) may occur during connection of pipes for transfer of the imported product to the mixing tank. It is expected that there will be a low potential for exposure during the automated and closed blending process. Workers involved in the reformulation process are expected to wear impermeable gloves, eye protection and protective clothing to further minimise exposure. Exposure to the notified polymer at concentrations < 5% during transfer of the formulated product to steel containers is expected to be low due to the largely automated processes and the personal protective equipment (PPE) used.

Inhalation exposure during reformulation is expected to be negligible given the very low estimated vapour pressure of the notified polymer and the expected use of local exhaust ventilation that would reduce exposure to any aerosols formed.

End-use
Dermal and ocular exposure to the notified polymer (< 5%) may occur during transfer of the paint to spray equipment and during spray application of the paint. Inhalation exposure may also occur during spray application although exposure is expected to be reduced through the use of dedicated spray booths with downdraft ventilation and the use of PPE such as full protective clothing and an air-fed respirator.

After the paint has dried the notified polymer (< 5%) will be bound within the paint matrix and is not expected to be available for exposure.

6.1.2. Public Exposure
The notified polymer is intended for industrial use only. Therefore the public may be exposed to the imported product (< 70% notified polymer) only in the event of an accident during transportation. The public may come into contact with articles/structures to which paint containing the notified polymer has been applied. However, exposure is not expected as the notified polymer will be bound within the paint matrix and not expected to be available for exposure.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution
The notified polymer is not expected to be dermally absorbed, based on the high molecular weight (Mn > 1,000 g/mol), however it contains a small proportion of low molecular weight species (< 1000 g/mol) that may be absorbed.

Irritation
The notified polymer contains a functional group which is a structural alert for irritation.

Mutagenicity/Genotoxicity
The notified polymer was not mutagenic in a bacterial reverse mutation assay.

Health hazard classification
As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer has the potential to be an irritant. The risk of irritation effects from exposure to the notified polymer may be reduced by the high molecular weight (> 1,000 g/mol), however the polymer contains some low molecular weight species < 1000 g/mol.

During reformulation workers will handle the notified polymer at concentrations of < 70%; however exposure is expected to be low given the proposed use of PPE and largely enclosed, automated processes. During end use workers will be exposed to industrial paints containing the notified polymer at concentrations < 5%, including through spray application. However exposure to the notified polymer during end use is also expected to be low due to the use of engineering controls and appropriate PPE.

Given the expected use of engineering controls and PPE to reduce exposure during reformulation and end-use, the risk to workers of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Paint products containing the notified polymer will not be sold to the public. The public may experience dermal exposure to articles/structures to which paint containing the notified polymer has been applied. However, exposure is not expected as the notified polymer (< 5%) will be bound within the paint matrix. Therefore the risk to the public from the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia; therefore, there will be no release from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified polymer is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

Reformulation of the notified polymer occurs in a closed system and release to atmosphere is expected to be negligible. Solvent used for equipment washing containing residues of the notified polymer is expected to be disposed of via accredited waste disposal contractors. Wastes and spills (1% of annual import volume) during reformulation activities will be contained on-site and disposed of in accordance with local regulations. Residues in import containers will be disposed of via the trade waste stream of the formulator in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

Paint products containing the notified polymer are only available to industrial users including industrial and protective paint facilities. Any losses from overspray (estimated at 30% of annual import volume) during industrial use are expected to be collected using standard engineering controls such as spray booths. These losses, together with other wastes generated during use, including residues in application equipment washings and empty paint containers (estimated at up to 5% and 2.5%, respectively, of the annual import volume), are expected to be disposed of in accordance with local regulations, namely to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in paints is expected to share the fate of metal substrates to which it has been applied. The notified polymer is likely to be either thermally decomposed during metal reclamation processes or disposed of to landfill at the end of the useful life of the article to which is has been applied.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be bound within an inert matrix as part of its normal use pattern as a component in industrial paints. The notified polymer bound within the paint matrix is not expected to be bioavailable or biodegradable. The majority of notified polymer in wastes disposed of to landfill is expected to be in solid cured paint and it is not expected to be water dispersible or mobile in this form. Based on the expected surface activity of the notified polymer, it is not likely to cross biological membranes, hence bioaccumulation is not expected. Furthermore, bioaccumulation of the notified polymer is unlikely due to limited bioavailability in its solid form in landfill and its limited release to surface waters. The notified polymer will eventually degrade in landfill, or by thermal decomposition during metal reclamation 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 for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The potentially cationic component of the notified polymer has a cationic charge density of < 5,000 g/mol and thus has the potential to be toxic to aquatic life. In addition, another functional group in the polymer may have chronic ecotoxicity.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a component in industrial paints for use on metal substrates. The majority of the environmental release of the notified polymer will be disposal of the cured paints to landfill and by thermal decomposition during metal reclamation processes. In cured paints the notified polymer is bound within the inert paint matrix and is unlikely to leach or be bioavailable. Thermal decomposition of the notified polymer will produce water and oxides of carbon and nitrogen. On the basis of the limited aquatic exposure and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Boilinging Point No melting temperature was found between -100 and 100 °C
A broad glass transition was found between about -80 and -40 ºC with a half-step temperature of -56 ºC in the first heating

Method OECD TG 102 Melting Point/Melting Range
Remarks Differential scanning calorimetry (DSC) method was used. DSC-diagram about -110 ºC to 50 ºC and TG/DTA (thermogravimetry/differential thermal analysis) diagram 20 ºC to 700 ºC were presented. A broad endothermic area starting at about 300 ºC with the weight loss up to 100% shows the vapourisation/decomposition of the test substance. No other thermic processes were observed.
Test Facility BASF (2012)

Vapour Pressure $< 1 \times 10^{-7}$ kPa at 20 °C
$< 1 \times 10^{-7}$ kPa at 25 °C
$< 1 \times 10^{-7}$ kPa at 50 °C

Method OECD TG 104 Vapour Pressure
Remarks The effusion method was used.
Test Facility BASF (2012)

Water Solubility 0.026 – 0.146 g/L at 20 °C

Method OECD TG 105 Water Solubility
Remarks Flask Method
Test Facility BASF (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Plate incorporation procedure (test 1)/Pre incubation procedure (test 2)
Species/Strain	*Salmonella. typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia. coli*: WP2uvrA
Metabolic Activation System	Liver S9 mix from induced rats
Concentration Range in Main Test	a) With metabolic activation: 0, 33,100, 333, 1,000, 2,800 and 5,600 µg/plate b) Without metabolic activation: 0, 33,100, 333, 1,000, 2,800 and 5,600 µg/plate
Vehicle	Acetone
Remarks - Method	GLP Certificate. No protocol deviations. There was no preliminary test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 2,800	≥ 2,800	negative
Test 2	≥ 2,800	≥ 2,800	negative
Present			
Test 1	≥ 5,600	≥ 2,800	negative
Test 2	≥ 5,600	≥ 2,800	negative

Remarks - Results	An increase in mutations was not noted either in the standard plate test or in the pre incubation test in the presence or absence of metabolic activation. The positive and negative controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.
CONCLUSION	The notified polymer is not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF (2011)

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