File No: LTD/1955

September 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Efka® PU 4061

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/1955	BASF Australia Ltd	Polymer in Efka® PU 4061	ND*	≤ 30 tonnes per annum	Component of paints

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no 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 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 isolation and engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed and automated system during reformulation, where possible
  - Sufficient ventilation
  - Spray booth for spray application 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:
  - Avoid contact with skin and eyes
  - Avoid inhalation of 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 notified polymer:
  - Protective clothing
  - Impervious gloves
  - Eye protection
  - Respiratory protection during spray application

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

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

- A copy of the SDS should be easily accessible to employees.

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

Disposal

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

Emergency procedures

- Spills and/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;

or

(2) Under Section 64(2) of the Act; if
  – the function or use of the polymer has changed from a component of 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 a 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 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada, China, Europe, Korea, Japan and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Efka® PU 4061 (product contains < 40% notified polymer)

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) > 10,000 Da

ANALYTICAL DATA
Reference IR and SEC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear to cloudy, yellow liquid*

Property	Value	Data Source/Justification
Freezing Point	Not determined	Not isolated from solvents
Boiling Point*	approx. 130 °C at 101.3 kPa	SDS
Density*	950 kg/m^3 at 20 °C	SDS
Vapour Pressure*	6.7×10^{-1} kPa at 20 °C	SDS (based on volatile solvents)
Water Solubility	Not determined	Expected to be insoluble in water
Hydrolysis as a Function of pH	Not determined	Expected to hydrolyse very slowly over the environmental pH range (4–9) at ambient temperature
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition from water to n-octanol on the basis of its expected insolubility in water.
Adsorption/Desorption	Not determined	Expected to bind to soil, sludge or sediments based on its high molecular weight, expected

		insolubility in water, and the presence of potential cationic groups
Dissociation Constant	Not determined	Contains potential cationic functionalities which may ionise in the environmental pH range (4 - 9)
Flash Point*	24 °C	SDS (based on flammable solvents)
Flammability	Not determined	Not isolated from flammable solvents
Autoignition Temperature*	315 °C	SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Properties of the imported formulation containing < 40% concentration of the notified polymer in volatile and flammable solvents

DISCUSSION OF PROPERTIES
No test data on physical and chemical properties of the notified polymer were submitted. The notified polymer is not isolated from volatile and flammable solvents during manufacture.

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the limited physico-chemical data provided, the notified polymer cannot be 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 formulations (at < 40% concentration) to be reformulated into automotive and industrial paints.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-10	1-10	1-10	10-30	10-30

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
Product Efka® PU 4061 containing the notified polymer at < 40% concentration will be imported and distributed in 18 kg plastic jerricans or 190 kg steel drums. Efka® PU 4061 will be reformulated and the resulting paint products containing the notified polymer at ≤ 4% concentration will be repacked in 1-10 L steel cans or 210 kg steel drums.

These containers will be transported by road for distribution.

USE
The notified polymer will be used as a pigment dispersant in automotive and industrial paints. The finished paints will contain the notified polymer at ≤ 4% concentration.

OPERATION DESCRIPTION

Reformulation
Efka® PU 4061 containing the notified polymer at < 40% concentration will be transferred to the mixing tank by gravity feed or low pressure pumps where it will be blended with other ingredients in the expected presence of local exhaust ventilation. Following blending, the finished coatings will be filled into containers through gravity

feed or low pressure pumps. At the end of the reformulation process the equipment will be flushed with solvent for cleaning. Quality control staff may test samples of the finished products.

End-use
The finished paints containing the notified polymer may be manually decanted and then applied primarily by spray and possibly by brush and roller. The majority of the finished paints will be for industrial and commercial use with a small portion for do-it-yourself (DIY) use.

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
Reformulation	2.5	40
Quality control	0.5	40
Packaging	2	40
Professional end-use	1	60

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Reformulation processes
Dermal and ocular exposure to the notified polymer at < 40% concentration may occur when weighing or mixing ingredients, connecting or disconnecting transfer hoses, cleaning or maintaining equipment and testing for quality control. Inhalation exposure to the notified polymer may also occur if aerosols are formed. Exposure should be minimised through the use of enclosed and automated systems, local exhaust ventilation and personal protective equipment (PPE: goggles, impervious gloves, protective clothing and respirators as anticipated by the notifier).

Paint application
Dermal, ocular and inhalation exposure to the notified polymer at ≤ 4% concentration may occur during application of the finished paints by spray (primarily), brush or roller. Exposure should be minimised through the use of semi-automatic processes (applicator-operated spray guns), good general ventilation, and PPE (including goggles, impervious gloves, protective clothing and respirators as anticipated by the notifier). The paints will be used in purpose-built spray facilities in a variety of locations including vehicle repair shops and industrial amenities.

Once the paint is dried and cured, the notified polymer will be bound into an inert solid matrix and will not be available for further exposure.

6.1.2. Public Exposure
Paints containing the notified polymer at ≤ 4% concentration may be applied by DIY users using brush, roller or spray. Similar to application workers, dermal, ocular and inhalation exposure to the notified polymer at ≤ 4% concentration may occur; however it is expected to be in low frequency. It is not known whether PPE would be used by DIY users during paint applications. DIY users are expected to avoid paint splashes, and wash any spills from the skin.

Once the paint is dried and cured, the notified polymer will be bound into an inert solid matrix and will not be available for further exposure.

6.2. Human Health Effects Assessment

Based on the high molecular weight (> 10,000 Da), low water solubility (insoluble) and very low percentage of low molecular weight species, the notified polymer is expected to have limited absorption across biological membranes.

No toxicological information was submitted. The notified polymer contains N-heterocyclic functional groups which are associated with sensitisation. However given the limited potential for dermal absorption, the notified polymer is not expected to present as a skin sensitiser.

The notified polymer is a high molecular weight polymer (Mn > 10,000 Da) and is expected to be water insoluble. Inhalation of water insoluble polymers with molecular weights > 70,000 Da has been linked to irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new, accessed on 23 August 2017). While there is also a concern for water insoluble polymers with molecular weights between 10,000 and 70,000 Da, it is acknowledged that there is a data gap for this range. Therefore, there is an uncertainty for the potential for lung overloading effects with respect to the notified polymer when used in spray applications with insufficient respiratory protection (especially for DIY users).

Health hazard classification

As no 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 potential for sensitisation effects cannot be ruled out based on the structures of the notified polymer. However, systemic toxicity is not expected based on the high molecular weight of the notified polymer making it unlikely to be absorbed across biological membranes.

There is potential for dermal, ocular and possible inhalation exposure of workers to the notified polymer at < 40% concentration during reformulation processes. Exposure should be minimised through the use of enclosed, automated processes, local exhaust ventilation and PPE.

There is also potential for dermal, ocular and inhalation exposure of workers to the notified polymer at ≤ 4% concentration during applications of paints containing the notified polymer. Such exposure is expected to be mitigated through the use of engineering controls (such as spray booth and sufficient ventilation) and PPE.

Once the paint is dried and cured, the notified polymer will be bound within an inert solid matrix and will not be bioavailable.

Therefore, under the conditions of the occupational settings, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Dermal, ocular and inhalation exposure of DIY users to the notified polymer at up to 4% concentration is possible when paints are applied by brush, roller or spray. The frequency and extent of exposure of DIY users is expected to be less than that of workers. Large scale spray applications involving significant quantity of the notified polymer are unlikely to occur in public place. The potential of risk to the DIY users is also expected to be minimised by following safe use instructions of the paint products.

Once the paint is dried and cured, the notified polymer will be bound within an inert solid matrix and will not be bioavailable.

Therefore, given the low end-use concentrations and low use frequency, the risk to the public from use of 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 be imported into Australia as a pigment dispersant in automotive and industrial paints. Release of the notified polymer to the environment during import, storage, and transport is expected to be limited to accidental spills or leaks. Spills or accidental release of the products containing the notified polymer are expected to be collected by suitable absorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve transferring the product containing the notified polymer to the paint mixing tank by gravity feed or low pressure pumps, where it will be blended with other ingredients. Blending equipment will be cleaned with solvents. The waste liquids containing the notified polymer will be disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the finished paints containing the notified polymer will be for industrial and commercial use, with a small fraction will be used by DIY users. During use, the paints will be applied primarily by spray and by brush and roller.

The main release of the notified polymer is likely from overspray during use, estimated by the notifier to account for up to 30% of the total import volume. The overspray will be collected using standard engineering controls such as spray booths before disposal of to landfill. The solvent waste from cleaning of the application equipment, estimated by the notifier to account for up to 5% of the total import volume, will 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 metals reclamation. Residual notified polymer in empty import and 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.

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 the sewer, drains, or ground from waste and washing of application equipment.

7.1.2. Environmental Fate

No environmental fate data were submitted. 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 metals reclamation. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. During metal reclamation, the notified polymer will thermally decompose to form water vapour and oxides of carbon and nitrogen. A small proportion of the paint used by DIY users may be incorrectly disposed of to sewers, and is expected to be efficiently removed through adsorption of the potential cationic polymer 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 due to its potential cationic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). The notified polymer is not expected to bioaccumulate given its high molecular weight and it contains no significant percentage of low molecular weight constituents. In landfill, soil, sludge and water, 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 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. The notified polymer is a potential cationic polymer with molecular weight > 10,000 Da, and based on previous study results, at least 90% of the notified polymer is expected to be removed by partition to sludge at sewage treatment plants (Boethling and Nabholz, 1997).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	30,000	kg/year
Proportion expected to be released to sewer	5	%
Annual quantity of chemical released to sewer	1,500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	4.11	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	90%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.08	µg/L
PEC - Ocean:	0.01	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/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^3). Using these assumptions, irrigation with a concentration of 0.08 µg/L may potentially result in a soil concentration of approximately 0.56 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 2.8 µg/kg and 5.6 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted by the notifier. The aquatic toxicity of the notified polymer has been estimated based on structure activity relationships (SARs) equations (Boethling and Nabholz, 1997), and summarised in the table below:

Endpoint	*Result*	*Assessment Conclusion*
Acute		
Fish Toxicity	96h LC50 = 12.19 mg/L	Predicted to be harmful to fish
Daphnia Toxicity	48h LC50 = 332.11 mg/L	Predicted not to be harmful to aquatic invertebrates
Algal Toxicity	96h EC50 = 20.46 mg/L	Predicted to be harmful to algae
Chronic		
Fish Toxicity	ChV = 0.68 mg/L	Predicted to be toxic to fish with long lasting effects
Daphnia Toxicity	ChV = 18.45 mg/L	Predicted not to be harmful to aquatic invertebrates
Algal Toxicity	ChV = 6.18 mg/L	Predicted to be harmful to algae with long lasting effects

The estimated toxicity values indicate that the notified polymer is potentially toxic to aquatic life in environmental waters. The SAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the notified polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the *Globally Harmonised System for the Classification and Labelling of Chemicals* (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The most sensitive endpoint from ecotoxicity estimation on the notified polymer is ChV for fish, and this was selected for the calculation of the predicted no-effect concentration (PNEC). A conservative assessment factor of 1,000 was used in this case as only estimated data are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ChV (Fish)	0.68	mg/L

Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	0.68	µg/L

7.3. Environmental Risk Assessment

Based on the above predicted PEC and PNEC, the following Risk Quotient (Q = PEC/PNEC) has been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.08	0.68	**0.124**
Q - Ocean	0.01	0.68	**0.012**

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity. Based on its high molecular weight, the notified polymer is not expected to be bioaccumulative. Therefore, on the basis of the predicted PEC/PNEC ratio, the maximum annual importation volume, and the assessed use pattern as a pigment dispersant in automotive and industrial paints, the notified polymer is not expected to pose an unreasonable risk to the environment.

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