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

PUBLIC REPORT

Polymer in Efka® PA 4400

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.

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
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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/1864	BASF Australia Ltd	Polymer in Efka® PA 4400	ND*	≤ 40 tonne/s per annum	Paint additive

*ND = not determined

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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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 assessed 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 control, work practices 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.

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.
- A copy of the (M)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 containment, physical 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;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a paint additive, 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.

(Material) Safety Data Sheet

The (M)SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)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 $M_n \geq 1,000$ 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, manufacture/import volume, and use details.

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 (2009), China (2011), Europe, Japan (2009), Korea (2004), New Zealand (2010), Taiwan and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Efka® PA 4400

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported in solution
Boiling Point	Not determined	Expected to decompose prior to boiling
Density*	0.96 kg/m ³ at 20 °C	(M)SDS
Vapour Pressure	< 1.3×10^{-9} kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	Immiscible in water	(M)SDS
Hydrolysis as a Function of pH	Not determined	Contains functional groups that are expected to hydrolyse very slowly in the environmental pH range.
Partition Coefficient (n-octanol/water)	$\log P_{ow} \geq 3.4$ at 20 °C	Analogue data
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and

Dissociation Constant	Not determined	sludge based on its high molecular weight and low water solubility
Flash Point	Not determined	Contains basic functionality (pKa ~ 7) which has the potential to be cationic under environmental conditions (pH 4-9)
Autoignition Temperature	Not self-igniting	Not expected to be flammable based on the high molecular weight and low vapour pressure.
Explosive Properties	Not determined	(M)SDS
Oxidising Properties	Not determined	Not expected to be explosive based on chemical structure.
		Not expected to be an oxidiser based on chemical structure.

* For the imported material Efka® PA 4400 containing the notified polymer in solvent solution at < 40% concentration.

DISCUSSION OF PROPERTIES

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 be imported as a component of Efka® PA 4400 (at < 40% concentration) in a solvent solution.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10 – 20	10 – 30	20 – 40	20 – 40	20 – 40

PORT OF ENTRY

Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS

BASF Australia Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a component of Efka® PA 4400 (at < 40% concentration) in 18 kg plastic containers and 190 kg closed head steel drums, which will be packed on wooden pallets and bound with a plastic shrink wrap. The wrapped pallets holding the containers of Efka® PA 4400 will be transported by road from the wharf to the third party warehouse for storage.

Finished paints containing the notified polymer (at < 4% concentration) will be stored and transported in lined 1, 4 and 10 L steel paint cans or 210 kg steel drums.

USE

The imported product containing the notified polymer (at < 40% concentration) will be used as a pigment dispersing agent in the manufacture of industrial and automotive paints. The end-use paints will contain the notified polymer at < 4% concentration. Paints will be applied in automotive repair facilities and industrial and protective coating facilities.

OPERATION DESCRIPTION

Reformulation

The imported products containing the notified polymer at < 40% concentration will be added by gravity feed or low pressure pump to a high speed paint mixer and combined with resin, solvent and pigments. Once mixing is complete, samples will be taken for quality control testing and the finished paint product containing < 4% of the notified polymer will be transferred to steel containers by a gravity feed or low pressure pump. Paint mixing and packaging will be conducted in under local exhaust ventilation. The paint manufacturing equipment will be cleaned by flushing with hydrocarbon solvents, with the washings either recycled for reuse in the paint manufacturing facility or disposed of in accordance with local regulations.

End-use

The finished paints containing the notified polymer at < 4% will be applied by brush, roller and spray in industrial facilities under local exhaust ventilation. Application equipment will be cleaned with hydrocarbon solvents and washings will be disposed of in accordance with local regulations. The notifier expects that < 1% of the introduced notified polymer will be used by the general public for DIY applications.

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 workers may come into contact with the imported product containing the notified polymer in Efka® PA 4400 (at < 40% concentration), only in the unlikely event of an accident.

During paint formulation processes, including transfer, quality control and cleaning and maintenance tasks, dermal and ocular exposure to the notified polymer (at < 40% concentration) may occur. Exposure is expected to be minimised through the use of local exhaust ventilation and personal protective equipment (PPE), including chemical goggles, impervious gloves and appropriate industrial clothing. Due to the nature of the processes and the expected low volatility of the notified polymer, inhalation exposure during reformulation is not anticipated.

At end-use sites, dermal, ocular and/or inhalation exposure to the paint containing the notified polymer (at < 4% concentration) may occur during transfer, application and cleaning processes. The potential for exposure is expected to be minimised through the use of PPE (goggles, impervious gloves, coveralls) by workers and use of respiratory protection during spray applications. Once the coating is dried, the notified polymer will be bound within the polymer matrix and will not be available for exposure.

6.1.2. Public Exposure

Paints containing the notified polymer (at < 4% concentration) are predominantly intended for industrial use and significant DIY use is not expected. If paints are used for DIY use it is expected to be on a less frequent basis than for professional users, although PPE may not be worn. Once the paints have 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 > 2090 mg/kg bw; low toxicity

* For the imported material Efka® PA 4400 containing the notified polymer in solvent solution at < 40% concentration.

Toxicokinetics.

The notified polymer is of high molecular weight ($M_n > 1,000$ Da) with a low percentage of low molecular weight species present (i.e. < 2% with a molecular weight less than 1,000 Da) and is not expected to absorb across biological membranes.

Acute toxicity.

The notified polymer is expected to have a low acute oral toxicity based on a study conducted on rats.

The notified polymer does not contain any structural alerts of concern and is therefore expected to be of low hazard to human health.

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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer was found to be of low acute oral toxicity and based on the high molecular weight ($M_n > 1000$ Da) and absence of structural alerts of concern, is expected to be of low hazard to human health.

Workers may be exposed to the chemical at < 40% concentration during reformulation processes and at < 4% concentration during application of paint products. Exposure is expected to be limited by the expected use of engineering controls and personal protective equipment (PPE).

Therefore, given the expected low hazardous nature of the notified polymer and the occupational settings described, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health

The public may experience dermal ocular or inhalation exposure to paint products containing the notified polymer at < 4% concentration. The public may also come into contact with the coatings containing the notified polymer, however, in such cases exposure is not expected as the notified polymer will be bound within the polymer matrix and will not be available for exposure.

Given the expected low hazardous nature of the notified polymer and the low exposure the risk to the public 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

No manufacturing of the notified polymer will take place in Australia. Release of the notified polymer to the environment during importation, storage, and transport is unlikely. The most likely source of a release to the environment during these activities will be a transport accident. 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 recycled for reuse on site or disposed of via accredited waste disposal contractors. Wastes and spills (1% of annual import volume) during reformulation activities are expected to be contained on-site and disposed of in accordance with local regulations. Residues in import containers are expected to 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 expected to only be used in industrial facilities for industrial and automotive paints. Therefore, 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 structures 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 it 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 of cured paints as part of its normal use pattern as a component in industrial paints. 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 bioavailable, biodegradable nor mobile in this form. Based on the high molecular weight 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 during use. 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 notified polymer has functionality that has the potential to be toxic to aquatic life. However, no significant exposure of the notified polymer to aquatic organisms is expected. Furthermore, the majority of the notified polymer will be cured with other chemical substances as part of the coating process and is not expected to be bioavailable.

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 ($Q = \text{PEC}/\text{PNEC}$) 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 and automotive paints. 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. On the basis of its limited aquatic exposure and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE Notified polymer at < 30%

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.

Species/Strain Rat/ Crl: (WI) BR - Wistar

Vehicle None

Remarks - Method Animals were dosed by oral gavage.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5 M, 5 F	2,090	0/10

LD50 > 2,090 mg/kg bw

Signs of Toxicity No mortalities or adverse clinical symptoms were observed.

Effects in Organs No adverse effects were observed.

Remarks - Results All animals gained the expected amount of body weight.

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

TEST FACILITY IBR (1989)

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