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

PUBLIC REPORT

EFKA® FA 4612

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
STD/1607	BASF Australia Ltd	EFKA® FA 4612	ND*	≤ 60 tonnes per annum	Component of automotive and industrial coatings

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As 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

Provided that the recommended controls are being adhered to, 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 reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation and end use:
 - Local exhaust ventilation
 - Enclosed, automated systems where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation and end use:
 - Avoid eye and skin contact
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation and end use:
 - Impervious gloves
 - Protective coveralls
 - Safety glasses
 - Respiratory protection 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 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
 - additional information becomes available on the toxicity of the notified polymer;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of automotive and 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 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

Standard: Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year).

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, 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 as follows: Boiling Point, Density, Partition Coefficient (n-octanol/water), Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability, Autoignition Temperature, Explosive Properties, Oxidising Properties, Acute Dermal Toxicity, Skin Irritation, Eye Irritation, Skin Sensitisation, Repeated Dose Toxicity and Genotoxic Damage *in vitro*.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2013), China (2013), Korea (2014), USA (2000)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

EFKA® FA 4612

MOLECULAR WEIGHT

> 500 Da

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 80%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No losses by volatilisation, exudation or leaching are expected from the notified polymer.

DEGRADATION PRODUCTS

Thermal decomposition may release toxic fumes containing products of combustion such as carbon monoxide, carbon dioxide and oxides of nitrogen (NO_x).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow to brownish liquid with characteristic odour

Property	Value	Data Source/Justification
Glass transition temperature	-53 °C	Measured
Boiling Point	151 °C at 101.3 kPa	SDS
Density	1,230 kg/m ³ at 20 °C	SDS

Property	Value	Data Source/Justification
Vapour Pressure	0.04 kPa at 20 °C	Measured
Water Solubility	26.3 g/L at loading of 29.9 g/L and 65.6 g/L at loading rate of 70.3 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups and is expected to hydrolyse very slowly in the environmental pH of 4-9
Partition Coefficient	< 1	Estimated based on the solubilities in water and n-octanol. However the notified polymer has a structure characteristic of a surfactant. Therefore, it is expected to partition to the n-octanol/water phase boundary.
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water in the environment based on its potential surface activity
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	> 100 °C (pressure unknown)	SDS
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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.

The notifier has classified the notified polymer as:

Corrosive to metals: Cat 1

Hazard statement H290 – May be corrosive to metals

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 its neat form for reformulation, or in end use coating products at < 10% concentration.

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

Year	1	2	3	4	5
Tonnes	10-30	10-30	30-60	30-60	30-60

PORT OF ENTRY

Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

BASF Australia Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 25 and 200 kg open head steel drums for reformulation. Coatings containing the notified polymer at < 10% concentration will be imported in 1, 4 and 10 L paint cans and 210 kg

lined steel drums. The notified polymer and products containing it will be transported throughout Australia by road or rail.

USE

The notified polymer will be used in automotive and industrial coatings at < 10% concentration.

OPERATION DESCRIPTION

When not imported in finished products, the notified polymer will be reformulated into coatings. At the reformulation sites the contents of the imported drums containing the notified polymer will be transferred to a mixing vessel, using a gravity or low pressure pump, into a paint mixer containing a mixture of solvents and resins. Once incorporated, dry pigment(s) are added to the liquid component under high speed mixing. Once the dispersion of the pigment into the liquid component is complete, samples will be taken for QC testing and the final coating or pigment slurry will be filled into lined steel containers for resale. The pigment slurry would be further reformulated into coatings. Coatings containing the notified polymer at < 10% concentration will be filled into containers, primarily by gravity feed or low pressure pump transfer by an operator. Paints in their sealed lined steel containers will then be loaded onto a pallet, transported to the general warehouse area of the paint manufacturer and then distributed into the stores of end users.

Coatings containing the notified polymer at < 10% concentration may be applied by brush, roller or spray in a variety of locations, predominantly vehicle collision repair shops, industrial and protective paint application facilities in purpose built spray facilities, and in coating large fibreglass mouldings such as boats and pools. The coatings will be applied by industrial users.

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 are unlikely to be exposed to the notified polymer except in the unlikely event of an accident.

Reformulation

Reformulation will be largely enclosed and automated; however, workers may be exposed (dermal and ocular) to the notified polymer itself when transferring the contents of the imported drums to the mixing equipment and during quality control testing. Dermal and ocular exposure to workers should be mitigated through the use of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles. Inhalation exposure is not expected given the low vapour pressure of the notified polymer and use of enclosed processes.

Coating applications

Exposure to the coatings containing the notified polymer at < 10% concentration may occur during transfer, application and cleaning processes. The potential for exposure should be minimised through the stated use of PPE (goggles, impervious gloves, coveralls) by workers.

During applications by brush or roller, coating applicators may have the potential for exposure to the notified polymer *via* dermal and ocular routes. The potential for exposure should be minimised through the stated use of PPE (goggles, impervious gloves, coveralls) by workers. In addition, spray application may also lead to inhalation exposure. As stated by the notifier, spray applications will be conducted under ventilation in

engineered facilities. Workers are expected to wear air fed respirators. These control measures are anticipated to mitigate the potential for exposure during spray application.

Workers may come into contact with the coatings containing the notified polymer after application to substrates. However, once the coatings have dried, the notified polymer will be bound within a polymer matrix and not expected to be available for exposure.

6.1.2. Public Exposure

The notified polymer will be for industrial use only and will not be sold to the general public.

The public may come into contact with the surface coatings containing the notified polymer after application to substrates. However, once the surface coatings have dried, the notified polymer will be bound within a polymer matrix and not expected to be available for exposure.

6.2. Human Health Effects Assessment

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

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

Toxicokinetics, metabolism and distribution

Absorption of the notified polymer across biological membranes is likely to be limited to some extent, based on the relatively high molecular weight (> 500 Da). However there are significant levels of low molecular weight species < 500 Da and therefore some absorption cannot be ruled out.

Acute toxicity

The notified polymer was found to have low acute oral toxicity in rats.

Irritation and sensitisation

No data on skin and eye irritation and skin sensitisation are available. The notified polymer may have irritation potential based on its surface activity.

The notified polymer contains impurities that are classified as hazardous for skin, eye and respiratory irritation or for skin corrosion (Category 1), with a hazard statement H314 – Causes severe burns and eye damage.

Mutagenicity/Genotoxicity

One in vitro assay was provided. Based on that, the notified polymer was not mutagenic in a bacterial reverse mutation study.

Health hazard classification

As 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.

The notifier has classified the notified polymer as follows:

Skin corrosion/irritation Cat 2 – H315 Causes skin irritation

Serious eye damage/eye irritation Cat 1 – H318 Causes serious eye damage

Depending on the impurities and their concentrations in the notified polymer, these classifications may be appropriate.

6.3. Human Health Risk Characterisation

Limited toxicological data are available on the notified polymer. Based on its structure, it may have irritation properties.

6.3.1. Occupational Health and Safety

During reformulation, worker exposure to the notified polymer is expected to be low given the use of PPE and enclosed and automated processes, as stated by the notifier.

During end use, workers will be exposed to surface coatings containing the notified polymer at concentrations of < 10%. Given the relatively high molecular weight, the potential risk posed by the notified polymer from dermal exposure is expected to be low. Furthermore, exposure to the notified polymer during end use is expected to be limited by the use of engineering controls and appropriate PPE.

Once the surface coatings have dried, the notified polymer will be bound within an inert matrix and will not be available for exposure, thereby limiting any further potential for exposure.

Given the proposed use of PPE and engineering controls in place to limit exposure during reformulation and end uses, the risk to workers from use of the notified polymer in industrial surface coatings is not considered to be unreasonable.

6.3.2. Public Health

The public is expected to have little or no exposure to the notified polymer in uncured form. Once the surface coatings have dried, the notified polymer will be bound within an inert matrix and is not expected to be available for exposure. Based on negligible exposure to the public, the risk to public health 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 may be imported as a component of finished coating products or as a raw material for local reformulation into solvent based industrial and automotive paints. Any spills of the notified polymer during transportation and storage are expected to be contained with adsorbent material and be disposed of to landfill.

Reformulation of the notified polymer occurs in a closed system. At the reformulation sites the notified polymer will be transferred to a mixing vessel, using a gravity or low pressure pump, into a paint mixer containing a mixture of solvents and resins and will be further reformulated into coatings. 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 in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

Coatings containing the notified polymer may be applied by brush, roller or spray, predominantly in vehicle collision repair shops and industrial and protective paint application facilities. It is assumed by the notifier that the paints containing the notified polymer will be applied in spray facilities. The main release of notified polymer during industrial spray painting operations will come from overspray, accounting for up to 30% of the annual import volume. Overspray, accidental spills, application equipment washings (up to 5% of the annual import volume) and residues in empty paint containers (up to 2.5% of the annual import volume) are expected to be collected and disposed of to landfill in accordance with local, State and Federal regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in paints is expected to share the fate of articles 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 for the notified polymer. It is estimated by the notifier that up to 10% of the total import volume of the notified polymer will be used in coatings of large fibreglass mouldings such as boats and pools. However, the majority of the notified polymer is expected to be incorporated into an inert matrix of cured paints as part of its use pattern as a component in automotive and in industrial paints. The notified polymer is not expected to be bioavailable nor biodegradable in this form. 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, phosphorus and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present at significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters when used in coatings. Therefore, the predicted environmental concentration (PEC) has not been calculated for the notified polymer.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. 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 quotients ($Q = \text{PEC}/\text{PNEC}$) for the notified polymer have not been calculated as PNEC was not calculated and release to the aquatic environment in ecotoxicologically significant concentrations is not expected based on its reported use pattern as a component in industrial and automotive paints. Moreover, after curing, the majority of the imported quantity of the notified polymer will be irreversibly incorporated into an inert matrix and it is not expected to be mobile, bioavailable or bioaccumulative. On the basis of the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Glass transition temperature** -53 °C

Method	OECD TG 102 Melting Point/Melting Range
Remarks	Differential scanning calorimetry method was used. The test substance has no melting point between -120 and 100 °C.
Test Facility	BASF (2013)

Vapour Pressure 0.04 kPa at 20 °C
0.055 kPa at 25 °C
0.191 kPa at 50 °C

Method	OECD TG 104 Vapour Pressure
Remarks	The static method was used.
Test Facility	BASF (2013)

Water Solubility 26.3-65.5 g/L at 20 °C

Method	OECD TG 105 Water Solubility
Remarks	Flask Method. The linear dependency between solubility and loading rates indicated that 95.92% of the test item was soluble. Concentrations of 26.3 to 65.5 g/L were found at applied loading rates of 29.9 to 70.3 g/L.
Test Facility	Institut Kuhlmann GmbH (2014a)

Partition Coefficient (n-octanol/water) log Pow = -3.42 and -3.82

Method	OECD TG 117 Partition Coefficient (n-octanol/water)
Remarks	Partition coefficient could not be determined by the HPLC method and flask methods due to analytical limitations. Estimated based on the solubilities in water and n-octanol.
Test Facility	Institut Kuhlmann GmbH (2014b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (2001). EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	None
Remarks - Method	No protocol deviations

RESULTS

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

LD50	> 2,000 mg/kg bw
Signs of Toxicity	In the first few hours after dosing, an impaired general state and piloerection were observed in 2/3 animals in Test 1 and all animals in Test 2.
Effects in Organs	No macroscopic pathological findings were noted in the animals sacrificed at the end of the observation period.
Remarks - Results	The mean body weight increase of the test group animals was within the normal range.

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

TEST FACILITY Bioassay (2014)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test (1997). EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Species/Strain	Plate incorporation procedure (Test 1)/Pre incubation procedure (Test 2) <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	Liver S9 mix from phenobarbital / β -naphthoflavone induced rats
Concentration Range in Main Test	0, 33, 100, 333, 1,000, 3,250 and 6,500 μ g/plate, with and without metabolic activation, for both Test 1 and Test 2.
Vehicle	DMSO
Remarks - Method	There was no preliminary test.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (μg/plate) Resulting in:</i>		
	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>			
Test 1	$\geq 6,500$	> 6,500	negative
Test 2	$\geq 6,500$	> 6,500	negative
<i>Present</i>			
Test 1	> 6,500	> 6,500	negative
Test 2	$\geq 6,500$	> 6,500	negative

Remarks - Results A bacteriotoxic effect was observed in the standard plate test at a

concentration of 6,500 µg/plate in the absence of S9 mix. In the preincubation assay bacteriotoxicity was observed at a concentration of 6,500 µg/plate with or without S9 mix.

No dose-related reproducible increase was seen in the number of revertant colonies, with or without 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 was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Bioassay (2013)

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