

File No: LTD/1891

December 2016

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

PUBLIC REPORT

Polymer in EFKA® PX 4350

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	5
1. APPLICANT AND NOTIFICATION DETAILS	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION.....	5
4. PHYSICAL AND CHEMICAL PROPERTIES	5
5. INTRODUCTION AND USE INFORMATION	6
6. HUMAN HEALTH IMPLICATIONS	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	8
6.2. Human Health Effects Assessment	8
6.3. Human Health Risk Characterisation	8
6.3.1. Occupational Health and Safety	8
6.3.2. Public Health	9
7. ENVIRONMENTAL IMPLICATIONS.....	9
7.1. Environmental Exposure & Fate Assessment	9
7.1.1. Environmental Exposure	9
7.1.2. Environmental Fate	10
7.1.3. Predicted Environmental Concentration (PEC).....	10
7.2. Environmental Effects Assessment.....	11
7.2.1. Predicted No-Effect Concentration	11
7.3. Environmental Risk Assessment	12
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES</u>	<u>13</u>
BIBLIOGRAPHY	14

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/1891	BASF Australia Ltd	Polymer in EFKA® PX 4350	ND*	≤ 15 tonnes per annum	Component of inks and coatings

*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, 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 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 engineering controls to minimise occupational exposure to the notified polymer during reformulation:
 - 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:
 - 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 during reformulation:
 - Chemical resistant gloves
 - Protective coveralls
 - Safety glasses

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.

- 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 with adsorbent material, 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 Da;

or

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

(Material) Safety Data Sheet

The (M)SDS of the product containing the notified polymer 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, polymer constituents, residual monomers/impurities, purity, 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: all physico-chemical endpoints except for melting point, vapour pressure and water solubility

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

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

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

EFKA® PX 4350 (containing the notified polymer at < 50%)

OTHER NAME(S)

EFKA®-K-260

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 98%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

DEGRADATION PRODUCTS

Degradation products are expected to be oxides of nitrogen and carbon.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow to red liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	1 °C	Measured
Boiling Point	140 °C at 101.3 kPa	SDS*

Density	1,040 kg/m ³ at 20 °C	SDS*
Vapour Pressure	< 1 × 10 ⁻⁷ kPa at 20 °C < 1 × 10 ⁻⁷ kPa at 25 °C < 1 × 10 ⁻⁷ kPa at 50 °C	Measured
Water Solubility	Miscible with water at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Expected to be hydrolytically stable under the environmental pH range of 4–9 as it does not contain readily hydrolysable functionalities
Partition Coefficient (n-octanol/water)	Not determined	Expected to have a low partition coefficient on the basis of its high water solubility
Adsorption/Desorption	Not determined	Due to its high water solubility and expected low partition co-efficient the notified polymer is not expected to adsorb to soils/sediment to any great extent.
Dissociation Constant	Not determined	Contains ionisable functionalities. Therefore, the notified polymer is expected to be ionised at the environmental pH range of 4–9.
Flash Point	43 °C	SDS*
Autoignition Temperature	Not self-igniting	SDS*
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

*Product SDS for EFKA® PX 4350 (containing the notified polymer at < 50%)

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

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

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured within Australia. The notified polymer will be imported at < 50% concentration in product EFKA® PX 4350, or as a component in solvent or water based ink and coating formulations at < 5% concentration.

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

Year	1	2	3	4	5
Tonnes	5–15	5–15	5–15	5–15	5–15

PORT OF ENTRY

Throughout Australia

IDENTITY OF RECIPIENTS

BASF Australia Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported at < 50% concentration for reformulation in 210 kg closed head steel drums or 20 kg plastic jerricans. Ink formulations containing the notified polymer at < 5% concentration will be

imported in sealed ink cartridges. Surface coatings containing the notified polymer at < 5% concentration will be imported in containers suitable for supply to both the industrial and domestic markets. The notified polymer and products containing it will be transported throughout Australia by road or rail.

USE

The notified polymer will be used in inks and surface coatings at < 5% concentration. The notified polymer will be used as a component of: solvent and water based ink formulations, inkjet inks, water based flexographic inks, overprint varnishes, paints, renders, primers and sealers. Products containing the notified polymer will be used by both the industrial and domestic markets.

OPERATION DESCRIPTION

When not imported in finished products, the notified polymer (at < 50% concentration) will be reformulated into surface coatings and printing inks. At the reformulation sites the contents of the imported drums and pails containing the notified polymer will be transferred to a mixing vessel, using a sparge, pail or jug, for blending with pigments and other ingredients to form the finished products. Following quality control analysis, the finished products (containing < 5% notified polymer) will be transferred to 5 and 20 L cans and pails for distribution to end-users.

Surface coatings containing the notified polymer may be applied by brush, roller or spray on a wide range of substrates by both commercial and domestic users. The use of flexographic inks and overprint varnishes containing the notified polymer is expected to require manual transfer from the cans and pails they are packaged in to the printing equipment, with the printing process itself being largely enclosed and automated. Flexographic inks and overprint varnishes are only expected to be used by industry, while inkjet cartridges will be used by both industry and consumers.

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	4–8	200
Service technicians	8	200
Office staff	0.17	5–10
Professional painters	8	200

EXPOSURE DETAILS

Transport and storage workers are unlikely to be exposed to the notified polymer (at < 50% concentration) 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 at < 50% concentration when transferring the contents of the imported drums and pails 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.

Printing applications

Dermal or ocular exposure may occur to the inks or overprint varnishes containing the notified polymer at < 5% concentration during transfer processes, cleaning and maintenance. Inhalation exposure is not expected given the low vapour pressure of the notified polymer. Exposure at other times is expected to be limited by the automated and enclosed nature of the printing processes. The stated use by the notifier of PPE by workers, such as goggles, impervious gloves and coveralls should minimise exposure.

Coating applications

Exposure to the surface coatings containing the notified polymer (at < 5% concentration) may occur during transfer, application and cleaning processes. The potential for exposure should be minimised through the stated use by the notifier of PPE (goggles, impervious gloves, coveralls) by workers.

During spray applications, coating applicators may have the potential for exposure to the notified polymer via inhalation, dermal and ocular routes. As stated by the notifier, spray applications will be conducted in spray booths equipped with exhaust ventilation and filtering systems. Workers are expected to wear spray suits with appropriate respirators in place. These control measures are anticipated to mitigate the potential for exposure during spray application.

Maintenance workers and cleaners may have the potential for exposure to residues of the final paints with the notified polymer at < 0.05% concentration when cleaning up equipment, spray booths, spills or leaks from the work processes. Exposure to the notified polymer for these workers is also expected to be mitigated through the use of PPE i.e. appropriate certified respirators, safety glasses with side shields, chemical resistant impervious gloves, chemical-resistant protective clothing and work boots.

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

6.1.2. Public Exposure

Ink-jet cartridges and surface coatings containing the notified polymer (at < 5% concentration) will be available for use by the public. Exposure (dermal, ocular and inhalation) to the notified polymer may occur during use of the surface coatings. The notified polymer will be applied to substrates such as paper, masonry, plasterboard, timber, metal and plastic. Given the inks containing the notified polymer will be contained within sealed cartridges, significant exposure is not expected.

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

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. The notified polymer contains a functional group which is a structural alert for irritation/corrosion and skin sensitisation. However, given the high molecular weight (> 1,000 Da) of the notified polymer, and the low proportion of the functional group as a percentage of total polymer (< 10%), the potential for irritation and sensitisation is not expected. Similarly, the notified polymer is not expected to cross biological membranes and cause systemic toxicity.

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, 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 is expected to be of low hazard. In addition, given the reformulation process is mostly automated and enclosed and workers are expected to use PPE the potential for exposure is expected to be limited.

During end use, workers will be exposed to inks or surface coatings containing the notified polymer at concentrations of < 5%. 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 inks and surface coatings have dried, the notified polymer will be bound within an inert matrix and will not be bioavailable.

Therefore, given the proposed use of PPE and engineering controls in place to limit exposure during reformulation, and the low end use concentration, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Ink-jet cartridges and surface coatings containing the notified polymer at < 5% concentration will be available for use by the public. Exposure to the notified polymer may occur during use of the surface coatings. Significant exposure is not expected from use of the ink-jet cartridges. Once the inks and surface coatings have dried, the notified polymer will be bound within an inert matrix and will not be bioavailable, thereby limiting any further potential for exposure.

Given the low concentration of the notified polymer in consumer products (< 5%) and expected low hazard, the risk to the public from use of the notified polymer is not considered 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 as a component of printing ink or over print varnish or will be reformulated locally into a printing ink or overprint varnish. It will also be imported as a surface coating formulation, including paint, render, primer or sealant or will be reformulated locally into a surface coating. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the product containing the notified polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. During formulation of the ink, the notifier estimates that up to 200 kg per annum of notified polymer waste will be generated. This will be derived from the spills (50 kg per annum) and equipment cleaning (150 kg per annum). Empty import drums are expected to be rinsed and either recycled or disposed of to landfill. The resulting rinsate will be added to the ink formulation process. However, if this rinsing process does not occur, up to a further 300 kg per annum of the notified polymer may be disposed of to landfill. It is anticipated that spills of the polymer solution and blended ink will be contained within the plant through the bunding systems in place. Spills will be collected and either recycled or removed by a licensed industrial waste contractor for incineration.

There is some potential for release of the polymer during the local formulation of surface coating products, which will take place at a number of sites within Australia. Spills will be contained by the plant bunding. It is expected that up to 2% of the imported material (equivalent to 200 kg of the notified polymer) may be left in the 20 kg containers and 210 kg drums after formulation. This would be either placed into landfill with the drums or, if the drums are recycled, removed with water or solvent and most likely sent to on-site effluent treatment facilities where solid material (including the notified polymer) is expected to become incorporated into waste sludge. The sludge would be sent to landfill for disposal.

Further losses from spills and leaks are possible when the surface coatings are formulated, with losses estimated at a maximum of 1% (100 kg of polymer each year). These losses would be contained within plant bunding and sent to an on-site water treatment plant where the polymer would associate with sludge and be disposed of by incineration or into landfill.

RELEASE OF CHEMICAL FROM USE

Ink

The ink cartridges are designed to prevent leakage and will not be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified polymer to the environment is not expected under such conditions. However, if leakage or spillage does occur, the ink will be contained with absorbent material, which will be disposed of to landfill along with empty cartridges and printer heads in accordance with local government regulations. The sealed cartridges are contained in the printer until they are removed for disposal. Residual ink (< 1 %) left in empty cartridges will most likely be disposed of to landfill. The majority of the ink will be bound to printed paper that will be disposed of to landfill or recycled.

Paints/coatings

Surface coatings containing the notified polymer will be used by both professional and Do-It-Yourself (DIY) users. During use, paints and coatings containing the notified polymer are expected to be applied by brush, roller and spray techniques. It is expected that some of the coating product will be in the form of overspray during spraying operations, and will typically entail disposal to landfill after being collected with adsorbents. During use, the notified polymer may also be released to the environment as accidental spills and container residues. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Ink

The notified polymer will be used in printer ink for printing onto paper substrates. The majority of the notified polymer is expected to share the fate of the printed articles to which it is bound. It is assumed that 50% of the printed paper will be disposed of to landfill, and the rest will undergo paper recycling processes. Empty ink cartridges containing residues of the notified polymer are expected to be recycled or disposed of to landfill. The ink remaining in the ink cartridges during the recycling process is not expected to be reused but disposed of to landfill. Hence, the majority of the notified polymer is expected to be disposed of to landfill, with a potential for some release to sewer through paper recycling processes. During paper recycling processes, waste paper is pulped using a variety of chemical treatments that results in ink detachment from the fibres.

Paints/coatings

The notified polymer in paints and coatings is expected to share the fate of the substrate to which it has been applied, and is predominantly expected to be disposed to landfill. Residues containing the notified polymer on application equipment are expected to be rinsed into containers, and then allowed to cure before disposal as solid wastes to landfill. As a worst case scenario, it is assumed that up to 5% of the paints and coatings 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 was submitted for the notified polymer. It is estimated that 20% of the total import volume of the notified polymer will be used as ink components and the rest 80% in surface coatings.

Ink

The notified polymer trapped in the ink matrices is expected to be disposed of to landfill with the unrecycled paper to which it is applied. Based on its high molecular weight, high water solubility and expected low partition coefficient, the notified polymer is not expected to bioaccumulate. The majority of the notified polymer is expected to enter the environment from disposal of printed paper products to which the printer ink containing the notified polymer is bound. Approximately 50% of the notified polymer is expected to be disposed of to landfill as part of printed waste paper. Notified polymer that is not cured and bound to paper in landfill may leach due to its high water solubility, where it may enter surface waters.

The remaining 50% of the notified polymer has the potential to be released to sewer after the de-inking of printed paper during recycling processes. The notified polymer is not expected to be removed during sewage treatment plant (STP) processes due to its high water solubility and expected low adsorption coefficient. Therefore, the notified polymer from paper recycling may be released from STPs to surface waters. Notified polymer released to surface waters from STPs and landfill leachate is expected to disperse and eventually degrade. In landfill and in surface waters, the notified polymer is expected to degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

Paints/coatings

The captured overspray and of articles to which the notified polymer will be applied will be disposed of to landfill. The majority of the notified polymer is expected to be cured within an inert polymer matrix adhering to articles following its use in coating applications. In its cured form it is not expected to be mobile, bioavailable or biodegradable. Ultimately, the notified polymer is expected to eventually degrade via biotic and abiotic processes 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 been calculated to assume a worst case scenario, with half of the paper products containing the notified polymer undergoing recycling (i.e. 10% of the import volume), and the notified polymer to be released into sewers with no removal during recycling or STP processes. As the notified polymer bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment

Total Annual Import/Manufactured Volume	15,000	kg/year
Proportion expected to be released to sewer	10%	
Annual quantity of chemical released to sewer	1,500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	5.77	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.28	µg/L
PEC - Ocean:	0.13	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/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/m³). Using these assumptions, irrigation with a concentration of 1.28 µg/L may potentially result in a soil concentration of approximately 8.50 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 42.52 µg/kg and 85.04 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. Ecotoxicological endpoints for aquatic organisms for the notified polymer were calculated based on structure-activity relationship (SAR) equations, assuming a worst case cationic charge density for the polymer (Boethling and Nabholz, 1997). The acute and chronic endpoints are summarised in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<u><i>Acute Toxicity</i></u>		
Fish	96 h LC50 = 38.08 mg/L	Predicted to be harmful to fish
Daphnia	48 h EC50 = 25.33 mg/L	Predicted to be harmful to aquatic invertebrates
Algae	96 h EC50 = 4.86 mg/L	Predicted to be toxic to algae
<u><i>Chronic Toxicity</i></u>		
Fish	ChV = 2.12 mg/L	Not predicted to be harmful to fish
Daphnia	ChV = 1.41 mg/L	Not predicted to be harmful to aquatic invertebrates
Algae	ChV = 1.26 mg/L	Not predicted to be harmful to algae

The notified polymer is predicted to be toxic to algae, and harmful to fish and aquatic invertebrates on an acute basis. The notified polymer is not predicted to be harmful to fish, aquatic invertebrates and algae on a chronic basis. The SAR estimation procedure used here is a standard approach, and is considered reliable to provide general indications of the likely environmental effects of a chemical. However, this method is not considered sufficient to formally classify the acute and chronic hazards of the notified polymer to aquatic life under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive acute endpoint for algae. A safety factor of 100 was used given modelled acute and chronic endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment

EC50 (Algae, 96 h)	4.86	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	48.6	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	1.28	48.6	0.026
Q – Ocean	0.13	48.6	0.003

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Although the notified polymer is not expected to be readily biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern as printing ink and surface coatings, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point/Freezing Point** 1 °C

Method OECD TG 102 Melting Point/Melting Range.
Remarks Differential scanning calorimetry was used.
Test Facility BASF (2014a)

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

Method OECD TG 104 Vapour Pressure.
Remarks Effusion method was used.
Test Facility BASF (2014b)

Water Solubility Miscible at 20 °C

Method OECD TG 105 Water Solubility.
Remarks Visual Method
Test Facility BASF (2014a)

BIBLIOGRAPHY

- BASF (2014a) Notified Polymer: Physico-chemical Properties (August 2014). Competence Centre Analytics, BASF SE, D-67056 Ludwigshafen, Germany (Unpublished report submitted by the notifier).
- BASF (2014b) Notified Polymer: Vapour pressure (July 2014). Chemical and Process Engineering, BASF, Germany (Unpublished report submitted by the notifier).
- Boethling, RS, Nabholz, JV (1997). "Environmental Assessment of Polymers under the US Toxic Substances Control Act", in: Hamilton, JD, Sutcliffe, R (ed). Ecological Assessment of Polymers: Strategies for product stewardship and regulatory programs. Van Nostrand Reinhold, New York.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- SWA (2015) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating>.
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.