File No: LTD/1572

January 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Efka SL 3239

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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/1572	BASF Australia Ltd	EFKA SL 3239	ND*	≤ 10 tonnes per annum	A component of industrial 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 for the 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.

However, the notified polymer is a potential precursor for perfluorohexanoic acid (PFHxA) and PFHxA is persistent in the environment. Due to the environmental distribution of PFHxA resulting from the use pattern of the notified polymer, secondary human exposure to PFHxA via the environment may occur. The notified polymer is replacing a long chain polyfluoroalkyl polymer, the latter of which is known to result in secondary human exposures to perfluorooctanoic acid (PFOA) and longer chain perfluorocarboxylic acids (PFCAs). PFOA and longer chain PFCAs are more hazardous to human health and have higher bioaccumulation potential, compared to PFHxA. The overall human health risk posed by the notified polymer is less than that of the substance it replaces.

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.

However, degradants of the notified polymer are potential precursors of the very persistent chemical, perfluorohexanoic acid (PFHxA). The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment during use and after disposal and the long-term environmental risk profile of PFHxA is currently unknown. Consequently, the long-term risk profile for the notified polymer and its degradation products is unknown.

No environmental fate data or degradation studies were provided by the notifier. The persistence of PFHxA in the environment is of concern because it has potential to be globally distributed. However, the ecotoxicological profile and bioaccumulation potential of PFHxA is considered to be less problematic when compared with long chain (C8 and above) perfluorocarboxylic acids, noting that current evidence suggests PFHxA is not bioaccumulative in aquatic ecosystems. Nonetheless, the introduction and use of chemicals that release very persistent PFHxA upon degradation should be considered a short-term measure until suitable alternatives, with less persistent chemistry, are identified.

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:
  - Enclosed, automated processes, 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 breathing of vapours, mists and sprays
  - Maintain good hygiene practices

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Gloves
  - Coveralls
  - Safety goggles

  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 for the 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.

Environment

- The notified polymer should only be introduced as part of a strategy to phase out the use of long chain perfluoroalkyl chemicals.

- The notifier should seek ways to minimise the level of residual polyfluoroalkyl monomers and impurities in the notified polymer. Such levels should be as low as practicable: where possible, the total weight of these constituents should not exceed the levels attainable utilising international best practice.

- The following control measures should be implemented by users of the notified polymer or products containing the notified polymer, to minimise exposure of the notified polymer to the environment:
  - Best practice on-site treatment of waste streams should be employed to maximise removal of the notified polymer from waste streams that are released to sewer.

Disposal

- If the notified polymer or products containing the notified polymer cannot feasibly be disposed of using a technique that will destroy the notified polymer, disposal should be to landfill where leaching to the water compartment will be managed.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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 importation volume exceeds 10 tonnes per annum notified polymer;
   - the polymer has a number-average molecular weight of less than 1000;
   - additional information has become available to the person as to an adverse effect of the perfluorohexanoic acid degradation product of the notified chemical;
   - the notified polymer is intended for use in spray products at > 1%;
   - further information on the inhalation toxicity of the notified polymer becomes available;
   - additional information has become available to the person as to an adverse effect of the polyfluoroalkyl degradation products of the notified polymer (such as perfluorohexanoic acid);
   - additional information has become available to the person as to the environmental fate of the notified chemical or its perfluorohexanoic acid degradation product in relation to degradation or partitioning behaviour, including during water treatment processes.

or

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

AICS Annotation

- When the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS) the entry is proposed to include the following statement(s):
  - This polymer has been assessed by NICNAS and there are specific secondary notification obligations that must be met. Potential introducers should contact NICNAS before introduction.

(Material) Safety Data Sheet
The (M)SDS of 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 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, use details, import volume and identity of manufacturer/recipients.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Efka SL 3239 (product containing the notified polymer at a concentration of > 95%)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR, SEC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 98%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Below cut-off concentrations

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Not expected to occur under normal conditions of use.

DEGRADATION PRODUCTS
The notified polymer is a potential precursor for PFHxA in the environment (PFHxA; perfluorohexanoic acid, CAS name: Hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-; CAS No. 307-24-4).

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	Liquid at room temperature
Boiling Point	~ 151 °C at 101.3 kPa	(M)SDS
Density	930 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	$< 1 \times 10^{-7}$ kPa at 25 °C	Measured
Water Solubility	≤ 3.5 mg/L.	Measured

Hydrolysis as a Function of pH	Not determined	The notified chemical contains functional groups which may undergo hydrolysis under extreme pH and temperature. However, hydrolysis is not expected to occur within the environmental pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	Not determined	A low partition coefficient is likely on the basis of its potential to disperse in water. However, it may be present in the form of dispersed particles at phase surfaces/boundaries due to its hydro/lipophobic tendencies.
Adsorption/Desorption	Not determined	Based on the structure the notified polymer is expected to be relatively immobile in soil.
Dissociation Constant	Not determined	The notified polymer does not contain any functional groups which may undergo hydrolysis within the environmental pH range of 4 – 9.
Flash Point	125 °C	(M)SDS
Autoignition Temperature	Not determined	Expected to decompose prior to any autoignition.
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

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 for the 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. The notified polymer will be imported into Australia as a component (> 95%) of the product Efka SL 3239 and reformulated into finished coating products containing the notified polymer at up to 1% concentration.

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

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

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
Efka SL 3239 containing the notified polymer (> 95% concentration) will be imported by sea in 18 kg or 180 kg steel drums, and transported within Australia by road. Finished paints containing the notified polymer will be packaged in 1 L, 4 L and 10 L paint cans and 210 kg steel drums.

USE
The notified polymer is intended to be introduced in order to phase out the use of partially fluorinated polymers containing fluorinated carbon chain lengths > 6 in various proportions (i.e., existing polymer). The use categories of the notified polymer are equivalent to those of the existing polymers that it replaces.

The notified polymer will be a component of industrial and automotive paints. The notified polymer will act as a slip and levelling agent and will be present in paints at concentrations of ≤ 1%. Paints containing the notified polymer are not intended for sale to the public.

OPERATION DESCRIPTION

The imported product, containing the notified polymer at > 95% concentration, will be transferred to the mixing tank by gravity feed or low pressure pumps. The product containing the notified polymer will be added under low speed mixing to a hydrocarbon solvent based solution, with the notifier stating that local exhaust ventilation is expected to be in use. Following blending in the mixing tank, the finished paints (containing the notified polymer at up to 1% concentration) will be filled into 1 L, 4 L and 10 L paint cans and 210 kg steel drums, through gravity feed and low pressure pumps. At the end of the formulation process the paint manufacturing equipment will be flushed with hydrocarbon solvents to clean them. Quality control staff may test samples of the finished products.

Paints and coatings containing the notified polymer (up to 1% concentration) will be used by professional painters and are expected to be applied by a variety of methods including brush, roller and spray.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

The notified polymer may undergo slow degradation in the environment. As such, most potential exposure to workers and the public is expected to be to the notified polymer itself, rather than to its degradation products. Exposure to the residual polyfluoroalkyl starting constituents of the notified polymer is also possible; however, exposure will be limited by their relatively low concentration.

The notified polymer is a potential precursor for perfluorohexanoic acid in the environment. This is likely to lead to secondary human exposure to PFHxA. This exposure is unquantifiable.

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transportation and storage	1	4
Process operator	2.5	40
Quality control	0.5	40
Professional painters	1	60

EXPOSURE DETAILS

Transport and storage workers

Transport and storage workers will only come into contact with the notified polymer (> 95% concentration) in the unlikely event of an accident.

Reformulation processes

Dermal and ocular exposure may occur when workers transfer the product containing the notified polymer (> 95% concentration) into weighing and/or mixing equipment and when connecting or disconnecting transfer hoses. Personal protective equipment (PPE) such as protective clothing, goggles and gloves are expected to be worn during these procedures. Dermal and ocular exposures are also possible during cleaning and maintenance operations. Inhalation exposures are not likely based on the low vapour pressure of the notified polymer and the notifier has stated that local exhaust ventilation is expected to be used to further reduce the possibility of exposure during reformulation processes. The remainder of the formulation process, including packaging, is expected to be mostly automated and exposure is expected to be low.

Paint application

Dermal and ocular exposure to the notified polymer (≤ 1%) may occur during brush, roller or spray application of the finished paints to automobile parts or other objects and when cleaning equipment. Exposure should be minimised where PPE consisting of protective clothing, gloves, and eye protection as recommended by the notifier are worn.

Due to the formation of aerosols, inhalation exposure is possible during spray application. The notifier has stated that respiratory protection and engineering controls such as spray booths will be used during spray application to minimise exposure to the notified polymer.

Workers will likely make dermal contact with the notified polymer after application. However, once the paint is cured, the notified polymer will be reacted into the polymer matrix and will not be bioavailable.

6.1.2. Public Exposure

Efka SL 3239 containing the notified polymer at > 95% will not be sold to the public. Finished paints containing the notified polymer up to 1% concentration may be used by the public; however the specialised equipment and training required to apply the paints would make them of limited and infrequent use. The public will likely make dermal contact with surfaces containing the notified polymer on automobiles and other objects, however once cured the notified polymer is bound within a polymer matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

Toxicokinetics, metabolism and distribution

The notified polymer is not expected to cross biological membranes (skin or gastrointestinal tract) based on its high molecular weight (> 1,000 Da), and the low proportion (< 1%) of low molecular weight species (< 500 Da) (ECHA, 2012).

Inhalation toxicity

Fluorinated polymers have been known to cause lung injury, which is characterised by respiratory problems ranging from mild to severe effects associated with acute or repeated exposures. These effects are generally considered to be of most concern when the compound has surface activity (Fischer *et al.*, 2012).

No repeated dose inhalation studies with the notified polymer have been submitted and thus uncertainties remain surrounding possible chronic respiratory tract effects following repeated exposures to the notified polymer.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Toxicology of break down products

The notified polymer contains perfluoroalkyl side-chains that are potential precursors for PFHxA in the environment (PFHxA; CAS No. 307-24-4). PFHxA is a perfluorocarboxylic acid consisting of 5 perfluorinated carbons (a short chain perfluorinated chemical). The polymer that is proposed for replacement by the notified polymer is expected to break down to perfluorooctanoic acid (PFOA; CAS No. 335-67-1) (consisting of 7 perfluorinated carbons) and other per- and polyfluorocarboxylic substances with longer perfluoroalkyl carbon chain lengths. The toxicokinetic and toxicological properties of the long chain break down products are generally less favourable compared to the short chain break down products with the properties becoming less favourable with increasing perfluoroalkyl carbon chain length. In addition, it has been established that the bioaccumulation potential of perfluorocarboxylic acids increases with perfluoroalkyl carbon chain length (Conder, 2008; Giesy 2010).

A review of the literature indicates that PFHxA has a less hazardous human health profile, compared to PFOA (refer to Appendix B for details). It is therefore inferred that the human health hazards associated with the expected break down product of the notified polymer (PFHxA) are likely to be similar or less than the human health hazards associated with the break down products (PFOA and longer chain perfluorocarboxylic acids) of many per- and polyfluoroalkyl chemicals currently on the market and that are intended for replacement by the notified polymer.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Repeated dermal and ocular exposure to the notified polymer at > 95% concentration by workers may occur during transfer of the imported Efka SL 3239 product to the weighing and/or mixing equipment. Exposure to the notified polymer at up to 1% concentration may also occur when workers apply the finished paints by brush, roller or spray. The use of PPE such as protective clothing, gloves and safety goggles is expected to lower exposure. The notified polymer is expected to have a low potential for systemic hazard due to the predicted negligible absorption across biological membranes based on the high molecular weight (> 1,000 Da) and low levels of low molecular weight species. The local effects of the notified polymer are unknown although the lack of reactive functional groups on the polymer and the low concentrations in the end use products (≤ 1% concentration) will limit its potential for irritancy. Given the expected low hazard of the notified polymer and that the exposure of workers is expected to be minimised through the use of PPE, the risk to workers from repeated exposure is not considered to be unreasonable.

Inhalation exposure to the notified polymer (≤ 1% concentration) will be possible when products containing it are applied by spray. The notifier has stated that respiratory protection and engineering controls such as spray booths will be used during spray application to minimise exposure to the notified polymer. Although lung effects cannot be ruled out, provided controls are in place to minimise exposure, the risk to workers is not considered to be unreasonable.

Systemic exposure of workers to break down products is not expected based on the stability of the notified polymer. Workers may also be exposed to perfluoroalkyl starting constituents of the notified polymer at relatively low concentrations. It is expected that the engineering controls and personal protective equipment utilised during these operations (as outlined above) will act to mitigate any risk associated with such exposure.

6.3.2. Public Health

Paint products containing the notified polymer (up to 1% concentration) may be used by the public on an infrequent basis, with widespread use of the paint products by the public not expected. The paint products will be applied by brush, roller or by spray. As with workers, the potential for systemic or local effects following dermal exposure is expected to be low due to the predicted low absorption and the low concentration in the end use products. However, lung injury from inhalation exposure to the notified polymer cannot be ruled out. Based on the expected infrequent exposure and relatively low concentration in the paint products, the risk to public health from use of paints containing the notified polymer is not considered to be unreasonable.

The public will likely make dermal contact with surfaces containing the notified polymer on automobiles or other objects, however once cured the notified polymer is bound within a polymer matrix and will not be bioavailable, and hence the risk to the public is not considered unreasonable.

The public may be exposed indirectly to PFHxA formed by degradation of the notified polymer in the environment. Such exposure may increase over time due to the persistence of PFHxA in the environment. A quantitative risk assessment for this exposure was not conducted. However, the available data indicates that PFHxA has a more favourable toxicological profile and bioaccumulation potential than the long chain perfluoroalkyl substances that are the ultimate break down products of the majority of perfluoroalkyl polymers currently in Australian commerce (such as PFOA). In particular, it is noted that the polymer being replaced contains perfluoroalkyl carbon chain lengths > 6. It is concluded that the risks to human health from indirect exposure to breakdown products of perfluoroalkyl substances will decrease following introduction of the notified polymer, on the basis that the notified polymer is intended to replace a currently available long chain perfluoroalkyl polymer.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

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

Reformulation of the notified polymer occurs in a closed system and release to atmosphere is expected to be negligible. Solvent used for equipment washing containing residues of the notified polymer are expected to be recycled for reuse on site or disposed of via accredited waste disposal contractors. Wastes and spills (estimated

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. 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 the 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 is has been applied.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be bound within an inert matrix 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 and degradation products containing polyfluoroalkyl functionality. The expected initial polyfluoroalkyl degradation products are assumed to undergo further degradation to form, among other compounds, the very persistent perfluorocarboxylic acid, PFHxA. It is noted that some volatile degradation intermediates have the potential to undergo long range atmospheric transport and thus may result in translocation of PFHxA in the environment.

PFHxA is expected to be recalcitrant in the environment, and potentially undergo long range transport while mainly staying in the water column. In water, it is expected to be very persistent and will not hydrolyse, photolyse or biodegrade.

High-temperature incineration is the preferred method of disposal of poly- and perfluoroalkyl chemicals (and polymers) due to the environmental persistence characteristics, when it results in mineralisation of the perfluoroalkyl functionality to oxides of carbon and hydrofluoric acid. Incomplete combustion of perfluoroalkyl functionality may produce an array of partially oxidised fluorocompounds. Therefore, disposal of the notified polymer and its degradation products by incineration should only take place at facilities that demonstrate complete combustion of the perfluoroalkyl functionality and have adequate measures in place to control release of hydrofluoric acid.

The notified polymer is not expected to bioaccumulate as, due to its high molecular weight, it is not expected to cross biological membranes. The available laboratory (Higgins et al., 2007; Martin et al., 2003a; Martin et al., 2003b; Woodcroft et al., 2010) and field (Falandysz et al., 2006; Falandysz et al., 2007, Furdui et al., 2007) evidence indicates that PFHxA is expected to be less bioaccumulative than PFOA although neither PHFxA nor PFOA are considered bioaccumulative. However, both are bioavailable and can be detected in wildlife as demonstrated by monitoring studies (Kumar et al., 2009; Ye et al., 2008ab; Wang et al., 2008). In general, the available evidence indicates that the bioaccumulation potential of perfluoroalkyl compounds is correlated with increasing carbon chain length (Giesy et al., 2010). Therefore, PFHxA has a lower bioaccumulation potential than PFOA and other long chain perfluoroalkyl substances.

7.1.3. Predicted Environmental Concentration (PEC)

The PEC has not been calculated for the notified polymer because, based on its reported use pattern (including during reformulation), 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 does not contain any functional groups which may undergo hydrolysis within the environmental pH range of 4 – 9. Additionally, significant exposure of the notified polymer to aquatic organisms is unlikely based on the reported use pattern. The majority of the notified polymer will be bound within an inert matrix of cured paints 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 = PEC/PNEC) for the notified polymer has not been calculated because release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a component in industrial 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. Therefore, 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.

Conclusions

On the basis of the assumed low hazard and assessed use pattern, the notified chemical is not considered to pose an unreasonable short-term risk to the environment. However, when the notified polymer is disposed of to landfill, it is expected to very slowly degrade and, potentially, form the persistent chemical, perfluorohexanoic acid (PFHxA). The assessed use pattern of the notified chemical does not control the release of breakdown products into the environment after disposal and the long-term environmental risk profile of PFHxA is currently unknown. Consequently, the long-term risk profile for the notified chemical and its degradation products is unknown.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

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

Method	OECD TG 104 Vapour Pressure.
Remarks	Determined via the effusion method.
Test Facility	BASF (2014)

Water Solubility ≤ 3.5 mg/L at 20 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method. (Column elution not suitable.)
Test Facility	BASF, Ludwigshafen.

APPENDIX B: TOXICOLOGY OF PERFLUOROHEXANOIC ACID (PFHXA)

The following conclusions can be drawn from the data on PFHxA to assess health effects:

1. Absorption of PFHxA in mice and rats was rapid, with C_{max} achieved within 1 hour. Systemic exposure (AUC) was higher in males than in females in both mice and rats, probably as a result of the more rapid clearance in females than in males. Low levels of PFHxA were found in various rat tissues; these decreased rapidly and could not be detected in most tissues by 24 hours. Excretion of unchanged PFHxA was rapid and was largely via the urine. Most of the PFHxA was excreted via the urine within 24 hours, indicating almost 100% bioavailability. There was no evidence of bioaccumulation following repeat exposure in rats. Similar kinetics were observed in monkeys, with rapid absorption, similar exposure for males and females, and rapid and comprehensive urinary excretion of unchanged PFHxA. The volume of distribution in rats and monkeys indicates distribution mainly to extracellular fluid. The serum half-lives were 2.4/5.3 hours (male/female) in monkeys and 1/0.42 hours (male/female) in rats (Chengelis, 2009a; Gannon, 2011).
2. In a study comparing the toxicokinetics of PFHxA to PFOA following repeated oral exposure for 10 days, results indicate that the AUC was 9 times lower for PFHxA, which is attributed to the more rapid excretion of PFHxA. The half-life for PFHxA was 3 times lower than PFOA and persistence in the liver was much lower for PFHxA than PFOA (DuPont, 2003).
3. During seasonal use of ski wax, PFHxA levels in the blood of workers increased during the ski season, then decreased to below the detection limit following cessation of exposure. PFOA levels in blood were also monitored and were found at mostly stable concentrations before, during and after the ski season (elevated compared to the general population). These data suggest that clearance of PFHxA from blood occurs soon after cessation of exposure (Nilsson, 2010).
4. The acute toxicity of PFHxA was low, with an LD_{50} value of >1750 mg/kg bw and <5000 mg/kg bw in female rats. Males are expected to be more sensitive to PFHxA based on higher exposure (AUC) and an expected lower LD_{50} for males (Loveless, 2009). No information was available to assess acute dermal toxicity or acute inhalation toxicity.
5. In repeat dose oral toxicity studies in rats (14 days, 90 days), there was evidence of effects on the liver and decreased haematological parameters at 500 mg/kg bw/day, with liver effects in males at 100 mg/kg bw/day. Nasal lesions (degeneration and atrophy of the olfactory epithelium) were observed at 100 mg/kg bw/day and above in the 90-day study and the NOAEL was 20 mg/kg bw/day in both sexes (DuPont, 2006a; DuPont, 2007a, Chengelis, 2009b).
6. In a 2-year chronic toxicity/carcinogenicity study in rats, there were treatment-related systemic effects (increased incidence of struggling, and papillary necrosis and tubular degeneration of the kidneys) at 100/200 mg/kg bw/day (male/female). The NOAEL for non-neoplastic effects was 15/30 mg/kg bw/day (male/female). There was no evidence of carcinogenicity in either male or female rats (AGC Chemicals, 2010).
7. NaPFHx showed no effect on fertility parameters in a one-generation reproduction study in rats. The NOAEL for maternal systemic toxicity in the P1 animals was 100 mg/kg bw/day based on excessive body weight gain during lactation. There were no biologically significant adverse effects on pups (DuPont, 2007a).
8. In a developmental toxicity study with NaPFHx in rats, there was evidence of maternal (reduced body weight and body weight gain) and foetal toxicity (reduced neonatal bodyweight) at 500 mg/kg bw/day (DuPont, 2007b). In a second developmental toxicity study in mice with ammonium PFHx, foetal toxicity (increased incidence of still births, perinatal death, and microphthalmia and corneal opacity) was noted at 175 mg/kg bw/day in the absence of maternal toxicity. There was no toxicity in pups post-weaning. The NOAEL was 35 mg/kg bw/day (Daikin Industries, 2011).
9. No evidence of genotoxicity was observed in an *in vitro* mutagenicity assay in bacteria (DuPont, 2006b) or in a test for chromosome aberrations in human peripheral blood lymphocytes (DuPont 2006c).

The toxicology of PFOA has been characterised previously (Environment Canada, 2012; Chemical Safety Report, 2009). Comparative analysis of the toxicokinetics of PFHxA and PFOA indicated the following:

- Bioavailability of PFHxA and PFOA after oral administration was high.

- In repeat oral exposure studies, PFHxA showed no evidence of bioaccumulation, whereas PFOA showed some evidence of bioaccumulation.
- Excretion of PFHxA via the urine was rapid and virtually complete over 24 hours, whereas excretion of PFOA was slower, with only 20% excreted over 24 hours.
- Half-lives of excretion of PFHxA after oral exposure were 2–3 hours, whereas the excretion half-life of PFOA was 4.8 days.

Comparative analysis of the toxicity of PFHxA and PFOA indicated the following:

- The acute toxicities of PFHxA and PFOA were low.
- No data were available to compare eye and skin irritation or sensitisation.
- In 90-day repeat dose studies in rats, the LOAEL for PFHxA (100 mg/kg bw/day) occurred at higher doses than for PFOA (0.64 mg/kg bw/day).
- In chronic toxicity studies in rats, the LOAEL for PFHxA (100/200 mg/kg bw/day [m/f]) was higher than for PFOA (14.2/16.1 mg/kg bw/day [m/f]).
- Reproduction studies with PFHxA produced no effect on reproductive parameters with a NOAEL of 500 mg/kg bw/day, whereas PFOA produced increased mortality, decreased bodyweight and delayed sexual maturity in the F1 generation with a NOAEL of 10 mg/kg bw/day in females.
- The LOAEL was 175 mg/kg bw/day for developmental effects in a rat study with ammonium PFHx. The NOEL for developmental effects for PFOA was 150 mg/kg bw/day in a rat study.
- There was no evidence of genotoxicity for PFHxA or PFOA.
- A carcinogenicity study in rats with PFHxA produced no evidence of a treatment-related increase in tumours, whereas a study in rats with PFOA produced an increased tumour incidence in males. The US EPA considers PFOA is “likely to be carcinogenic to humans” (US EPA, 2012).

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