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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Fluoropolymer in Print Cartridge GC Series

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

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

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1962	Ricoh Australia Pty Ltd	Fluoropolymer in Print Cartridges GC Series	Yes	≤ 0.1 tonnes per annum	Component of inkjet printing ink.

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is 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 recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Specific target organ toxicity, repeated exposure (Category 2)	H373 – May cause damage to organs through prolonged or repeated exposure

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.

However, the notified polymer is anticipated to degrade in the environment to release fluorinated degradants similar to perfluorohexanoic acid (PFHxA) that is known to be persistent. Due to environmental distribution of the persistent chemicals, the use of the notified polymer may lead to secondary human exposure to the fluorinated degradants via the environment. The notified polymer is proposed to replace perfluoroalkyl polymers that may release longer chain perfluorocarboxylic acids (PFCAs) in the environment. Longer chain PFCAs are known to be more hazardous to human health with higher bioaccumulation potential compared to shorter chain PFCAs. The overall human health risk posed by the notified polymer is anticipated to be less than that of the perfluoroalkyl polymers it replaces.

Environmental risk assessment
On the basis of the assessed use pattern, the notified polymer itself is not considered to directly pose an unreasonable short-term risk to the environment. However, the notified polymer contains fluorinated carbon groups that have the potential to degrade to the exceptionally persistent short-chain perfluorinated carboxylic acid, 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.

The persistence of chemicals similar to PFHxA in the environment is of concern because they have potential to be globally distributed. Based on the currently available environmental hazard information, PFHxA is considered to have lower overall ecotoxicity concerns than homologous long-chain perfluorocarboxylic acids, which contain seven or more perfluorinated carbon atoms, such as perfluorooctanoic acid (PFOA).

The environmental degradation of the notified polymer is expected to contribute to the cumulative emissions of perfluorohexanoic acid to the environment. Based on the currently available evidence, the concentrations of PFHxA and other short chain perfluorinated carboxylic acids are not considered to pose a concern for the environment. However, if additional hazard information becomes available to indicate that short-chain

perfluorinated carboxylic acids have hazard characteristics of high concern for the environment (such as PBT properties), then the risks posed by industrial uses of precursors to these environmental degradants may need to be re-assessed.

The introduction and use of chemicals that release very persistent fluorinated degradants upon degradation should be considered a short-term measure until suitable alternatives, with less persistent chemistry, are identified.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified polymer should be classified as follows: Specific target organ toxicity, repeated exposure (Category 2): H373 – May cause damage to organs through prolonged or repeated exposure.

  Classification of products/mixtures containing the notified polymer should be considered based on the concentration of the notified polymer present.

CONTROL MEASURES

Occupational Health and Safety

- 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.

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

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

Environment

- The notified polymer should only be introduced as part of a strategy to phase out the use of long chain perfluorinated chemicals, or chemicals that degrade to long chain perfluorinated chemicals.

- The notifier should seek ways to minimise the level of residual polyfluoroalkyl monomers and impurities in the notified polymers. 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 wastewaters.

Disposal

- If the notified polymers or products containing the notified polymers cannot feasibly be disposed of using a technique that will destroy or irreversibly transform the fluoroalkyl components of the notified polymers, disposal should be to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- additional information has become available to the person as to an adverse effect of the fluorinated degradation products of the polymer on human health or the environment
- the importation volume exceeds 100 kg per annum notified polymer
- reformulation or repackaging involving the notified polymer occurs in Australia
- further information becomes available on the genotoxicity of the notified polymer
- further information becomes available on the fluoroalkyl impurity profile 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 inkjet printing ink, or is likely to change 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.

AICS Annotation

- When the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS) the entry is proposed to be annotated with 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.

Safety Data Sheet
The SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Ricoh Australia Pty Ltd (ABN: 30 000593 171)
2 Richardson Place
NORTH RYDE NSW 2113

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1,000 Da (1 tonne or less 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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, 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: vapour pressure, hydrolysis as function of pH, partition co-efficient, adsorption/desorption, particle size, flammability limits, autoignition temperature, explosive properties, oxidising properties, reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/873

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Print Cartridge GC Series (product containing the notified fluoropolymer)

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) < 1,000 Da

ANALYTICAL DATA
Reference GPC, FT-IR, UV, MS and 1H NMR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 80%

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

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Red-brown liquid (ink containing the notified polymer).

Property	Value	Data Source/Justification
Melting Point/Freezing Point	3.3 °C	Measured
Boiling Point	156.2°C at 101.3 kPa	Measured
Density	1,300 to 1,450 kg/m^3 at 20°C	SDS
Vapour Pressure	1.15 x 10^{-10} kPa at 20°C	Calculated
Water Solubility	0.061 g/L at 24 °C	Measured
Hydrolysis as a Function of pH	Not Determined	Contains hydrolysable functionality and may slightly hydrolyse under

		environmental conditions.
Partition Coefficient (n-octanol/water)	Not Determined	Expected to be surface active and expected to partition to phase boundaries.
Adsorption/Desorption	Not Determined	May have low adsorption based on the presence of perfluoroalkyl functionalities that are known to be surface active.
Dissociation Constant	Not Determined	The notified polymer does not contain dissociable functional groups.
Particle Size	Not determined	Imported in liquid product.
Flash Point	188°C at 101 kPa	SDS
Autoignition Temperature	Not determined	Not expected to undergo autoignition based on high flash point.
Explosive Properties	Not determined	Not expected to have explosive properties on basis of structure.
Oxidising Properties	Not determined	Not expected to have oxidising properties on basis of structure.
Surface tension	17.7 mN/m (0.1% in water) at 23°C	Technical data sheet

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 in Australia. The notified polymer will be imported as a component of a finished inkjet printing ink in sealed cartridges at a maximum concentration of < 0.1%. The sealed cartridge capacity is < 100 mL.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Ricoh Australia P/L

TRANSPORTATION AND PACKAGING
The inks containing the notified polymer will be imported in sealed cartridges of capacity < 100 mL. The sealed cartridges will be delivered to the end-user in the original packaging.

USE

The notified polymer (a non-ionic fluoropolymer) will be used as a component of inkjet printing ink (up to 0.1% concentration). Printing is expected to occur mostly on paper. Ink products containing the notified polymer will be used for office and home printing.

The notified polymer is intended to be introduced in order to phase out the use of a partially fluorinated polymer containing fluorinated carbon chain lengths > 8 and higher in various proportions (i.e. existing polymer). The use categories of the notified polymer are identical to those of the existing polymer it replaces.

OPERATION DESCRIPTION

No reformulation or repackaging of the products containing the notified polymer will be carried out in Australia.

Sealed ink cartridges containing the notified polymer will be warehoused before delivery to the end-user in the original packaging. The cartridges will be handled by service technicians, office workers or the public, who will replace spent cartridges in the printers as necessary. The cartridges will be used for printing in offices, retail premises and homes.

When empty, the spent cartridges will be removed from the printer and disposed of to landfill in domestic waste. Refilling of empty cartridges is not recommended by the manufacturer and the manufacturer does not supply refill kits. Spent cartridges are not recycled.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

The notified polymer is expected to 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 and/or impurities of the notified polymer is also possible. Such exposure is limited by the low concentration of polyfluoroalkyl impurities in the notified polymer in the imported products and end-use products.

The notified polymer is a potential precursor for PFHxA in the environment. This may lead to secondary human exposure to PFHxA-like chemicals. This exposure is unquantifiable.

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport workers	2	12-24
Warehouse workers	2-6	260
Printer Service Staff	4	260
Retail workers	8	300
Office workers	8	260

EXPOSURE DETAILS

Transport and storage

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

End use

Workers may be exposed to the notified polymer while changing spent cartridges or during printing processes. Potential routes of exposure to this product during normal use are skin contact and inhalation of vapours and/or aerosols, and possible incidental ocular exposure. However, the concentration of the notified polymer is low (up to 0.1%) and the sealed design of the cartridges is such that exposure to the notified polymer would be limited. In addition, the notified polymer has a relatively low calculated vapour pressure (1.15×10^{-10} kPa). Printing equipment is also supplied with a filter to capture any vapours/mists.

Users of the printers may also be exposed to the notified polymer during handling of printed paper, however, the notified polymer is adsorbed to the paper matrix and not expected to be readily bioavailable except if the paper is handled before the ink has dried (< 5 seconds drying time).

Based on the method of use, worker exposure to the notified polymer is expected to be low.

6.1.2. Public Exposure

The public may be exposed to the notified polymer while changing cartridges, carrying out printing in retail kiosks or at home, or if they handle printed material that has not dried. The exposure is likely to be similar to that of workers, but lower. Overall the exposure of the public to the notified polymer is expected to be low.

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.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50=2710 mg/kg bw (female rats); low toxicity LD50=4300 mg/kg bw (male rats); low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 >5.0 mg/L/4 hour; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation (up to 50%)
Rat, repeat dose oral toxicity –28 days.	NOAEL = 10 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosome aberration test	genotoxic
Genotoxicity – *in vivo* micronucleus test in mice	non genotoxic

Toxicokinetics, metabolism and distribution
Absorption of the notified polymer across biological membranes may be limited by the relatively high molecular weight (> 500 Da) and the expected hydrophobicity. However there are significant levels (40% < 500 Da) of low molecular weight species and the likelihood of absorption cannot be ruled out.

Acute toxicity
The acute oral toxicity of the notified polymer was tested in rats and indicated the notified polymer to be of low acute oral toxicity.

In an acute dermal toxicity study in rats, no clinical signs of toxicity were observed at a dose rate of 2000 mg/kg and it was concluded that the notified polymer is of low toxicity via the dermal route.

An acute inhalation toxicity study in rats indicated low inhalation toxicity for the polymer, however this study did not report any confirmation of the concentration reached in air, or of the particle size.

Irritation and sensitisation
A dermal irritation study showed no evidence of skin irritation in rabbits.

The notified polymer was tested for its eye irritation potential in two rabbits. It is reported to be a slight eye irritant as the slight irritation effects disappeared by 72 hours.

A local lymph node assay in mice indicated that the notified polymer up to 50% concentration was not a skin sensitiser under the conditions of the test.

Repeated dose toxicity
A 28-day repeated dose oral toxicity study of the notified chemical was conducted in rats. Clinical effects were seen in the teeth, liver and kidneys in both male and female animals at a dose of 250 mg/kg bw/day. However, increased relative weight of the kidneys in males was first seen at a dose of 50 mg/kg bw/day, and based on this the NOAEL was established to be 10 mg/kg bw/day. Adverse effects in the kidney included vacuolisation of the tubular epithelium in both males and females and were considered sufficient for classification under the GHS.

Mutagenicity/Genotoxicity
The notified polymer was negative in a bacterial reverse mutation assay.

Although the notified chemical was clastogenic to Chinese hamster lung fibroblasts treated *in vitro,* it was not clastogenic in an *in vivo* mouse micronucleus test. Generally an *in vivo* test will take precedence over an *in vitro* test. However, no clinical signs of toxicity or significant reductions in the PCE/NCE ratio (cytotoxicity) in the *in vivo* test were observed with test substance treatment, therefore it is not known whether the test substance reached the bone marrow.

Health hazard classification
Based on the available information, the notified polymer is 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 recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Specific target organ toxicity, repeated exposure (Category 2)	H373 – May cause damage to organs through prolonged or repeated exposure

Hazard implication of breakdown products
The notified polymer contains polyfluoroalkyl side-chains that are potential precursors of PFHxA in the environment. PFHxA is a perfluorocarboxylic acid consisting of 5 perfluorinated carbons (a short chain perfluorinated chemical). The notified polymer is proposed to replace polymers that are expected to breakdown to form degradants with perfluoroalkyl carbon chain lengths ranging from 6 to 12. It has been known that the toxicokinetic and toxicological properties of fluorinated substances are generally becoming less favourable with increase of perfluoroalkyl carbon chain length. It has also been reported 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 (NICNAS, 2015a). It is therefore inferred that the human health hazards associated with the expected breakdown products of the notified polymer (PFHxA) are likely to be similar or less than those associated with PFOA or longer chain perfluorocarboxylic acids, which are known degradants of many perfluoroalkyl polymers currently on the market and that are intended for replacement by the notified polymer.

6.3. Human Health Risk Characterisation
The notified polymer was not acutely harmful by the oral, dermal and inhalation routes of exposure when tested in rats. It was non-irritating to skin and slightly irritating to eyes in studies carried out in rabbits. Similarly, it was devoid of skin sensitisation potential when tested in a mouse LLNA assay. It was not mutagenic in an *in vitro* Ames assay or in a mammalian erythrocyte micronucleus test *in vivo*, but was clastogenic to Chinese hamster lung fibroblasts treated *in vitro*. Adverse effects in the kidney in a 28-day oral repeated dose study in rats were sufficient for classification according to the GHS criteria.

6.3.1. Occupational Health and Safety
Transport and storage workers will only come into contact with the notified polymer (up to 0.1% concentration) in the unlikely event of an accident.

Exposure of workers to the notified polymer (up to 0.1% concentration) during the use of ink products containing it is expected to be low due to the enclosed automated nature of the printing processes. Workers required to intervene in the process may undergo dermal, ocular and inhalation exposure. Service technicians are expected to wear disposable gloves. Systemic exposures may result from dermal contact with substrates to which ink containing the notified polymer has been applied, however, based on the relatively low concentration in the end-use products and the fact that the majority of the polymer will remain bound to the substrate to which it was applied, exposure is expected to be low.

Some of the notified polymer is expected to be absorbed dermally and therefore workers exposed to the polymer at up to a 0.1% concentration could be at risk of systemic toxicity. In addition, service technicians are expected to use disposable gloves, thereby reducing dermal exposure. Based on the automated and enclosed nature of the processes, the relatively low concentration of the notified polymer in the end use products, and the use of PPE the risk of systemic toxicity to workers is not considered to be unreasonable.

Workers may also be exposed to per- and polyfluoroalkyl impurities of the notified polymer at low concentrations (< 0.1%), during use. It is expected that the PPE utilised during these operations (as outlined above) will mitigate any risk associated with such exposure.

6.3.2. Public Health

The public may also be exposed to the notified polymer and low levels of per- and polyfluoroalkyl impurities from direct dermal contact with articles that have been printed with inks containing the notified polymer. This exposure may be on a long term repeated basis. However, dermal transfer from the treated article is expected to be low as the notified polymer will be present at low concentrations and will predominantly remain absorbed to the substrate to which it was applied. Thus, the risk to public health from repeated dermal exposure to the notified polymer from treated articles is not considered to be unreasonable. The risk to public health from long term repeated dermal exposure to per- and polyfluoroalkyl impurities of the notified polymer from treated articles may be mitigated by the extremely low concentrations at which they are present in end use products.

The public may be exposed indirectly to the ultimate break down product of the notified polymer, PFHxA, via the environment. Such exposure may increase over time due to the persistence of PFHxA in the environment. However, the available data indicates that PFHxA has lower bioaccumulation potential than the long chain perfluoroalkyl substances (such as PFOA) that are the ultimate break down products of long chain perfluoroalkyl polymers currently in Australian commerce. 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 polymers.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a component of inkjet printer ink in sealed ready-to-use ink cartridges. Release of the ink solution to the environment is not expected, as manufacturing, reformulation and packaging of the ink containing the notified polymer will not take place in Australia. Environmental release of the notified polymer is likely to be limited to accidental spills and leaks (estimated by the notifier to be about 10 g of the notified polymer per year).

RELEASE OF CHEMICAL FROM USE

During use, the majority of the notified polymer will be cured within an inert ink matrix and bound to paper substrates, and will not be released from printed paper substrates. It is estimated by the notifier that approximately 10% of the ink containing the notified polymer will remain in spent cartridges. The ink remaining in the ink cartridges during the cartridge recycling process will not be reused, and will be disposed of to landfill

with the packaging in accordance with local government regulations. Environmental release of the notified polymer is possible during paper recycling and from the disposal of used print cartridges.

RELEASE OF CHEMICAL FROM DISPOSAL
Following use, spent ink cartridges containing residues of the notified polymer will be collected for recycling by the distributor, or be disposed of to landfill in accordance with local government regulations. Ink residues containing the notified polymer separated from the spent cartridges will be disposed of in accordance with local government regulations, most likely to landfill.

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 remainder will undergo paper recycling processes. During paper recycling processes, waste paper is repulped using a variety of chemical treatments which, amongst other things, will enhance ink detachment from the fibres. Waste water containing the notified polymer will be released to sewer.

7.1.2. Environmental Fate

The notified polymer is not readily biodegradable (1 % in 28 days). For details of the environmental fate study, please refer to Appendix C. 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.

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 likely to be mobile in the environment, due to its limited solubility in water and potential to adsorb to soil and sediment, based on its expected surfactant properties. Therefore, a significant portion of the notified polymer is expected to partition to sludge during wastewater treatment processes in sewage treatment plants (STPs). Thus, very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. However, the notified polymer has the potential to bioaccumulate given the polymer is a polyfluoroalkyl polymer with significant levels (40% < 500 Da) of low molecular weight species.

The notified polymer will eventually degrade in landfill and has the potential to release per- and polyfluoroalkyl degradation products, including short-chain perfluorinated carboxylic acids, such as perfluorohexanoic acid (PFHxA).

PFHxA is a globally distributed pollutant and is expected to be recalcitrant in the environment, 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 under environmental conditions (NICNAS, 2016a).

PFHxA is expected to be less bioaccumulative than perfluorooctanoic acid (PFOA) and other long-chain perfluoroalkyl acids, supported by the available laboratory (Higgins et al., 2007; Martin et al., 2003a, b; Woodcroft et al., 2010) and field (Falandysz et al., 2006; Falandysz et al., 2007, Furdui et al., 2007) evidence. In general, bioaccumulation potential decreases when the length of the perfluorinated carbon chain is decreased (Ng and Hungerbühler, 2014, Giesy et al., 2010). The short-chain perfluorocarboxylic acids, including PFHxA, have been assessed to have low bioaccumulation potential based on the currently available information (NICNAS, 2016a, b).

7.1.3. Predicted Environmental Concentration (PEC)

PEC for the notified polymer
Under a worst case scenario, 50 kg per year (i.e. 50% of the import volume) of the notified polymer bound to printed paper will enter sewers during recycling processes. A rough predicted environmental concentration (PEC) calculation showed that the amount of the notified polymer released to the environment from sewage effluent is expected to be negligible. Thus, a PEC has not been calculated for the notified polymer because, based on its reported use pattern and import volume, significant quantities are not expected to be released to the aquatic environment.

PEC for PFHxA and other perfluorocarboxylic acids
The notified polymer has the potential to degrade and ultimately form the persistent degradant, PFHxA. However, the yield and rate of conversion of the notified polymer to PFHxA has not been established.

Environmental monitoring data shows that PFHxA and PFOA are widely found in the environment, particularly in fresh water close to industrial sources, but also in some biota. Water appears to be the main compartment where PFHxA is found. High measured concentrations of both PFHxA and PFOA in surface waters in Germany have been associated with the legal application of waste materials to agricultural soils (Skutlarek et al., 2006), indicating that these chemicals have the potential to enter the aquatic compartment following initial release into the soil compartment.

Some larger available data sets from the literature (McLachlan et al., 2007; Skutlarek et al., 2006; Nakayama et al., 2007; So et al., 2007; Ahrens et al., 2009) include monitoring from a range of rivers in Europe, the USA and China, along with data from the Atlantic Ocean. Using these data (n ≥60), the 10th, 50th and 90th percentile concentrations for PFHxA are 1.0, 6.15 and 22.5 ng/L respectively, while those for PFOA are 2.94, 11.85 and 231.9 ng/L respectively. As use of chemicals that degrade to form PFHxA increases, levels of PFHxA may build up further in the environment.

Analyses of drinking water samples from Europe, Canada, the USA, Japan, India and China have also detected PFHxA and other short chain perfluoroalkyl compounds. PFHxA was recently detected in all samples taken from the Parramatta River (main tributary of Sydney Harbour), with a mean concentration of 2.9 ng/L. Sampling of the Brisbane River catchment following a major flooding event in 2011 also found PFHxA present in water at Somerset Dam, Wivenhoe Dam, Jindalee, Oxley Creek, West End, Bulimba and Moreton Bay. The chemical was detected in all samples obtained at these sites in concentrations ranging between 0.06 and 6.2 ng/L (NICNAS, 2016a).

PFHxA and other poly- and perfluoroalkyl compounds have also been found in landfill leachate, with concentrations of PFHxA ranging from 270 – 790 ng/L (Huset et al., 2011). As landfills are reservoirs of solid waste, and receive waste water treatment plant sludge, which may contain poly- and perfluoroalkyl compounds, landfills have the potential to continue to release PFHxA and homologous perfluorinated carboxylic acids well into the future.

The lifetime of PFHxA in the aquatic environment is unknown, but is expected to be comparable to the very long lifetimes established for homologous perfluorinated acids such as PFOA and PFOS (NICNAS, 2016 c, d).

7.2. Environmental Effects Assessment

Effects of the notified polymer
The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 60 mg/L	Not harmful to fish up to the limit of solubility
Daphnia Toxicity	48 h EC50 > 61 mg/L	Not harmful to aquatic invertebrates up to the limit of solubility
Algal Toxicity	72 h E_rC50 > 57 mg/L 72 h NOE_rC = 1.9 mg/L	Not harmful to algae up to the limit of solubility

Based on the above ecotoxicological endpoints, the notified polymer is not expected to be harmful to aquatic life up to the limit of its water solubility. No chronic data was provided. Therefore, it is unclear whether the notified polymer has long-term intergenerational effects to aquatic life. The notified polymer is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic toxicities.

Effects of PFHxA and other perfluorocarboxylic acids
The current available data, summarised in the *NICNAS IMAP Environment Tier II Assessment for Short-Chain Perfluorocarboxylic Acids and their Direct Precursors*, indicate that PFHxA and other short-chain perfluorinated acids (i.e. those with five or fewer perfluorinated carbon atoms) have low toxicity to aquatic life (NICNAS, 2016a,b) compared to PFOA and perfluorooctanesulfonic acid (PFOS) (NICNAS 2016c,d). However, no long-term intergenerational studies were identified for PFHxA and other short chain PFCAs. Emerging

evidence suggests that the most significant aquatic toxicity effects of PFOA and PFOS may manifest in offspring when the parent generation is exposed to PFOA or PFOS (NICNAS, 2016 c, d)

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 and import volume, 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 significant quantities is not expected based on its use pattern as a component of inkjet printing ink and its import volume.

However, the notified polymer has the potential to eventually degrade to form very persistent PFHxA. PFHxA is currently understood to have low potential for bioaccumulation (NICNAS, 2016a). The currently available data also indicate that PFHxA and other short-chain perfluorocarboxylic acids and their direct precursors have low toxicity to aquatic life (NICNAS, 2016a, b).

The main environmental risks associated with polyfluoroalkyl polymers relate to the release of perfluorinated degradation products such as PFHxA. It is not possible to quantify the release of PFHxA to the environment from the use of the notified polymer at present. However, as use of chemicals/polymers that degrade to form PFHxA increases, levels of PFHxA may build up in the environment. Hence, there is potential for environmentally significant concentrations to eventually be reached following its accumulation in the environment. In this eventuality, precursors of PFHxA such as the notified polymer cannot be recalled after release and are potential sources of PFHxA releases into the environment even long after their use ceases. Thus, use and disposal of the notified polymer will likely lead to increases in the levels of PFHxA in the environment.

Conclusions

On the basis of the assessed use pattern, the notified polymer itself is not considered to directly pose an unreasonable short-term risk to the environment. However, the notified polymer contains fluorinated carbon groups that have the potential to degrade to the exceptionally persistent short-chain perfluorinated carboxylic acid, perfluorohexanoic acid (PFHxA).

The environmental degradation of the notified polymer is expected to contribute to the cumulative emissions of perfluorohexanoic acid to the environment. Based on the currently available evidence, the concentrations of PFHxA and other short-chain perfluorinated carboxylic acids are not considered to pose a concern for the environment. However, if additional hazard information becomes available to indicate that short-chain perfluorinated carboxylic acids have hazard characteristics of high concern for the environment (such as PBT properties), then the risks posed by industrial uses of precursors to these environmental degradants may need to be re-assessed.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/ 3.3 °C

Method	OECD TG 102 Melting Point/Melting Range. State Environmental Protection Administration (SEPA) of China, No. 102.
Remarks	Differential scanning calorimetry (DSC). Purity of test substance > 99%.
Test Facility	Guizhou (2009a).

Boiling Point 156.2 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point. State Environmental Protection Administration (SEPA) of China, No. 103.
Remarks	Dynamic method. Purity of test substance > 99%.
Test Facility	Guizhou (2009b).

Water Solubility 0.061 g/L at 24 °C

Method	Conducted in the preliminary test of OECD TG 203 Fish, Acute Toxicity Test
Remarks	The test sample and dilution water were mixed and stirred for 24 to 48 hours
Test Facility	CERI (2009f)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified polymer

METHOD: Similar to OECD TG 401 Acute Oral Toxicity (carried out according to Guidelines for the Testing of Chemicals Section 4: Health Effects (ministry of environmental protection of People's Republic of China).

Species/Strain: Rat/SD
Vehicle: Oil
Remarks - Method: No significant protocol variations. The study included Quality Assurance certificate.
The acute oral toxicity of the notified polymer was tested at doses of 1000, 2150, 4640 and 10,000 mg/kg bw with 5 animals per sex in each group, as well as the control group.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*	
			Male	*Female*
1	5/sex	0	0/5	0/5
2	5/sex	1,000	0/5	0/5
3	5/sex	2,150	0/5	1/5
4	5/sex	4,640	3/5	5/5
5	5/sex	10,000	5/5	5/5

LD50: 2,710 mg/kg bw for females
4,300 mg/kg bw for males
Signs of Toxicity: All deaths occurred within 3 days of dosing and all clinical signs in surviving animals had resolved by day 6. Clinical signs included cachexia (weakness), blood discharge, slow breathing, unbalanced movement, dirty perineum and urine incontinence.
Effects in Organs: None.
Remarks - Results: No obvious abnormalities were noted at necroscopy in any of the treated or control animals.

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

TEST FACILITY: IAT (2009a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified polymer

METHOD: Similar to OECD TG 402 Acute Dermal Toxicity (carried out according to Guidelines for the Testing of Chemicals Section 4: Health Effects (ministry of environmental protection of People's Republic of China).

Species/Strain: Rat/SD
Vehicle: None.
Type of dressing: Occlusive
Remarks - Method: No significant protocol deviations. The study included GLP certificate.
The study was conducted in two groups, the single dose group of 2000 mg/kg bw and a control group, with 5 females and 5 males per group. The test substance was administered to the sheared area on the back of the animal as supplied (purity ≥ 99%). Clinical signs and mortality were observed for 14 days after dosing.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	0	0/5
2	5/sex	2,000	0/5

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks - Results	No mortalities. No abnormal clinical findings.

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

TEST FACILITY IAT (2009b)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE Notified polymer

METHOD Similar to OECD TG 403 Acute Inhalation Toxicity (carried out according to Guidelines for the Testing of Chemicals Section 4: Health Effects (ministry of environmental protection of People's Republic of China).

Species/Strain	Rat/SD
Vehicle	Oil
Method of Exposure	Whole-body exposure.
Exposure Period	4 hours
Physical Form	Liquid aerosol
Remarks - Method	The protocol may vary from that of OECD TG 403, in that the actual concentration in air or the particle size generated was not reported, and may not have been measured. The study included a quality assurance certificate. The study was conducted in two groups, the single dose group of 5 mg/L and a control group, with 5 females and 5 males per group.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <units>*		*Mortality*
		Nominal	*Actual*	
1	5/sex	0 mg/L	0 mg/L	0/5
2	5/sex	5 mg/L	Not determined	0/5

LC50	> 5 mg/L/ 4 hours
Signs of Toxicity	Cachexia and salivation.
Effects in Organs	None
Remarks - Results	No mortalities. No abnormal clinical findings at the end of the study.

CONCLUSION The notified polymer is of low toxicity via inhalation.

TEST FACILITY IAT (2009c)

B.4. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

	EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 males.
Vehicle	None
Observation Period	3 days.
Type of Dressing	Semi-occlusive.
Remarks - Method	A pre-screen test was performed using the Transcutaneous Electrical Resistance (TER) Assay, which confirmed that the notified polymer is not corrosive. No significant protocol variations. Two rabbits were tested. GLP certificate was included. 0.5 ml of the test substance as supplied (purity ≥ 99%) were applied to three sites on the animal's back. The patches were removed at 3 min, 1 and 4 hours, and the test sites were examined for skin irritation immediately after the patch removal and 1, 24, 48 and 72 hours later.
Remarks - Results	No erythema/oedema were observed in the tested animals at any of the exposure times.
CONCLUSION	The notified polymer is non-irritating to the skin.
TEST FACILITY	Harlan (2009a)

B.5. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	2
Observation Period	3 days
Remarks - Method	Two animals were used. GLP certificate was included. 0.1 ml of the test substance as supplied was administered into the right eye of the animal. The assessment of the ocular damage/irritation was made 1, 24, 48 and 72 hours following the treatment. The assessment and scoring was done according to a modified Kay and Calandra classification system.

RESULTS

Lesion	*Mean Score* Animal No.*		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2			
Conjunctiva: redness	1	1	2	< 72 h	0
Conjunctiva: chemosis	0.66	0.33	2	< 72 h	0
Conjunctiva: discharge	0.33	0.33	2	< 48 h	0
Corneal opacity	0	0	0	0	0
Iridial inflammation	0	0	0	0	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	No corneal or iridal inflammation effects were noted during the test. The average conjunctival irritation scores for the 2 animals were 1, 0.5 and 0.33 for redness, chemosis and discharge, respectively. All signs of redness and chemosis had disappeared by the 72 hour of observation and signs of discharge by the 48 hour of observation.
CONCLUSION	The notified polymer is slightly irritating to the eye.

TEST FACILITY Harlan (2009b)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified polymer

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Dimethyl formamide
Preliminary study	Yes
Positive control	15% v/v α-Hexylcinnamaldehyde (HCA) in dimethyl formamide.
Remarks - Method	No significant protocol deviations. Four female mice per dose group were used in the main test and one mouse per group was used in the preliminary test with the control (vehicle only). The stimulation index for the 3 dose groups is shown below.

RESULTS

Test Substance Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
0 (vehicle control)	4F	582.12	n/a
10	4F	829.48	1.42
25	4F	1065.99	1.83
50	4F	1167.59	2.01
Positive Control (periodic study)			
0 (vehicle control)	5	Not reported	n/a
15	5	Not reported	4.24

Remarks - Results Based on the stimulation index not exceeding 3 at any of the dose rates tested, the notified polymer at up to 50% concentration was not considered to be a skin sensitiser under the conditions of the test. As there was a dose response relationship in the sensitisation values and the maximum concentration tested was 50%, the possibility that the notified polymer may eventually reach a stimulation index of 3 at concentrations above 50% (and thereby be a weak sensitiser) cannot be ruled out.
The periodic positive control study indicated that α-Hexylcinnamaldehyde had a stimulation index >3, confirming the validity of the test protocol.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer up to 50% concentration.

TEST FACILITY Harlan (2009c)

B.7. Repeat dose toxicity

TEST SUBSTANCE Notified polymer

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain	Rats/SD
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 Dose regimen: Daily from day 1 to 28. Post-exposure observation period: 14 days
Vehicle	Purified water
Remarks - Method	The study was conducted at three dose rates (10, 50 and 250 mg/kg bw/day) as well as a vehicle control group with 5 rats per sex in each group. Additional recovery groups were also used for the control (vehicle only) and the high dose group.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5/sex	vehicle only	0/10
low dose	5/sex	10	0/10
mid dose	5/sex	50	0/10
high dose	5/sex	250	0/10
control recovery	5/sex	vehicle only	0/10
high dose recovery	5/sex	250	0/10

Mortality and Time to Death	None
Clinical Observations	Whitish change of the incisors and mottled teeth were observed in high dose males. During the recovery period, whitish and mottled teeth in high dose males and mottled teeth in high dose females were observed. Salivation was observed just after dosing in high dose males and females. Body weights were decreased in high dose males. Food consumption was decreased in high dose males and females and in high dose males on day 4 and 8 of recovery.
Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis	No effects of the tested substance on haematological examinations were observed. Increased alkane phosphatase (ALP) and γ-glutamyl transpeptidase (γ-GTP) were observed in high dose males. Increased urine volume and decreased urine osmotic pressure were noted in high dose males and increased epithelial cells in one high dose female, however the significance of these effects is not clear.
Effects in Organs	In the liver, increased absolute and relative weights of the liver, enlargement of the liver, hypertrophy of the centrilobular hepatocytes and microgranuloma were observed in the high dose groups. In the kidney, vacuolization of the tubular epithelium in the high dose groups was observed. Increase in the relative kidney weights were also observed in males in all dose groups and in high dose females.
Remarks – Results	Apart from mottled teeth, all adverse effects had resolved or been significantly reduced in the recovery group animals. The study authors considered that the effects seen in teeth, liver and kidneys were likely to be caused by fluorine toxicity.

CONCLUSION	The No Observed Adverse Effect Level (NOAEL) was established by the study authors as 10 mg/kg bw/day in this study based on increased (12.5%) relative weight of the kidneys in males in the 50 mg/kg bw/day dose group. Kidney effects (increased relative weight and vacuolisation of the tubular epithelium) were observed in both, male and female rats at 250 mg/kg bw/day.
TEST FACILITY	CERI (2009a)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria (2008).
Species/Strain	*Salmonela typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 microsomal fraction from phenobarbital/5, 6-benzoflavone-induced rat liver
Concentration Range in	All *Salmonella* strains and *E. coli* strain
Main Test	With and without metabolic activation: 313-5000 µg/plate
Vehicle	Purified water
Remarks - Method	There were no deviations from the standard protocol. GLP certificate was included. Dose-range finding test (5-5000 µg/plate) and two main tests (313-5000 µg/plate) were performed by the pre-incubation method in the presence and absence of metabolic activation in all *Salmonella* and one *E. coli* strains. The number of revertant colonies was counted after incubation at 37ºC for 48 hours. The dose-range finding test was performed to determine the toxicity of the test material in the presence and absence of metabolic activation in all test strains. Main test-2 was carried out at same doses set in the main test-1 to confirm the reproducibility of the results. <u>Dose range finding test</u>: All *Salmonella* strains and *E. coli* strain with and without S9: 5, 20, 78, 313, 1250 and 5000 µg/plate <u>Main test 1 and 2</u>: All *Salmonella* strains and *E. coli* strain with and without S9: 313, 625, 1250, 2500 and 5000 µg/plate

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2		> 5000	> 5000	Negative
Present				
Test 1		> 5000	> 5000	Negative
Test 2		> 5000	> 5000	Negative

Remarks - Results	There was no test substance precipitation or inhibition of bacterial growth observed. The notified polymer did not significantly increase the number of revertant colonies in any of the tested strains.

CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	CERI (2009b)

B.9. Genotoxicity – *in vitro*

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	Lung fibroblasts (CHL/IU cells)
Metabolic Activation System	S9 microsomal fraction from phenobarbital/5, 6-benzoflavone-induced rat liver
Vehicle	DMSO
Remarks - Method	There were no deviations from the standard protocol. GLP certificate was included. The positive controls used were mitomycin C and cyclophosphamide monohydrate in the absence and presence of metabolic activation respectively. A test was also conducted with a 24 hour exposure period but chromosome aberrations in this test were not recorded, as the clastogenicity of the test substance had been demonstrated in the short-term tests.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	8, 20*, 50*, 125*, 313*, 625*, 1250*, 2500*, 5000	6 hours	24 hours
Present			
Test 1	8, 20*, 50*, 125*, 313*, 625*, 1250*, 2500*, 5000	6 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 2500	≥ 2500	≥ 2500	positive
Present				
Test 1	≥ 2500	≥ 1250	≥ 2500	positive

The frequency of the structural and numerical aberrations in the absence and presence of metabolic activation are shown in the table below.

Without metabolic activation		
Dose (µg/mL)	Structural aberration (% cells)	Numerical aberration (% cells)
0	3.0	0
20	3.5	1.5
50	4.5	5.0
125	1.5	3.5
313	3.0	2.5
625	7.0	2.0
1250	10.5	0.5
2500	20.5	0
mitomycin	54.5	1.5

With metabolic activation		
Dose (µg/mL)	Structural aberration (% cells)	Numerical aberration (% cells)
0	0	1.5
20	3.0	1.0
50	0.5	1.5
125	1.0	7.0
313	4.0	5.0
625	8.0	3.5
1250	16.5	1.0
cyclophosphamide	38.5	0

Remarks – Results

The notified polymer produced significant increases in structural aberrations and a slight increase in numerical aberrations over the control values in both the presence and absence of metabolic activation. The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

The notified polymer was clastogenic to Chinese hamster lung fibroblasts treated *in vitro* under the conditions of the test.

Test Facility

CERI (2009c)

B.10. Genotoxicity – *in vivo*

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mouse/ICR

Route of Administration: Oral – gavage

Vehicle: Corn oil

Remarks - Method: There were no deviations from the standard protocol. GLP certificate was included.

Doses were determined on the basis of a preliminary toxicity test. The ratio between polychromatic and normochromatic erythrocytes was determined in the same sample and reported as number of polychromatic erythrocytes (PCEs) per 2000 erythrocytes in order to detect any cytotoxic effect due to the treatment with the test item.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5M	0	24
II (low dose)	5M	500	24
III (mid dose)	5M	1000	24
IV (high dose)	5M	2000	24
V (positive control*)	5M	1	24

*M=mitomycin C

RESULTS

Group	*Dose mg/kg bw*	*PCEs with micronuclei (Mean ± SD)*	*PCE/2000 erythrocytes (Mean ± SD)*
I (vehicle control)	0	2.0 ± 0.7	0.4 ± 0.01
II (low dose)	500	1.2 ± 0.8	0.39 ± 0.01
III (mid dose)	1000	2.4 ± 1.1	0.38 ± 0.01
IV (high dose)	2000	1.6 ± 0.7	0.38 ± 0.01
V (positive control)	1	26.6 ± 5.3	0.37 ± 0.02

Doses Producing Toxicity	None
Genotoxic Effects	None
Remarks - Results	The test substance induced no statistically significant increases in micronucleated polychromatic erythrocytes (PCEs). No clinical abnormalities were observed in the negative control or treated animals during the test period and there were no significant changes in body weights in any of the test groups. Although the PCE/NCE ratio seemed to have a dose related decrease, the study authors reported that this change was not statistically significant. The positive control caused a significant increase in the frequency of micronucleated immature erythrocytes, demonstrating the sensitivity of the test. In animals treated with the positive control a statistically significant decrease in the proportion of erythrocytes was observed, indicating bone marrow cell toxicity at this dose. As no clinical signs of toxicity or significant reductions in the PCE/NCE ratio (cytotoxicity) were observed with test substance treatment, it is therefore not known if the test substance reached the bone marrow.
CONCLUSION	The notified polymer was not clastogenic under the conditions of this *in vivo* mouse micronucleus test.
TEST FACILITY	Medvill (2010)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Determination of carbon dioxide by chemical titration
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles. As the test substance was difficult to dissolve in water, stock solution was not prepared. The test substance (61 mg) was directly added to the test system. The degradation was determined by the amount of production of carbon dioxide.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	0	14	75
7	3.2		
10	13		
14	20		
20	25		
28	26		

Remarks - Results	The percentage degradation of the reference compound (sodium benzoate) was determined to be 75% after 14 days, passed the threshold level of 60% for ready biodegradability. Therefore, the tests indicate the suitability of the inoculums. The toxicity control showed 48% biodegradation on day 14, indicating the notified chemical did not inhibit the microbial degradation of the reference substance.
CONCLUSION	The notified polymer is not considered to be readily biodegradable.
TEST FACILITY	LEES (2009)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	Method for Testing the Biodegradability of Chemical Substances by Microorganisms (Testing Methods for New Chemical Substances, No.1121002, Ministry of Environment, Japan)
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical oxygen demand (BOD) measured with an oxygen measuring apparatus Test substance measured with HPLC
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
28	1	14	73

Remarks - Results	The percentage degradation of the reference compound (aniline) surpassed the threshold level of 60% after 14 days (73%). The difference of extremes of replicate values of percentage biodegradation is <20%. The degree of degradation of the test substance after 28 days was 1% based on BOD. Therefore, the validity criterion of the test are satisfied.
CONCLUSION	The notified polymer is not considered to be readily biodegradable.
TEST FACILITY	CERI (2009d)

C.1.3. Bioaccumulation

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 305 Bioconcentration: Flow-through Fish Test.
Species	
Exposure Period	Exposure: 60 days Depuration: Not reported
Auxiliary Solvent	None
Concentration Range	Nominal: 1 and 10 µg/L Actual: 0.96 – 0.99 µg/L and 9.54 – 9.74 µg/L
Analytical Monitoring	Liquid chromatography-tandem mass spectrometry
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles. The test was conducted under flow-through conditions, using groundwater from the premises of the laboratory. Fish were fed twice a day in halves at about 2% total body weight. Fish were starved for 24 hours before sampling. Pentachlorophenol sodium salt was used as the reference compound. Lipid content in the control test fish were determined using gravimetric analysis.
RESULTS	
Bioconcentration Factor	BCF = < 260
CT50	Not determined
Remarks - Results	The change of lipid content of the sample after the experiment completion was ±39% compared to the sample before the experiment, exceeds ±25%, due to the extremely long exposure period. This change is not expected to affect the evaluation of bioconcentration as a steady-state was reached after 60 days. All validity criteria for the test were satisfied. No abnormality in behaviour or appearance were observed during the uptake test period. The measured concentrations of the test item was maintained more than 92% of each nominated concentration. The depuration phase was not reported in the test report.
CONCLUSION	The notified polymer is not considered to be bioaccumulative.
TEST FACILITY	CERI (2009e)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer

METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Medaka (*Oryzias latipes*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	32 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles. The test sample and dilution water was mixed to produce 100 mg/L (nominal concentration). The mixture was stirred with a magnetic stirrer for approximately 24 hours to prepare the test solution.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Actual		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	8	0	0	0	0	0
60	8	0	0	0	0	0

LC50	> 60 mg/L at 96 hours.
NOEC (or LOEC)	Not determined
Remarks – Results	All validity criteria of the test guideline were satisfied. This study was conducted as a limit test to confirm the effect of the test substance on fish around the solubility of the test item in dilution water. The water solubility was measured at 61 mg/L. The test item in the test solution were maintained within ± 20% of the nominal concentrations. The 96 h LC50 for fish was determined to be > 60 mg/L based on geometric mean of the measured concentrations.
CONCLUSION	Under the study conditions, the notified polymer is not harmful to fish up to the limit of its water solubility.
TEST FACILITY	CERI (2009f)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	32 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted in accordance to the test guidelines above with a deviation that water hardness in the test solutions is 32 mg $CaCO_3$/L, which is out of the range 140-250 mg $CaCO_3$/L as recommended by the test guideline. The test was conducted in compliance with GLP standards and principles. The test sample and dilution water was mixed to produce 100 mg/L (nominal concentration) and stirred for approximately 24 hours. They were then filtered to prepare the stock solution which was diluted accordingly with dilution water to prepare the test solutions.

RESULTS

Concentration mg/L		*Number of D. magna*	*Immobilised (%)*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
Control	Control	20	0	0

35	21	20	0	0
46	29	20	0	0
59	36	20	0	0
77	47	20	0	0
100	61	20	10	35

EC50	> 61 mg/L at 48 hours
NOEC (or LOEC)	Not determined
Remarks - Results	All validity criteria of the test guideline were satisfied. This study was conducted to confirm the EC50 of the test item on the test organisms at concentrations below the solubility of the test item in dilution water. The test solutions were not renewed during the 48 h test period. The measured concentrations of the test item in the test solution at the end of the exposure were between 95-101% of those at the start of exposure. The maximum concentration causing no immobility at 48 hours was 47 mg/L. The 48 h EC50 for Daphnia was determined to be > 61 mg/L based on geometric mean measured concentrations.
CONCLUSION	Under the study conditions, the notified polymer is not harmful to aquatic invertebrates up to the limit of its water solubility.
TEST FACILITY	CERI (2009g)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 1.0, 3.2, 10, 32 and 100 % of stock solution content Actual: Control, 0.52, 1.9, 5.9, 18 and 57 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	HPLC
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles. The test sample and medium were mixed to produce 100 mg/L (nominal concentration) and stirred for approximately 24 hours. They were then filtered to prepare the stock solution which was diluted accordingly with medium to prepare the test solution.

RESULTS

Biomass		*Growth*	
EC50 *mg/L at 72 h*	*NOEC* *mg/L*	*EC50* *mg/L at 72 h*	*NOEC* *mg/L*
Not reported	Not reported	>57	1.9

Remarks - Results	All validity criteria of the test guideline were satisfied. The 72 h EC50 and NOEC based on growth rate for algae were determined to be >57 mg/L and 1.9 mg/L, respectively, based on geometric mean measured concentrations. The concentrations of the test item in the test solutions were kept within ±20% of those at the start of exposure.
CONCLUSION	Under the study conditions, the notified polymer is not harmful to algae up to the limit of its water solubility.

TEST FACILITY	CERI (2009h)

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