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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Fluorosurfactant Polymer #2 in HP inkjet inks

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett Packard Australia Pty Ltd (ABN 74 004 394 763), of 3 Richardson Place, North Ryde, NSW 2113

NOTIFICATION CATEGORY
Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, Import Volume, Concentration of notified polymer in ink, and Marketing name of ink.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada and the EU

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Fluorosurfactant Polymer #2 in HP inkjet inks

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >1000

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

Although the notified polymer contains perfluorinated carbon chains, it meets the PLC criteria as these groups are of less than or equal to four carbons in length.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Viscous hazy colourless liquid
Melting Point/Glass Transition Temp	<2°C (temperature at which liquid ceased movement)
Boiling point	>275°C (Value from MSDS)
Density	1,250 kg/m^3 at 20°C
Water Solubility	<3.94 mg/L at 20.2 ± 0.8°C (OECD TG 105)
Partition Coefficient	$logP_{ow}$ = >5.4 at 20°C Estimated from the solubility of the test substance in n-octanol (>967 g/L) and water (<3.94 mg/L) at 20.2 ± 0.8°C.
Reactivity	Stable under normal environmental conditions. Exothermic reaction or decomposition occurs at ≥115°C.
Degradation Products	None under normal conditions of use. Does not contain any groups that could potentially undergo hydrolysis.

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Volume	< 50 kg	< 50 kg	< 50 kg	< 50 kg	< 50 kg

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported as a component of inkjet printing inks in pre-packed cartridges. The inks will contain a maximum of <1% notified polymer.

Reformulation/manufacture processes

No reformulation or repackaging of the imported product containing the notified polymer occurs in Australia.

Use

The notified polymer is a component of inkjet printing inks (<1%) where it acts as a surface-active agent. Sealed ink cartridges containing the notified polymer will be used as necessary to replace spent cartridges in inkjet printers. Office workers and the public will use these printers for varied printing work. The ink cartridges containing the notified polymer are designed for a single use, and will not be refilled.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport and storage

Waterside, warehouse and transport workers are unlikely to be exposed to the notified polymer except if the packaging and cartridge were breached.

Printing and changing of cartridges (eg Office, imaging and printing service workers)

The notified polymer will be contained in sealed ink cartridges containing 130 ml of ink (<1% notified polymer concentration). These cartridges are sealed, and worker exposure to the ink should be minimised by following the replacement procedures recommended by the manufacturer. Exposure should be limited to accidental dermal exposure. Due to the design of the cartridges and the low concentration of the notified polymer in the ink, exposure to the notified polymer should be low.

Dermal exposure during use of the printer could occur if printed pages were touched before the ink dried, or if ink-stained parts of the printer were touched. Such exposure is expected to be low and will be avoided by workers. Once dried, the notified polymer will be bound to the paper matrix and is not expected to be bioavailable.

Printer maintenance workers

Printer maintenance workers may be intermittently exposed to the notified polymer during repair maintenance and cleaning of the printers. Exposure is controlled through the design of the cartridges and the printing machines. Printer maintenance personnel often wear cotton disposable gloves to minimise incidental exposure.

PUBLIC EXPOSURE

The notified polymer will be used in inks designed for home use by consumers and in printing kiosks in shopping malls. During these uses, the possible exposure scenarios are similar to those for office or imaging workers. However, it is expected that the public will be using printers less often, and will therefore experience a lower overall exposure to the notified polymer than will workers.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria, and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on a lower molecular weight form of the notified polymer.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 > 2,000 mg/kg bw	no	yes	OECD TG 423
2. Rat, acute dermal	LD50 > 2,000 mg/kg bw	no	yes	OECD TG 402
4. Rabbit, skin irritation	Slightly irritating	no	yes	OECD TG 404
5. Rabbit, eye irritation	Slightly irritating	no	yes	OECD TG 405
6. Skin sensitisation - LLNA	No evidence of sensitisation.	no	yes	OECD TG 429
7. Rat, oral gavage repeat dose toxicity - 28 days	NOAEL = 1,000 mg/kg bw/day	no	no	OECD TG 407
8. Genotoxicity - bacterial reverse mutation	Not mutagenic	no	yes	OECD TG 471
9. Genotoxicity – *in vitro* chromosome aberration (cultured peripheral human lymphocytes)	Not clastogenic	no	no	OECD TG 473

Description of observed toxicological effects:

Rat, acute oral – On day 1, in animals treated with 2,000 mg/kg, treatment-related toxic effects were observed. In all three female animals, lethargy, hunched posture, and uncoordinated movements were observed. Hunched posture and uncoordinated movements were seen in all three male animals. One male showed an accentuated lobular pattern of the papillary process of the liver and an enlarged mandibular lymph node. No further macroscopic abnormalities were observed.

Rat, acute dermal – Signs of toxicity on the treated area of skin at 2,000 mg/kg bw includes local yellow staining (all animals) and scales and/or scabs (two females). Systemically, flat posture was noted in all males and three females on day 1. In addition, chromodacryorrhoea or ventrolateral recumbency was observed in two females on days 1 and/or 2.

Rabbit, skin irritation – All three animals showed very slight erythema and oedema in the treated skin areas that resolved within 24 or 48 hours.

Rabbit, eye irritation – Irritation of the conjunctivae was observed; redness and discharge that completely resolved within 24 hours in two animals, and within 48 hours in the other animal.

Skin sensitisation – LLNA – Result for sensitisation was negative: the S.I. values calculated for animals treated with 5, 50 and 100% notified polymer were 0.9, 1.1 and 1.7, respectively. On the sixth day of treatment, three animals out of four in the high dose group (100% notified polymer), exhibited an emaciated appearance, piloerection and lethargy. One of these animals also exhibited significant body weight loss.

Genotoxicity – bacterial reverse mutation – In one bacterial strain, the test substance induced up to a 2.0-fold increase in revertant colonies at 1,000 μg/plate (with S9-mix). This was related to low mean solvent control values, and as the extent of the increase was within the historical control data range, it was not considered biologically relevant. All other bacterial strains showed no dose-related increases in the number of revertants in two independently repeated experiments.

Discussion:

The notified polymer is of high molecular weight (>1,000 Da), and is therefore unlikely to be significantly absorbed across biological membranes. However, toxicological test results show systemic effects following high oral and dermal doses (2,000 mg/kg bw, or repeated exposure to pure polymer in the LLNA assay), indicating that systemic absorption is possible. However, these results were not corroborated in a rat 28-day oral study at lower doses (≤1,000 mg/kg bw/day). Slight irritation of the skin and eyes of experimental animals were observed, but these effects occurred following exposure to the pure notified polymer, which will not be imported into Australia.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The primary route of exposure of workers to the notified polymer is likely to be dermal, during the use or maintenance of inkjet printers and/or handling of inkjet cartridges. Skin contact is likely to be avoided by workers to avoid staining of skin. The notified polymer is will be imported as a component of inkjet ink at low levels (<1%) in small inkjet cartridges, and is therefore unlikely to cause significant levels of exposure by any route.

The notified polymer is therefore considered to present a low risk to the health of workers, based on its low toxicity, low concentration in inkjet inks and low potential for exposure.

PUBLIC HEALTH

The public's potential for exposure to the notified polymer during the handling of inkjet ink cartridges is similar to that of workers. Therefore, the notified polymer is likely to present a low risk to public health, based on its low toxicity, low concentration in inkjet inks and low potential for exposure.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer will not be manufactured or reformulated in Australia. The sealed cartridges will be imported from overseas. Thus, there will be no environmental release associated with this process in Australia.

Release of the ink solution to the environment is not expected under normal use because the cartridges are designed to prevent leakage. If leakage or accidental spills occur when changing cartridges for new cartridges, the ink will be contained with absorbent material that will likely be disposed of in a landfill.

Empty cartridges will be recycled at Hewlett Packard recycling in Australia. The cartridges will be crushed and the various parts recycled. Ink residues, estimated at <10% of the ink, will be separated from the cartridge and be incinerated. Empty cartridges will also be disposed of with normal office waste and eventually sent to landfill.

In the end use process, it would be expected that the notified polymer would be bound to the paper, with the fate of the notified polymer dictated by paper disposal trends. The three main routes of paper disposal are landfill, incineration and recycling. Recent literature suggests that current paper recycling rates in Australia are 70-92%*. Consequently, most of the paper containing the notified polymer could be recycled. Where recycling does not occur the notified polymer will be disposed of in landfills where it is expected to remain bound to the treated paper.

Paper recycling is carried out in paper mills, where it is likely that at least primary sedimentation occurs, with some facilities also having biological treatment facilities. Therefore, in these facilities the notified polymer is expected to partially partition into sludge under the usual waste treatment pH, and eventually be disposed of in landfill with other waste sludge. However, due to the expected low water solubility, limited amounts will stay in the water column. It is anticipated that prolonged residence in an active landfill will eventually degrade the notified polymer contained in sludge or in papers disposed of directly through normal garbage.

Following its use in Australia, it is assumed that 20% of notified polymer will eventually be released into the aquatic environment as a result of the paper recycling process. A calculated worst-case scenario daily PEC in the sewer effluent is 0.007 µg/L. In calculating the PEC, the following were assumed:

(1) That usage of the maximum import volume of 50 kg is evenly distributed over a 365 day period;

(2) That usage is nationwide, with a population of 20 million contributing 200 L of water per person per day to the sewer;

(3) That there is no adsorption or degradation in the sewer prior to release.

Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the approximate PECs of the notified polymer in rural areas and coastal water are 0.007 µg/L and 0.0007 µg/L, respectively.

* Australian Environmental Review (2001). On track for best ever recycling rates. 16(1); 16.

ENVIRONMENTAL FATE

The notified polymer is considered to be not readily biodegradable based on the modified Sturm test (OECD test guideline 301B). It has a $\log P_{ow}$ of >5.4 and a low water solubility, and thus it is likely to partition to sludge during the paper recycling process. A majority of the notified polymer after end use will be disposed of to landfill and eventually degrade through biotic and abiotic processes. Incineration of the waste paper will destroy the notified polymer with the generation of water vapours, carbon dioxide and hydrogen fluoride.

7.2. Environmental Hazard Characterisation

The notified polymer meets the PLC criteria, and therefore it can be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified or analogue polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Fish Toxicity (carp)	96 h LC50 >100 mg/L	no	OECD TG 203
Daphnia Toxicity	48 h EC50 >100 mg/L	no	OECD TG 202
Algal Toxicity	96 h EC50 >100 mg/L	no	OECD TG 201
Inhibition of Bacterial Respiration	EC50 >100 mg/L	no	OECD TG 209

All results were indicative of low hazard. The notified polymer is considered to be non-toxic to aquatic organisms at least up to its limit of water solubility (<3.94 mg/L). No significant biological effects were observed for the species tested. The final solution used in the tests for fish (100 mg/L limit test) and *Daphnia* (hazy at ≥32 mg/L) were considered as homogeneous emulsions, whereas the water accommodated fractions used in the algal test were clear and colourless. The algal 96 h EC50 for both cell growth and growth rate corresponded with an actual concentration of 68 mg/L based on TOC analysis. The average concentrations (TOC) for the fish and *Daphnia* tests were 31 and 22 mg/L, respectively.

The Predicted No Effect Concentration (PNEC) is 1,000 µg/L, using *Daphnia* acute toxicity of 48 h EC50 of >100 mg/L and a safety factor of 100 as toxicity data are available for three trophic levels.

7.3. Environmental Risk Assessment

The risk quotients indicate an acceptable risk (Q = PEC/PNEC = 0.007/1,000 = <<0.1) for both marine and freshwater organisms.

Given the diffuse and widespread use of the ink product and the low volume usage, the concentration of the notified polymer in the aquatic compartment is likely to be very low. Furthermore, the low Q values indicate that there is unlikely to be an environmental risk to the aquatic compartment.

It is expected that any waste generated during use will be disposed of by incineration or to landfill. In landfill, the notified polymer contained in sludge or in papers will undergo *in situ* degradation. Incineration of the waste paper will destroy the notified polymer generating water vapour, carbon dioxide and hydrogen fluoride. Therefore, an environmental risk from the reported use pattern of the notified polymer is likely to be low.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

The notified polymer does not pose a significant risk to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is no significant risk to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

Based on the notified polymer's reported use pattern and the PEC/PNEC ratio, it is not considered to pose a risk to the environment.

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

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

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by incineration or landfill.

Emergency procedures

- No special precautions necessary (cartridges).

10.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 64(1) of the Act; if

- the notified polymer is introduced in a chemical form that does not meet the PLC criteria
- other uses are proposed.
- further information becomes available regarding transformations and degradation of the notified polymer including any adverse health and environmental effects of the breakdown products. This information is to be provided to NICNAS as soon as practicable in order to determine if additional recommendations, if relevant, are required.

or

(2) Under subsection 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.