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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in DP6001

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Polymer in DP6001

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
DuPont (Australia) Ltd (ABN: 59 000 716 469)
49-59 Newton Road
Wetherill Park NSW 2164

Brother International Pty Ltd (ACN: 001 393 835)
7 Khartoum Road
North Ryde NSW 2113

NOTIFICATION CATEGORY
Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, % Amount in Product, Import Volume, and Site of Manufacture/Reformulation

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
TSCA, 7th February 2003 (File USA EPA P-03-334).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
DP6001

METHODS OF DETECTION AND DETERMINATION
METHOD Infrared (IR) spectroscopy. A reference spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
>70%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
There are no hazardous impurities/residual monomers present at levels above the cutoff that would result in classification as a hazardous substance.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Importation as a component of ink.

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

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

USE
As an ink resin at <10% in aqueous formulations supplied in non-refillable cartridges ready for use in ink jet printers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Brother International (Aust)
DuPont (Australia) Ltd

TRANSPORTATION AND PACKAGING
The ink products (containing <10% notified polymer) will be imported in cartridges as part of mixed full container load consignments. Currently these cartridges contain 18-30 ml of ink, however in the future larger cartridges containing up to 1 L of ink may be imported.

5.2. Operation description

Mixed full container loads are transported by courier to the warehouses, where the bulk cartons are removed from the container and stored. The sale units, currently consisting of sealed cartridges containing 18-30 ml of ink (<10% notified polymer), packaged in cardboard cartons, are distributed by courier to retail businesses for resale to the public and large commercial houses. In the future, a small amount of the notified polymer may be imported in larger cartridges, up to 1 L, for use in high volume output printing applications. Cartridges will be used to replace used cartridges in inkjet printers, and this process will generally be carried out by untrained personnel, following replacement procedures recommended by the manufacturer. During the copying or printing operation, the toner will be transferred onto the paper and firmly fixed by heat. Used ink cartridges are disposed into domestic and non-hazardous industrial refuse.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency days/year*
Transport driver inwards	1	4 hrs	8
Warehousing	16	0.5 hrs	240
Transport drivers Outwards	30	0.25 hrs	240
Retail	1200	0.25 hrs	240
Office workers	72000	0.25 hrs	240
Home users	225000	0.25 hrs	240
Equipment repairmen	200	4 hrs	240

Exposure Details
Workers involved in transport, warehousing and retailing are only likely to be exposed to the notified polymer in the case of an accidental breach of the cartridge.

Office workers, home users and equipment repairmen may be exposed to the notified polymer when changing the cartridge, however this is very unlikely due to the design of the cartridge. Exposure would be limited to a very small amount of dermal contact. Once the printing is completed, the ink is bound to the printed page and thus there will be no exposure to the notified polymer.

There is potential for dermal exposure of users if printing to a non absorbent substrate occurs and the ink remains wet.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as part of ink formulation contained in inkjet ink cartridges and no reformulation or refilling will occur locally. Thus there will be no environmental exposure associated with this process in Australia.

RELEASE OF CHEMICAL FROM USE

The notified polymer as part of the formulation contained in the cartridges will be used in printers. The notified polymer can potentially be released to the environment from spent inkjet cartridges that are disposed of to landfill or by incineration. It is estimated that 3-6% of the notified polymer will remain in the used cartridges. The residual ink is absorbed onto foam contained within the cartridges and can only be removed if the integrity of the cartridges is compromised.

In the end use process it would be expected that the notified polymer will be bound to the paper which is landfilled, burnt or recycled. The notifier indicates that should the notified polymer be released by degradation from landfill or leaching it will show a high affinity for the organic phase of the soil and sediments.

5.5. Disposal

The notified polymer is expected to bind firmly to the paper substrate, which would be landfilled, burnt or recycled. When the paper is recycled the ink will be either oxidized by bleaching or deposited from wastewater in the paper mill wastewater treatment process.

5.6. Public exposure

Pages printed with the dried ink will be readily available to a wide cross section of office workers and consumers who undertake domestic printing. Once printed onto paper the notified polymer is bound and unavailable for release. However, there is potential for dermal exposure of users if printing to a non absorbent substrate occurs and the ink remains wet.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear to light yellow polymer solution.

Melting Point/Freezing Point Not determined. The notified polymer is supplied only in an aqueous dispersion.

Boiling Point 100-125°C at 101.3 kPa

Test substance	DP6001 product
Remarks	Estimated based on components. No test report was provided.
TEST FACILITY	EI DuPont Marshal labs

Density 1100-1200 kg/m^3

Test substance	DP6001 product
Remarks	Estimated based on components. No test report was provided.
TEST FACILITY	EI DuPont Marshal labs

Vapour Pressure Not determined.

Remarks	Expected to be very low based on the high MW and ionic form.

Water Solubility ≥ 10 g/L at 25ºC

Test substance Analogue polymers

Remarks Water solubility of the precursor polymer was performed in a GLP study but no test report was provided. The notifier also indicates that the solubility of a related analogue is expected to be approximately 15% in water. On the basis of the structure provided and the presence of anionic groups, the notified polymer is expected to be water-soluble.

Hydrolysis as a Function of pH Not determined.

Test substance Analogue polymer

Remarks A stability test was performed in aqueous buffer solution after 24 h (pH 1.2) and 14 days (pH 2.0, 7.0 and 9.0) at 40ºC. The analogue polymer did not show any significant changes in molecular distribution determined by GPC analysis comparing to the untreated samples. It was concluded that the analogue polymer was stable under the acidic and basic conditions.

TEST FACILITY LabFrontier Co., Ltd (2003)

Partition Coefficient (n-octanol/water) Not determined.

Remarks As the notified polymer is expected to be water-soluble, it is likely to partition into the aqueous phase.

Adsorption/Desorption Not determined.

Remarks Based on its estimated water solubility the notified polymer may be mobile in the environment. However, given its ionic form, the notified polymer may bind to soil and sediments.

Dissociation Constant Not determined.

Remarks The notified polymer is likely to dissociate under normal environmental conditions because of the presence of the ionisable acidic group.

Particle Size Not applicable.

Flash Point 60.5-93.3 ºC at 101 kPa

Test substance DP6001 product containing <40% notified polymer and 1-5% isopropanol

Remarks Test report not supplied.

TEST FACILITY DuPont Labs

Autoignition Temperature 390ºC

Test substance DP6001 product containing <40% notified polymer and 1-5% isopropanol

Remarks Test report not supplied.

TEST FACILITY DuPont Labs

Explosive Properties Not determined.

Remarks No structural groups that are expected to be explosive.

Reactivity

Remarks Stable under normal environmental conditions. Degradation products include CO, CO_2, acrylate monomers, and hydrocarbons.

7. TOXICOLOGICAL INVESTIGATIONS

The precursor polymer meets the PLC criteria and can therefore be considered to be of low toxicity. This precursor polymer has been neutralised using an existing chemical, an alkali metal, at a concentration of <5%. The majority of the alkali metal will be associated with the polymer, and thus be bioavailable.

A report summarising the toxicity of this alkali metal was supplied by the notifier (DuPont, 2004). In general, soluble salts of the alkali metal are slightly acutely toxic in mammalian studies. Acute oral toxicity LD_{50} values exceeded 500 mg/kg. Four-hour acute inhalation studies indicated an LD_{50} ranging from 900-2000 mg/m^3. The oxides and hydroxides of the alkali metal are corrosive, and other salts are likely to be irritating. This metal, as with almost all alkali metals, is classed as R34 ≥ 10% and R36/38 at concentrations between 5-10%.

A 20-week repeat-dose exposure to the chloride salt of the alkali metal produced significant toxicity at 20 mg/kg/day, with the primary targets being the nervous and developmental systems. Developmental toxicity effects appear to have a NOEL of around 10 mg/kg/day. Repeat dose inhalation studies fail to indicate any toxicity. The weight of evidence indicates that salts of the alkali metal is unlikely to pose a risk of genetic toxicity.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted for the notified polymer. The precursor polymer meets the PLC criteria and can therefore be considered to be of low hazard. A summary of the acute toxicity data of the alkali metal to fish was provided as follows, but no test reports were supplied (DuPont, 2004).

Acute 96-hour toxicity LC_{50} in fish (mummichog, bonytail, striped bass, Colorado squawfish, and razorback sucker) ranged from 15-315 mg/L with the majority of the species above 50 mg/L.

The 96-hour LC_{50} of the carbonate of the alkali metal for mummichog fish was 8-40 mg/L.

On these bases the ionised form of the alkali metal is not expected to be highly toxic to aquatic organisms.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Most of the notified polymer will be bound to paper and its fate will be dictated by paper disposal trends. The 3 main routes of paper disposal are landfill, incineration and recycling. Recent literature suggests that current paper recycling rates in Australia are 70-92% (Australian Environmental Review, 2001). Consequently, most of the paper containing the notified polymer could be recycled.

During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, toner detachment from the fibres, pulp brightness and the whiteness of the paper. The aqueous wastes are expected to go to the sewer. Therefore, in these facilities it is expected that the notified polymer will partially partition to sludge under the usual waste treatment pH, and eventually be disposed of in landfill with other waste sludge. Due to the expected high water solubility, the remainder (about 50%) 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 50% 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 3.0 µg/L. In calculating the PEC, the following were assumed: (1) usage of the maximum import volume is evenly distributed over a 365 day period; (2) usage is nationwide, with a population of 20 million contributing 200 L of water per person per day to the sewer, and (3) 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 PECs of the notified chemical in rural areas and coastal water may approximate 3.0 and 0.3 µg/L, respectively.

Incineration of the waste paper will destroy the notified polymer with the generation of water vapours and oxides of carbon and alkali metal salts.

Except for paper recycling, the polymer is not expected to enter the aquatic environment. In any case, the polymer's high molecular weight will preclude absorption across biological membranes. Hence the notified polymer is not expected to bioaccumulate.

9.1.2. Environment – effects assessment

The notified polymer is likely to be anionic under normal environmental pH conditions. Alkali metal based anionic polymers have a moderate indirect impact on green algae at pH 7, while toxicity to fish and invertebrates is generally low (LC_{50} >100 mg/L) (Boethling and Nabholz, 1997).

The moderate toxicity of anionic polymers to algae appears to be associated with polymer chelation of nutrient elements needed by algae for growth. Algal toxicity is thus dependent on the structure of the anionic polymer, with 96 h EC_{50} ranging from 3.13 to 500 mg/L depending on the distance between the acid groups in the polymer. Given the nature of the notified polymer it is predicted that chelation of the nutrients elements are unlikely to occur and thus toxicity of the notified polymer to algae is likely to be reduced.

The LC_{50} of any free alkali metal associated with the polymer is likely to be >5 mg/L, based on the summary of the environmental risks associated with the metal.

9.1.3. Environment – risk characterisation

The PEC is calculated to be 3.0 µg/L for freshwater release from paper recycling. Although no aquatic toxicity data were provided for the notified polymer, toxic levels will not be below 3.0 mg/L, allowing at least a 3 orders of magnitude safety factor.

Given the diffuse and widespread use of the ink product, the concentration of the notified polymer in the aquatic compartment is likely to be 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 (3-6%) will be disposed of by incineration or to landfill. In landfill the notified polymer contained in sludge or in papers will degrade slowly via biotic or abiotic processes. Therefore, environmental risk from the reported use pattern of the notified polymer is likely to be low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

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

The notified polymer will be imported in pre-packed ink cartridges. Dermal exposure to the notified polymer may occur when replacing spent cartridges and servicing the printers. However, the concentration of the notified polymer in the ink is low, and the design of the cartridges is such that exposure to the notified polymer should be low.

There is potential for dermal exposure of users if printing to a non absorbent substrate occurs and the ink remains wet.

9.2.2. Public health – exposure assessment

The notified chemical will be imported in prepacked cartridges. Dermal exposure to the notified chemical may occur infrequently when replacing spent cartridges. However, the concentration of the notified chemical in the ink is low, and the design of the cartridges is such that exposure to the notified chemical should be low.

There is potential for dermal exposure of users if printing to a non absorbent substrate occurs and the ink remains wet.

9.2.3. Human health – effects assessment

The precursor polymer meets the PLC criteria and can therefore be considered to be of low hazard.

The associated alkali metal is used to neutralise the precursor polymer, and thus is mainly associated with the polymer. The overall concentration of the alkali metal ions is <5%, and thus the amount of free metal is <<5%. Based on existing data on this metal, there are not expected to be any adverse effects at this concentration.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Exposure to the notified polymer will be low and thus the OHS risk is expected to be low.

The main potential for dermal exposure of users occurs if printing to a non absorbent substrate occurs and the ink remains wet. Under worst-case conditions, each piece of A4 paper can be assumed to incorporate 1mg of notified chemical. Based on a 50% transfer on contact when handling wet ink, and the relative areas of finger ends and paper size, it is estimated that potential removal is <1% of the applied ink in each event.

Estimated Exposure
Area of contact with finger ends (four fingers on one hand) = 8 cm^2
A4 sized paper substrate = ca. 600 cm^2

% Removal = (8/600) × 0.5 × 100 = < 1%
Therefore total removal to finger ends at point of contact would be < 1% of 1 mg notified chemical per event = < 0.01 mg

For extensive contact (i.e. > 10 events per day) the daily body burden of the notified polymer, assuming no washing between events, 70 kg person and 100% absorption, would be < 0.01 × 10/70 = ca. 0.0014 mg/kg/day.

Assuming that the alkali metal is at a concentration of 5%, exposure to the alkali metal would be < 0.07 µg/kg/day. The toxicological effects of the alkali metal have a NOEL of 10 mg/kg/day.

The Margin of Exposure (MOE = NOEL/Estimated Exposure) is 142857. As the MOE exceeds 100, the notified chemical does not pose a regulatory concern.

9.2.5. Public health – risk characterisation

Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible, as MOE >> 100 as calculated above.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

The notified polymer cannot be classified using the GHS.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a component of inks for use in ink jet printers.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for products containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. 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.
- 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 chemical should be disposed of by landfill, incineration or recycling.

Emergency procedures

- No specific precautions necessary.

12.1. 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 Section 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.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

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