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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Magenta Dye 3

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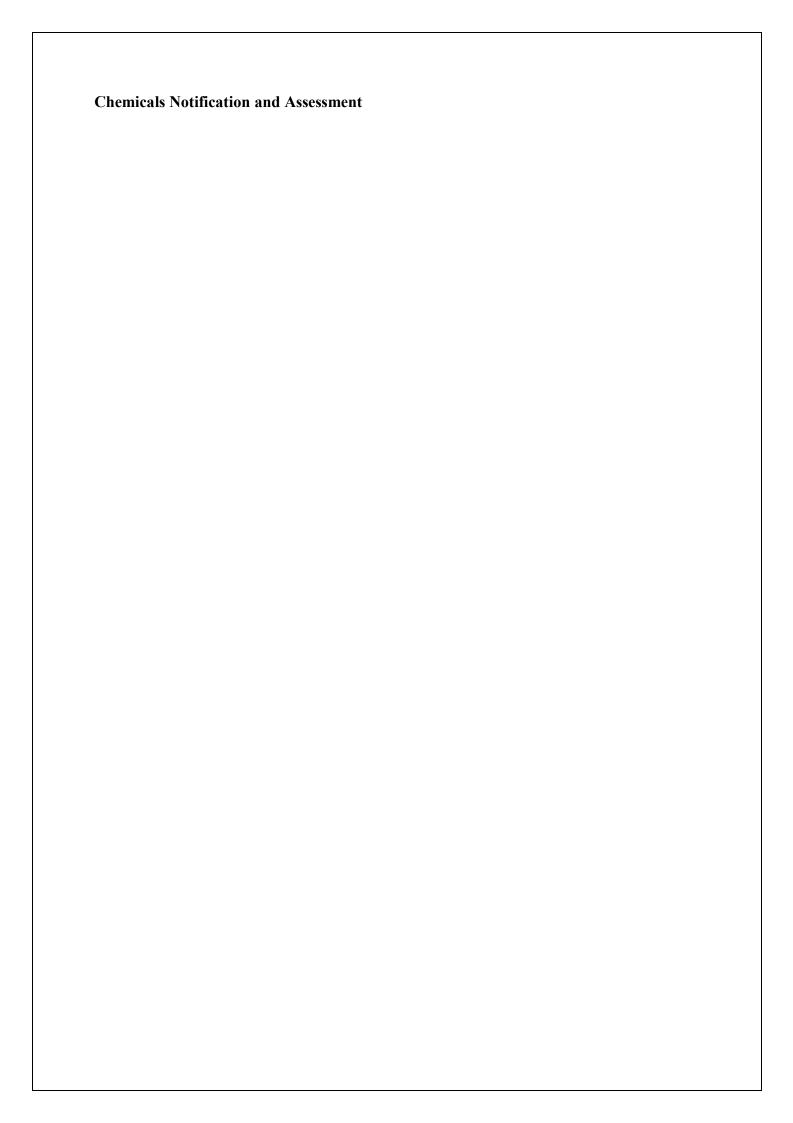


TABLE OF CONTENTS

FULL PUBLIC REPORT	Error! Bookmark not defined.
1. APPLICANT AND NOTIFICATION DETAILS	Error! Bookmark not defined.
2. IDENTITY OF CHEMICAL	Error! Bookmark not defined.
3. COMPOSITION	Error! Bookmark not defined.
4. INTRODUCTION AND USE INFORMATION	Error! Bookmark not defined.
5. PROCESS AND RELEASE INFORMATION	
5.1. Distribution, Transport and Storage	Error! Bookmark not defined.
5.2. Operation Description	
5.3. Occupational exposure	
5.4. Release	
5.5. Disposal	
5.6. Public exposure	
6. PHYSICAL AND CHEMICAL PROPERTIES	
7. TOXICOLOGICAL INVESTIGATIONS	
8. ENVIRONMENT	
8.1. Environmental fate	
9. RISK ASSESSMENT	
9.1. Environment	
9.2. Human health	
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN	
HUMANS	
10.1. Hazard classification	
10.2. Environmental risk assessment.	
10.3. Human health risk assessment	
11. MATERIAL SAFETY DATA SHEET	
11.1. Material Safety Data Sheet	
11.2. Label	
12. RECOMMENDATIONS	
12.1. Secondary notification	
13. BIBLIOGRAPHY	
15. DIDLIUUKAPHI	Error: Dookmark not denned.

FULL PUBLIC REPORT

Magenta Dye 3

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Toxikos Pty Ltd
293 Waverly Road
MALVERN EAST VIC 3145

Hewlett-Packard Australia Pty Ltd 31-41 Joseph Street BLACKBURN VIC 3130

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

- Chemical name(s)
- Other name(s)
- CAS Number
- Molecular formula
- Structural formula
- Molecular weight
- Spectral data
- Purity
- % Weight of toxic or hazardous impurities
- Non-hazardous impurities
- Identity of Additives/Adjuvants
- % Weight of additives/adjuvants

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

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) Magenta dye 3

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL MS, IR, UV/Vis

METHOD Remarks

TEST FACILITY Confidential

3. COMPOSITION

4. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years

The notified chemical is imported into Australia as part of sealed inkjet printing cartridges. The volume of the cartridges ranges up to 30 mL. Cartridges will be delivered to consumers by road transport.

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

Year	1	2	3	4	5
Kg	998	998	998	998	998

Use

The notified chemical is a dye used in preparations in ink-jet reprographic processes. The notified chemical will be imported as part of the dye which is imported within sealed ink-jet cartridges at a typical concentration of 5%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Not known

IDENTITY OF MANUFACTURER/RECIPIENTS

The inkjet printing systems will be potentially supplied to offices nationwide.

TRANSPORTATION AND PACKAGING

The inkjet printing system containing the notified chemical is not a dangerous good, hazardous substance or scheduled poison, and therefore no special transport or packaging requirements are necessary. Cartridges are transported by road.

5.2. Operation Description

No reformulation or repackaging of the product occurs in Australia. The product is delivered to the end-user as it is imported into Australia. The sealed inkjet printing system will be handled by service technicians or office workers replacing the spent cartridges in the printer.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	Number	Exposure Duration	Exposure Frequency
Importation/Waterside workers	10	4	40 days per year
Storage and transport	100	6	240 days per year
Office worker/Service	10 000	< 0.1	20
technician/Consumer			

Exposure Details

The notified chemical is contained in sealed cartridges. The volume of the notified chemical in any single cartridge would typically be approximately 1.5 mL. Normal handling, involving replacement of the cartridge would not normally result in exposure. Exposure would only result if the cartridge were faulty or ruptured.

5.4. Release

RELEASE OF CHEMICAL AT SITE Not applicable

RELEASE OF CHEMICAL FROM USE

Release of the ink solution to the environment is not expected under normal use as ink cartridges are designed to prevent leakage. These will be changed by office workers and the public. However, if leakage or spill does occur, the ink will be contained with absorbent material which will presumably be disposed of in landfill.

Ultimately, practically all the notified chemical will be released to the environment. Paper to which the notified chemical will be bound will eventually be buried in landfill or incinerated, or the chemical may be released in effluent from de-inking processes. Residues left in empty cartridges (estimated as <10% of ink) will most likely be disposed of to landfill.

Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is repulped using a variety of chemical treatments which result in fibre separation and ink detachment from the fibres. The wastes are expected to go to trade waste sewers. The notifier estimated that about 50% of the ink printed on paper will enter paper recycling and up to 60% of the ink is recovered during recycling. Together with the low percentage of notified chemical in the ink, release to the aquatic compartment will be in a highly diffuse manner.

5.5. Disposal

No special precautions are required. The substance enclosed in cartridges can be disposed of through the usual channels for handling domestic waste.

5.6. Public exposure

The public will be exposed to the dye after use, when it is expected to be fixed to the paper. Limited exposure may occur while changing inkjet cartridges, however this will be relatively infrequent and should only result in very limited exposure to small quantities of the notified chemical.

Consumer exposure to the notified chemical via the printed paper has been estimated by the manufacturer. One kilogram of pure dye would be expected to produce several million sheets of A4 coloured text or graphics. Under worst-case conditions, each piece of A4 paper can be assumed to incorporate 1mg of notified polymer. Based on a 50% transfer on contact when handling printed paper (assuming only partially dry 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.

Area of contact with finger ends (four fingers on one hand) = 8 cm²

A4 sized paper substrate = $ca. 600 cm^2$

% Removal = $(8/600) \times 0.5 \times 100 = < 1\%$

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, assuming no washing between events, 70 kg person and 100% absorption, would be $< 0.01 \times 10/70 = \text{ca. } 0.0014 \text{ mg/kg/day}$.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Red-brown powder

Melting Point >300°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Melting point was determined using a metal block apparatus

TEST FACILITY Confidential

Boiling Point Decomposes without boiling

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.

Remarks

TEST FACILITY Confidential

 1710 kg/m^3 **Density**

METHOD Not provided

Remarks

TEST FACILITY Not provided

Vapour Pressure Not provided

Remarks Assumed to be low

Water Solubility 380-430 g/L at ambient temperature

Метнор Methods for Determination of Physico-Chemical Properties; Official Journal of the

European Communities L383A, Vol. 35, 29th December 1992.

Remarks Tests were prepared in vials with a 10 mL meniscus level marked on each. The test

substance was weighed into the vials and diluted to the mark with distilled/deionised water. Tests were then treated ultrasonically for 5 minutes and shaken vigorously before placing them in a constant temperature bath at 25° C overnight. After allowing the samples to come to room temperature the tests were stirred and shaken before being examined visually to determine if any solid

substance was present.

It was difficult to obtain a precise figure for the water solubility of the test substance due to gel formation. No evidence of chemical instability of the test

substance was observed.

Confidential TEST FACILITY

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH. No supportive test report provided by the notifier.

pН	T (°C)	% hydrolysis after 5 days
4	50	40
7	50	40
9	50	10

Partition Coefficient (n-octanol/water) log Pow at 20° C = -3.2

Метнор A8 Shake flask method.

Remarks Solutions of the test substance were prepared in n-octanol saturated distilled water.

Concentrations of the test substance in water phases were determined spectrophotometrically by comparison to a calibrated curve prepared in distilled/deionised water containing 5% v/v n-octanol saturated water. The noctanol phases were examined directly without dilution and as no appreciable absorbance due to the test substance was obtained, a detection limit was

determined for the substance.

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Adsorption/Desorption

Log Koc <5 at pH 2, <1.5 at pH 10

- main test

OECD Guideline for testing of chemicals 121. Estimation of the Adsorption **METHOD**

Coefficient (K_{OC}) on Soil and on Sewage Sludge using High Performance Liquid

Chromatgraphy (HPLC). (2001)

Remarks The adsorption coefficient (K_{OC}) of the test substance was estimated

using a high performance liquid chromatography (HPLC) correlation

technique.

The test described has been validated for the quantitative estimation of $log_{10}K_{OC}$ values in the range 1.5 to 5.0 (OECD 2001). In those instances where the statistical treatment of the experimental data produced a calculated $log_{10}K_{OC}$ value outside this range then the final

result is quoted as either <1.5 or >5.0, as was the case here.

TEST FACILITY Confidential

Dissociation Constant pKa₁=8.0 pKa₂=3.0

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks The pKa was investigated spectrophotometrically using dilute aqueous solutions of

the test substance (notified chemical). The pH of the test solutions was adjusted using potassium hydroxide and hydrochloric acid. A UV/Visible spectrum was

obtained at each pH value.

The ionic strength of the solution was maintained at a constant level by the

addition of potassium chloride (0.15M).

TEST FACILITY Confidential

Particle Size Not applicable.

Метнор

Flash Point Not applicable to solids

Flammability Limits Not flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks

TEST FACILITY Confidential

Autoignition Temperature No information available. Likely to be greater than 300 °C

Explosive Properties Not explosive based on flammability testing.

Reactivity No oxidising or explosive properties known.

7. TOXICOLOGICAL INVESTIGATIONS

Test reports were not provided for the results tabled below.

Endpoint and Result	Assessment Conclusion
Rat, acute oral	$LD_{50} > 2500 \text{ mg/kg}$: low toxicity
Rat, acute dermal LD50	$LD_{50} > 2000 \text{ mg/kg low toxicity}$
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation.
Genotoxicity - bacterial reverse mutation	non mutagenic

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

Not readily biodegradable (<10%) degradation in 28 day test, however, no supportive test report has been provided by the notifier.

8.1.2. Bioaccumulation

No bioaccumulation study was conducted. In view of the negative logPow and high water solubility, the bioaccumulation potential is considered to be low (Connell 1990).

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

Notified chemical

In an acute toxicity test the 96 h LC50 to Mirror Carp was >1500 mg/L but no further details are available.

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE

Notified chemical

In acute toxicity tests the 48 h EC50 to Daphnia magna was >120 mg/L but no further details are available.

8.2.3. Algal growth inhibition test

TEST SUBSTANCE

Notified chemical

In acute toxicity tests the 72 h EbC50 and ErC50 to Green Algae were 6.8 mg/L and 53.2 mg/L respectively (for exposure solutions). In shaded solution these were 8.1 and 41.3 mg/L. All NOECs were 1 mg/L, but no further details are available.

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Notified chemical

In acute toxicity tests the 3 hr EC50 to bacteria (sewage sludge organisms) was >100 mg/L with a 3hr NOEC = 100 mg/L but no further details are available.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported in the form of a 5% w/w solution in sealed tricolour inkjet cartridge. No release of the notified substance is expected during transportation, except in the event of an accidental spill. The Material Safety Data Sheet (MSDS) contains suitable procedures for containing spills. The notified chemical is an ink dyestuff for use by the general public in colour inkjet electronic printers for producing quality prints. Very limited environmental release may occur indirectly from the disposal of printed paper (for recycling, to landfill or for incineration) and the disposal of spent ink cartridges at landfill sites. The notified chemical is very water-soluble and is

expected to remain within the aquatic environment.

Following its use in Australia, the notifier indicated that virtually all of the notified chemical (998 kg) will end up on paper and 50 % of the paper will be recycled (500 kg of the notified chemical). It was assumed that 60% de-inking occurred during the recycling process.

Using a worst-case scenario, (0.6×500) 300 kg of the notified chemical per year will be discharged to sewer and none is attenuated within these systems. Australia has a population of 20 million people and an average value for water consumption of 200 L/person/day has been adopted for this national-level assessment (4000 ML/day for total population). Therefore, the concentration for the notified chemical in the Australian sewerage network may approximate 2.1 X 10^{-4} mg/L (ie. 300 X 10^{6} mg \div 365 days/year \div 4000 \times 10^{6} L = 2.1 \times 10^{-4} mg/L). Based on dilution factors of 0 and 10 for inland and ocean discharges of STP-treated effluents, the predicted environmental concentrations (PECs) of the notified chemical in fresh water and marine surface waters may approximate 2.1×10^{-4} mg/L and 2.1×10^{-5} mg/L, respectively.

Using the SIMPLETREAT model for modelling partitioning and losses in sewage treatment plants [STP] (European Commission, 1996), the percentage removal from solution by STP may potentially approximate 0% through volatilisation and in sludge. Virtually all of the inflow concentration of the notified chemical may potentially remain in solution, passing through the STP. Thus the PEC concentrations in treated effluents and irrigation re-use waters may actually be 100% of that estimated with allowance for potential STP removal (ie estimated average effluent concentration of 2.1×10^{-4} and 2.1×10^{-5} mg/L for freshwater and marine waters, respectively).

The effluent re-use (eg. irrigation purposes) concentration of the notified chemical may potentially approximate 2.1×10^{-4} mg/L, assuming 100% remaining in solution during the STP process. STP effluent re-use for irrigation in Australia occurs throughout Australia. The agricultural irrigation application rate is assumed to be $1000~\text{L/m}^2/\text{year}$ (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density $1000~\text{kg/m}^3$). Using these assumptions, irrigation with a concentration of 2.1×10^{-4} mg/L may potentially result in a soil concentration of approximately 2.1×10^{-2} mg/kg assuming accumulation of the notified chemical in soil for 10 years under repeated irrigation. Thus, 2.1~x $10^{-2}~\text{mg/kg}$ is an estimated worst case PEC for the notified chemical in soils following effluent irrigation.

On the basis of log Pow of <-3.2 and the high water solubility of the notified substance, there is unlikely to be bioconcentration of the notified chemical in exposed aquatic organisms.

9.1.2. Environment – effects assessment

In summary the toxicity data indicate:

 Mirror Carp: 96 h LC50
 >1,500 mg/L

 Daphnia magna: 48 h NOEC
 >120 mg/L

 Green Algae: 72 h ErC50
 41.3 mg/L

Using the lowest LC50 of 41.3 mg/L for algae a predicted no effect concentration (PNEC) of 4.13×10^{-1} mg/L has been derived by dividing the LC50 value by a safety factor of 1000 since toxicity data are available for all three trophic levels, but no reports are available.

The results obtained for algal growth inhibition are considered to be, at least in part, due to the light absorbing properties of the notified chemical. As it is not possible to distinguish toxic effects from reduced growth due to light attenuation, the notified chemical cannot be classified and labelled under the OECD (2001) Globally Harmonised System for the Classification and Labelling of Chemicals:

9.1.3. Environment – risk characterisation

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (for recycling, to landfill or for incineration) and by direct release from discarded printer cartridges at landfill sites. Based on the import volume, method of packaging and low concentration in ink (5%), release of the notified chemical to the environment is expected to be low and widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and any of the notified chemical partitioned to the supernatant water will be released to sewer.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 5.1×10^{-3} ($2.1 \times 10^{-4}/4.1 \times 10^{0}$) and 5.1×10^{-4} , for freshwater and marine water, respectively. These values are significantly less than 1, indicating no immediate concern to the aquatic compartment. This value is expected to be much lower given that not all paper to which the ink is applied will be recycled thus limiting the exposure of the notified chemical to sewer.

Location	PEC (mg/L) or mg/kg	PNEC (mg/L)	Risk Quotient (RQ) ^(a)
Australia-wide STPs			
Ocean outfall	2.1×10^{-5} mg/L	$4.1 \times 10^{-1} \text{ mg/L}$	5.1×10^{-4}
Inland River	$2.1 \times 10^{-4} \text{mg/L}$	$4.1 \times 10^{-1} \text{ mg/L}$	5.1×10^{-3}
a. $RQ = PEC \div PNEC$			

On the basis of the low volumes used (ie. 998 kg/year) and nationwide and diffuse use of the notified chemical, it is not considered to pose an unacceptable risk to the health of aquatic life based on its reported use and estimated disposal patterns. The low RQ value further indicates the unlikelihood of an environmental risk to the aquatic life.

Based on low exposure potential and effluent for agricultural purposes, it is unlikely to result in unacceptable risk to soil organisms.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

There is low potential for worker exposure to the notified chemical when replacing spent cartridges as the notified chemical is at low concentration (<5%) in the ink formulations which are sealed within the cartridge. Service technicians may occasionally experience skin contact with the notified chemical during maintenance; however, the notified chemical is at low concentrations in the ink formulations. Exposure to the notified chemical on printed paper is low as the dye is bound to the paper matrix.

The notified chemical will be imported in pre-packed sealed cartridges. During transport and storage, workers are unlikely to be exposed to the notified chemical except when cartridges are accidentally breached.

9.2.2. Public health – exposure assessment

Public exposure through importation, transportation or storage is assessed as negligible. There is little potential for exposure during cartridge changes. Ink containing the notified chemical on the printed page is bound to the paper and is not biologically available. Public exposure is assessed as low.

The submission to EU indicated that as a conservative estimate, the daily body burden would be 0.0014 mg/kg.

9.2.3. Human health - effects assessment

The notified chemical has a molecular weight slightly greater than 500 and a very low octanol/water partition coefficient, indicating a low degree of lipophilicity and low potential to cross biological membranes.

The notified chemical was reported to be of low acute oral toxicity with a median lethal dose of 2500 mg/kg bw/day. Dermal irritation studies found the notified chemical did not cause

irritation to rabbit skin but was a slight to mild eye irritant. Water soluble nickel salts are normally classified as skin sensitisers, however, skin sensitisation studies on guinea pigs revealed no evidence of reactions indicative of skin sensitisation to the notified chemical. No genotoxic effects were observed in a Bacterial Reverse Mutation Test.

Based on the limited data available Magenta dye 3 is not determined to be hazardous in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002) based on the data available at the time of the assessment.

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low given that the notified chemical is present in the ink at 5%, is not determined to be hazardous, and the ink is contained in enclosed cartridges.

9.2.5. Public health – risk characterisation

Members of the public are not likely to make contact with the notified chemical during cartridge changes unless the cartridge is ruptured or otherwise tampered with. Additionally the notified chemical is present at low concentrations in a formulation that is not classified as hazardous. Ink containing the notified chemical on the printed pages is bound to the paper and is not readily bioavailable, with a worst-case estimate of 0.0014mg/kg/day.

Therefore, based on the low hazard and low potential for exposure the risk to public health from exposure to the notified chemical is considered low.

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 (NOHSC, 2002).

As a comparison only, the classification of notified chemical 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 chemical cannot be classified

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 in the intended manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). They are 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 the notified chemical and products containing the chemical provided by the notifier were 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

- Avoid skin and eye contact when handling the notified chemical.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing Magenta dye 3 are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

 Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

• The notified chemical should be disposed of in landfill or be destroyed through incineration

Emergency procedures

Spills/release of the notified chemical should be handled by collecting the cartridge intact and landfilled. Contain the spill and absorb with sawdust, sand or earth. Place used absorbent in suitable sealed containers and follow state or local regulation for the disposal of the waste.

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 Subsection 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical; or
 - the full toxicological studies for summary data become available.

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.

If imports rise above 1 tonne then full toxicological, ecotoxicological and physico-chemical test reports, including aquatic toxicity results and hydrolysis as a function of pH, should be provided.

13. BIBLIOGRAPHY

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

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