File No: LTD/1611

December 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Aryl Ketone in HP Scitex Inks

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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

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

Street Address: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: + 61 2 8577 8800 FAX + 61 2 8577 8888 Website: www.nicnas.gov.au

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 SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1611	Hewlett-Packard Australia Pty Ltd	Aryl Ketone in HP Scitex Inks	Not determined	≤ 1 tonne per annum	Component of ultraviolet/electron beam curable inkjet printing inks

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2009) is presented below. The environmental classification under this system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	Hazard statement
Aquatic Environment	Chronic Category 1	H410 - Very toxic to aquatic life with long lasting effects

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should consider classification of the notified chemical for irritation and skin sensitisation under the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004)
- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in inks:
 - Local exhaust ventilation where inhalation may occur
 - Use of closed processes where possible.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in inks:

- Avoid contact with eyes, skin and clothing
- Avoid inhaling ink vapours
- Clean up any spills promptly.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in inks:
 - Chemical goggles
 - Chemical resistant clothing
 - Chemical resistant gloves
 - Respiratory protection (if local ventilation is inadequate)

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 chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by importers and users to minimise environmental exposure during (manufacture, formulation, use) of the notified chemical:
 - The products containing the notified chemical, should not be released to sewer or surface waters
 - The products containing the notified chemical should not be applied to paper

Disposal

• The notified chemical should be disposed of to landfill.

Emergency procedures

• Spills or accidental release of the notified chemical 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 chemical is listed on the Australian Inventory of Chemical Substances (AICS).

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

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical;
 - the notified chemical is introduced in a form other than in formulated ink products;
 - the inks containing the notified chemical are to be applied to paper; in this situation, further
 information would be needed to demonstrate that the notified chemical does not meet the national
 environmental Persistence, Bioaccumulation and Toxicity (PBT) criteria.

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from being an additive in ink for industrial use, or is likely to change significantly;

- the amount of chemical being introduced has increased from less than 1 tonne per annum, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical
 on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett-Packard Australia Pty Ltd (ABN 74 004 394 763)
353 Burwood Highway
Forest Hill, VIC 3131

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, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, identity of analogue chemical and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

HP Scitex Inks (products containing the notified chemical up to 5%)

MOLECULAR WEIGHT

< 500 Da

ANALYTICAL DATA

Reference EI-MS spectra was provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported in an ink solution
Boiling Point	Not determined	Imported in an ink solution
Density	Not determined	Imported in an ink solution
Vapour Pressure	$6.34 \times 10^{-9} \text{ kPa at } 25^{\circ}\text{C}$	Calculated using the Modified Grain
		Method (US EPA, 2009)
Water Solubility	$8.84 \times 10^{-5} \text{ g/L}$	Calculated using WSKOW v1.42 (US
		EPA, 2011)
Hydrolysis as a Function of pH	Not determined	Does not contain readily hydrolysable
		functional groups
Partition Coefficient	$\log \text{Kow} = 5.99$	Calculated using KOWWIN v1.68 (US
(n-octanol/water)		EPA, 2011)
Adsorption/Desorption	$\log K_{oc} = 4.43$	Calculated using KOCWIN v2.00 (US
•		EPA, 2011)
Dissociation Constant	Not determined	Does not contain any dissociable
		functionality
Particle Size	Not determined	Imported in an ink solution
Flash Point/Flammability	Not determined	Not expected to be flammable under
		normal conditions of use.
Autoignition Temperature	Not determined	Not expected to autoignite under normal
		conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no
		explosophores.
Oxidising Properties	Not expected to be oxidising	Estimated based on chemical structure.

DISCUSSION OF PROPERTIES

Reactivity

The notified chemical is expected to be stable under the proposed storage and handling conditions. The notified chemical is expected to react when exposed to ultraviolet (UV) and electron beam (EB) radiation. The notified chemical may react if exposed to strong oxidants.

Dangerous Goods classification

Based on the limited physico-chemical data in the above table, the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured within Australia. The notified chemical will be imported in finished printing inks at a maximum concentration of 5%.

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

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

PORT OF ENTRY Melbourne and Sydney

TRANSPORTATION AND PACKAGING

The notified chemical will be imported as a component of ink in 5 kg plastic bottles. The inks containing the notified chemical will be transported by road in the original import containers.

Use

The notified chemical will be used as a component (photoinitiator) at up to 5% in industrial printing inks. The inks containing the notified chemical will be cured using UV/EB radiation. The notified chemical will be used in inks for printing on a variety of non-paper substrates, including vinyl, canvas, mesh vinyl and shade cloth.

OPERATION DESCRIPTION

The notified chemical will not be manufactured or reformulated within Australia. Printing inks containing the notified chemical at concentrations of up to 5% will be imported in the finished packaging ready for use. During printing, the imported ink will be transferred directly from the container to the printing head via automated lines. The printing machines will be automated and the notified chemical will be cured through exposure to UV/EB radiation at the end of the printing process. Local exhaust ventilation is expected to be in place for the areas surrounding the printing machines. Residual ink within printing equipment will be wiped clean using rags and solvents, which are expected to be disposed of by the printing companies through licensed waste disposal contractors.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport and storage	4-8	200
Service technicians	8	200
Printer operators	0.5	5

EXPOSURE DETAILS

Exposure to the notified chemical during transport and storage of the printing inks containing the notified chemical is not expected, except in the unlikely event of an accident where the packaging may be breached.

Dermal and ocular exposure to the notified chemical in inks at concentrations up to 5% may occur during attachment of the ink bottles to the automated lines on the printing machines and during cleaning and maintenance of printing equipment. Further exposure is not expected as the printing process is mainly automated. Personal protective equipment (PPE) such as gloves is also expected to be worn during the printing process to further reduce exposure.

Inhalation exposure is not expected due to the expected low vapour pressure of the notified chemical, the enclosed/automated nature of the printing process and the use of local exhaust ventilation in areas surrounding the printing machines.

Once the ink is applied to the substrates and cured, the notified chemical will be bound within the print matrix and will not be bioavailable.

6.1.2. Public Exposure

The finished printing inks containing the notified chemical will not be sold to the public. The public may come into contact with the inks containing the notified chemical after application to substrates. However, once the inks are cured and dried, the notified chemical will be bound within the print matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted. The notified chemical is a photoinitiator and thus expected to be reactive. It contains a functional group that is of potential concern for skin irritation and sensitisation, and the possibility of these and other health effects cannot be ruled out.

Toxicokinetics

The notified chemical has a low molecular weight < 500 and may be absorbed across biological membranes, including skin. Dermal absorption may be limited by the high log Kow, estimated at 5.99.

Health hazard classification

As no toxicity data were provided, the notified chemical cannot be classified according to the *Approved Criteria* for Classifying Hazardous Substances (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

No toxicological data were provided for the notified chemical. The notified chemical contains a functional group that is a structural alert for skin irritation and sensitisation, and is expected to be reactive.

Printer operators and service technicians handling ink products containing the notified chemical (at up to 5%) may have frequent dermal and ocular exposure to the notified chemical, particularly during manual replacement of ink containers, cleaning of ink residues and maintaining the printing machine. Inhalation exposure is expected to be limited by the local exhaust ventilation and the enclosed nature of the printing process. The use of adequate PPE (i.e., chemical goggles and chemical resistant gloves) is expected to further minimise exposure. In addition, the controls in place for other hazardous ingredients of the ink would also serve to reduce worker exposure to the notified chemical.

Once the ink is applied to the substrates and cured, the notified chemical would be incorporated in the print matrix and is not expected to be bioavailable. Therefore, based on the proposed use scenario, the risk of the notified chemical to the workers is not considered to be unreasonable.

6.3.2. Public Health

The HP Scitex ink containing the notified chemical at up to 5% will not be sold to the public. The public may have contact with the dried printed materials. However the notified chemical will be bound in the print matrix and will not be bioavailable to the consumers. Therefore, public exposure to the notified chemical is not expected and the risk to the public is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured, reformulated or repackaged in Australia. Environmental release of the notified chemical is unlikely to occur during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE

The majority of the release to the environment from use is expected to be from ink spills (0.3% of total import volume), cleaning of printing equipment (0.5%) and from disposal of empty containers containing residual ink (2%). The notified chemical is likely to be stable within an inert matrix on printed substrate once the ink is UV-cured and is not expected to be released to the environment. Ink residues within the printer are anticipated to be cleaned using suitable solvent and rags and these rags are expected to be disposed of to landfill. Similarly, empty containers containing residual ink are expected be disposed of to landfill. Spills are anticipated be cleaned up using a suitable adsorbent material, which will be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to be disposed of to landfill and is expected to remain associated with the plastic substrates to which it has been applied. Some plastic articles printed with the ink containing the notified chemical may be recycled.

7.1.2. Environmental Fate

No environmental fate data were submitted.

The majority of the notified chemical is expected to be trapped in an inert ink matrix on plastic substrates during its normal use as a component in ink. The notified chemical in the inert matrix is not expected to be mobile, bioavailable nor readily biodegradable. The majority of the notified chemical is expected to be disposed of to landfill where it will eventually degrade by biotic and abiotic processes to form water and oxides of carbon and sulphur. During plastic recycling, the notified chemical is likely to be incorporated into recycled plastic but may be thermally decomposed or separated with impurities and disposed of to landfill. Based on its high predicted adsorption/desorption coefficient (log K_{oc}), the majority of the notified chemical is anticipated to

sorb to sludge and sediment in the unlikely event that it is released to sewers or surface waters.

The notified chemical is predicted to be not readily biodegradable (BIOWIN v4.10; US EPA, 2011) and contains no readily hydrolysable functional groups. Therefore the notified chemical is expected to persist in the aquatic environment. The notified chemical has the potential for bioaccumulation based on its predicted n-octanol/water partition coefficient (log Kow = 5.99). However, an analogue was submitted by the notifier with a low measured bioconcentration factor (BCF) in fish (BCF \leq 190) which suggests that the notified chemical is not likely to bioaccumulate. Since the proposed analogue has a Kow approximately nine times greater than the notified chemical and some significant structural differences, it is considered that the analogue may not be entirely representative with respect to read across for the bioaccumulation endpoint of the notified chemical. However, the notified chemical will be incorporated into inert ink matrices on plastics with the majority being disposed of to landfill or recycled. The notified chemical is therefore not expected to be bioavailable, and is consequently not expected to be available to bioaccumulate in aquatic organisms, nor is it expected to be able to undergo long-range transport.

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical is not expected to be disposed of to the aquatic compartment based on the reported use and disposal pathways. Therefore, the predicted environmental concentration (PEC) could not be calculated as very limited aquatic exposure is expected for the notified chemical.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Modelled estimates for ecotoxicological endpoints for the notified chemical have been calculated by quantitative structure activity relationships (QSARs) and are tabulated below. Based on the predicted high log Kow and low solubility of the notified chemical, no acute toxic effects are predicted to fish, aquatic invertebrates, or algae at saturation.

Chronic Toxicity Endpoint	Result (mg/L)*	Assessment Conclusion
Fish	$30 \text{ d ChV} \ddagger = 0.010$	Very toxic with long lasting effects
Daphnia	$ChV_{\ddagger} = 0.016$	Very toxic with long lasting effects

^{*}Modelled estimates (ECOSAR v1.00, class – neutral organics, US EPA, 2011).

The ecotoxicity endpoints of the notified chemical were generated using validated QSARs and the notified chemical is considered to be within the domain of the model and selected class. Therefore, the calculated QSAR results are considered reliable for the purposes of classification under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

Based on the prediction that the notified chemical will not exhibit acute effects to fish, aquatic invertebrates and algae the notified chemical is formally not classified under the GHS for acute hazard.

The GHS classifications for long-term hazard are based on NOEC (or equivalent EC_x) endpoints, whereas the available endpoints are chronic values $[ChV = (LOEC \times NOEC)^{1/2}]$, i.e. the geometric mean of the LOEC and NOEC. Since the LOEC is by definition greater than the NOEC it follows that, for each endpoint, the NOEC must be less than the ChV. Under the GHS the notified chemical is considered to be chronically very toxic to fish and aquatic invertebrates. Therefore, based on its predicted chronic toxicity to fish (i.e. NOEC < 0.010 mg/L) and lack of measured data to demonstrate rapid degradability in the aquatic environment, it is formally classified for long-term hazard under the GHS as "Chronic Category 1; Very toxic to aquatic life with long lasting effects".

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the estimated chronic fish toxicity of the notified chemical and an assessment factor of 50. A conservative assessment factor is appropriate, in this case, as chronic endpoints (ChV = (LOEC \times NOEC)^{1/2}) for two trophic levels are available and these chronic endpoints are greater than no-observed effect concentrations (NOECs).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment					
Fish 30 d	0.010	mg/L			
Assessment Factor	50				
PNEC	0.20	μg/L			

[‡] ChV (Chronic Value) = (LOEC × NOEC)^{1/2}

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified chemical has not been calculated, as release to the aquatic environment is not expected based on its reported use pattern as a component in UV-curable inks for use on plastic substrates. The majority of the notified chemical is expected to be disposed of to landfill in cured ink where it will be trapped in an inert matrix, and is unlikely to be bioavailable nor mobile in this form.

The notified chemical is predicted to be chronically toxic to fish and daphnia and to be persistent in the environment. The notified chemical's calculated n-octanol/water partition coefficient (log Kow = 5.99) indicates that it has the potential to bioaccumulate. Based on this information, the notified chemical potentially meets the criteria for an environmentally persistent chemical as adopted in Australia for the classification of persistence, bioaccumulation and toxicity (PBT) of chemicals.

An analogue was submitted by the notifier with a low measured bioconcentration factor (BCF) in fish which suggests that the notified chemical is not likely to bioaccumulate. Given that the analogue has a Kow approximately nine times greater than the notified chemical and some significant structural differences, the possibility that the notified chemical may bioaccumulate cannot be dismissed in the absence of further supporting data.

However, the notified chemical will be incorporated into inert ink matrices on plastics with the majority of articles containing the notified chemical being disposed of to landfill or recycled. The notified chemical is therefore not expected to be bioavailable, and is consequently not expected to be available to bioaccumulate in aquatic organisms, nor is it expected to be able to undergo long-range transport.

Thus, based on its expected low aquatic exposure and assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment when used as a component of ink that is applied to plastic substrates. If the use pattern was changed such that notified chemical was expected to be released to the aquatic environment (such as through paper recycling) further information would be required to demonstrate that the notified chemical does not meet the PBT criteria.

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