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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Hydropalat 3204

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full 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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kodak (Australasia) Pty Ltd (ABN 49 004 057 621)
181 Victoria Parade
Collingwood, VIC 3066

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, use details, import volume and identity of recipients.

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)
CEC/751

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Hydropalat 3204 (45-55% notified chemical in water)
1080 Thermal Plate Developer (contains < 5% notified chemical)

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR, IR, GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY There are no known impurities in the notified chemical.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Translucent light yellow liquid

Property	Value	Data Source/Justification
Freezing Point	-50.5°C ± 0.1°C	Measured
Boiling Point	102.7°C ± 0.1°C at 100.4 kPa	Measured
Density	1241.4 kg/m^3 at 20°C	Measured
Vapour Pressure	1.65×10^{-8} kPa	Calculated
Water Solubility	> 540.85 g/L at 20°C	Measured
Hydrolysis as a Function of pH	$t_{1/2}$ > 1 year at 25°C	Measured

Partition Coefficient (n-octanol/water)	log Pow < -3.12 at 20°C	Measured
Adsorption/Desorption	Not determined	The notified chemical is expected to adsorb strongly to soil and sediment based on its chemical structure
Dissociation Constant	pKa = 1.63, 2.72, 7.11, 8.20	Calculated
Flash Point	> 108ºC at 100.2 kPa	Measured
Flammability	Not expected to be highly flammable	Estimated from measured flash point.
Autoignition Temperature	> 400ºC	Measured
Explosive Properties	Not explosive	Estimated

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notifier states that the notified chemical is incompatible with strong oxidising agents and strong acids. The notified chemical is expected to be stable under the proposed conditions of use (RCC, 2008i).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported as a component of a lithographic printing plate processing solution at a 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
Sydney

TRANSPORTATION AND PACKAGING
The products containing the notified chemical will be imported in 20 L plastic containers.

USE
The notified chemical will be used as a component of a lithographic printing plate processing solution at a concentration of < 5%.

OPERATION DESCRIPTION
The lithographic printing plate processing solution containing the notified chemical at < 5% will be used by commercial image printing operators. The printing operators will either manually pour the processing solution directly into the lithographic plate processing equipment or insert a tube into the import container and pump it directly into the processing equipment. The processes undertaken in the processing equipment are closed and automated.

Once the lithographic plate processing solution containing the notified chemical has been used up it will be drained from the processing equipment into a waste bottle by opening a tap at the bottom of the machine.

Periodically, the equipment will be cleaned by inserting a circulating cleaner inside the equipment and, by manual removal and washing of the scrub rollers.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
There is potential for dermal and ocular exposure to the lithographic printing plate processing solution containing the notified chemical at a concentration of < 5% during the transfer of this solution to the plate processing equipment, and during maintenance and cleaning of the plate processing equipment. Printer operators and service engineers are expected to use PPE (gloves, goggles and coveralls) that should minimise exposure. Inhalation exposure is not expected given the expected low vapour pressure (1.65×10^{-8} kPa calculated) of the notified chemical

6.1.2. Public exposure
The lithographic printing plate processing solution containing the notified chemical at < 5% will only be supplied to industry for use in commercial lithographic printing processes, hence public exposure to the notified chemical is not expected.

6.2. Human health effects assessment

The results from toxicological investigations conducted on Hydropalat 3204 containing 45-55% notified chemical are summarised in the table below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw
Rabbit, skin irritation	non-irritating
Rat, repeat dose oral toxicity – 4 days.	NOAEL > 1000 mg/kg bw/day

Toxicokinetics.
The notified chemical is highly water soluble (> 540.85 g/L at 20°C) and has a low partition coefficient (log Pow < -3.12 at 20°C), hence dermal absorption is expected to be low. The notified chemical is ionised and would be expected to remain in the ionised in the GI tract. As absorption across biological membranes is generally thought to be limited for ionised substances, absorption across the GI tract is also expected to be low. This is supported by the results of the acute and sub-acute oral toxicity studies.

Acute toxicity.
Hydropalat 3204 containing 45-55% notified chemical was found to be not harmful via the oral route (LD50 > 2000 mg/kg bw) in a study conducted in rats. No acute dermal or inhalation toxicity data were provided.

Irritation and Sensitisation.
Hydropalat 3204 containing 45-55% notified chemical was found to be non-irritating to the skin in a study conducted on one rat. No studies were submitted for eye irritation or sensitisation, however the MSDS for the notified chemical states that it may cause transient eye irritation. The notified chemical does not contain structural alerts for sensitisation.

Mutagenicity
No mutagenicity toxicity data was provided.

Repeated Dose Toxicity (sub-acute).
In a repeat dose oral toxicity study in rats, Hydropalat 3204 containing 45-55% notified chemical produced no signs of systemic toxicity at doses up to 1000 mg/kg bw/day for 4 days.

Health hazard classification
Based on the limited data provided, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Due to the limited toxicity data available, the hazard profile of the notified chemical is not conclusive. The notified chemical may have some eye irritation potential based on information in the MSDS. Given the Low concentration of the notified chemical (< 5%) in the imported product, the risk of eye irritation is not expected. Given the hazard profile of the notified chemical is not conclusive, the risk to workers from use of the notified chemical is not considered unacceptable provided workers wear PPE (including gloves and coveralls) as a precautionary measure when handling the notified chemical as introduced.

6.3.2. Public health

Exposure to the notified chemical by the public is not expected except in the unlikely event of a transport accident or spill. Hence the risk to the public from the notified chemical when used in the proposed manner is not considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of finished lithographic printing plate processing solution in 20 L sealed plastic containers. Release of the solution to the environment is not expected as manufacturing and reformulation of the solution containing the notified chemical will not take place in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation. In the event of a spill the notified chemical will be absorbed with vermiculite or other inert material and disposed according to State/Territory regulations.

RELEASE OF CHEMICAL FROM USE

The lithographic printing plate processing solution containing the notified chemical will only be supplied to the photographic industry and will not be used by the public. The printing operators will either manually pour the processing solution directly into the lithographic plate processing equipment or insert a tube into the import container and pump it directly into the processing equipment. The processes undertaken in the processing equipment are closed and automated.

It is estimated that < 1% of processing solution will be disposed of to the sewer. Processing solution overflow will either be recirculated into the processor, pumped to a waste drum or settling tank. The processing solution in waste drums or settling tanks will be disposed of by a licensed waste handler.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical will remain in overflow processing solution and will be disposed of by a licensed waste handler.

7.1.2 Environmental fate

No environmental fate data were submitted.

The majority of the notified chemical will be disposed of by a licensed waste handler. The release of the notified chemical to the aquatic environment is not expected based on its reported use pattern. In the unlikely event of release to sewer or surface waters, the notified chemical would be removed from the water column by sorption to sediment and sludge. The notified chemical is not readily biodegradable (Madsen et al., 2001). However, the notified chemical has a low log Pow and is therefore not likely to bioaccumulate.

7.1.3 Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated since no significant release of the notified chemical to the aquatic environment is expected, based on its reported use pattern.

7.2. Environmental effects assessment

No ecotoxicity data were submitted by the notifier. Several ecotoxicity studies have been conducted on the notified chemical at three trophic levels and on different species (Hutzinger, 1992). In the studies, the notified chemical was found to be not harmful to fish or aquatic invertebrates. The notified chemical was found to inhibit algal growth under laboratory conditions, however the effects are expected to be mitigated under environmental conditions. Furthermore, the notified chemical is not expected to reach ecotoxicologically significant concentrations in surface waters based on the reported use pattern.

7.2.1 Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified chemical as no significant aquatic exposure is expected based on its reported use pattern.

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 of finished lithographic printing plate processing solution. The majority of the notified chemical will share the fate of the lithographic printing plate processing solution and be disposed of by a licensed waster handler. Due to its limited environmental exposure, the risk of the notified chemical to the environment is expected to be low based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the limited data provided, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

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

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

Environmental risk assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid skin contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Gloves
  - Coveralls

  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.

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;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of a lithographic printing plate processing solution at < 5%, or is likely to change significantly;
  - the amount of chemical being introduced has increased from one 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 notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -50.5°C ± 0.1°C

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	No significant protocol deviations. GLP compliant.
Test Facility	RCC (2008a)

Boiling Point 102.7°C ± 0.1°C at 100.4 kPa

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Determined using DSC. No significant protocol deviations. GLP compliant.
Test Facility	RCC (2008a)

Density 1241.4 kg/m^3 at 20°C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using an oscillating densitimeter. No significant protocol deviations. GLP compliant.
Test Facility	RCC (2008b)

Vapour Pressure 1.65×10^{-8} kPa

Method	MPBWIN v1.41 (US EPA 2009)
Remarks	The vapour pressure was calculated for the notified chemical.
Test Facility	RCC (2008c)

Water Solubility > 540.85 g/L at 20°C

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Simplified Flask Method. Duplicate samples of approximately 5 g of the product containing the notified chemical were mixed with 5 mL water and stirred for 24 hours. The solutions were filtered with 0.2 µm Nylon and diluted 500 times with water. The notified chemical concentration was analysed by HPLC.
Test Facility	RCC (2008d)

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.

pH	*T (°C)*	*Hydrolysis after 5 days [%]*
4	50°C	< 10
7	50°C	< 10
9	50°C	< 10

Remarks Approximately 2 g of the product containing the notified chemical was dissolved in each of 3 (pH 4.0, 7.0 and 9.0) 100 mL buffered solutions. Two aliquots from each solution of approximately 50 mL were transferred into Erlenmeyer flasks to perform duplicate tests. Nitrogen was passed through the solutions to reduce the dissolved oxygen. The solutions were incubated at 50°C and the notified chemical analysed by HPLC. The notified

chemical is estimated to have a half life > 1 year at 25°C under environmental conditions.
Test Facility RCC (2008e)

Partition Coefficient (n-octanol/water) log Pow < -3.12 at 20°C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Log Pow was estimated from the solubility of the notified chemical in n-octanol and water solubility test result. Duplicate samples of approximately 0.5 g of the product containing the notified chemical were mixed with 25 mL n-octanol and stirred for 24 hours. The samples were centrifuged at ~2900 g for 10 minutes, the supernatants filtered (Filter 0.2 PTFE) and diluted in a 1:2 ratio with acetonitrile. The notified chemical was quantified by HPLC.
Test Facility RCC (2008d)

Dissociation Constant pKa = 1.63, 2.72, 7.11, 8.20

Method Calculated using the Taft correlation
Test Facility RCC (2008f)

Flash Point > 108ºC at 100.2 kPa

Method EC Directive 92/69/EEC A.9 Flash Point, A.12 Flammability in Contact with Water and A.13 Pyrophoric Properties.
EN22719
ASTM D 93-85
DIN 51755
Remarks The test was stopped when the test material started boiling, no flash point was observed up to this point.
The chemical did not show any spontaneous ignition or formation of flammable gasses when in contact with water.
No significant protocol deviations.
GLP compliant.
Test Facility RCC (2008g)

Autoignition Temperature > 400ºC

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks No significant protocol deviations.
GLP compliant.
Test Facility Safepharm (2008)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The structure of the notified chemical was assessed for chemical groups that imply explosive properties.
The exothermic decomposition energy was also measured up to 500°C using DSC.
No significant protocol deviations.
Test Facility RCC (2008h)

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