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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

KUDE-9

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

This Public Report is 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:

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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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1852	Epson Australia Pty Ltd	KUDE-9	ND*	≤ 1 tonne per annum	Component of inkjet printer ink

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R36: Irritating to eyes

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 3)	H402 - Harmful to aquatic life

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 PEC/PNEC ratio and 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

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with eyes and skin

- No specific engineering controls are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation.

- Service personnel should wear disposable gloves during routine maintenance and repairs.

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are unavailable or impracticable, dispose of the chemical in an environmentally sound manner in accordance with relevant Commonwealth, State, Territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, physical 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;
- additional information becomes available on the genotoxicity of the 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 inkjet printer ink, or is likely to change significantly;
- the amount of chemical being introduced has increased, 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 (M)SDSs of the notified chemical and a product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDSs remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Epson Australia Pty Ltd (ABN: 91 002 625 783)
3 Talavera Road
NORTH RYDE NSW 2113

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, import volume, and identity of manufacturer.

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
Korea (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
KUDE-9

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, LCMS, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: black powder

Property	Value	Data Source/Justification
Melting Point/Boiling Point	> 400 °C	Measured
Density	1,716 kg/m^3 at 20 °C	Measured
Vapour Pressure	2 × 10^{-3} kPa at 20 °C	Measured
Water Solubility	186 ± 18 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{½}$ > 1 year at 25 °C, pH 4, 7 and 9	Measured
Partition Coefficient (n-octanol/water)	log P_{OW} < -4.5	Measured
Adsorption/Desorption	log K_{OC} < 1.25	Measured
Dissociation Constant	The dissociation of the ionisable groups is very weak (negligible).	Measured

Particle Size	Inhalable fraction (< 100 μm): 62.55 % (estimated from data) 63.98% < 104.713 μm Respirable fraction (< 10 μm): 7.37% MMAD* = 89.65 μm	Measured
Flammability	Not highly flammable	Measured
Autoignition Temperature	271.4 ± 7.8 °C	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Predicted negative	The chemical contains one functional group that could imply oxidising properties; however, based on molecular structure and calculation of oxygen balance, the notifier considered the potential for oxidation to be low.

* MMAD = Mass Median Aerodynamic Diameter

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

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured or reformulated in Australia. The notified chemical will be imported into Australia as a component of ink formulations to be used in commercial inkjet printing systems.

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 notified chemical will be imported as a component of inkjet printer ink in sealed bottles. Ink bottles (≤ 100 mL in size) containing the notified chemical at < 5% concentration will be transported within Australia (to/from warehousing facilities and retail outlets/end-users) by road.

USE
The notified chemical will be used as a component (< 5%) of inkjet printing ink which will be potentially supplied to offices and retail outlets.

OPERATION DESCRIPTION
The notified chemical will not be manufactured, reformulated or repackaged in Australia.

Following distribution of the imported ink containing the notified chemical (in the sealed bottles) to end-use sites, printer service technicians, office workers and home users will open the packaging and transfer the ink from the bottle into the ink tank of the corresponding printers. The empty bottle will be disposed of.

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 workers	1 – 3	48
Warehouse workers	2 – 6	240
Printer technicians	8	240
Office workers	8	240

EXPOSURE DETAILS

During transport and storage, workers are unlikely to be exposed to the notified chemical (unless the packaging is accidentally breached).

Printer technicians and office workers may be exposed to the ink containing the notified chemical (at < 5% concentration) during removal of ink bottle seal, transfer of the ink from the bottle to the ink tank, printer maintenance and cleaning and contact with printed substrates before they have dried. Dermal exposure is expected to be the most likely route of exposure, although incidental ocular exposure is possible. However, given the design of the ink bottles, exposure to the notified chemical is expected to be limited if users follow the instructions for transfer. Further exposure is possible if ink is accidentally spilt from the bottle.

Occasional dermal exposure during use of printers could also occur if the printed pages were touched before the ink had dried. Once the ink dries, the notified chemical will be bound to the paper matrix and is not expected to be bioavailable. Inhalation exposure to the notified chemical is not expected given the low vapour pressure of the notified chemical and the low likelihood of aerosols being generated.

6.1.2. Public Exposure

The public may use inkjet printer bottles containing the notified chemical (at < 5% concentration) for printing purposes at home. Exposure of these users to the notified chemical is expected to be of a similar or lesser extent than the exposure experienced by office workers.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD_{50} > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly to moderately irritating
Mouse, skin sensitisation – LLNA BrdU-ELISA	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Mutagenicity – bacterial reverse mutation (incorporating Prival and Mitchell modification for azo colourants)	non-mutagenic
Genotoxicity – in vitro chromosomal aberration test	genotoxic
Genotoxicity – in vivo micronucleus assay	non genotoxic

Toxicokinetics, metabolism and distribution.

Many azo dyes are unlikely to be absorbed through the skin because of their size and polarity (Øllgaard, 1998). Given the high molecular weight (> 1,000 Da), high water solubility (186 ± 18 g/L at 20 °C) and low partition coefficient (log Pow < -4.5 at 20 °C) of the notified chemical, dermal absorption is limited. However, bacterial skin microflora have been reported to be able to break down azo dyes into smaller species, which may be more readily absorbed through azo reduction (SCCNFP, 2002).

Given the coloured faeces seen in the acute oral toxicity study, it is likely that the notified chemical can be absorbed from the gastrointestinal tract following oral exposure.

Acute toxicity.

The notified chemical is of low acute oral toxicity based on studies conducted in rats.

Irritation.
The notified chemical is non-irritating to the skin but irritating to eyes based on studies conducted in rabbits.

In the skin irritation study no erythema or oedema was noted throughout the 72-hour observation period.

In the eye irritation study conjunctival irritation was observed that was fully resolved in all animals at the 7-day observation. Black staining during the study meant that effects on the cornea and iris, and conjunctival redness, could not be accurately measured at the early observation times. The study authors took a conservative approach to the missing scores, and as a result classified the chemical as causing serious eye damage/eye irritation (Category 2B). This class of eye irritation is not adopted under the GHS in Australia. Using the precautionary scores, the chemical would be classified as R36 - Irritating to eyes *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Sensitisation.
The notified chemical was not found to be a sensitiser when tested at up to 25% concentration in a local lymph node assay (LLNA: BrdU-ELISA). In the LLNA study a 25% test concentration of the notified chemical (the highest dose tested) resulted in a stimulation index (SI) of 1.0 ± 0.1 (mean ± SD), comparable with that of the vehicle control.

Repeated dose toxicity
No repeated dose toxicity data was submitted.

Mutagenicity/Genotoxicity
The notified chemical was negative in two bacterial reverse mutation assays (using both the standard and the Prival-Mitchell (Prival MJ and Mitchell VD 1982) modified test). In an *in vitro* chromosomal aberration study in Chinese hamster lung fibroblasts, the notified chemical did not induce numerical aberrations but induced structural aberrations in the absence of metabolic activation. The notified chemical was negative in an *in vivo* mouse micronucleus assay, however it was not established that the test substance had reached the bone marrow.

On the basis of the available information, while the notified chemical is not expected to be clastogenic, this cannot be ruled out, given the positive chromosome aberration test result on the notified chemical.

Carcinogenicity of breakdown products
The notified chemical is not expected to be reductively cleaved to release any of the aromatic amines with carcinogenic potential listed in EU SCCNFP/0495/01 (SCCNFP, 2002).

Health hazard classification
Based on the available information, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R36: Irritating to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the available information the notified chemical is expected to be of low hazard, presenting only as a slight eye irritant. Based on the available data, the notified chemical is not expected to be clastogenic; however, on the balance of available information the risk cannot be ruled out. .

Dermal or possibly incidental ocular exposure to workers may occur during removal of ink bottle seal, transfer of the ink from the bottle to the ink tank, printer maintenance and cleaning and contact with printed substrates before they have dried. This exposure is expected to be infrequent or only incidental in nature, given the containment of the notified chemical within small ink bottles/tanks and its low concentration in the ink (< 5%). In addition, Inhalation exposure is not expected, given the low vapour pressure of the notified chemical.

Therefore, although the potential risk of the notified chemical following repeated exposure has not been ruled out based on the available information, the risk is not expected to be of concern in the proposed use manner.

Where more frequent and/or more significant contact may occur, e.g. to printer technicians, any exposure potential would be further controlled through the use of personal protective equipment (PPE). It is noted that the product (ink) label lists precautions to avoid exposure e.g. avoiding leakage when handling bottle, washing any spills from skin or eyes, avoiding ingestion.

Overall, based on the limited expected exposure and dermal absorption potential, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The types of public exposure to the notified chemical during the use of inkjet printers is expected to be similar to that experienced by workers, but much less frequent. The public may also come into contact with printed substrates containing the notified chemical. However, once dried the notified chemical is bound into a solid matrix and not bioavailable. Therefore, based on very low potential exposure, the risk to the public is not considered to be unreasonable.

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 into Australia as a component of inkjet printer ink in sealed ready-to-use ink bottles. No release of the ink solution containing the notified chemical to the environment is expected, as no manufacturing or reformulation will occur in Australia. Environmental release of the notified chemical during importation, transport and storage is likely to be limited to accidental spills and leaks.

RELEASE OF CHEMICAL FROM USE

The ready-to-use ink bottles are designed to prevent leakage and will not be unsealed during transport, installation, use or replacement. Therefore, release of the printer ink containing the notified chemical to the environment is not expected under normal conditions. During use, the majority of the notified chemical will be cured within an inert ink matrix and bound to paper substrates, and is not expected to be mobile. In the event of accidental spills or leaks, the printer ink containing the notified chemical will be contained and collected with absorbents, and is expected to be disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will be used in printer ink for printing onto paper substrates. The majority of the notified chemical is expected to share the fate of the printed articles to which it is bound. It is assumed that 50% of the printed paper will be disposed of to landfill, and the rest will undergo paper recycling processes. Empty ink bottles containing residues of the notified chemical are expected to be disposed of to landfill. Hence, the majority of the notified chemical is expected to be disposed of to landfill, with a potential for some release to sewer through paper recycling processes. During paper recycling processes, waste paper is pulped using a variety of chemical treatments that results in ink detachment from the fibres. Waste water containing the notified chemical will be released to sewer.

7.1.2. Environmental Fate

The notified chemical is not readily biodegradable (≤ 2% in 28 days). For details of the environmental fate studies, please refer to Appendix C. Based on its high water solubility and low partition coefficient (log Kow < -4.5), the notified chemical is not expected to bioaccumulate. The majority of the notified chemical is expected to enter the environment from disposal of printed paper products to which the printer ink containing the notified chemical is bound. Approximately 50% of the notified chemical is expected to be disposed of to landfill as part of printed waste paper. Notified chemical that is not cured and bound to paper in landfill may leach due to its high water solubility and low adsorption coefficient (log KOC < 1.25), where it may enter surface waters.

The remaining 50% of the notified chemical has the potential to be released to sewer after the de-inking of printed paper during recycling processes. The notified chemical is not expected to be removed during sewage

treatment plant (STP) processes due to its high water solubility and low adsorption coefficient. Therefore, the notified chemical from paper recycling may be released from STPs to surface waters. Notified chemical released to surface waters from STPs and landfill leachate is expected to disperse and eventually degrade. In landfill and in surface waters, the notified chemical is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 50% of the paper products containing the notified chemical undergoing recycling, and the notified chemical to be released into sewers with no removal during recycling or STP processes. As the notified chemical bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.425	µg/L
PEC - Ocean:	0.043	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.425 µg/L may potentially result in a soil concentration of approximately 2.835 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 14.17 µg/kg and 28.35 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	72 h E_rC50 = 18 mg/L	Harmful to algae
Inhibition of Bacterial Respiration	3h EC50 > 1000 mg/L	Not inhibitory to bacterial respiration

Based on the above acute ecotoxicological endpoints, the notified chemical is expected to be harmful to algae. Therefore, the notified chemical is formally classified as “Acute Category 3; Harmful to aquatic life” under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Although the notified chemical is not readily biodegradable, based on its acute toxicity and low bioaccumulation potential, the notified chemical is not formally classified under the GHS for chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 1000 was used, given that acute endpoints for two trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment

E_rC50 (Algae, 72 h)	18	mg/L
Assessment Factor	1000	
PNEC:	18	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.425	18	0.02
Q - Ocean	0.043	18	0.002

The Risk Quotients for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Whilst the notified chemical is not readily biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume, and assessed use pattern in printing ink, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting/Boiling Point > 400°C

Method	OECD TG 102 Melting Point/Melting Range. OECD TG 103 Boiling Point.
Remarks	Determined using differential scanning calorimetry (DSC). At ~ 385°C a small portion of the test item sublimated. Melting was detected > 400°C, this was taken to equate to the boiling point threshold of the test item also.
Test Facility	CiToxLAB (2014a)

Relative Density 1,716 kg/m^3 at 20 ºC

Method	EU Regulation (EC) 440/2008, Annex Part A test A3.
Remarks	Determined using a gas comparison stereopycnometer.
Test Facility	Chilworth (2014a)

Vapour Pressure 0.002 kPa at 20 °C

Method	EU Regulation (EC) 440/2008, Annex Part A test A4.
Remarks	Determined using the Static Method. 3 tests were conducted as curving was seen in the plot of the first test. The study authors attributed such results to possible decomposition or a lack of time being allotted for the vapour pressure to reach equilibrium at each test temperature.
Test Facility	Chilworth (2014b)

Water Solubility 186 ± 18 g/L at 20 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method
Test Facility	CiToxLAB (2014b)

Hydrolysis as a Function of pH $t_{½}$ > 1 year at 25 °C, pH 4, 7 and 9

Method	OECD TG 111 Hydrolysis as a Function of pH. EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ <hours or days>*
4	50	> 1 years
7	50	> 1 years
9	50	> 1 years

Remarks	After 5 days under the accelerated conditions of 50 ± 1 °C the stability of the notified chemical was 100% at pH 4, 102% at pH 7, and 99% at pH 9. Therefore, it can be concluded that under the conditions of the test, the notified chemical is expected to be stable.
Test Facility	CiToxLAB (2014c)

Partition Coefficient (n-octanol/water) log P_{OW} < -4.5

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	Shake flask method
Test Facility	CiToxLAB (2014d)

Adsorption/Desorption – screening test $\log K_{OC} < 1.25$

Method	OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks	HPLC method
Test Facility	CiToxLAB (2014e)

Dissociation Constant Negligible at 20 °C

Method	OECD TG 112 Dissociation Constants in Water.
Remarks	Titration method. It was found from the study that the dissociation of the ionisable groups is very weak (negligible).
Test Facility	CiToxLAB (2014f)

Particle Size 62.55 % < 100 µm (estimated from data)
63.98% < 104.713 µm
MMAD = 89.65 µm

Method	ISO 13320:2009 Particle Size Analysis – Laser Diffraction Methods OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (µm)	*Mass (%)*
> 2,000	12.2
< 2,000	87.8

Range (µm)	*Mass (%)*
< 235.090	90
< 104.713	63.98
< 68.440	50
< 12.112	10
< 10	7.37

Remarks	Conducted via manual sieve analysis and a laser diffraction test, using a small volume (wet) module (SVM) with silicone as the dispersant.
Test Facility	Chilworth (2014c)

Flammability Not highly flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks	Pile of test substance powder ignited by gas flame.
Test Facility	CiToxLAB (2014g)

Autoignition Temperature 271.4 ± 7.8°C

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	Self-ignition was observed at temperatures between 268.3 to 274.6°C in 3 test runs.
Test Facility	CiToxLAB (2014h)

Explosive Properties Determined not to have explosive properties

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	Trio of tests were conducted. 1) BAM friction test: there were no signs of ignition or explosion. In 5/6 tests, a brown metallic mark was noted indicating some degree of decomposition. 2) BAM fall hammer test: there were no signs of ignition, explosion or decomposition in any of the tests. 3) Koenen steel tube test: the flame observations noted were deemed to signify negative results by the study authors.
Test Facility	Harlan (2015)

Oxidizing Properties Potentially oxidising

Method	Structural Group Evaluation was performed examining the structural properties of the chemical and an Oxygen Balance (OB) Calculator was used to determine the percentage value.
Remarks	One group of the notified chemical was predicted to confer oxidising potential. However, the OB calculations estimated that the chemical was not potentially oxidising.
Test Facility	CSR (2014)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
- Species/Strain: Rat/RccHan:(WIST)
- Vehicle: Distilled water
- Remarks - Method: No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	2000	0/3
2	3F	2000	0/3

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: Clinical signs were limited to liquid, dark, purplish discolouration of the faeces on Day 1, which resolved by Day 2.
- Effects in Organs: No macroscopic findings were noted.
- Remarks - Results: No test substance-related effects on body weight gains of the treated animals.

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: CiToxLAB (2014i)

B.2. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 404 Acute Dermal Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3M
- Vehicle: Test substance moistened with water
- Observation Period: 72 hours
- Type of Dressing: Occlusive
- Remarks - Method: No significant protocol deviations

RESULTS

- Remarks - Results: The individual mean scores for erythema and oedema were 0.00 at 24 hours, 48 hours or 72 hours observation.

CONCLUSION: The notified chemical is non-irritating to the skin.

TEST FACILITY: CiToxLAB (2014j)

B.3. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3M
- Observation Period: 7 days
- Remarks - Method: No significant protocol deviations

RESULTS

Lesion	*Mean Score Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.5[1]	1.7[3]	0.5[1]	2	< 7 days	0
Conjunctiva: chemosis	0[3]	0[3]	0.3[3]	1	< 48 hours	0
Conjunctiva: discharge	0[3]	1[3]	0.7[3]	3	< 7 days	0
Corneal opacity	0[1]	0[3]	0[1]	0	-	0
Iridial inflammation	0[1]	0[2]	0[1]	0	-	0

[1] Calculated on the basis of the scores at 48 and 72 hours as no visible results at 24 hours due to the black discoloration of the eye by the test substance.
[2] Calculated on the basis of the score at 72 hours as no visible results at 24 hours and 48 hours due to the black discoloration of the eye by the test substance.
[3] Calculated on the basis of the scores at 24, 48, and 72 hours.

Remarks - Results	No corneal or iridial effects were noted during the study, however these effects could not be evaluated at the early observation times. Conjunctival effects were noted in all treated eyes 1 hour after treatment. Two treated eyes appeared normal at the 72-hour observation and 1 treated eye appeared normal at the 7-day observation. There was no permanent staining of the eye. The above results may not accurately reflect the scores, as the readings at some stages were obscured by black staining. Where data was missing, the study authors applied a precautionary opacity score of < 2 to animals 1 and 3 and precautionary 24 h conjunctival redness scores of 3.
CONCLUSION	The notified chemical is slightly to moderately irritating to the eye.
TEST FACILITY	CiToxLAB (2014k)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 422B Skin Sensitisation: Local Lymph Node Assay: BrdU-ELISA
Species/Strain	Mouse/CBA/J
Vehicle	Acetone/olive oil (4:1) (suspension)
Preliminary study	As systemic toxicity or excessive irritation were not observed in any of the groups in the pre-screen, the doses for the main study were set at 25%, 10% and 1%.
Positive control	Conducted in parallel with the test substance using α-hexylcinnamaldehyde.
Remarks - Method	A translation of the study report was provided.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (lymph node weight (mg) Mean ± SD)*	*Stimulation Index (Mean ± SD)*
Test Substance			
0 (vehicle control)	4F	5.1 ± 1.0	1.0 ± 0.1
1%	4F	4.7 ± 0.3	1.0 ± 0.1
10%	4F	4.8 ± 0.4	1.3 ± 0.2
25%	4F	4.7 ± 0.7	1.0 ± 0.1
Positive Control			
25%	4F	8.6 ± 1.5	2.1 ± 0.1

SIs < 1.6

Remarks - Results	There were no mortalities or clinical abnormalities. All treated animals gained weight comparable to that of the vehicle control group. The stimulation index did not exceed 1.6.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	CERI (2013a)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 mix from phenobarbital/5,6-benzoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 313-5000 µg/plate b) Without metabolic activation: 313-5000 µg/plate
Vehicle	Water for injection
Remarks - Method	Concentrations for the main test were chosen on the basis of a preliminary test. Vehicle and positive controls were run concurrently with the notified chemical. Positive controls: With metabolic activation: 2-aminoanthracene (TA1535, WP2uvrA); benzo(a)pyrene (TA1537, TA98, TA100) Without metabolic activation: 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide (TA98, TA100, WP2uvrA); sodium azide (TA1535); 6-Chloro-9-[3-(2-chloroethylamino)propylamino]-2-methoxyacridine dihydrochloride (TA1357)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative
Present				
Test 1	> 5000	> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative

Remarks - Results	In both tests, no increases in the frequency of revertant colonies were observed in the presence or absence of metabolic activation. No growth inhibition of the test strains by the test substance was noted. No precipitates of the test substance on the plates were observed. The positive and negative controls gave a satisfactory response confirming the validity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BML (2014)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure – Prival and Mitchell modification
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA102, TA98, TA100
Metabolic Activation System	S9 mix from phenobarbital/β-naphthoflavone induced rat liver S9 mix from uninduced hamster liver
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Distilled water
Remarks - Method	Vehicle and positive controls were run concurrently with the notified chemical. Positive controls: With metabolic activation (S9 mix from induced rat liver): 2-aminoanthracene (TA1535, TA1537, TA100); benzo(a)pyrene (TA98); 1,8-dihydroxyanthraquinone (TA102) Without metabolic activation: mitomycine C (TA102); N-ethyl-N'-nitro-N-nitrosoguanidine (TA1535, TA100); 9-aminoacridine (TA1537); 4-nitroquinoline-1-oxide (TA98) With metabolic activation (S9 mix from uninduced hamster liver): congo red (TA100, TA98)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	*Cytotoxicity in Preliminary Test**	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative
Present				
Test 1	> 5000	> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative

* Test strain was TA100.

Remarks - Results	In both tests, no increases in the frequency of revertant colonies were observed in the presence or absence of metabolic activation. No growth inhibition of the test strains by the test substance was noted. No precipitates of the test substance on the plates were observed. The positive and negative controls gave a satisfactory response confirming the validity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan (2014)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	Lung fibroblasts
Metabolic Activation System	S9 mix from phenobarbital/5,6-benzoflavone induced rat liver

Vehicle	Distilled water
Remarks - Method	Growth inhibition tests were carried out at 78.1 – 5000 µg/mL and the results were used to determine the dose levels for the main tests. Vehicle and positive controls (mitomycin C and cyclophosphamide) were run concurrently with the notified chemical.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1250*, 2500*, 5000*	6h	24h
Test 2	4.88, 19.5, 78.1, 313*, 1250*, 5000*	24h	24h
Present			
Test 1	1250*, 2500*, 5000*	6h	24h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	IC_{50} > 5000	IC_{50} > 5000	> 5000	negative
Test 2	IC_{50} > 5000	IC_{50} > 5000	> 5000	positive
Present				
Test 1	IC_{50} > 5000	IC_{50} > 5000	> 5000	negative

Remarks - Results	In both main tests, no statistically significant increases in the frequencies of cells with numerical chromosome aberrations were observed in the presence or absence of metabolic activation. However, there were statistically significant increases in the frequencies of cells with structural chromosome aberrations in a dose-related manner in the 24 hours continuous treatment without metabolic activation. The positive and negative controls gave a satisfactory response confirming the validity of the test system.
CONCLUSION	The notified chemical did not induce numerical aberrations but induced structural aberration to Chinese hamster lung fibroblasts treated in vitro under the conditions of the test.
TEST FACILITY	CERI (2013b)

B.8. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/Crlj:CD1(ICR)
Route of Administration	Oral – gavage (intraperitoneal administration for positive control)
Vehicle	Distilled water
Remarks - Method	The selection of doses used in the main study was based on the results of a preliminary study. Toxicity was indicated by the ratio of polychromatic erythrocytes to erythrocytes (PCE/TE) and mutagenic response was indicated by the relevant increase of micronucleated PCEs.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*

vehicle control	6M/5E	0	24 h
low dose	6M/5E	500	24 h
mid dose	6M/5E	1000	24 h
high dose 1	6M/5E	2000	24 h
positive control, MMC	6M/5E	2	24 h

MMC = mitomycin C
5E: 5/6 animals were used for the evaluation.

RESULTS

Doses Producing Toxicity	No mortality or clinical signs were noted.
Genotoxic Effects	There were no statistically significant increases in the frequency of micronucleated PCEs.
Remarks - Results	As no significant changes were noted in the PCE/TE ratio and there were no clinical signs indicating toxicity, the exposure of the bone marrow to the test substance cannot be confirmed. The positive and negative controls gave a satisfactory response confirming the validity of the test system.

CONCLUSION The notified chemical was not clastogenic under the conditions of this in vivo mammalian erythrocyte micronucleus test.

TEST FACILITY CERI (2014a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated sludge from 10 locations in Japan, including from surface waters, surface soils of rivers, lakes, and inland seas, and return sludge from sewage treatment plants
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks - Method	The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*<Reference Substance>*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	59
14	0	14	75
21	0.5	21	76
28	1	28	76

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, aniline, surpassed the threshold level of 60% by 14 days (75%), and attained 76% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The notified chemical attained ≤ 2% degradation by 28 days. Therefore, the notified chemical cannot be classified as readily biodegradable according to the OECD (301C) guideline.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	CERI (2012)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202, *Daphnia sp.* Acute Immobilisation Test – Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	39 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Cumulative Immobilised (%)*	
Nominal	*Actual*		24 h	48 h
Control	Control	20	0	0
100	98.6	20	0	0

LC50	> 100 mg/L at 48 hours
NOEC (or LOEC)	Not determined
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The 48 h EC50 for daphnids was determined to be > 100 mg/L, based on measured concentrations.

CONCLUSION The notified chemical is not considered to be harmful to the aquatic invertebrates

TEST FACILITY CERI (2014b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Council Regulation No 440/2008 C.3 Algal Inhibition Test.

Species	*Pseudokirchneriella subcapitata* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 0.1-100 mg/L Actual: 0.1-110 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOE_b* mg/L at 72 h	*E_rC50* mg/L at 72 h (95% confidence interval)	*NOE_rC (* mg/L at 72 h
Not determined	Not determined	18 (17-20)	1

Remarks - Results 18 mg/L (17-20 mg/L) at 72 hours

CONCLUSION The notified chemical is considered to be harmful to algae

TEST FACILITY CERI (2013c)

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