File No: LTD/1981

August 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

ESI-M003

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 and Energy.

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/1981	Epson Australia Pty Ltd	ESI-M003	ND*	< 0.15 tonne/s per annum	Component of inkjet printing ink

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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 as introduced in inkjet printing ink:
  - Avoid skin and eye contact

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

- Service personnel should wear disposable gloves and ensure adequate ventilation is present when handling inkjet printing ink containing the notified chemical and during routine maintenance and repairs.

- A copy of the 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 not appropriate, dispose of the notified 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;
- the notified chemical is intended to be introduced at concentration greater than 5%;
- additional information has become available as to potential for genotoxicity and carcinogenicity of the notified chemical;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of printing 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.

Safety Data Sheet
The SDS of products containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Epson Australia Pty Ltd (ABN: 91 002 625 783)
3 Talavera Rd
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, spectral data, degree of purity, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for hydrolysis as a function of pH, adsorption/desorption, and dissociation constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
ESI-M003

MOLECULAR WEIGHT
> 1,000 Da

3. COMPOSITION

DEGREE OF PURITY
> 80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Deep red purple to reddish brown powder

Property	Value	Data Source/Justification
Melting Point	> 400 °C	Measured
Boiling Point	Not determined	Expected to decompose before reaching boiling point
Density	1,448 kg/m^3 at 20 °C	Measured
Vapour Pressure	Not determined	Expected to be very low based on its high molecular weight
Water Solubility	455 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable groups but significant hydrolysis is not expected at environmental pH range 4-9
Partition Coefficient (n-octanol/water)	log Pow < 0.3 at 20 °C	Measured
Surface Tension	72.4 mN/m at 20 °C	Measured
Adsorption/Desorption	Not determined	The notified chemical is not expected to significantly bind to sludge, soil or

		sediment based on its high water solubility and negatively charged properties
Dissociation Constant	Not determined	The notified chemical is a salt that will be ionised under environmental conditions
Particle Size	Inhalable fraction (< 100 µm): 45.12% Respirable fraction (< 10 µm): 12.60% MMAD* = 154.45 µm	Measured (imported in liquid solution).
Flash Point	> 200 °C (closed cup)	Measured
Flammability	Not highly flammable	Measured
Flammability in Contact with Water	Non-flammable	Measured
Autoignition Temperature	279 °C	Measured
Explosive Properties	Non-explosive	Measured
Oxidising Properties	Non-oxidising	Measured

* MMAD = Mass Median Aerodynamic Diameter

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

Neat form of the notified chemical is a solid with 45.12% and 12.60% of particles in inhalable (< 100 µm) and respirable (< 10 µm) sizes respectively. However, neat form of the notified chemical will not be imported. It will be imported at a maximum concentration of < 5% in aqueous solutions.

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 in Australia. The notified polymer will be imported as a component of finished inkjet printer ink at a concentration of < 5 %.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.15	< 0.15	< 0.15	< 0.15	< 0.15

PORT OF ENTRY
The main ports of each state

IDENTITY OF RECIPIENTS
Epson Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by sea as a component of inkjet printing ink in 120 mL plastic bottles, and will not be reformulated or repackaged within Australia. The ink bottles will be transported by road to the notifier's warehouse for further distribution.

USE
The notified chemical will be used as a component of inkjet printing ink for office and commercial use at a concentration < 5%. No home use of the ink containing the notified chemical is expected.

OPERATION DESCRIPTION
The ink bottles containing the notified chemical will be handled by service technicians and office workers. An end-user will remove the screw cap of the bottle and attach a supplied decanting nozzle to it. The ink will be decanted from the bottle into the ink tank within the printer. Emptied bottles will be re-sealed and disposed of as domestic garbage.

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 warehousing	2 – 4	150
Service technicians	1	200
Office workers	8	200

EXPOSURE DETAILS
Transport and Storage
Transport and storage workers will handle the notified chemical at < 5% concentration in sealed bottles. These workers may come into contact with the notified chemicals only in the unlikely event of an accident when the packaging is breached. These workers are expected to wear overalls and safety boots during handling.

End use
Service technicians and office workers may come into contact with the ink containing the notified chemical. Dermal or possibly incidental ocular exposure to the notified chemical at < 5% concentration may occur during operations including replacing spent ink bottles, transferring the ink from ink bottles to printers, and cleaning or maintaining printers. However, the exposure is expected to be infrequent or incidental, given the containment of the notified chemical within purposely designed ink bottles and the provision of safe use instructions.

Potential for incidental dermal and ocular exposure where ink leaks will be discovered during maintenance and will be minimised through the proposed use of appropriate personal protective equipment (PPE) including gloves. Occasional dermal exposure during printing may also occur if the printed pages are handled when wet, or if the ink-stained parts of the printer are touched.

Once the ink dries, the notified chemical will be bound to the matrix of the substrates and is not expected to be bioavailable for exposure.

Inhalation exposure to the notified chemical is not expected, given the expected low vapour pressure of the chemical and the low likelihood of aerosols being released from the printers.

6.1.2. Public Exposure
The inkjet printer inks containing the notified chemical will not be made available to the general public for home use. Therefore, direct public exposure is unlikely to occur.

Members of the public may come into contact with printed materials. However, once the ink dries, the notified chemical will be bound to the matrix of the substrates and is not expected to be bioavailable for exposure.

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	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating

Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution
No information on the toxicokinetics, metabolism and distribution of the notified chemical was provided. Based on the relatively high molecular weight (> 1,000 Da), absorption of the notified chemical across the skin or biological membranes is expected to be limited.

Acute toxicity
The notified chemical was found to have low acute oral and dermal toxicity in rats. No information was submitted on acute inhalation toxicity.

Irritation and sensitisation
Based on studies conducted in rabbits, the notified chemical was considered to be non-irritating to the skin and slightly irritating to the eyes. The notified chemical did not show any evidence of sensitisation in a local lymph node assay (LLNA) in mice.

Repeated dose toxicity
No repeated dose toxicity studies were provided for the notified chemical.

Mutagenicity/Genotoxicity
The notified chemical was not mutagenic in a bacterial reverse mutation study. However, the notified chemical contains aromatic amine groups and, in the absence of further *in vitro* or *in vivo* study data, the potential for genotoxicity, especially clastogenicity, of the notified chemical cannot be ruled out.

Carcinogenicity
Based on the structural formula provided, the notified chemical may potentially be metabolised *in vivo* to release aromatic amines. A small number of the aromatic amines are classified as being carcinogenic or potentially carcinogenic to humans (SCCNFP, 2002). However, the carcinogenic amines listed in the SCCNFP report is unlikely to be generated from the notified chemical. In the absence of a carcinogenicity study, the potential for the notified chemical to cause carcinogenic effects cannot be completely ruled out.

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The potential for the notified chemical to cause genotoxic and carcinogenic effects cannot be completely ruled out. Workers may come into contact with the notified chemical at a concentration < 5% in inkjet print ink. Given the enclosed nature of the ink bottles and ink tanks in the printers, exposure to the notified chemical is expected to be infrequent or incidental. Exposure potential may further be reduced by following the safe use instructions and using protective gloves during servicing activities. As there is no toxicology data on the carcinogenicity of the notified chemical, safe work practices such as avoiding skin and eye contact is recommended.

Once the ink dries, the notified chemical will be bound to the matrix of the substrates and is not expected to be bioavailable.

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

6.3.2. Public Health
The printing ink containing the notified chemical will not be directly available to the general public, but the public may come into contact with printed substrates containing the notified chemical. However, once dried, the notified chemical is expected to be bound into the substrates and will not be bioavailable. Therefore, based on the proposed use patterns, the risk of the notified chemical 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 in ink bottles. No release of the notified chemical to the environment is expected from manufacturing or reformulation as these activities will not occur in Australia. Release of the notified chemical to the environment is unlikely during importation, storage and transportation given ink bottles are designed to minimise release.

RELEASE OF CHEMICAL FROM USE

Based on its use as ink products, most of the notified chemical will be fixed within an inert ink matrix adhering to paper and is not expected to be released to the environment once cured. The release of the notified chemical may occur from leakage of ink during use, installation or replacement of ink bottles. Any releases are expected to be contained with absorbent material and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Following its use as printing ink, the majority of the notified chemical is anticipated to share the fate of printed paper and be disposed of to landfill or subjected to paper recycling processes. Up to half of the printed paper is expected to be recycled, and the notified chemical may be released to sewage treatment plants (STPs) during paper recycling processes.

Residual ink left in empty ink bottles may contain up to 5% of the total annual import volume of the notified chemical. The used ink bottles are expected to be collected for reuse, recycling or be disposed directly to landfill. The ink residues separated from the recycled bottles are expected to be disposed of under the local regulation. Residual ink remaining the used ink bottles is expected to be disposed of to landfill along with the used items if the used ink bottles are not subjected for reuse or recycling.

7.1.2. Environmental Fate

Most of the notified chemical is expected to be disposed of to landfill along with printed paper or released to recycling wastewaters when used paper is recycled. Given that it is highly water soluble, the notified chemical has the potential to partition to the supernatant water and be released to sewer during paper recycling processes. During waste water treatment processes in STPs, the notified chemical is not expected to be efficiently removed from influent due to its high water solubility. Some notified chemical may be released to surface waters.

The notified chemical is hydrolytically stable under environmental conditions and is not readily biodegradable. However, the notified chemical is not expected to bioaccumulate due to its low n-octanol/water partition coefficient (log Pow < 0.3). The notified chemical is likely to be mobile based on its high water solubility in landfill and soil. For the details of the environmental fate studies please refer to Appendix C.

In surface waters, soil, landfill, sediment or sludge, the notified chemical is expected to eventually degrade by biotic and abiotic processes to form water, oxides of carbon, nitrogen and sulphur, and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) can be estimated as outlined below assuming that 50% of the annual import volume of the notified chemical will be released to sewer during recycling of the used paper. For the worst case scenario, it is assumed that no removal of the notified chemical from influent at STPs. It is assumed that release of the notified chemical occurs over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	150	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	75	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.29	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:	0.06	µg/L
PEC - Ocean:	0.006	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.064 µg/L may potentially result in a soil concentration of approximately 0.43 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 2.13 µg/kg and 4.25 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*
Fish Toxicity	LC50 > 100 mg/L	Not harmful to fish
Daphnia Toxicity	EC50 > 100 mg/L	Not harmful to invertebrates

Based on the above ecotoxicological endpoints, the notified chemical is not expected to be harmful to aquatic life. Therefore, the notified chemical is not classified under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009) for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated using the acute endpoint from fish. A safety factor of 250 was used given acute endpoints for two trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish)	> 100.00	mg/L
Assessment Factor	250.00	
Mitigation Factor	1.00	
PNEC:	> 400.00	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	0.06	> 400	< 0.001
Q - Ocean	0.006	> 400	< 0.001

The Risk Quotients (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be less than 1 for the river and ocean compartments. This indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters based on its maximum use volume and assessed use pattern. Therefore, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment based on its assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point > 400 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Capillary method; no melting point observed up to 400 °C
Test Facility	CiToxLAB Hungary Ltd (2017a)

Density 1,488 kg/m^3 at 20 °C

Method	EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Liquid pycnometer
Test Facility	Chilworth Technology Ltd, UK (2017a)

Water Solubility 455 g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method
Test Facility	CERI Kurume, Japan (2017a)

Partition Coefficient (n-octanol/water) log Pow < 0.3 at 20 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method
Test Facility	CERI Kurume, Japan (2017b)

Surface Tension 72.4 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions.
Remarks	Concentration: 1 g/L
Test Facility	CERI Kurume, Japan (2017c)

Particle Size MMAD = 154.45 µm

Method In house method similar to OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (µm)	*Mass (%)*
< 100 µm	45.12
< 10 µm	12.60

Remarks	Small volume module (SVM) in kerosene with laser diffraction analysis
Test Facility	Chilworth Technology Ltd, UK (2017b)

Flash Point > 200 °C (closed cup)

Method	EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks	Miniflash FLP Flash Point Tester (continuously closed cup with electric arc); no flash point observed up to 200 °C
Test Facility	CiToxLAB Hungary Ltd (2017b)

Flammability Not highly flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks	Two preliminary tests showed no ignition and therefore no main test was performed.
Test Facility	CiToxLAB Hungary Ltd (2017c)

Flammability in Contact with Water Non-flammable

Method	EC Council Regulation No 440/2008 A.12 Flammability (Contact with Water).
Remarks	No gas generation or spontaneous ignitions were observed during the tests.
Test Facility	Chilworth Technology Ltd, UK (2017c)

Autoignition Temperature 279 °C

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	Three replicate tests were performed.
Test Facility	CiToxLAB Hungary Ltd (2017d)

Explosive Properties Non-explosive

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	BAM fall hammer, BAM friction and Koenen steel tube test, no explosions observed.
Test Facility	Chilworth Technology Ltd, UK (2017d)

Oxidizing Properties Non-oxidising

Method	EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).
Remarks	Maximum burning rate of the test substance was found to be lower than the reference substance (barium nitrate).
Test Facility	CiToxLAB Hungary Ltd (2017e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Crl: WI Wistar
Vehicle	Distilled water
Remarks - Method	GLP Certificate No significant protocol deviations Applied dose corrected for purity of the test substance

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	2,000	0/3
2	3F	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No signs of toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	Consumption of the notified chemical caused the animals to excrete reddish coloured faeces and urine on Days 0-2. All animals showed expected gains in bodyweight over the study period.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	CiToxLAB Hungary Ltd (2017f)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Crl: WI Wistar
Vehicle	None. Notified chemical was directly applied with moistening with water.
Type of dressing	Semi-occlusive
Remarks - Method	GLP Certificate No significant protocol deviations Applied dose corrected for purity of the test substance

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M	2,000	0/5
2	5F	2,000	0/5

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks - Results	There were no deaths or signs of systemic toxicity. The treated area of the skin was coloured red in all animals and persisted up to Day 5-7, but this change had no toxicological impact. All animals showed expected

bodyweight gain over the study period.

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

TEST FACILITY CiToxLAB Hungary Ltd (2017g)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (males)
Vehicle	None. Notified chemical was directly applied with moistening with water.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP Certificate No significant protocol deviations Applied dose corrected for purity of the test substance

RESULTS

Remarks - Results There were no skin reactions observed on the skin of the treated animals.

Discolouration by the test substance of the hair on the treated area was observed in all animals; however, it did not preclude the scoring for erythema.

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

TEST FACILITY CiToxLAB Hungary Ltd (2017h)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (males)
Observation Period	72 hours
Remarks - Method	GLP Certificate. No significant protocol deviations Applied dose corrected for purity of the test substance

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	0.33	0.33	0	1	< 48 h	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge	0.67	0.33	0	2	< 48 h	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results A purple-coloured staining of the fur around all treated eyes was noted at the 1 hour observation period. No corneal or iridial effects were noted

during the study. Moderate conjunctival irritation was noted in all treated eyes 1 hour after treatment. All effects on treated eyes were fully reversible within 48 hours.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY CiToxLAB Hungary Ltd (2017i)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain	Mouse/CBA/CaOlaHsd strain
Vehicle	1% aqueous Pluronic PE9200
Preliminary study	Yes – notified chemical in vehicle at 10% and 25% w/v
Positive control	Conducted in parallel with the test substance: α-hexylcinnamaldehyde (HCA) in vehicle at 25% w/v
Remarks - Method	GLP Certificate No significant protocol deviations Applied doses corrected for purity of the test substance

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	5F	213.8	1.0
5%	5F	275.7	1.1
10%	5F	264.9	1.2
25%	5F	230.4	1.3
Positive Control (HCA)			
25%	5F	2406.5	11.3**

** = Significantly different from vehicle control group ($p < 0.01$)

Remarks - Results No deaths or signs of systemic toxicity observed.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical up to 25% concentration.

TEST FACILITY CiToxLAB Hungary Ltd (2017j)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Pre incubation procedure

Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 from Phenobarbitone (PB)/5,6-benzoflavone (BF) induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 313 – 5,000 µg/plate b) Without metabolic activation: 313 – 5,000 µg/plate
Vehicle	Distilled water
Remarks - Method	No GLP certificate No significant protocol deviations Applied doses corrected for purity of the test substance

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (preliminary)	> 5,000	-	> 5,000	Negative
Test 2 (main)	-	> 5,000	> 5,000	Negative
Present				
Test 1 (preliminary)	> 5,000	-	> 5,000	Negative
Test 2 (main)	-	> 5,000	> 5,000	Negative

Remarks - Results

The notified chemical did not increase the number of revertant colonies more than 2-fold compared to the negative control for all dose concentrations tested, in the presence or absence of metabolic activation, on all strains tested.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

FUJIFILM Corporation, Japan (2016)

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
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical oxygen demand (BOD) measured with an *in situ* oxygen consumption measuring equipment Test substance measured with HPLC
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	-1	7	81
14	-1	14	90
21	-2	21	91
28	-2	28	92

Remarks - Results	The percentage degradation of the reference compound (aniline) surpassed the threshold level of 60% after 14 days (90%). Therefore, the validity criterion of the test was satisfied. The average degree of degradation of the test substance after 28 days was 0% based on the BOD method.
CONCLUSION	The notified chemical is not considered to be readily biodegradable.
TEST FACILITY	FUJIFILM Corporation, Japan (2017)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static.
Species	Medaka (*Oryzias latipes*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	28 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles. The weighted test sample of 350 mg was mixed with 2.8 L of water in a test vessel and stirred to prepare the test solution.

RESULTS

Concentration mg/L		*Number of Fish*	*Cumulative Mortality (%)*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*

Concentration mg/L		*Number of Fish*	*Cumulative Mortality (%)*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	ND	7	0	0	0	0	0
100	105	7	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC (or LOEC)	Not reported
Remarks – Results	All validity criteria of the test guideline were satisfied. The test item concentration in the test solution was maintained within ± 20% of the nominal concentration during exposure. The 96 h LC50 for fish was determined to be > 100 mg/L based on the nominal concentrations.

CONCLUSION The notified chemical is not harmful to fish.

TEST FACILITY CERI Kurume, Japan (2017d)

C.2.2. 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	28 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted in accordance to the test guidelines above with a deviation that water hardness in the test solutions is 28 mg $CaCO_3$/L, which is out of the range 140-250 mg $CaCO_3$/L as recommended by the test guideline. The test was conducted in compliance with GLP standards and principles. 100 mg of the test sample was mixed with 801 mL of dilution water in a container and stirred to prepare the test solution.

RESULTS

Concentration mg/L		*Number of D. magna*	*Immobilised (%)*	
Nominal	*Actual*		*24 h*	*48 h*
Control	ND	20	0	0
100	99.5	20	0	0

LC50	> 100 mg/L at 48 hours
NOEC (or LOEC)	Not determined
Remarks - Results	All validity criteria of the test guideline were satisfied. The measured test item concentration in the test solution was within the range of ±20% of the nominal concentration. The 48 h EC50 for Daphnia was determined to be >100 mg/L, based on the concentrations tested.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates.

TEST FACILITY CERI Kurume, Japan (2017e)

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