File No: LTD/1893

March 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Equamide™ M100

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/1893	Ricoh Australia Ltd	Equamide™ M100	ND*	< 1 tonne per annum	Component of commercial 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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Local exhaust ventilation and adequate general ventilation

- 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 skin and eyes
  - Avoid breathing in vapours
  - Compliance with Safe Work Australia Guidance Control guidance sheet *P39 Wide-format inkjet printing with solvent-borne inks*

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Protective clothing
  - Impervious gloves

  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 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 with non-combustible absorbent material, 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 chemical is intended to be used in ink products available to the public;

or

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

(Material) Safety Data Sheet
The (M)SDS of the notified chemical and product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Ricoh Australia Pty Ltd (ABN: 30 000 593 171)
2 Richardson Place
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 and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (1998), EU (2010), Japan (2014), Korea (2010) and USA (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Equamide™ M100

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
> 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at ambient temperature
Boiling Point	215.2 °C	SDS
Density	994 kg/m^3 at 20 °C	SDS
Vapour Pressure	0.0755 kPa at 20 °C	SDS
Water Solubility	Soluble	SDS
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities, however, significant hydrolysis is not expected to occur under normal environmental conditions (pH 4 – 9)
Partition Coefficient (n-octanol/water)	Not determined	Not expected to significantly partition to n-octanol based on its expected high water solubility

Property	Value	Data Source/Justification
Adsorption/Desorption	Not determined	Due to its high water solubility and expected low partition co-efficient the notified chemical is not expected to adsorb to soils/sediment to any great extent
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	99 °C	SDS
Flammability	Combustible liquid*	Based on flash point
Autoignition Temperature	219 °C	SDS
Explosive Properties	Not potentially explosive	SDS
Oxidising Properties	Not potentially oxidising	SDS

* Based on *Australian Standard AS1940* definitions

DISCUSSION OF PROPERTIES

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.

The notified chemical has a flash point of 99 °C. Based on *Australian Standard AS1940* definitions for combustible liquids, a liquid that has a flash point of 150 °C or less is a Class C1 combustible liquid.

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. It will be imported as a component of inkjet printer ink at < 10% concentration in sealed cartridges.

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

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

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The inkjet printing ink containing the notified chemical will be imported into Australia in 220 mL sealed cartridges packaged in cardboard boxes. The ink cartridges will be distributed by road nationwide.

USE
The notified chemical will be used as a component of inkjet printing ink at < 10% concentration for commercial/office printing. The printing substrate will mainly be paper.

OPERATION DESCRIPTION
No manufacture, reformulation or repackaging processes will occur for the notified chemical in Australia.

The sealed ink cartridges containing the notified chemical will be manually fitted into printers and replaced as necessary. The printing operations are expected to be computerised and automated. Cleaning and maintenance of the printers will occur as required.

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)*
Storage and transport workers	2 – 3	10 – 15
Printer operators	0.1 – 0.3	200

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

During normal use, significant exposure to the notified chemical is not expected as the printing process is largely enclosed and automated. Printer operators may be dermally exposed to the notified chemical at < 10% concentration during replacement of ink cartridges and cleaning. The notifier states that printer operators will wear protective clothing and impermeable gloves during these operations. As the notified chemical is expected to evaporate after application to the substrate, inhalation exposure to the notified chemical may also occur. The notifier states that local exhaust ventilation will be employed in areas surrounding the printing machines to reduce the potential for inhalation.

Service engineers may come in contact with the notified chemical at < 10% concentration during printer maintenance, where dermal, ocular or inhalation exposure to the notified chemical is possible. The notifier states that printer maintenance personnel will wear disposable rubber gloves and safety glasses, and local exhaust ventilation will be used surrounding the printing areas.

6.1.2. Public Exposure
The ink cartridges containing the notified chemical will only be used for commercial purposes. The general public may come into contact with the printed substrate. However, the majority of the notified chemical is expected to evaporate from the print matrix during printing. The exposure of the public to the notified chemical is therefore not expected to be significant.

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 A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics
No toxicokinetic data were submitted. Based on the low molecular weight (< 500 Da) of the notified chemical, absorption across biological membranes may occur.

Acute toxicity
Acute oral toxicity study on the notified chemical suggests that the chemical is of low toxicity via the oral route with LD50 > 2,000 mg/kg bw. Although no mortality at the dose level of 2,000 mg/kg bw was observed, clinical signs including hunched posture and ataxia were recorded in the test animals for two to three days following the oral administration.

No acute dermal and inhalation toxicity information was provided for the notified chemical.

Sensitisation
In a mouse local lymph node assay, the notified chemical did not showed evidence of skin sensitisation when tested up to 100% concentration.

Mutagenicity/Genotoxicity
In a bacterial reverse mutation study, the notified chemical did not show evidence of mutagenicity.

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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
As only limited toxicological information is available on the notified chemical, the hazard status of the chemical cannot be fully determined. The notified chemical is of low molecular weight and thus there is potential for absorption by all routes. Based on the available studies, the notified chemical is of low acute oral toxicity, not a skin sensitiser and non-mutagenic.

There is potential for dermal and ocular exposure to the notified chemical at < 10% concentration during replacement of ink cartridges, printer cleaning and maintenance. The notifier stated that service technicians and printer operators are required to wear protective clothing and gloves during operations to minimise the potential for exposure.

Since the notified chemical is likely to volatilise during printing and drying, repeated inhalation exposure for workers is possible if vapour of the notified chemical is formed in workplaces. The health effects of repeated or prolonged exposure to the notified chemical are uncertain. The notifier has stated that local exhaust ventilation will be used at the printing machines at all sites. In addition to the local exhaust ventilation proposed by the notifier, the Safe Work Australia (SWA) guidance document, *P39 –Wide-format inkjet printing with solvent-borne inks*, also recommends providing a good standard of general ventilation, and that ventilation equipment is maintained and working effectively. Safe work practices and use of appropriate PPE as proposed by the notifier are expected to reduce the potential for exposure.

Provided that adequate workplace controls are in place to reduce potential for exposure to the inks containing the notified chemical, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health
The ink products containing the notified chemical will not be available to the public. The public may have contact with dry printed materials. However, the majority of the notified chemical is expected to be evaporated from the ink matrix during heat-drying before the substrate leaves the printer. The exposure of the public to the notified chemical is therefore not expected to be significant. Therefore, based on the use scenario, the risk of the notified chemical to the health of 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 cartridges. 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 cartridges 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. The applied notified chemical is expected to be semi-volatile (vapour pressure < 1 hPa at 20 °C) and it is expected to evaporate from the ink matrix during heat-drying before the substrate leaves the printer. 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 be released to the atmosphere during drying. However, a very small amount may remain within the dried ink matrix and will be disposed of to landfill and is expected to remain associated with the substrate to which it has been applied. 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 cartridges containing residues of the notified chemical are expected to be disposed of to landfill. During paper recycling processes, waste paper is pulped using a variety of chemical treatments that results in ink detachment from the fibres.

7.1.2. Environmental Fate

The notified chemical contains groups that are known to be readily biodegradable. Based on its high water solubility and expected low partition coefficient, the notified chemical is not expected to bioaccumulate.

The majority of the notified chemical is expected to be released to the atmosphere. The half-life of the notified chemical in air is calculated to be 3.08 hours based on reactions with hydroxyl radicals (AOPWIN v1.92; US EPA, 2011). Therefore, the notified chemical is not expected to persist in the atmospheric compartment.

Notified chemical trapped in the ink matrices is expected to be disposed of to landfill with the substrate to which it is applied. Given the high water solubility and low log Koc, the notified chemical may leach from landfill and enter surface waters. A small proportion of the notified chemical may be released to sewer during paper recycling. Given the high water solubility and low absorption coefficient (log Koc < 1.25), the notified chemical is not expected to partition to sludge during waste water treatment processes in sewage treatment plants (STPs). Therefore, the notified chemical is expected to remain in waste water and be released to aquatic environments.

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. It is also assumed that there is no removal of the notified chemical from the ink matrix through the drying process. 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	1,000	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)	22.61	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC - River:	0.43	µg/L
PEC - Ocean:	0.04	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 0.425 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 B.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h EC50 > 100 mg/L	Not harmful to fish
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	72 h E_rC50 > 100 mg/L	Not harmful to algae

Based on the endpoints for toxicity of the notified chemical to aquatic organisms, the notified chemical is not considered to be harmful to aquatic organisms under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Therefore, the notified chemical is not formally classified under the GHS. Based on its measured acute toxicity, biodegradability and expected low bioaccumulation potential, the notified chemical is not formally classified under the GHS for the chronic hazard.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated since the notified chemical is not expected to be harmful to aquatic life, based on the studies provided by the notifier.

7.3. Environmental Risk Assessment

A risk quotient (PEC/PNEC) for the notified chemical was not calculated as a PNEC was not derived. The notified chemical is unlikely to result in ecotoxicologically significant concentrations in the aquatic environment from the assessed use pattern. Further, the notified chemical is expected to be readily biodegradable, thus it is unlikely to persist in surface waters or soils. The notified chemical is considered to have low potential for bioaccumulation due to its high water solubility. Therefore, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment from the assessed use pattern.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method EC Commission Directive 2004/73/EC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/Sragues-Dawley CD (Crl: CD® (SD) IGS BR)
Vehicle	Distilled water
Remarks - Method	No significant deviations of the protocol were recorded.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3 F	300	0/3
2	3 F	2,000	0/3
3	3 F	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	There was no mortality during the study. There were no signs of systemic toxicity noted in animals treated at a dose level of 300 mg/kg. Signs of systemic toxicity noted in animals treated at a dose level of 2,000 mg/kg were hunched posture and ataxia. These signs were absent two or three days after dosing.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	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	Safepharm Laboratories (2006)

A.2. 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/Ca (CBA/CaBkl)
Vehicle	Acetone/olive oil (4:1)
Preliminary study	Yes
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde.
Remarks - Method	No significant deviations of the protocol were recorded.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	4 F	688.09	1.00
25	4 F	1,145.61	1.66
50	4 F	1,237.87	1.80
100	4 F	1,263.53	1.84
Positive Control (Historical)			
5	5	-	2.50
10	5	-	4.03

25	5	-	9.13

Remarks - Results	Preliminary screening test using one mouse treated at 100% for 3 days did not show signs of systemic toxicity or excessive local irritation.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	Safepharm Laboratories (2007)

A.3. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 mix; S9 fraction was prepared from rat liver homogenate induced with phenobarbital and 5,6-benzoflavone.
Concentration Range in Main Test	a) With metabolic activation: 156 – 5,000 µg/plate b) Without metabolic activation: 156 – 5,000 µg/plate
Vehicle	Water
Remarks - Method	No significant deviations of the protocol were recorded. The purity of the test substance was reported as > 98%.

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	No inhibition of cell growth and precipitation was observed in both the range finding and the main tests. Positive controls showed expected positive results.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	UBE (2006)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Ecotoxicological Investigations

B.1.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test –Semi-static "Acute toxicity test in fish" stipulated in "Order Prescribing the Tests Relating to the New Chemical Substances" (Yaku-shoku-Hatsu No. 1121002, Heisei 15.11.13 Seikyoku No. 2, Kanpoki-Hatsu No. 031121002 dated November 21, 2003)
Species	Killifish (*Oryzias latipes*)
Exposure Period	96 hours
Auxiliary Solvent	None reported
Water Hardness	37 mg $CaCO_3$/L
Analytical Monitoring	HPLC method
Remarks – Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	8	0	0	0	0	0
100	8	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The nominal concentration was: 100 mg/L. No death of test organisms was observed during exposure period at the test concentration.
CONCLUSION	The notified chemical is not harmful to fish.
TEST FACILITY	Kurume Laboratory (2007a)

B.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static. "Acute swimming immobilization test in water flea" stipulated in "Order Prescribing the Tests Relating to the New Chemical Substances" (Yaku-shoku-Hatsu No. 1121002, Heisei 15.11.13 Seikyoku No. 2, Kanpoki-Hatsu No. 031121002 dated November 21, 2003)
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	37 mg $CaCO_3$/L
Analytical Monitoring	HPLC method
Remarks - Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h [acute]	*48 h [acute]*
Control	20	0	0
100	20	0	0

LC50	> 100 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied.

CONCLUSION	The notified chemical is not harmful to aquatic invertebrates.
TEST FACILITY	Kurume Laboratory (2007b)

B.1.3. Algal growth inhibition test

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. "Algal growth inhibition test" stipulated in "Order Prescribing the Tests Relating to the New Chemical Substances" (Yaku-shoku-Hatsu No. 1121002, Heisei 15.11.13 Seikyoku No. 2, Kanpoki-Hatsu No. 031121002 dated November 21, 2003, partially amended on November 20, 2006)
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	None reported
Water Hardness	None reported
Analytical Monitoring	HPLC method
Remarks - Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Biomass		*Growth*	
E_yC50 (mg/L at 72h)	*NOE_yC (mg/L at 72h)*	*E_rC50 (mg/L at 72 h)*	*NOE_rC (mg/L at 72h)*
> 100	100	> 100	100

Remarks - Results	All validity criteria for the test were satisfied. No abnormality was observed in the control medium. The same observation was noted in 100 mg/L area.

CONCLUSION	The notified chemical is not harmful to algae.
TEST FACILITY	Kurume Laboratory (2007c)

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