File No: LTD/1938

January 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

CIM-44

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/1938	Canon Australia Pty Ltd.	CIM-44	No	< 1 tonne per annum	A component of printing ink

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.

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

- No specific engineering controls, work practices or personal protective equipment 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.

  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 removing spent printer cartridges containing the notified chemical and during routine maintenance and repairs.

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

Environment
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 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;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a 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 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)
Canon Australia Pty Ltd. (ABN: 66 005 002 951)
Building A, The Park Estate
5 Talavera Rd
MACQUARIE PARK 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, molecular and structural formulae, molecular weight, analytical data, degree of purity, residual monomers, impurities, additives/adjuvants, use details, manufacture/import volume, site of manufacture/reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: specific gravity/density, vapour pressure, hydrolysis as a function of pH, absorption/desorption, dissociation constant, particle size, flash point, flammable limits, autoignition temperature, explosive properties, oxidising properties and reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
China (2016), Korea (2016), Japan (2016), USA (2016), Philippines (2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CIM-44

CAS NUMBER
Not assigned

MOLECULAR WEIGHT
800 - 1,800 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 99 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Magenta solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 337 °C	Measured
Boiling Point	Not determined	Expected to decompose prior to boiling
Density	Not determined	Estimated to be > 1000 kg/m^3

Vapour Pressure	Not determined	Expected to be low, based on the high MW and polarity.
Water Solubility	318 - 346 g/L at 20 ± 0.5 °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 = -2.00 at 24 ± 1.0 °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): ≤ 50.3 % Respirable fraction (< 10 μm): ≤ 0.507 % Respirable fraction (< 5 μm): ≤ 4.5×10^{-2} %	Measured
Flash Point	Not determined	Expected to be high based on the predicted low vapour pressure
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Not expected to be explosive based on the chemical structure
Oxidising Properties	Not determined	Not expected to be oxidising based on the chemical structure

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.

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 as a component of finished printer ink at a concentration of < 7 %.

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 Airport and Port of Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Canon Australia Pty Ltd.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in ink cartridges and bottles and will not be reformulated or repackaged within Australia.

USE
The notified chemical will be used as a component in printing ink at a concentration < 7%.

OPERATION DESCRIPTION
No manufacture or reformulation/repackaging of the ink cartridges/ink bottles containing the notified chemical at < 7% concentration will occur in Australia.

Sealed ink cartridges and ink bottles containing the notified chemical will be handled by service technicians, office workers or members of the public, who will use the inkjet printers and replace spent cartridges or transfer the ink from the ink bottles into the ink tank as necessary. The inks in the printers will be used for a variety of printing work.

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	< 8	10-50
Service technicians	1	170
Retail workers	< 8	10-50
Office workers	< 0.5	2

EXPOSURE DETAILS

During transport and storage, worker exposure is not expected unless the packaging is breached or the containers are damaged and leak.

Printer technicians and office workers may be exposed to the ink containing the notified chemical (at ≤ 7% concentration) during normal operations including removal of empty ink cartridges to replace with new ones, transfer of the ink from ink bottles to ink tanks, printer maintenance/cleaning, and the handling of wet printed substrates. Dermal exposure is expected to be the main route, although incidental ocular exposure is possible. However, given the design of the ink cartridges and printers, exposure to the notified chemical is expected to be limited if workers follow the safety instructions provided.

Occasional dermal exposure during printing may also occur if the wet printed substrates are handled inappropriately. Once the ink dries, the notified chemical will be bound to the matrix of the substrates and is not expected to be bioavailable. Inhalation exposure to the notified chemical is not expected given the low vapour pressure of the chemical and the low likelihood of aerosols being released from the cartridges and printers.

6.1.2. Public Exposure
The public may be exposed when replacing the ink cartridges in their printers, and during the transfer of the ink from ink bottles to ink tanks in the printers. Exposure of these users to the notified chemical is expected to be of a similar or lesser extent compared to 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	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating*

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

* Product containing the notified chemical at < 7% concentration.

Toxicokinetics, metabolism and distribution
The notified chemical has a moderately high molecular weight (800 – 1800 Da) and is a hydrophilic substance (water solubility 318 - 346 g/L and log Pow -2) and is expected to be ionised at pH 7.4. Therefore, the notified chemical is not expected to be absorbed through the skin or across cell membranes.

Acute toxicity
The notified chemical was of low acute oral toxicity in rats.

No acute dermal or inhalation toxicity data were provided for the notified polymer.

Irritation
A product containing the notified chemical at < 7% was non-irritating to the skin of rats.

No eye or respiratory irritation data were provided.

Sensitisation
In an LLNA study, a product containing the notified chemical at a concentration of < 7% showed no evidence of inducing skin sensitisation.

Mutagenicity/Genotoxicity
In an *in vitro* bacterial reverse mutation study using *S. typhimurium* strains TA1537, TA1535, TA100 and TA98 and *E. coli* strain WP2uvrA, the notified chemical tested negative to mutations.

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 notified chemical is of low acute oral toxicity and non-mutagenic and is expected to have minimal absorption across the skin. Additionally the imported product containing the notified chemical at < 7% concentration was not irritating to the skin or sensitising.

Dermal or possibly incidental ocular exposure to the notified chemical at < 7% concentration may occur during operations including replacing spent ink cartridges, during transfer of the ink from ink bottles to printers, and during printer maintenance and cleaning. Dermal exposure is also possible when handling printed substrates before the ink dries. However, the exposure is expected to be infrequent or only incidental in nature, given the containment of the notified chemical within purposely designed ink cartridges and ink bottles at a relatively low concentration (up to 7%), and the provision of instructions for safe use of the ink cartridges and ink bottles. 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 expected exposure, low hazard 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 the exposure is expected to be 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 the substrates and will not be bioavailable. Therefore, based on low exposure potential, 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 cartridges and 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 printer cartridges or bottle are designed to minimise release.

RELEASE OF CHEMICAL FROM USE

The sealed ink cartridges are designed to prevent leakage and will not be opened during use, installation or replacement. Therefore, release of ink containing the notified chemical to the environment is not expected under normal conditions. However, the notified chemical has potential to be released to environment as a result of spills from the ink bottles. Spills containing the notified chemical (account for up to 1% of the total import volume of the notified chemical) will be wiped with absorbent material and be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Following its use as printer 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 these processes.

Residual ink left in empty cartridges and ink bottles may contain up to 5% of the notified chemical. The used cartridges or ink bottles are expected to be collected for reuse, recycling or be disposed directly to landfill. The ink residues separated from the recycled cartridges and bottles are expected to be disposed of under the local regulation. Residual ink remaining the used ink cartridges and bottles is expected to be disposed of to landfill along with the used items if the used ink cartridges and 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. 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	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	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.43	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 2.84 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 14.2 µg/kg and 28.3 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified chemical were submitted. Similar ink dyes are generally not expected to be harmful to fish and aquatic invertebrates (L(E)C50 > 100 mg/L), but can be moderately toxic to green algae. Effects on algae are mostly related to the colour of dyes, which can reduce the light needed for the algae's growth, rather than from direct toxic effects. Based on the algal toxicity found for similar chemicals, the acute toxicity for algae is estimated to be greater than 1 mg/L for the notified chemical.

The estimation procedure used here is based on data for similar chemicals and is considered acceptable for the purpose of risk assessment. However, this toxicity estimation is not considered sufficient to formally classify the acute and long term hazard of the notified chemical to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The endpoint for the most sensitive species (Algae) is used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 1000 was used because no measured ecotoxicological data were available and the estimated data were used to predict the environmental effects of the notified chemical.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae)	> 1	mg/L
Assessment Factor	1000	
PNEC:	> 1	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.43	> 1	< 0.43
Q - Ocean	0.043	> 1	< 0.04

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/Freezing Point 337 °C

Method OECD TG 102 Melting Point/Melting Range.
EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks Determined using differential scanning calorimetry (DSC). After heating, the DSC indicated the test material started to decompose at 337 °C.
Test Facility ENVIGO (2016b)

Water Solubility 318 – 346 g/L at 20 °C

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method. The standard OECD 105 methodology was not applicable to this test substance due to its very high saturation level. Therefore, the saturated point of the test substance was visually assessed.
Test Facility ENVIGO (2016b)

Partition Coefficient (n-octanol/water) log Pow = -2.00 at 24 °C

Method OECD TG 107 Partition Coefficient (n-octanol/water).
EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks Flask Method
Test Facility ENVIGO (2016b)

Particle Size

Method Compatible with EUR20268 – Determination of Particle Size Distribution, Fibre Length and Diameter Distribution of Chemical Substances (2002).

Range (µm)	*Mass (%)*
< 100	50.3
< 10	≤ 0.507
< 5.5	≤ $4.5x10^{-2}$

Remarks The screening test was conducted using Inclyno Sieve Shaker (100 um mesh) and the cascade impactor, Marple Miller 160 was used to separate smaller particles
Test Facility ENVIGO (2016b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure; and EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed dose method.
Species/Strain	Rat/Wistar
Vehicle	Water
Remarks - Method	No significant protocol deviations. Animals were administered the chemical via gavage. Observations were made at 30 minutes, 1, 2 and 4 h after dosing and then daily for 14 days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1 female	2000	0/1
2	4 female	2000	0/4

LD50	> 2000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted. Red coloured staining of the faeces and urine was noted up to 10 days after dosing. Red coloured staining of the tail was also reported in 4 of the treated animals 10-14 days after dosing.
Effects in Organs	No macroscopic findings were observed at necropsy.
Remarks - Results	Bodyweight gains were as expected apart from a single animal that showed no bodyweight gain from 7 to 14 days after dosing.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	ENVIGO (2016a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified chemical – 7%
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	Two
Vehicle	None
Observation Period	1, 24, 48 and 72 hours
Type of Dressing	Occlusive
Remarks - Method	No significant protocol deviations.
Remarks - Results	Positive skin reactions were not observed. Purple staining was observed at all observations.
CONCLUSION	The test substance is non-irritating to the skin.
TEST FACILITY	ENVIGO (2016c)

B.3. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical – 7%
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 (Female)
Vehicle	Pluronic L92 (1% in distilled water)
Preliminary study	No
Positive control	Not conducted in parallel with the test substance
Remarks - Method	Doses were selected based on available data suggesting that the test item would not produce systemic toxicity or excessive local irritation. No deviations from test protocol.

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 female	1187.06	-
25%	4 female	1371.49	1.16
50%	4 female	1384.57	1.17
100%	4 female	1673.34	1.41

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.
TEST FACILITY	ENVIGO (2016d)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1537, TA1535, TA100, TA98 *E. coli*: WP2uvrA
Metabolic Activation System	Sprague-Dawley Rat liver homogenate metabolising system, from rats induced with phenobarbitone/5,6-benzoflavone
Concentration Range in Main Test	a) With metabolic activation: 313 – 5000 µg/plate b) Without metabolic activation: 156 – 5000 µg/plate
Vehicle	Water
Remarks - Method	A preliminary toxicity test (0, 1.2, 4.9, 20, 78, 313, 2150, and 5000 µg/plate) was performed to determine the toxicity of the test material. *Salmonella typhimurium a*nd *E. coli* strains were treated with the test material using the Ames plate incorporation method at seven dose levels, in triplicate, both with and without the addition of a rat liver homogenate metabolising system. The highest dose was diluted 5 times for *S.tymphimurium* TA strains without metabolic activation and diluted 4 times for the *S. tymphimurium* strains with activation and *E. coli* WP2uraA without metabolic activation. Vehicle and positive controls were used in parallel with the test material.

RESULTS

Metabolic Activation	*Test Substance Concentration (5000 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 the preliminary test, growth inhibition in all strains of *S. tymphimurium* was observed at the highest dose without metabolic activation. No significant increases in the frequency of revertant colonies were recorded in the main tests for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation. The positive controls gave satisfactory responses, 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 (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	Biological oxygen demand
Remarks - Method	Conducted in accordance with the test guidelines above. GLP standards and principles are compliant.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation(BOD)*
7	0	7	84
14	0	14	93
21	0	21	93
28	0	28	93

Remarks - Results	All relevant test validity criteria were met and the results are considered to be reliable.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	CERI (2016)

BIBLIOGRAPHY

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ENVIGO (2016b) CIM-44: Determination of General Physico-Chemical Properties (Study No. NY73TG, March, 2016). Derbyshire, UK, Envigo Research Limited (Unpublished report submitted by the notifier).

ENVIGO (2016c) [Product containing the notified chemical at < 7% concentration]: Acute Dermal Irritation in the Rabbit (Study No. BG89WR, December 2016). Derbyshire, UK, Envigo Research Limited (Unpublished report submitted by the notifier).

ENVIGO (2016d) [Product containing the notified chemical at < 7% concentration]: Local Lymph Node Assay in the Mouse – Pooled Method (Study No. NG92BQ, December 2016). Derbyshire, UK, Envigo Research Limited (Unpublished report submitted by the notifier).

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United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.