

File No: LTD/1987  
LTD/1988

August 2017

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME  
(NICNAS)**

**PUBLIC REPORT**

**CIM-48 (LTD/1987)  
CIM-49 (LTD/1988)**

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/1987	Canon Australia Pty Ltd	CIM-48 (LTD/1987)	ND*	≤ 1 tonne per annum	Component of inkjet printing ink
LTD/1988		CIM-49 (LTD/1988)			

\*ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Hazard classification**

Based on the available information, the notified chemicals are 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 chemicals are not considered to pose an unreasonable risk to the health of workers.

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

### **Environmental risk assessment**

On the basis of the maximum annual importation volume and the reported use pattern, the notified chemicals are 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 chemicals themselves. 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 chemicals 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/polymer 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 chemicals 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 chemicals should be handled by physical containment, collection and subsequent safe disposal.

## Regulatory Obligations

### *Secondary Notification*

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum of each notified chemical;
  - the notified chemicals are introduced in solid form for reformulation in Australia;
  - ecotoxicological studies become available on the notified chemicals;or
- (2) Under Section 64(2) of the Act; if
  - the function or use of the notified chemicals has changed from component of inkjet printing ink or is likely to change significantly;
  - the amount of the notified chemicals being introduced has increased, or is likely to increase, significantly;
  - the notified chemicals have begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the notified chemicals 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 chemicals and products containing the notified chemicals provided by the notifier were reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

## **ASSESSMENT DETAILS**

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified chemical by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on the safe use of the notified chemical were carried out by NICNAS.

### **1. APPLICANT AND NOTIFICATION DETAILS**

#### APPLICANT

Canon Australia Pty Ltd (ABN: 66 005 002 951)  
Building A, The Park Estate, 5 Talavera Road  
MACQUARIE PARK NSW 2113

#### NOTIFICATION CATEGORY

##### LTD/1987

Limited-small volume (reduced fee notification): Chemical other than polymer (1 tonne or less per year) – assessed by a comparable agency.

##### LTD/1988

Limited-small volume (reduced fee notification): Chemical other than polymer (1 tonne or less per year) - Chemical is being notified at the same time as a similar chemical.

#### 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, analytical 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 as follows:

LTD/1987 - All physicochemical endpoints except particle size

LTD/1988 - All physicochemical endpoints

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Previous permits

#### NOTIFICATION IN OTHER COUNTRIES

USA - EPA (2016)

Japan – MHLW (2016)

### **2. IDENTITY OF CHEMICAL**

#### MARKETING NAME

LTD/1987: CIM-48

LTD/1988: CIM-49

#### MOLECULAR WEIGHT

LTD/1987 and LTD/1988: > 10,000 Da (estimated)

#### ANALYTICAL DATA

LTD/1987: Reference IR spectrum was provided.

### **3. COMPOSITION**

#### DEGREE OF PURITY

> 98%

### **4. PHYSICAL AND CHEMICAL PROPERTIES**

The following physicochemical data applies to LTD/1987 and LTD/1988.

APPEARANCE AT 20 °C AND 101.3 kPa: black powder

Property	Value	Data Source/Justification
Boiling Point	Not determined	Expected to be high based on molecular weight
Density	Not determined	Expected to be > 1000 kg/m <sup>3</sup>
Vapour Pressure	Not determined	Estimated to be low based on molecular weight and chemical structure of the notified chemicals
Water Solubility	Not determined	The notified chemicals are expected to be insoluble but readily dispersible in water
Hydrolysis as a Function of pH	Not determined	The notified chemicals are expected to hydrolyse very slowly in the environmental pH range (4-9)
Partition Coefficient (n-octanol/water)	Not determined	The notified chemicals are expected to partition to octanol from water based on their expected insolubility in water and their predominantly hydrophobic structure
Adsorption/Desorption	Not determined	The notified chemicals are expected to adsorb to soil and sediment based on their expected insolubility in water and presence of ionic functionalities
Dissociation Constant	Not determined	The notified chemicals contain anionic functionalities which are expected to dissociate in the environmental pH range (4 - 9)
Particle Size	MMAD* = 43 nm	LTD/1987 – Measured LTD/1988 is expected to have a similar particle size
Flash Point	Not determined	Based on their relatively high molecular weight, it is expected that no significant level of flammable vapour will occur
Flammability	Not determined	Based on their relatively high molecular weight, it is expected that no significant level of flammable vapour will occur
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	The notified chemicals do not contain chemical groups which are associated with explosive properties
Oxidising Properties	Not determined	The notified chemicals do not contain chemical groups which are associated with oxidising properties

\* MMAD = Mass Median Aerodynamic Diameter

#### DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties that were not assessed by the US EPA, refer to Appendix A.

#### Reactivity

The notified chemicals are 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 chemicals are 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 chemicals will not be manufactured or reformulated in Australia. The notified chemicals will be introduced as a component of finished inkjet printer ink at < 7% concentration in sealed cartridges and bottles.

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

#### LTD/1987

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	≤ 1	≤ 1	≤ 1	≤ 1	≤ 1

#### LTD/1988

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	≤ 1	≤ 1	≤ 1	≤ 1	≤ 1

### PORT OF ENTRY

Sydney (by sea and air)

### TRANSPORTATION AND PACKAGING

The printer ink containing the notified chemicals will be imported into Australia in cartridges and bottles sealed in plastic bags. The cartridges and bottles will vary in size between 2.5-2,600 mL (cartridges) and 50-300 mL (bottles).

### USE

The notified chemicals will be used as a component of inkjet printer ink at < 7% concentration (for each notified chemical) for commercial and household printers.

### OPERATION DESCRIPTION

The notified chemicals will be imported as a component of ink in cartridges and bottles. No reformulation of the notified chemical will take place in Australia.

The printer ink will be used for varied printing work in workplace office printers and home office printers. Ink cartridges containing the notified chemicals will be manually fitted into printers and replaced with new ink cartridges as necessary. Printer ink (containing the notified chemicals) inside the ink bottles will be manually transferred into the printer ink tank as required.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

#### CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehousing	< 8	10 - 50
Service technicians	1	170
Retail workers	< 8	10 - 50
Office workers	< 0.5	2

#### EXPOSURE DETAILS

Waterside, storage and transport workers may come into contact with the notified chemicals, as a component of ink at < 7% concentration, only in the unlikely event of an accident.

Service technicians and office workers may be exposed to the ink containing the notified chemicals at < 7% concentration when replacing spent cartridges, during transfer of the ink from ink bottles to printers, and during repair and cleaning of ink jet printers. Dermal exposure is expected to be the main route of exposure, although incidental ocular exposure is possible. However, given the design of the ink cartridges and ink bottles, exposure

to the notified chemicals is expected to be limited if workers follow the safety instructions provided with the ink cartridges and ink bottles.

Occasional dermal exposure during use of printers could also occur if the printed pages were touched before the ink had dried. Once the ink dries, the notified chemicals will be bound to the paper and are not expected to be bioavailable, thus further dermal contact should not lead to exposure. Inhalation exposure to the notified chemicals is not expected under the proposed use scenario.

### 6.1.2. Public Exposure

The ink cartridges and ink bottles containing the notified chemicals at < 7% concentration will be made available to the public for home use. Exposure of the public to the notified chemicals is expected to be similar, though less frequent, than that described above for office workers.

## 6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemicals are summarised in the following table. For full details of the studies, refer to Appendix B. The notified chemicals are a modified carbon black; therefore information on carbon black was also used to estimate the hazard profile of the notified chemicals.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – <i>in vitro</i> micronucleus test*	non genotoxic

\*Full study reports not provided

### *Toxicokinetics*

Given the high molecular weight (> 10,000 Da) and low water solubility of the notified chemicals, absorption across the skin and gastrointestinal tract is not expected. The notified chemicals have a particle size at the nanoscale (MMAD = 43 nm). Based on studies conducted on carbon black there is potential for absorption if inhaled (NICNAS).

### *Acute toxicity*

The notified chemicals were of low acute oral toxicity in studies conducted in rats. Based on the limited potential for dermal absorption, the notified chemicals are expected to be of low acute dermal toxicity.

### *Irritation and Sensitisation*

The notified chemicals may have potential to be irritating to the skin, eyes, lungs and mucous membranes based on the pH of the notified chemicals (pH = 8-9).

The notified chemicals do not contain structural alerts for skin sensitisation.

### *Repeated dose toxicity*

The notified chemicals are expected to be of low repeated dose toxicity via the oral or dermal routes based on studies conducted on carbon black (NICNAS).

Based on the available data for carbon black, the notified chemicals may have the potential to cause serious adverse effects from repeated inhalation exposure (including pulmonary inflammation, fibrosis and possible induction of lung tumors) due to particle overload, rather than inherent chemical toxicity (NICNAS). This is consistent for the health concern for respirable, poorly soluble particulates (US EPA, 2017).

### *Mutagenicity/Genotoxicity*

The notified chemicals were found to be negative in a bacterial reverse mutation test. The notified chemicals were also negative in an *in vitro* micronucleus test, however the full study reports were not provided.

### *Health hazard classification*

Based on the available information, the notified chemicals are 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

Based on the available information the critical health effect of the notified chemicals is potential inhalation toxicity from repeated exposure. High lung burden from particle overload can impair the clearance mechanism, causing adverse health effects including possible induction of lung tumours. There is also the potential for skin, eye and respiratory irritation.

The notified chemicals will be imported as a component of inkjet printer ink (at < 7% concentration) contained within purposefully designed ink cartridges and ink bottles, therefore as imported exposure to the notified chemicals is expected to be negligible. Shi *et al* (2015) evaluated inkjet printer emissions in a clean room and found that they did not emit detectable particulate emissions; therefore inhalation exposure to particle emissions of the notified chemicals during use in inkjet printers is not expected. Once the ink dries, the notified chemicals will be bound to the matrix of the substrates and are not expected to be bioavailable.

Overall, based on the limited potential for exposure under the proposed use scenario, the risk to workers is not considered to be unreasonable.

#### 6.3.2. Public Health

Exposure to the notified chemicals 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. Therefore, based on the very low exposure potential, the risk of the notified chemicals 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 chemicals will be imported as a component of aqueous printing ink in sealed cartridges. Release of the ink solution to the environment is not expected as manufacturing, reformulation and packaging of the ink containing the notified chemicals will not take place in Australia. Environmental release of the notified chemicals is likely to be limited to accidental spills. In the event of spills, the ink containing the notified chemicals are expected to be collected on suitable absorbents, and disposed of to landfill in accordance with local government regulations.

##### RELEASE OF CHEMICAL FROM USE

During use, the majority of the notified chemicals will be cured within an inert ink matrix and bound to paper substrates; therefore release from printed paper substrates is not expected. It is estimated by the notifier that up to 5% of the ink containing the notified chemicals will remain in used cartridges which will be collected for recycling or be disposed of to landfill in accordance with local government regulations. Environmental release of the notified chemicals is possible during paper recycling and from the disposal of used print cartridges. Any spills during use, estimated by the notifier to account for up to 1% of the total annual import volume, is expected to be wiped with paper or cloth, and will be disposed of to landfill in accordance with local government regulations.

##### RELEASE OF CHEMICAL FROM DISPOSAL

Following use, empty ink cartridges containing residues of the notified chemicals will be collected for recycling by a licenced contractor, or be disposed of to landfill in accordance with local government regulations. Ink residues containing the notified chemicals separated from the used cartridges will be disposed of in accordance with local government regulations, most likely to landfill.

The majority of the notified chemicals are expected to share the fate of the printed papers to which they are bound, to be either subject to paper recycling or disposed of to landfill. According to the recent Australian paper recycling rate (APC, 2015), 76% of the paper to which the notified chemicals is applied is expected to undergo paper recycling processes, and the remaining 24% is expected to end up in landfill.

### 7.1.2. Environmental Fate

No environmental fate data were submitted by the notifier. Based on the use in printing ink, the majority of the notified chemicals are expected to share the fate of the printed papers to which they are bound, to be either subject to paper recycling or disposed of to landfill. During paper recycling processes, waste paper is repulped using a variety of chemical treatments which, amongst other things, enhance ink detachment from the fibres. Waste water from paper recycling processes containing the notified chemicals is expected to be treated at an onsite wastewater treatment plant before potential release to surface waters. Based on published literature (Sharif et al, 2008; Ma et al., 2010; Ma et al., 2013; and Han et al., 2017), the notified chemicals are expected to form micronized aggregates and be effectively removed during coagulation/flocculation processes. Therefore, the majority of the notified chemicals are expected to be removed during wastewater treatment processes and not expected to be released to the environment with particle sizes in the nanosize range.

Sludge containing the notified chemicals from wastewater treatment processes is expected to be disposed of to landfill in accordance with local governmental regulations. In landfill, the notified chemicals are not likely to be mobile in the environment, due to their potential to adsorb to soil and sediment, based on their expected insolubility in water and their predominantly hydrophobic structure. Based on its low water solubility and high molecular weight, the notified chemicals are not expected to cross biological membranes, and are therefore unlikely to bioaccumulate. In landfill, soil, sludge and water, the notified chemicals are expected to undergo very slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

### 7.1.3. Predicted Environmental Concentration (PEC)

Based on Australian paper recycling rate (APC, 2015), 76% of the waste paper containing the notified chemicals could be recycled and be potentially released in wastewater from paper recycling process. The predicted environmental concentration (PEC) in the table below has been calculated to assume 76% release of the notified chemicals into paper recycling wastewater over 260 working days per year, and 96% removal of the notified chemicals through onsite wastewater treatment plants based on results from published literature (Ma et al., 2010; Ma et al., 2013).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	2000	kg/year
Proportion expected to be released to sewer	76%	
Annual quantity of chemical released to sewer	1520	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	5.85	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	96%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.05	µg/L
PEC - Ocean:	0.005	µg/L

Wastewater treatment plant effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m<sup>2</sup>/year (10 ML/ha/year). The notified chemicals in this volume are assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m<sup>3</sup>). Using these assumptions, irrigation with a concentration of 0.05 µg/L may potentially result in a soil concentration of approximately 0.32 µg/kg. Assuming accumulation of the notified chemicals in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemicals in the applied soil in 5 and 10 years may be approximately 1.60 µg/kg and 3.20 µg/kg, respectively.

## 7.2. Environmental Effects Assessment

No ecotoxicity data were submitted by the notifier. As the notified chemicals are expected to form aggregates and effectively removed during wastewater treatment (Sharif et al, 2008; Ma et al., 2010; Ma et al., 2013; Han et al., 2017), they are not expected to be released to the environment with particle sizes in the nanosize range. The US EPA predicted the ecotoxicity of the notified chemicals based on the structure activity relationship of the nearest analogous anionic dyes with equal to or higher than three acid groups. The estimated results indicate

the acute LC/EC50 to Fish and Daphnia > 100 mg/L, and the chronic toxicity > 10 mg/L. Green Algae appears to be the most sensitive endpoint with acute EC50 < 1 mg/L and chronic value < 0.3 mg/L. Based on these estimated hazard values from the analogous chemicals, the US EPA concluded that the notified chemicals have moderate environmental hazard from potential shading of aquatic plants in aquatic environment (US EPA, 2016).

#### **7.2.1. Predicted No-Effect Concentration**

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated since measured ecotoxicity data for the notified chemicals is not available.

#### **7.3. Environmental Risk Assessment**

A Risk Quotient (PEC/PNEC) has not been calculated since the PNEC is not available for the notified chemicals.

The notified chemicals in wastewater from paper recycling processes are expected to form aggregates and effectively removed at onsite treatment plants (Sharif et al, 2008; Ma et al., 2010; Ma et al., 2013; Han et al., 2017), therefore they are not expected to be released to the environment with particle sizes in the nanosize range. The calculated PEC in onsite waste water facility is estimated as 0.05 µg/L which is substantially lower than the acute and chronic EC50 to algae estimated by the US EPA (US EPA, 2016). Therefore, the release of the notified chemicals during the recycling and deinking processes is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment.

Therefore, on the basis of their expected maximum annual importation volume and assessed use pattern in printing ink, the notified chemicals are not expected to pose an unreasonable risk to the environment.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES****Particle Size**

Method ISO 13320:2009 "Particle size analysis – Laser diffraction methods".

<i>Range (<math>\mu\text{m}</math>)</i>	<i>Mass (%)</i> *
< 0.1 $\mu\text{m}$	100
< 0.05 $\mu\text{m}$	77.4

\* Average from three separate measurements

Remarks CIM-48 (LTD/1987) analysed as a 10% (w/v) dispersion in purified water. Laser diffraction particle size analyser and multi-function sample were employed. The test substance was determined to have a median size of 0.043  $\mu\text{m}$ .

Test Facility CERI (2017)

**APPENDIX B: TOXICOLOGICAL INVESTIGATIONS****B.1. Acute toxicity – oral (LTD/1987)**

TEST SUBSTANCE	Notified chemical (LTD/1987)
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method. EC Directive 92/69/EEC B.1 bis Acute Toxicity (Oral) Fixed Dose Method.
Species/Strain	Rat/RccHan <sup>TM</sup> :WIST
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations. A sighting study using one female animal was conducted prior to the main study.

## RESULTS

**Sighting Study**

<i>Dose mg/kg bw</i>	<i>Administered</i>	<i>Evident Toxicity</i>	<i>Mortality</i>
2000	1F	No	0/1

Signs of Toxicity  
Effects in Organs

None.  
No organ abnormalities were noted at necropsy.

**Main Study**

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	4F	2,000	0/4

LD50

&gt; 2,000 mg/kg bw

Signs of Toxicity

There were no mortalities. No signs of systemic toxicity observed except a black staining of the faeces.

Effects in Organs

No abnormalities were noted at necropsy. All animals showed expected gains in body weights except one animal which showed expected gain in body weight during the first week but no gain in body weight during the next week.

Remarks

There were no mortalities during the study.

## CONCLUSION

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

## TEST FACILITY

Envigo (2016a)

**B.2. Acute toxicity – oral (LTD/1988)**

TEST SUBSTANCE	Notified chemical (LTD/1988)
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method. EC Directive 92/69/EEC B.1 bis Acute Toxicity (Oral) Fixed Dose Method.
Species/Strain	Rat/Female Wistar (RccHan <sup>TM</sup> :WIST)
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations. A sighting study using one female animal was conducted prior to the main study.

## RESULTS

**Sighting Study**

<i>Dose mg/kg bw</i>	<i>Administered</i>	<i>Evident Toxicity</i>	<i>Mortality</i>
2000	1F	No	0/1

Signs of Toxicity  
Effects in Organs

None  
At necropsy, the uterus was found to be filled with fluid. This was

considered by the study authors to be a genetic defect and not related to the treatment

Main Study			
Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	4 F	2,000	0/4
LD50	> 2,000 mg/kg bw		
Signs of Toxicity	Laboured respiration and/or noisy respiration were noted in all test animals, with hunched posture noted in 3 of the 5 animals during the day of administration. All animals appeared normal 1 day after dosing. Black staining of the faeces was noted in all test animals up to 7 days after dosing.		
Effects in Organs	No tissue/organ abnormalities were noted in the main-study animals. All animals showed expected gains in body weight.		
Remarks - Results	There were no mortalities during the study.		
CONCLUSION	The notified chemical is of low toxicity via the oral route.		
TEST FACILITY	Envigo (2016b)		

### B.3. Genotoxicity – bacteria (LTD/1987)

TEST SUBSTANCE	Notified chemical (LTD/1987)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Commission Regulation 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Both plate incorporation procedure (Test 1) and pre incubation procedure (Test 2) were used.
Species/Strain	<i>Salmonella typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>Escherichia coli</i> : WP2uvrA
Metabolic Activation System	S9 mix from phenobarbital/β-naphtoflavone induced rat liver
Concentration Range in Main Test	All <i>Salmonella</i> strains and <i>E. coli</i> strains with and without metabolic activation: Test1: 1.5 - 5,000 µg/plate Test2: 15 - 5,000 µg/plate
Vehicle	Sterile distilled water
Remarks - Method	No significant protocol deviations

### RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	-	> 5,000	≥ 500	negative
Test 2	-	> 5,000	≥ 500	negative
<i>Present</i>				
Test 1	-	> 5,000	≥ 500	negative
Test 2	-	> 5,000	≥ 500	negative

Remarks - Results	There was no visible reduction in the growth of the bacterial background lawn at any dose level (both in the presence and absence of metabolic activation).
	Small reductions in revertant colony frequency were observed to WP2uvrA in both absence and presence of metabolic activation at 5000 µg/plate following the incubation modification. However, there was no

visible reduction in the quality of the bacterial background lawns.

A black/grey test item induced colouration was noted from 50 µg/plate with precipitate at and above 500 µg/plate. These observations did not prevent the scoring of revertant colonies.

There were no significant increases in the frequency of revertant colonies recorded for any of the bacterial strains with any dose of the test item either with or without metabolic activation in both experiments (plate incorporation and pre-incubation methods).

The negative and 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	Envigo (2016c)

#### B.4. Genotoxicity – bacteria (LTD/1988)

TEST SUBSTANCE	Notified chemical (LTD/1988)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Commission Regulation 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Both plate incorporation procedure (Test 1) and pre incubation procedure (Test 2) were used.
Species/Strain	<i>Salmonella typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>Escherichia coli</i> : WP2uvrA
Metabolic Activation System	S9 mix from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	All <i>Salmonella</i> strains and <i>E. coli</i> strains with and without metabolic activation: Test1: 1.5 - 5,000 µg/plate Test2: 15 - 5,000 µg/plate
Vehicle	Sterile distilled water
Remarks - Method	No significant protocol deviations

#### RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	-	> 5,000	≥ 1,500	negative
Test 2	-	> 5,000	≥ 1,500	negative
<i>Present</i>				
Test 1	-	> 5,000	≥ 1,500	negative
Test 2	-	> 5,000	≥ 1,500	negative

Remarks - Results

There was no visible reduction in the growth of the bacterial background lawn at any dose level (both in the presence and absence of metabolic activation).

A grey, test substance induced, colouration was noted from 50 µg/plate becoming black with powdery precipitation at and above 1,500 µg/plate. None of these observations prevented the scoring of revertant colonies.

There were no significant increases in the frequency of revertant colonies recorded in both tests for the bacterial strains tested at any dose level

either with or without metabolic activation.

The negative and 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

Envigo (2016d)



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