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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

CIM-17

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, 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 Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full Public Report is also 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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty Ltd. (ABN 66 005 002 951)
1 Thomas Holt Drive
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, non hazardous impurities, 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: hydrolysis as a function of pH, absorption/desorption

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CIM-17

OTHER NAME(S)
TM09-092, A-2, C-A2

MOLECULAR WEIGHT
> 500 Da

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

3. COMPOSITION

DEGREE OF PURITY > 80%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: dark purple powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Decomposes from 316°C	Measured
Boiling Point	Not determined	Decomposes prior to melting
Density	1620 kg/m^3 at 20.0°C	Measured

Vapour Pressure	< 3.3×10^{-7} kPa at 25°C	Measured
Water Solubility	320-343 g/L at 20ºC	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical has a hydrolysable functional group but it is expected to hydrolyse slowly at environmental pH (4 – 9)
Partition Coefficient (n-octanol/water)	log Pow = -4.2 at 22.5°C	Measured
Adsorption/Desorption	log K_{oc} < 1.25	Analogue
Dissociation Constant	Not determined	The notified chemical is a salt and is expected to be ionised under environmental conditions
Particle Size	Inhalable fraction (< 100 µm): 38.9% Respirable fraction (< 10 µm): 0.455%	Measured. Too few particles were of a size less than 10.0 µm to allow accurate assessment of the mass median aerodynamic diameter.
Flammability (solid)	Not highly flammable	Measured
Autoignition Temperature	356ºC	Measured
Explosive Properties	Predicted negative	There are no chemical groups within the structure that would imply explosive properties.

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical is predicted to be stable under normal conditions of use (stated by the notifier).

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported as a component (< 7%) of inkjet printer ink solution contained within sealed ink 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

Sydney airport and Sydney harbour

IDENTITY OF RECIPIENTS

The ink cartridges will be stored at the notifier's warehouse prior to distribution to offices nationwide and office equipment retailers.

TRANSPORTATION AND PACKAGING

The transport of ink cartridges (5 to 900 mL) containing the notified chemical in ink at < 7% will be by road.

USE

The notified chemical will be used as an ink component at < 7% in sealed ink cartridges for use in inkjet printers.

OPERATION DESCRIPTION

No manufacture or reformulation will occur in Australia. Sealed ink cartridges containing the notified chemical will be distributed to commercial and retail centres and handled by service technicians, office workers or the public, who will replace spent cartridges in printers as necessary.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Importation/Waterside	50	< 8	10-50
Storage and Transport	15	< 8	10-50
Office worker	> 1000	10 seconds/day	2
Service Technicians	100	1	170

EXPOSURE DETAILS
Storage and transport workers will only handle the sealed cartridges containing the notified chemical and therefore exposure is not expected unless the packaging is accidentally breached.

Service technicians and office workers may be exposed to the ink containing the notified chemical (< 7%) when replacing used ink cartridges and repairing and cleaning ink jet printers. Dermal exposure is expected to be the most likely route of exposure. Instructions on how to replace the cartridges safely are included with the cartridge to minimise exposure. However, occasional dermal exposure during use of the printer may occur if the printed pages were handled inadvertently before the ink had dried, or if ink-stained parts of the printer were touched. Once the ink dries, the chemical would be bonded to the printed paper, and therefore dermal exposure to the notified chemical from contact with dried ink is not expected.

6.1.2. Public exposure
Home users may encounter dermal exposure to the ink containing the notified chemical (< 7%) when replacing used ink cartridges similar to the exposure experienced by office workers. However, home users are expected to handle ink cartridges and print less frequently, therefore exposure is expected to be less frequent when compared to that of office workers.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution.
Absorption through the skin is expected to be limited by the chemical's relatively high molecular weight (> 500 Da), high water solubility (320-343 g/L), and low partition coefficient (log Pow = -4.2). These parameters demonstrate its low lipophilicity, indicating that it is not likely to cross the stratum corneum (European Commission, 2003).

Acute toxicity.
The notified chemical was found to be of low acute oral toxicity in rats (LD50 > 2,000 mg/kg bw).

Mutagenicity.
The notifier supplied test results showing that the notified chemical was not mutagenic in bacteria (under the conditions of the Ames test used).

Health hazard classification
Based on the limited data provided, the notified chemical cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Based on the limited data supplied, the notified chemical has no identified hazards. Dermal exposure of workers to the notified chemical should occur infrequently and be of small amounts, given the containment of the notified chemical within ink cartridges.

Overall, the risk presented by the notified chemical to the health and safety of workers is not considered to be unacceptable.

6.3.2. Public health
The exposure of the notified chemical to the members of the public during the use of inkjet printers are expected to be similar or less frequent to that experienced by office workers. Therefore, the risk of the notified chemical to the health of the public is not considered to be unacceptable.

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 ready-to-use cartridges. Release of the ink solution to the environment is not expected as manufacturing and reformulation of the ink containing the notified chemical will not take place in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE
The notified chemical will not be released from the printed paper. Approximately 5% of the ink containing the notified chemical will remain in spent cartridges. The ink remaining in the ink cartridges during the recycling process is not reused and will be disposed of with the packaging. Environmental release of the notified chemical is possible during paper recycling and from the disposal of used print cartridges.

RELEASE OF CHEMICAL FROM DISPOSAL
The notifier collects the used cartridges from collection boxes in general merchandising stores and post offices, etc. The collected cartridges are sent to a subcontractor who disassembles the used cartridges and recycles them into raw materials, for example a plastic material to be used to made plastic goods. The remaining ink separated from the used cartridges is disposed of under State/Territory regulations. Uncollected cartridges will be disposed of to landfill.

Half of the paper to which the notified chemical will be applied is expected to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of toner from the fibres.

7.1.2 Environmental fate

No environmental fate data were submitted. The majority of the notified chemical will enter the environment from disposal of printed paper products on which ink containing the notified chemical will be used. Approximately 45% of the notified chemical will be disposed of to landfill by binding on the printed waste paper, and eventually degrade *in-situ* by abiotic and biotic processes into water, inorganic salts and oxides of carbon, nitrogen and sulfur. Notified chemical not bound to paper in landfill may leach due to the expected low K_{OC} and high water solubility.

The remaining 50% of the notified chemical is expected to be released to sewer, after the de-inking of paper during recycling. Assuming a worst-case scenario, the entire amount of notified chemical from paper recycling will be released from sewage treatment plants into aquatic ecosystems, where the notified chemical is expected to be mobile. However, the notified chemical is not expected to bioaccumulate due to its very low Pow and high solubility in water.

7.1.3 Predicted Environmental Concentration (PEC)

Under a worst case scenario, it was assumed that 50% of the paper products containing the notified chemical will be recycled and released into sewers with no removal of the notified chemical by the sewerage treatment plant. As the notified chemical is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur on 260 days into the Australian effluent volume. The resultant Predicted Environmental Concentration (PEC) in sewage effluent nationwide is estimated as follows:

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	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.45	µg/L
PEC - Ocean:	0.05	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 0.454 µg/L may potentially result in a soil concentration of approximately 3.029×10^{-3} mg/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 1.515×10^{-2} mg/kg and 3.029×10^{-2} mg/kg, respectively.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. Based on QSAR calculations (ECOSAR v1.00) on the non-ionised form of the notified chemical, the chemical is not expected to be acutely harmful to fish or daphnia (L(E)C50 > 100 mg/L) and is potentially harmful to algae (EC50 (96 hr) = 48 mg/L).

7.2.1 Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Algae (EC50)	48	mg/L
Assessment Factor	1000	
PNEC:	48	µg/L

A conservative assessment factor of 1000 has been used to derive a PNEC as acute toxicity endpoints were calculated by QSAR for the notified chemical on aquatic species from three trophic levels.

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.45	48	0.0095
Q - Ocean	0.05	48	0.0009

The Risk Quotients (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be << 1 for both river and ocean compartments. This indicates the notified chemical is not expected to pose an unacceptable risk to the aquatic environment based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited data provided, the notified chemical cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment
On the basis of the reported use pattern, the notified chemical is not expected to pose a 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.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical 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(2) of the Act; if
  - the function or use of the chemical has changed from an ink component introduced at < 7% in sealed ink cartridges for use in inkjet printers, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 1 tonne per year, 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.

No additional secondary notification conditions are stipulated.

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Decomposes from 316 ± 0.5ºC

Method	ASTM E537-86 designed to be compatible with OECD TG 102 Melting Point/Melting Range and Method A.1 Melting/Freezing Temperature of Commission Regulation (EC) No. 440/2008
Remarks	Differential scanning calorimetry was used. The test substance decomposed before melting.
Test Facility	Harlan Laboratories Ltd (2010a)

Boiling Point Not determined

Method	OECD TG 103 Boiling Point. Method A.2 Boiling Point of Commission Regulation (EC) No. 440/2008
Remarks	The test substance decomposed prior to melting.
Test Facility	Harlan Laboratories Ltd (2010a)

Density 1620 kg/m^3 at 20.0 ± 0.5ºC

Method	OECD TG 109 Density of Liquids and Solids. Method A.3 Relative Density of Commission Regulation (EC) No. 440/2008
Remarks	A gas comparison pycnometer was used.
Test Facility	Harlan Laboratories Ltd (2010a)

Vapour Pressure < 3.3×10^{-7} kPa at 25ºC

Method	OECD TG 104 Vapour Pressure. Method A.4 Vapour Pressure of Commission Regulation (EC) No. 440/2008
Remarks	Measured with a vapour pressure balance. No statistical analyses were performed because the balance readings were too variable for a line of best fit to be meaningful. Instead it was considered more appropriate to impose a historically determined regression slope on a chosen data point to provide an estimate of the upper limit for the vapour pressure at 25ºC.
Test Facility	Harlan Laboratories Ltd (2010b)

Water Solubility 320 – 343 g/L at 20.0 ± 0.5ºC

Method	OECD TG 105 Water Solubility (modified) Method A.6 Water Solubility of Commission Regulation (EC) No. 440/2008 (modified)
Remarks	A preliminary test found that the solubility of the notified chemical was between 303 and 400 g/L and hence that the flask method was appropriate for the definitive test. The definitive test was carried out by the flask method and based on visual inspection.
Test Facility	Harlan Laboratories Ltd (2010a)

Partition Coefficient (n-octanol/water) log Pow = -4.20 at 22.5 ± 0.5ºC

Method	OECD TG 107 Partition Coefficient (n-octanol/water): Shake Flask Method EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	The shake flask method was employed with spectrophotometric analysis to determine the concentration of the test substance in octanol and water. The stock solution was adjusted to pH 7.1 and the test substance was expected to be ionised.
Test Facility	Harlan Laboratories Ltd (2010a)

Adsorption/Desorption log K_{oc} < 1.25 (analogue of the notified chemical)

Method	OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)

Remarks The HPLC screening method was used with the use of 12 reference standards with known adsorption coefficients. The retention time of the test substance was 1.63 minutes which was less than that for acetanilide (4.001 minutes) which has a known log K_{oc} of 1.25, therefore the log adsorption coefficient is less than 1.25.

The test was done at pH 7 and therefore reflects the ionised substance.

Particle Size

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Mass (%)*
< 100 (sieve)	38.9
< 10.0 (cascade impactor)	0.455
< 5.5 (cascade impactor)	0.169

Remarks Sieve method was used for screening test and the cascade impactor method was used for definite test.
Sampling for the cascade impactor determinations was performed by rolling the test substance container for approximately 10 minutes then sampled from the top, middle and bottom.
Too few particles were of a size less than 10.0 μm to allow accurate assessment of the mass median aerodynamic diameter.
Test Facility Harlan Laboratories Ltd (2010a)

Solid Flammability The test substance was determined to be not highly flammable as it failed to ignite in the preliminary screening test.

Method Method A.10 Flammability (Solids) of Commission Regulation (EC) No. 440/2008
Remarks In the preliminary test, a mould (250 × 20 × 10 mm) was loosely filled with test substance (tested as received). A non-combustible, no-porous board was placed onto the mould which was then inverted. The mould was removed and an air-rich Bunsen burner flame applied to one end of pile for two minutes.
The pile failed to ignite during two minutes that the Bunsen flame was applied. The results of the preliminary screening test obviated the need to perform the main test.
Test Facility Harlan Laboratories Ltd (2010b)

Autoignition Temperature 356°C

Method Method A.16 Relative Self-Ignition Temperature for Solids of Commission Regulation (EC) No. 440/2008
Test Facility Harlan Laboratories Ltd (2010b)

Explosive Properties Predicted negative

Method Method A.14 Explosive Properties of Commission Regulation (EC) No. 440/2008
Remarks There are no chemical groups within the structure that would imply explosive properties.
Test Facility Harlan Laboratories Ltd (2010b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Method. Method B1 *bis* Acute Toxicity (oral) of Commission Regulation (EC) No. 440/2008
Species/Strain	Rat/Wistar
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted. Red stained urine and faeces were noted in all animals during the study. The bedding of all animals was also stained red. Although the finding was not explained by the study author, the staining may be related to the colour of the notified chemical.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All animals showed expected gains in bodyweight over the observation period.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Harlan Laboratories Ltd (2010c)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Method B13/14 of Commission Regulation (EC) No. 440/2008 Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	S9 was prepared from the livers of phenobarbitone/β-naphthoflavone induced male Sprague-Dawley rats.
Concentration Range in Main Test	a) With metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Sterile distilled water
Remarks - Method	No significant protocol deviations. Test 1 was carried out by the plate incorporation method and test 2 by the pre incubation method.

RESULTS

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

Remarks - Results

The test substance caused no visible reduction in the growth of the bacterial background lawn at any dose level and was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. No test substance precipitate was observed on the plates at any of the doses tested in either the presence or absence of S9-mix. An intense test substance induced pink colour was noted at and above 1500 µg/plate. This observation did not affect the scoring of revertant colonies.

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, at any dose level either with or without metabolic activation or exposure method.

The vehicle (sterile distilled water) control plates gave counts of revertant colonies within the normal range. All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies, both with or without metabolic activation, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

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

TEST FACILITY

Harlan Laboratories Ltd (2010d)

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