File No: LTD/1882

August 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in 889481

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/1882	BASF Australia Ltd SICPA Australia Pty Ltd	Chemical in 889481	ND*	≤ 1 tonne per annum	Component of commercial UV-cured 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 reported use pattern and limited expected aquatic exposure, the notified polymer 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 where possible to minimise occupational exposure to the notified chemical:
  - Enclosed systems where possible
  - Measures to reduce generation of mists or aerosols during printing, or to contain them.

- 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 generation of mists or aerosols during printing
  - Avoid contact with skin and eyes
  - Avoid breathing mists or aerosols
  - Clean up spills promptly

- 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:
  - Coveralls, impervious gloves
  - Respiratory protection if inhalation exposure to the chemical may occur

  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, physical collection and subsequent safe disposal.

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical;
- the notified chemical is imported for reformulation in Australia
- further information becomes available on the bioavailability or sensitisation potential of the notified chemical

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of commercial UV-cured 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 a product containing the notified chemical provided by the notifier was 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

APPLICANTS
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

SICPA Australia Pty Ltd (ABN: 69 103 247 945)
2/59 Lara Way
CAMPBELLFIELD VIC 3061

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, use details, import volume, site of manufacture/reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAMES
889481 (Ink containing the notified chemical)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Dark brown to black powder with product specific odour (product)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified chemical did not show a melting/freezing point in the temperature range of 30 °C to 310 °C, and decomposed before melting.
Density	1,496 kg/m^3 at 20 °C	Measured
Vapour Pressure	2.8×10^{-10} kPa at 25 °C	Measured
Water Solubility	2.3×10^{-3} g/L at pH 6.4 at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities.

Partition Coefficient (n-octanol/water)	log Pow < -0.36 at 20 °C	Measured. Estimated based on its solubility in water and n-octanol.
Adsorption/Desorption	Not determined	The notified chemical is expected to be immobile in soil based on its high molecular weight and presence of ionic functionality which will adsorb to soil and sediment.
Dissociation Constant	Not determined	Contains no dissociable functionalities.
Particle Size	Inhalable fraction (< 100 μm): 62.2% Respirable fraction (< 10 μm): 37.6%	Measured
Flash Point	Not determined	The notified chemical decomposes before reaching melting point
Solid Flammability	Not considered highly flammable	Measured
Flammability (contact with water)	Not considered highly flammable	Measured
Autoignition Temperature	Not self-igniting	Measured
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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. It was considered stable in a screening study on thermal stability, carried out according to OECD TG 113.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported into Australia as a component of UV-cured inks.

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

TRANSPORTATION AND PACKAGING
The notified chemical will be imported via sea in inks at ≤ 1% concentration. Within Australia it will be distributed by road to the sites of use.

USE
The notified chemical will be used in UV-cured inks for commercial printing on plastic materials. The final concentration of the notified chemical in end-use inks will be ≤ 1%.

OPERATION DESCRIPTION
At the site of use, the formulated inks containing the notified chemical at ≤ 1% concentration will be either used as is or will be diluted or modified with additives to adjust ink behaviour and facilitate printing. The ink will be pumped, poured or scooped out of the container into the ink reservoirs of the printing machine and will be

replenished either manually or automatically as required. At the end of each printing process, the machine will be cleaned using a wet or dry rag. The inks will be UV cured onto the substrate.

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 warehouse	4	20
Quality control laboratory staff	1.5	10
Printing (decanting and cleaning)	1.5	240

EXPOSURE DETAILS

Transport and storage workers are not expected to be exposed to the notified chemical except in the unlikely event of an accident where the packaging is breached. Dermal and ocular exposure may occur in such an event and also during the clean-up of leakages and spills.

Printing and quality control workers involved in using the inks containing the notified chemical at ≤ 1% concentration may be exposed to the notified chemical via the dermal and ocular route during the addition of additives to the ink, mixing, quality control, transfer of ink into the reservoir tanks of printing machines and during the cleaning and maintenance of printing machines. Inhalation exposure could also occur if mists or aerosols are generated during the printing process. Exposure during handling and or packaging of printed products is expected to be low, as the chemical would be incorporated into the dried ink matrix.

The notifier has proposed the use of engineering controls (local exhaust ventilation) and personal protective equipment (PPE) including impervious gloves, coveralls and goggles to reduce worker exposure to the notified chemical during handling and printing.

6.1.2. Public Exposure

The inks containing the notified chemical will only be used for commercial printing and will not be available for use by the public. The general public may come into contact with the dried printed products. However, once the ink is dried, the notified chemical is expected to be contained within the cured ink matrix and is not expected to be bioavailable.

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

Toxicokinetics, metabolism and distribution.
No toxicokinetics, metabolism and distribution data was submitted on the notified chemical. Dermal absorption of the notified chemical is expected to be limited by the high molecular weight (> 500 Da) and expected low partition coefficient (Log Pow) of < -0.36.

Acute toxicity.
No data on acute toxicity potential of the notified chemical was submitted.

Irritation and sensitisation.
No irritation studies were submitted on the notified chemical.

The notified chemical has a structural alert for skin sensitisation. Although it did not cause skin sensitisation in a local lymph node assay (LLNA) at the highest tested concentration of 10%, it contains a metallic component and this methodology may not be reliable for some metals (Basketter et al. 1999). Therefore, the potential of the notified chemical to cause skin sensitisation cannot be ruled out based on the LLNA study alone.

Repeated dose toxicity.
No data on repeated dose toxicity was provided on the notified chemical.

Mutagenicity/Genotoxicity.
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation assay.

Carcinogenicity
No information on carcinogenicity was provided on the notified chemical. The notified chemical contains a metallic component which is classified as a carcinogen via the inhalation route by the International Agency for Research on Cancer (IARC). Therefore the potential of the notified chemical to cause cancer cannot be ruled out, and is likely to be dependent on the bioavailability of the metal in ionic form. The chemical is stated by the notifier to be stable and not likely to break down to release the metal in ionic form.

Health hazard classification
Based on the limited 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
The notified chemical contains a metallic component which is classified as carcinogen via the inhalation route, and is potentially a skin sensitiser. Exposure to the metal in ion form and consequential risk of adverse effects would be reduced if the chemical is stable and does not easily release metal ions. The parameters in the water solubility study suggest that the chemical is stable. The notifier has also stated that the chemical is not soluble in the formulated ink and is not expected to dissociate in ink. Further information on the bioavailability of the notified chemical would decrease the uncertainty regarding its hazard potential.

Dermal and ocular exposure of printing workers to the notified chemical at up to 1% concentration in formulated inks may occur during ink dilution/modification and addition of ink to ink reservoirs and cleaning and maintaining the printing machines. Inhalation exposure is not expected to occur, unless aerosols are generated during printing.

As there is still a degree of uncertainty about the potential of the notified chemical to cause adverse effects, risk should be managed by measures that would reduce worker exposure. During use of inks containing < 1% notified chemical, measures should be taken to avoid generation of mists or aerosols. Safe work practices and PPE such as coveralls and impervious gloves, and respiratory protection if required, would reduce exposure.

Dermal exposure may occur during the handling of printed material by workers involved in packaging and distribution. At this stage the notified chemical is expected to be incorporated in the dried ink matrix and is not expected to be bioavailable.

Overall, provided that adequate workplace controls are in place to reduce exposure to the notified chemical, the risk to workers is not considered unreasonable.

6.3.2. Public Health
The notified chemical will not be available to the public, except after the ink has been applied and cured and the notified chemical becomes bound within the dried ink matrix. By this stage, the notified chemical is not expected to be available for exposure, hence the risk to the public is not considered 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 finished inks, and will not be reformulated or repackaged in Australia. Therefore, no environmental release is expected from manufacturing or reformulation in Australia. Environmental release of the notified chemical is unlikely during importation, transport and storage, and is likely to be limited to accidental spills and leaks. Spills or accidental release of the products containing the notified chemical are expected to be collected with absorbents, and disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

During use, the ink containing the notified chemical will either be manually transferred or automatically pumped into the ink reservoir of printing machines. At the end of each printing job, the machine will be cleaned using absorbents. After application the notified chemical will be cured within an inert ink matrix and bound to the substrate, and is not expected to be released from printed substrate. Wastes containing the notified chemical including cleaning materials and spilt materials are expected to be collected and disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will be used in commercial printing inks for printing onto mainly plastic substrates. The majority of the notified chemical is expected to share the fate of the printed articles to which it is bound. The printed substrate may be disposed of to landfill or combusted, which will entail thermal decomposition of the notified chemical. Following use, empty ink drums containing residues of the notified chemical will be collected for recycling or disposal by licensed industrial waste contractors.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified chemical. The majority of the notified chemical in printing inks will be bound within an inert ink matrix, and will share the fate of the printed articles. Based on its molecular structure and low water solubility, both cured and uncured notified chemical in landfill would be expected to adsorb strongly to soil and sediment and is not expected to be mobile or bioavailable.

Based on its molecular structure and low water solubility, the notified chemical is not expected to be readily biodegradable. Bioaccumulation of the notified chemical is not likely as it is not expected to cross biological membranes due to its low water solubility and low estimated partition coefficient (log P_{OW} < -0.36). After disposal to landfill or thermal decomposition, the notified chemical would eventually degrade through biotic and abiotic processes to form water and oxides of carbon, nitrogen and sulphur.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified chemical, since no significant release of the notified chemical to the aquatic environment is expected from the reported import volume and use pattern.

7.2. Environmental Effects Assessment

The results from an ecotoxicological investigation conducted on the notified chemical are summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	48 h EL50 > 100 mg/L (WAF*)	Not harmful to *Daphnia* up to the limit of water solubility

* Water Accommodated Fraction

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

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated since the notified chemical is not considered to be harmful to aquatic organisms up to the limit of its solubility in water, and no significant release of the notified chemical to the aquatic environment is expected.

7.3. Environmental Risk Assessment

A risk quotient (PEC/PNEC) for the notified chemical was not calculated, as neither a PEC nor PNEC was derived. Release of the notified chemical to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. The notified chemical is not expected to be bioaccumulative and is expected to slowly degrade in the environment. Based on the assessed use pattern of the notified chemical and limited expected aquatic exposure, it is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point No melting/freezing temperature determined

Method OECD TG 102 Melting Point/Melting Range.
Remarks Differential scanning calorimetry method. The test substance did not show a melting/freezing temperature in the temperature range of 30 to 310 °C. The test item showed decomposition in the temperature range of 310 to 350 °C.
Test Facility Allessa GmbH (2013a)

Density 1496 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
Remarks Pycnometric method. The data is derived from three independent determinations.
Test Facility Allessa GmbH (2013b)

Vapour Pressure 1.7×10^{-10} kPa at 20 °C
2.8×10^{-10} kPa at 25 °C
2.6×10^{-10} kPa at 50 °C

Method OECD TG 104 Vapour Pressure.
OECD TG 113 Screening Test for Thermal Stability and Stability in Air
Remarks The vapour pressure was measured by effusion method: vapour pressure balance. The vapour pressure was measured at 5 different temperatures within the range of 143 to 165 °C. In a preliminary test on thermal stability, no endothermic or exothermic effects were detected up to 300°C.
Test Facility Consilab (2013)

Water Solubility 2.3×10^{-3}g/L at pH 6.4 at 20 °C

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method
Test Facility Allessa GmbH (2013c)

Partition Coefficient (n-octanol/water) log Pow < -0.36 at 20 °C

Method EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks Due to low solubility, the analytical methods in the test guideline could not be used. The partition coefficient was therefore calculated using the maximum solubility in n-octanol and the measured solubility in water.
Test Facility Allessa GmbH (2013d)

Particle Size Inhalable fraction (< 100 µm): 62.2%
Respirable fraction (< 10 µm): 37.6%

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

Range (µm)	*Mass (%)(Cumulative)*
≤ 2	7.8
≤ 4	18.2
≤ 10	37.6
≤ 100	62.2

Remarks The particle size distribution was determined by applying laser diffraction. No particles with size greater than 875 µm were found. Three determinations were performed.
Test Facility Allessa GmbH (2013e)

Solid Flammability Not considered highly flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks	Localized burning or glowing with practically no spreading was observed in preliminary test.
Test Facility	BASF (2013a)

Flammability (Contact with water) Not flammable

Method	EC Council Regulation No 440/2008 A.12 Flammability (Contact with Water).
Remarks	The test substance did not ignite and no gas was evolved when in contact with water.
Test Facility	BASF (2013a)

Autoignition Temperature Not self-igniting up to 400 °C

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	At 217 °C a temperature rise of 89 °C in the sample was noted. However, as the temperature did not reach 400 °C, it was not interpreted as self-ignition.
Test Facility	BASF (2013a)

Stability Testing Considered to be stable

Method	OECD TG 113 Screening Test for Thermal Stability and Stability in Air.
Remarks	Differential thermal analysis was conducted using a differential scanning calorimeter (DSC). Exothermic events were noted at 155, 295 and 375 °C. As none of these events occurred below 150 °C, the test substance was considered stable under the criteria of the test.
Test Facility	BASF (2013a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Acetone : olive oil (4:1 v/v)
Preliminary study	Yes
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexyl cinnamalehyde dissolved in acetone: olive oil (4:1 v/v), giving the expected sensitisation results.
Remarks - Method	No significant deviations from the OECD guidelines. A preliminary study was conducted using 2 test animals to determine systemic toxicity and local skin irritation. One animal was treated at 10% and the other at 25%. As the irritation limit was exceeded at 25% at two of the observations, 10% was chosen as the highest dose tested in the main study. Ear weight and thickness and lymph node weight and cell counts were also performed for all test animals and used for evaluation of stimulation index.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	5 F	170.8	–
2	5 F	324.6	1.90
5	5 F	289.7	1.70
10	5 F	373.3	2.19

Remarks - Results	No mortality, signs of systemic toxicity or local irritation were seen. All stimulation index values were below the threshold of 3 for sensitisation.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	Harlan (2013)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure and Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33, 100, 333, 2,650 & 5,300 µg/plate b) Without metabolic activation: 33, 100, 333, 2,650 & 5,300 µg/plate
Vehicle	Dimethyl sulphoxide
Remarks - Method	No significant deviations from the OECD guidelines.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1 (SPT)	≥ 1,000	≥ 100	Negative
Test 2 (PIT)	≥ 2,650	≥ 2,650	Negative

Present			
Test 1 (SPT)	≥ 1,000	≥ 100	Negative
Test 2 (PIT)	≥ 2,650	≥ 2,650	Negative

SPT – Standard Plate Test
PIT – Pre-incubation Test

Remarks - Results: Different degrees of cytotoxicity were observed with different bacterial strains.

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

TEST FACILITY: BASF (2013b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi-static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	160 mg $CaCO_3$/L
Analytical Monitoring	None reported
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A saturated solution of the test substance was prepared in water then filtered using a membrane filter. Following the range finding test, the definitive test was conducted at the nominal loading rate of 100 mg/L of the test substance. A total of 20 daphnids (5 daphnids/replicate across 4 replicates) were used. No significant deviations in protocol were reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Cumulative Immobilised (%)*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
100	Not determined	20	0	0

EL50	> 100 mg/L (WAF) 48 hours
NOEL	Not determined
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were renewed every 24 h during the 48 h test period. The 48 h EL50 for daphnids was determined to be > 100 mg/L, based on the nominal concentration.
CONCLUSION	Under the study conditions, the notified chemical is not considered to be harmful to aquatic invertebrates up to the limit of its water solubility.
TEST FACILITY	Dr U Noack-Laboratorien (2013)

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Allessa GmbH (2013e) [Notified chemical] Particle size Distribution (Study No. VP 005/2013, June, 2013). Germany, Allessa GmbH (Unpublished report submitted by the notifier).

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BASF (2013b) [Notified chemical] Salmonella Typhimurium / Escherichia Coli Reverse Mutation Assay (Study No, 40M0681/12M364, July, 2013). Ludwigshafen, Germany, BASF SE Experimental Toxicology and Ecology (Unpublished report submitted by the notifier).

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Consilab (2013) [Notified chemical] Determination of Physico-Chemical Properties: Vapour Pressure (Study No. CSL-13-0035.01, June, 2013). Germany, Consilab Gesellschaft für Anlagensicherheit mbH (Unpublished report submitted by the notifier).

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