File No: LTD/1929

September 2016

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

# PUBLIC REPORT

## Benzamide, 3,3'-[(2-chloro-1,4-phenylene)bis[imino(1-acetyl-2-oxo-2,1-ethanediyl)-2,1-diazenediyl]]bis[4-methyl-

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/1929 | Clariant (Australia) Pty Ltd | Benzamide, 3,3'-[(2-chloro-1,4-phenylene)bis[imino(1-acetyl-2-oxo-2,1-ethanediyl)-2,1-diazenediyl]]bis[4-methyl- | ND* | ≤ 0.5 tonne per annum | Component of industrial printer toners |

*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**
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 low hazard and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

**Recommendations**

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during toner preparation:
  - Enclosed, automated processes, where possible
  - Adequate local exhaust ventilation when dusts are expected to occur

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified chemical during toner preparation:
  - Avoid contact with eyes
  - Avoid inhaling of dusts

- 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 during toner preparation:
  - Respiratory protection when dusts are expected to 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 physical containment, collection and subsequent disposal.

**Regulatory Obligations**

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

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

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of industrial printer toners, or is likely to change significantly;
  - the amount of chemical being introduced has increased, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

*(Material) Safety Data Sheet*
The (M)SDS of the notified chemical 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

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Level 3, 3 Acacia Place
296-324 Ferntree Gully Road
NOTTING HILL VIC 3168

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements are claimed for hydrolysis as a function of pH, absorption/desorption and dissociation constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Germany (2000), USA (2002) and Korea (2007)

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PV Fast Yellow H9G

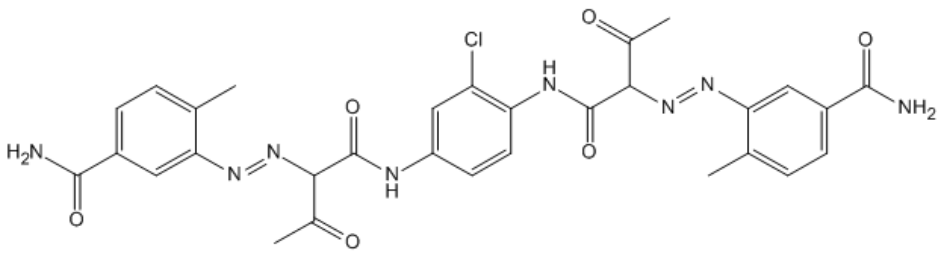
CAS NUMBER
253430-12-5

CHEMICAL NAME
Benzamide, 3,3'-[(2-chloro-1,4-phenylene)bis[imino(1-acetyl-2-oxo-2,1-ethanediyl)-2,1-diazenediyl]]bis[4-methyl-

OTHER NAME(S)
P 14269
C.I. Pigment Yellow 214
Pigment Yellow P 14269
PV Fast Yellow H9G VP 2430

MOLECULAR FORMULA
$C_{30}H_{29}ClN_8O_6$

STRUCTURAL FORMULA




MOLECULAR WEIGHT
633.05 Da

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

## 3. COMPOSITION

DEGREE OF PURITY
99.5%

IMPURITIES
0.5% extractable unknown impurities

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow solid

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point/Freezing Point | > 350 °C | Measured |
| Boiling point | 656 °C | Calculated |
| Density | 1,349 kg/m$^3$ at 20 °C | Measured |
| Vapour Pressure | 1.49 × 10$^{-22}$ kPa at 25 °C | Calculated |
| Water Solubility | < 2.0 × 10$^{-5}$ g/L at 20 °C | Measured |
| Hydrolysis as a Function of pH | Not determined | The notified chemical is expected to be hydrolytically stable under the environmental pH range of 4 – 9 as it is slightly soluble in water and does not contain readily hydrolysable functionalities. |
| Partition Coefficient (n-octanol/water) | log Pow = 2.7 | Calculated |
| Adsorption/Desorption | Not Determined | The notified chemical is expected to be immobile in soil based on its low water solubility. |
| Dissociation Constant | Not Determined | The notified chemical does not contain dissociate groups and is not expected to dissociate under environmental conditions. |
| Particle Size | D10 = 0.74 μm<br>D50 = 4.3 μm<br>D90 = 11.4 μm | Measured |
| Flammability | Not highly flammable | Measured |
| Autoignition Temperature | Not auto-flammable | Measured |
| Explosive Properties | Predicted negative | Based on the chemical structure |
| Oxidising Properties | Predicted negative | Based on the chemical structure |

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

*Reactivity*
The notified chemical is expected to be stable under normal conditions of use.

***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 in the neat form or as part of articles such as refill powder toner in cartridges.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 0.04 | 0.2 | 0.3 | 0.5 | 0.5 |

PORT OF ENTRY
Melbourne, Sydney and Brisbane

IDENTITY OF MANUFACTURER
Clariant Plastics and Coatings GmbH (Germany)

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in the neat form in 10 kg paper bags, or as a component of toners in printer cartridges, and transported within Australia (to/from warehousing facilities and industrial end-users) by road.

USE
The notified chemical will be used as a component of industrial printer toners at ≤ 5% concentration for paper substrates.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. Following distribution to end-use sites, printer operators will incorporate and encapsulate the notified chemical into a polyester or styrene acrylic toner resin which will be loaded into printer cartridges. The finished printer toner will contain the notified chemical at ≤ 5% concentration. Printer operators may also connect the imported cartridges containing the notified chemical to printers. Printing processes are expected to be mostly automated, with local exhaust ventilation in place. Printer operators will manually change print heads and cartridges. Workers are also expected to manually handle printed items.

## 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)* |
|---|---|---|
| Stevedores | 8 | 10-15 |
| Transport | 6 | 260 |
| Warehousing | 6 | 260 |
| Industrial workers (printing) | 8 | 260 |
| Maintenance workers and cleaners at industrial sites | 1 | 260 |

EXPOSURE DETAILS
Transport and storage workers will only come into contact with the notified chemical in the unlikely event of an accident.

During toner preparation, dermal, ocular or inhalation exposure to the neat powdered notified chemical may occur. Exposure should be mitigated by the use of enclosed and automated systems, local exhaust ventilation and personal protective equipment (PPE: goggles, impervious gloves, protective clothing and respiratory protection when dusts are expected).

During printing, significant exposure to the notified chemical is not expected, given the toner will be contained within purpose-built cartridges and the notified will only be present in the toner at low concentrations (≤ 5% concentration).

Once the toner is applied and dried, the notified chemical will be bound to the substrate and is not expected to be available for exposure in significant quantities.

### 6.1.2. Public Exposure

The notified chemical will be used in industrial settings only and will not be made available to the public. The public may make dermal contact with surfaces that have had toners containing the notified chemical at ≤ 5% concentration applied to. However, once applied and dried, the notified chemical will be bound to the substrate and is not expected to be available for exposure in significant quantities.

## 6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

| *Endpoint* | *Result and Assessment Conclusion* |
|---|---|
| Rat, acute oral toxicity | LD50 > 2000 mg/kg bw; low toxicity |
| Rat, acute dermal toxicity | LD50 > 2000 mg/kg bw; low toxicity |
| Rabbit, skin irritation | non-irritating |
| Rabbit, eye irritation | slightly irritating |
| Guinea pig, skin sensitisation – adjuvant test | no evidence of sensitisation |
| Rat, repeat dose oral toxicity –28 days | NOEL = 1000 mg/kg bw |
| Mutagenicity – bacterial reverse mutation | non-mutagenic |
| Genotoxicity – *in vitro* chromosomal aberration test | non-genotoxic |

*Toxicokinetics*

Given the relatively high molecular weight (> 500 Da) and low water solubility (< $2 \times 10^{-5}$ g/L) of the notified chemical, absorption across biological membranes is not expected.

The notified chemical is an azo compound. Azo compounds may break down to their component amines. The azo linkage is the most labile portion of an azo colourant molecule, and it is readily enzymatically metabolised in mammals, including man (SCCNFP, 2002). Liver azo reductase enzymes reductively cleave the molecules into component amines. Some metabolism of azo colourants may also occur in the cells of the bladder wall, and during percutaneous absorption. Intestinal bacteria are also capable of catalysing reductive cleavage of the azo bond. The notified chemical may be broken down to the aromatic amine, 3-amino-4-methylbenzamide (CAS RN 19406-86-1). 3-Amino-4-methylbenzamide is not on the restricted list of carcinogenic amines in the European Union; however, there is a report of a positive response in an Ames assay. Given the low bioavailability of the notified chemical reductive cleavage is not expected to occur via the dermal route. However there is potential for formation of the aromatic amine in the GI tract, although this is expected to be limited given the low water solubility of the notified chemical, which is expected to be strongly absorbed.

The majority of the notified chemical is of respirable (< 10 μm) particle size and therefore could reach the lower respiratory tract (tracheobronchial and pulmonary regions) if inhaled. Due to the low water solubility of the notified chemical particles lodging in the tracheobronchial region are likely to be cleared by the mucociliary mechanism and swallowed. However, inhaled respirable particulates of the notified chemical lodging in the pulmonary region may not be readily cleared due to their low water solubility. Absorption across the respiratory tract epithelium is not expected; however higher exposure concentrations may be expected to result in increased impairment of clearance mechanisms.

*Acute toxicity*

The notified chemical was found to be of low toxicity via the oral and dermal routes in studies conducted in rats.

*Irritation*

In studies conducted in rabbits, the notified chemical was found to be non-irritating to the skin and slightly irritating to eyes. Eye irritation was limited to slight conjunctival irritation and swelling which was fully resolved at the 72-hour observation.

*Sensitisation*
In a skin sensitisation maximisation study conducted in guinea pigs, the notified chemical was not a skin sensitiser.

*Repeated dose toxicity*
A repeated dose oral (gavage) toxicity study on the notified chemical was conducted in rats, in which the test substance was administered at 50, 200 and 1,000 mg/kg bw/day for 28 consecutive days, with a 14-day recovery period for high dose and control animals.

The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day (the highest dose tested) in the study, based on the absence of treatment-related toxicological effects at any dose tested.

*Mutagenicity/Genotoxicity*
The notified chemical is an azo compound which may be metabolised to form the aromatic amine, 3-amino-4-methylbenzamide (CAS RN 19406-86-1) (see Toxicokinetics section). The aromatic amine has been reported to give a positive response in an Ames assay.

Using the modified procedure for azo compounds, the notified chemical was negative in an Ames assay. Furthermore the notified chemical was negative in an *in vitro* chromosomal aberration study in Chinese hamster V79 cells. Therefore, the notified chemical is not expected to be mutagenic or genotoxic.

***Health hazard classification***
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety
Based on the available information, the notified chemical is expected to be of low hazard, presenting only as a slight eye irritant. However, the notified chemical as introduced is of a respirable particle size and lung overloading effects may occur if large amounts are inhaled.

Workers at risk of lung overloading and slight eye irritating effects will be those handling the neat notified chemical during toner preparation. Toner preparation is expected to occur in a closed system with local exhaust ventilation, and appropriate PPE (goggles, impervious gloves, protective clothing and respiratory protection when dusts are expected) is expected to be used to limit worker exposure.

Therefore, under the occupational settings described, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

#### 6.3.2. Public Health
The notified chemical will be used in industrial settings only and will not be made available to the public. Members of the public may come into contact with paper substrates printed with toners containing the notified chemical. However, once the printer tonners have dried, the notified chemical will be bound within the solid matrix and will not be available for exposure.

Based on the assessed use patterns, the risk to the public from use of the notified chemical is not considered to be unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported into Australia in the neat form or as part of articles such as refill powder toner in cartridges. Environmental release of the notified chemical is not expected during importation, transport and storage.

Following distribution to end-use sites, printer operators will incorporate and encapsulate the notified chemical into a polyester or styrene acrylic toner resin. The accidental spills during this process are expected to be collected and be disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be used as a component of printer toners for paper printing. During its use, the notified chemical will be fixed within ink matrix adhering to paper and is not expected to be released to the environment once cured. Wastes containing the notified chemical including cleaning materials and spills are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL
Following its use, the notified chemical is anticipated to share the fate of printed paper to be disposed of to landfill or subjected to paper recycling processes. Half the amount of used paper is expected to be recycled. During paper recycling processes, small amount of the notified chemical is expected to be released to sewer and surface waters after sewage treatment processes due to its low water solubility. Residues of the notified chemical in empty cartridges are expected to be disposed of to landfill along with the empty cartridges.

### 7.1.2. Environmental Fate

The notified chemical will be imported into Australia as a component of toners used for paper printing. The notified chemical is expected to remain fixed to paper for its useful life. At the end of its useful life, the notified chemical is expected to be disposed of to landfill along with printed paper. Limited amount of the notified chemical is expected to be released to sewer during the paper recycling process.

During paper recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The detached notified chemical will predominately partition to sediment or sludge and small amount of the notified chemical is expected to partition to the supernatant water due to its low water solubility ($< 2.0 \times 10^{-5}$ g/L). Sediment and sludge containing the notified chemical are expected to be disposed of to landfill. In landfill, the notified chemical is unlikely to be mobile based on its low water solubility.

The notified chemical is not readily biodegradable (4% over 28 days) and hydrolysis is expected to be negligible at environmental conditions due to the lack of hydrolysable functionalities. The notified chemical is not expected to bioaccumulate due to the low n-octanol/water partition coefficient (log Pow = 2.7) and relatively high molecular weight (> 500 Da). The notified chemical is expected to eventually degrade by biotic and abiotic processes to form water, oxides of carbon and nitrogen. For the details of the environmental fate studies please refer to Appendix C.

### 7.1.3. Predicted Environmental Concentration (PEC)

Worst-case aquatic PECs have been calculated assuming that 50% of notified chemical will reach the aquatic compartment due to releases from paper recycling. This is a conservative upper limit as the notified chemical is not expected to enter aquatic compartment to such a significant extent. It is also assumed that there would be no removal of the notified chemical by sewerage treatment plants (STPs) and release of the notified chemical will occur over 260 days per annum into the total Australian effluent volume, corresponding to release only on working days.

| ***Predicted Environmental Concentration (PEC) for the Aquatic Compartment*** | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | 500 | kg/year |
| Proportion expected to be released to sewer | 50% | |
| Annual quantity of chemical released to sewer | 250 | kg/year |
| Days per year where release occurs | 260 | days/year |
| Daily chemical release: | 0.96 | kg/day |
| Water use | 200.0 | L/person/day |
| Population of Australia (Millions) | 22.613 | million |
| Removal within STP | 0% | |
| Daily effluent production: | 4,523 | ML |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River: | 0.21 | µg/L |

| | | |
|---|---|---|
| PEC - Ocean: | 0.02 | 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 0.213 µg/L may potentially result in a soil concentration of approximately 1.417 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 7.087 µg/kg and 14.17 µg/kg, respectively.

### 7.2. Environmental Effects Assessment

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

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| Fish Toxicity | 96 h LL50 > 100 mg/L (WAF*) | Not harmful to fish up to water solubility limit |
| Daphnia Toxicity | 48 h EL50 > 100 mg/L (WAF*) | Not harmful to aquatic invertebrate up to water solubility limit |
| Algal Toxicity | 72 h EL50 > 100 mg/L (WAF*) | Not harmful to algae up to water solubility limit |
| Inhibition of Bacterial Respiration | 3 h EC50 > 1000 mg/L | Not inhibitory to microbial respiration |

* Water Accommodated Fraction

Based on the above ecotoxicological endpoints, the notified chemical is not expected to be harmful to aquatic life up to the limit of its solubility in water. 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.

### 7.3. Environmental Risk Assessment

The risk quotient (RQ = PEC/PNEC) was not calculated as PNEC has not been calculated because no effects to aquatic organisms were reported up to the limit of solubility of the notified chemical in the submitted ecotoxicity studies. The exposure of the chemical to aquatic compartment is expected to be very low as the majority of notified chemical released from recycling processes is expected to sorb to sludge and sediment in STPs resulting in a limited potential for release to surface waters. The notified chemical is not expected to pose an unreasonable risk to the aquatic environment based on the low ecotoxicity and assessed use pattern.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Melting Point/Freezing Point** > 350 °C

| | |
|---|---|
| Method | OECD TG 102 Melting Point/Melting Range. |
| Remarks | Determined by differential scanning calorimetry |
| Test Facility | RCC (2000a) |

**Density** 1,349 kg/$m^3$ at 20 °C

| | |
|---|---|
| Method | OECD TG 109 Density of Liquids and Solids. |
| Remarks | Pycnometer method |
| Test Facility | RCC (1999a) |

**Vapour Pressure** $1.49 \times 10^{-22}$ kPa at 25 °C

| | |
|---|---|
| Method | OECD TG 104 Vapour Pressure. |
| Remarks | Estimated based on calculated boiling point of 656 °C |
| Test Facility | RCC (2000b) |

**Water Solubility** $< 2.0 \times 10^{-5}$ g/L at 20 °C

| | |
|---|---|
| Method | OECD TG 105 Water Solubility. |
| Remarks | Column Elution Method |
| Test Facility | RCC (2000c) |

**Partition Coefficient (n-octanol/water)** log Pow = 2.7

| | |
|---|---|
| Method | Calculation |
| Remarks | Calculated based on theoretical fragmentation |
| Test Facility | RCC (2000d) |

**Particle Size**

| | |
|---|---|
| Method | ISO 13320-1. |
| Results | D10 = 0.74 µm<br>D50 = 4.3 µm<br>D90 = 11.4 µm |
| Remarks | Particle size measured by laser diffraction. The sample showed a bimodal distribution with a first maximum at ~ 1 µm and a second maximum at ~ 7 µm. Report not in English (an English summary provided by the notifier). |
| Test Facility | Siemens (2010) |

**Flammability** Not highly flammable

| | |
|---|---|
| Method | EC Council Regulation No 440/2008 A.10 Flammability (Solids). |
| Remarks | Determined by measuring burning rate |
| Test Facility | RCC (2000e) |

**Autoignition Temperature** Not auto-flammable

| | |
|---|---|
| Method | EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids. |
| Test Facility | RCC (2000f) |

**Explosive Properties** Predicted negative

| | |
|---|---|
| Method | Expert judgement. |
| Remarks | Predicted based on the chemical structure |
| Test Facility | RCC (2000g) |

**Oxidizing Properties** Predicted negative

| | |
|---|---|
| Method | Expert judgement. |
| Remarks | Predicted based on the oxygen balance |
| Test Facility | RCC (2000h) |

# APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

## B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
- Species/Strain: Rat/HanIbm:WIST
- Vehicle: Polyethylene glycol 300
- Remarks - Method: No significant protocol deviations

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 3F | 2000 | 0/3 |
| 2 | 3M | 2000 | 0/3 |

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: No signs of systemic toxicity were noted.
- Effects in Organs: No abnormalities were noted at necropsy.
- Remarks - Results: The body weight of the animals was within the range commonly recorded for this strain and age.

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

TEST FACILITY: RCC (1999b)

## B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 402 Acute Dermal Toxicity.
- Species/Strain: Rat/HanIbm:WIST
- Vehicle: Polyethylene glycol 300
- Type of dressing: Semi-occlusive
- Remarks - Method: No significant protocol deviations

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 5 per sex | 2000 | 0/10 |

- LD50: > 2000 mg/kg bw
- Signs of Toxicity - Local: Yellow staining and test substance remnants on the treatment sites were noted in all animals, and persisted in 2 male animals and 3 female animals until Day 13.
- Signs of Toxicity - Systemic: No signs of systemic toxicity were noted.
- Effects in Organs: No abnormalities were noted at necropsy.
- Remarks - Results: The body weight of the animals was within the range commonly recorded for this strain and age.

CONCLUSION: The notified chemical is of low toxicity via the dermal route.

TEST FACILITY: RCC (1999c)

### B.3. Irritation – skin

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 404 Acute Dermal Irritation/Corrosion. |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 (1M/2F) |
| Vehicle | Distilled water (moisten the test substance) |
| Observation Period | 72 hours |
| Type of Dressing | Semi-occlusive |
| Remarks - Method | No significant protocol deviations |

RESULTS

| | |
|---|---|
| Remarks - Results | No mortality or signs of systemic toxicity were noted.<br><br>No signs of irritation were noted for any animal during the course of the study. Yellow staining was noted for all the animals until the 48-hour observation. |
| CONCLUSION | The notified chemical is non-irritating to the skin. |
| TEST FACILITY | RCC (2000i) |

### B.4. Irritation – eye

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 405 Acute Eye Irritation/Corrosion. |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 (1M/2F) |
| Observation Period | 72 hours |
| Remarks - Method | No significant protocol deviations |

RESULTS

| *Lesion* | *Mean Score* Animal No.* | | | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | | | |
| *Conjunctiva: redness* | 0 | 0 | 0.3 | 1 | < 48 h | 0 |
| *Conjunctiva: chemosis* | 0 | 0 | 0.7 | 1 | < 72 h | 0 |
| *Corneal opacity* | 0 | 0 | 0 | 0 | - | 0 |
| *Iridial inflammation* | 0 | 0 | 0 | 0 | - | 0 |

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

| | |
|---|---|
| Remarks - Results | No mortality or signs of systemic toxicity were noted.<br><br>Yellow remnants around eye and/or lids were noted for all animals at 1, 24, 48 and 72 hour observations.<br><br>Slightly reddened conjunctiva was noted in all animals at the 1-hour observation and persisted to the 24-hour observation in 1 female animal. In the same female also slight swelling was observed until the 48-hour observation. |
| CONCLUSION | The notified chemical is slightly irritating to the eye. |
| TEST FACILITY | RCC (2000j) |

### B.5. Skin sensitisation

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 406 Skin Sensitisation - Magnusson and Kligman. |
| Species/Strain | Guinea pig/Ibm: GOHI |
| PRELIMINARY STUDY | Maximum Non-irritating Concentration:<br>topical: 5% |
| MAIN STUDY | |
| Number of Animals | Test Group: 10 Control Group: 5 |
| Vehicle | Polyethylene glycol 400 |
| Positive control | Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using 2-mercaptobenzothiazole. |
| INDUCTION PHASE | Induction Concentration:<br>intradermal: 5%<br>topical: 25% |
| Signs of Irritation | A possible erythema reaction could not be determined in all test animals due to a yellow discoloration produced by the test substance. However, no oedema was noted. |
| CHALLENGE PHASE | |
| Challenge | topical: 5% and vehicle only |
| Remarks - Method | No significant protocol deviations |

RESULTS

| *Animal* | *Challenge Concentration* | *Number of Animals Showing Skin Reactions after: challenge* | |
|---|---|---|---|
| | | *24 h* | *48 h* |
| *Test Group* | 5% | 0 | 0 |
| | 0% | 0 | 0 |
| *Control Group* | 5% | 0 | 0 |
| | 0% | 0 | 0 |

| | |
|---|---|
| Remarks - Results | No mortality or signs of systemic toxicity were noted.<br><br>No skin reactions were noted after the challenge. |
| CONCLUSION | There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test. |
| TEST FACILITY | RCC (2000k) |

### B.6. Repeat dose toxicity

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. |
| Species/Strain | Rat/Wistar |
| Route of Administration | Oral – gavage |
| Exposure Information | Total exposure days: 28 days<br>Dose regimen: 7 days per week<br>Post-exposure observation period: 14 days |
| Vehicle | Polyethylene glycol 300 |
| Remarks - Method | No significant protocol deviations |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw/day* | *Mortality* |
|---|---|---|---|
| control | 5 per sex | 0 | 0/10 |

| | | | |
|---|---|---|---|
| low dose | 5 per sex | 50 | 0/10 |
| mid dose | 5 per sex | 200 | 0/10 |
| high dose | 5 per sex | 1000 | 0/10 |
| control recovery | 5 per sex | 0 | 0/10 |
| high dose recovery | 5 per sex | 1000 | 0/10 |

*Mortality and Time to Death*
There were no unscheduled deaths.

*Clinical Observations*
No treatment-related signs of toxicity were noted. No treatment-related differences to the controls were noted in grip strength, locomotor activity, food consumption and body weight development.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*
There were no treatment-related differences to the controls noted in the haematology, clinical biochemistry or urinalysis data.

*Effects in Organs*
No treatment-related differences were noted in organ weight changes. No morphological evidence of toxic changes was noted in the necropsy or histopathology.

Remarks – Results
Soft faeces noted in all animals was considered by the study authors to be caused by the vehicle. Treatment-related discoloration faeces was considered by the study authors to be a non-toxic effect of a dyestuff.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study, based on the absence of treatment-related toxicological effects at any of the doses tested.

TEST FACILITY RCC (2000l)

**B.7. Genotoxicity – bacteria**

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Modified pre incubation procedure to detect mutagenic effects of azo or nitroso compounds

| | |
|---|---|
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA98, TA100<br>*E. coli*: WP2uvrA |
| Metabolic Activation System | S9 mix from uninduced hamster liver |
| Concentration Range in Main Test | a) With metabolic activation: 33-5000 µg/plate<br>b) Without metabolic activation: 33-5000 µg/plate |
| Vehicle | Dimethyl sulphoxide |
| Remarks - Method | A preliminary study was conducted and reported as main test 1 as it met the criterion “evaluable plates at 5 concentrations or more”.<br><br>Vehicle and positive controls were run concurrently with the notified chemical.<br><br>Positive controls:<br>- Without metabolic activation: sodium azide (TA1535, TA100); 4-nitro-o-phenylene-diamine (TA1537, TA98); methyl methanesulfonate (WP2uvrA)<br>- With metabolic activation: 2-aminoanthracene (TA1535, TA1537, TA100, WP2uvrA); congo red (TA98) |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/plate) Resulting in:* | | |
|---|---|---|---|
| | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |

| | | | |
|---|---|---|---|
| *Absent* | | | |
| Test 1 | > 1000 | > 5000 | negative |
| Test 2 | > 333 | > 5000 | negative |
| *Present* | | | |
| Test 1 | > 5000 | > 5000 | negative |
| Test 2 | > 1000 | > 5000 | negative |

Remarks - Results

No significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

The positive and negative controls gave a satisfactory response confirming the validity of the test system.

CONCLUSION

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

TEST FACILITY

RCC (2000m)

**B.8. Genotoxicity – in vitro**

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain: Chinese hamster

Cell Type/Cell Line: V79

Metabolic Activation System: S9 mix from phenobarbitone/β-naphthoflavone induced rat livers

Vehicle: Dimethyl sulphoxide

Remarks - Method: A dose range-finding study was carried out at 0.8-100 µg/mL. The dose selection for the main experiments was based on precipitation of the test substance noted in the range-finding study as no toxicity was noted at up to the highest dose.

Culture medium and vehicle controls and positive controls (ethyl methanesulfonate and cyclophosphamide) were run concurrently with the notified chemical.

| *Metabolic Activation* | *Test Substance Concentration (µg/mL)* | *Exposure Period* | *Harvest Time* |
|---|---|---|---|
| *Absent* | | | |
| Test 1 | 3.1*, 6.3*, 12.5*, 25, 50, 100 | 4h | 18h |
| Test 2 | 3.1*, 6.3*, 12.5*, 25, 50, 100 | 18h | 18h |
| Test 2 | 3.1, 6.3, 12.5*, 25, 50, 100 | 28h | 28h |
| *Present* | | | |
| Test 1 | 3.1, 6.3*, 12.5*, 25*, 50, 100 | 4h | 18h |
| Test 2 | 3.1*, 6.3*, 12.5*, 25*, 50, 100 | 4h | 28h |

*Cultures selected for metaphase analysis.

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/mL) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 | > 100 (4h/24h) | > 100 | > 6.3 | negative |
| Test 2 | > 100 (24h/24h) | > 100 | > 6.3 | negative |
| Test 2 | | > 100 | 12.5 | negative |
| *Present* | | | | |
| Test 1 | > 100 (4h/24h) | > 100 | > 12.5 | negative |
| Test 2 | | > 100 | > 6.3 | negative |

| | |
|---|---|
| Remarks - Results | In both main tests, no statistically significant increases in the frequency of cells with structural or numerical chromosome aberrations were observed in the presence or absence of the metabolic activation.<br><br>The positive and negative controls gave a satisfactory response confirming the validity of the test system. |
| CONCLUSION | The notified chemical was not clastogenic to Chinese hamster V79 cells treated in vitro under the conditions of the test. |
| TEST FACILITY | RCC (2000n) |

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

## C.1. Environmental Fate

### C.1.1. Ready biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test |
| Inoculum | Activated sludge |
| Exposure Period | 28 days |
| Auxiliary Solvent | No |
| Analytical Monitoring | Oxygen consumption |
| Remarks - Method | The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported. |

RESULTS

| *Test substance* | | *Sodium benzoate (reference substance)* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 7 | 3 | | |
| 14 | 3 | 14 | 76 |
| 21 | 4 | | |
| 28 | 4 | 28 | 78 |

| | |
|---|---|
| Remarks - Results | All validity criteria for the test were satisfied. The reference compound reached the 60% pass level by day 4, indicating the suitability of the inoculums. The test substance had no inhibitory effect on activated sludge microorganism based on the 43% and 34% biodegradation of the reference substance, greater than 25%, in 14 days. |
| CONCLUSION | The notified chemical is not readily biodegradable. |
| TEST FACILITY | RCC (2000o) |

## C.2. Ecotoxicological Investigations

### C.2.1. Acute toxicity to fish

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 203 Fish, Acute Toxicity Test -Static |
| Species | Zebra fish (*Branchydanio rerio*) |
| Exposure Period | 96 h |
| Auxiliary Solvent | No |
| Water Hardness | 250 mg $CaCO_3$/L |
| Analytical Monitoring | UV/VIS spectrometer |
| Remarks – Method | The test was conducted in accordance with the test guideline above. No significant deviations from the test guidelines were reported.<br><br>The test substance was prepared as water accommodated fraction (WAF) due to its low water solubility. A saturated stock solution with a nominal loading rate of 100 mg/L was prepared by dispersing the test substance in water with ultrasonic treatment for 15 minutes, followed by continuously stirring for 24 hours at room temperature. The suspension was filtered through a glass microfiber filter and the undiluted filtrate was used in the test. |

RESULTS

| *Concentration mg/L* | | *Number of Fish* | *Mortality* | | | | |
|---|---|---|---|---|---|---|---|
| *Nominal* | *Actual* | | *3h* | *24 h* | *48 h* | *72 h* | *96 h* |
| Control | Control | 7 | 0 | 0 | 0 | 0 | 0 |
| 100 | < 0.02 – 0.05 | 7 | 0 | 0 | 0 | 0 | 0 |

| | |
|---|---|
| LL50 | > 100 mg/L at 96 hours (WAF) |
| NOEL | 100 mg/L at 96 hours (WAF) |
| Remarks – Results | All validity criteria for the test were satisfied. The mean concentration of the test substance in the test medium was determined to be 0.05 mg/L at the start of the test, higher than the reported water solubility of < 0.02 mg/L for the test substance. |

CONCLUSION The notified chemical is not considered to be harmful to fish up to the limit of its water solubility.

TEST FACILITY RCC (2000p)

**C.2.2. Acute toxicity to aquatic invertebrates**

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static

| | |
|---|---|
| Species | *Daphnia magna* |
| Exposure Period | 48 hours |
| Auxiliary Solvent | None |
| Water Hardness | 250 mg $CaCO_3$/L |
| Analytical Monitoring | UV/VIS spectrometer |
| Remarks - Method | The test was conducted in accordance with the test guideline above. No significant deviations from the test guidelines were reported.<br><br>The test substance was prepared as water accommodated fraction (WAF) due to its low water solubility. A saturated stock solution with a nominal loading rate of 100 mg/L was prepared by dispersing the test substance in water with ultrasonic treatment for 15 minutes, followed by continuously stirring for 24 hours at room temperature. The suspension was filtered through a glass microfiber filter and the undiluted filtrate was used in the test. |

RESULTS

| *Concentration mg/L* | | *Number of D. magna* | *Number Immobilised* | |
|---|---|---|---|---|
| *Nominal* | *Actual* | | *24 h* | *48 h* |
| Control | control | 20 | 0 | 0 |
| 100 | < 0.02 – 0.04 | 20 | 0 | 0 |

| | |
|---|---|
| EL50 | > 100 mg/L at 48 hours (WAF) |
| NOEL | 100 mg/L at 48 hours (WAF) |
| Remarks - Results | All validity criteria for the test were satisfied. The mean concentration of the test substance in the test medium was determined to be 0.041 mg/L at the start of the test, higher than the reported water solubility of < 0.02 mg/L for the test substance. |

CONCLUSION The notified chemical is not considered to be harmful to aquatic invertebrate up to the limit of its water solubility.

TEST FACILITY RCC (2000q)

### C.2.3. Algal growth inhibition test

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 201 Alga, Growth Inhibition Test - Static |
| Species | *Scenedesmus subspicatus* |
| Exposure Period | 72 hours |
| Concentration Range | Nominal: 100 mg/L<br>Actual: 0.038-0.079 mg/L |
| Auxiliary Solvent | None |
| Water Hardness | 24 mg $CaCO_3$/L |
| Analytical Monitoring | UV/VIS spectrometer |
| Remarks - Method | The test was conducted in accordance with the test guideline above. No significant deviations from the test guidelines were reported.<br><br>The test substance was prepared as water accommodated fraction (WAF) due to its low water solubility. A saturated stock solution with a nominal loading rate of 100 mg/L was prepared by dispersing the test substance in water with ultrasonic treatment for 15 minutes, followed by continuously stirring for 24 hours at room temperature. The suspension was filtered through a glass microfiber filter and the undiluted filtrate was used in the test. |

RESULTS

| *Biomass* | | *Growth* | |
|---|---|---|---|
| *EL50* | *NOEL* | *EL50* | *NOEL* |
| *mg/L (WAF) at 72 h* | *mg/L(WAF)* | *mg/L(WAF) at 72h* | *mg/L(WAF)* |
| > 100 | 100 | > 100 | 100 |

| | |
|---|---|
| Remarks - Results | All validity criteria for the test were satisfied. The test substance is not soluble enough to reach a toxic level to inhibit algae growth. |
| CONCLUSION | The notified chemical is not considered to be harmful to algae up to the limit of its water solubility. |
| TEST FACILITY | RCC (2000r) |

### C.2.4. Inhibition of microbial activity

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 209 Activated Sludge, Respiration Inhibition Test |
| Inoculum | Activated sludge |
| Exposure Period | 3 hours |
| Concentration Range | Nominal: 10, 32, 100, 320 and 1000 mg/L<br>Actual: Not determined |
| Remarks – Method | The test was conducted in accordance with the test guideline above. No significant deviations from the test guidelines were reported.<br>A blank control and reference (3,5-dichlorophenol) control were run in parallel. The rate of respiration was determined after 3 h contact time and compared to the results from the control and reference material. |
| RESULTS | |
| EC50 | > 1000 mg/L (based on nominal loading rate) |
| NOEC | 1000 mg/L |
| Remarks – Results | The test substance was determined to have no significant inhibitory effect on the respiration rate of activated sludge at all the test concentrations (nominal) in 3 hours. The validation criteria for the control respiration |

| | |
|---|---|
| | rates and reference material, (3,5-dichlorophenol) $EC_{50}$ were satisfied. |
| CONCLUSION | The notified chemical is not expected to inhibit microbial respiration. |
| TEST FACILITY | RCC (2000s) |

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