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September 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Phosphinic acid, *P*-phenyl-*P*-(2,4,6-trimethylbenzoyl)-, ethyl ester

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1575	BASF Australia Ltd	Phosphinic acid, *P*-phenyl-*P*-(2,4,6-trimethylbenzoyl)-, ethyl ester	Yes	< 10 tonnes per annum	Component of inks, overvarnishes and surface coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin Sensitisation (Category 1B)	H317 – May cause an allergic skin reaction

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):
R43: May cause sensitisation by skin contact

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 2	H401 – Toxic to aquatic life
Chronic Category 2	H411 – Toxic to aquatic life with long lasting effects

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 PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Skin Sensitisation (Category 1B): H317 – May cause an allergic skin reaction

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

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 reformulation and/or end use processes:
  - Enclosed, automated processes, where possible
  - Use of well-ventilated environments

- 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 during reformulation and/or end use processes:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols

- 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 reformulation and/or end use processes:
  - Gloves
  - Goggles
  - Coveralls
  - Respiratory protection, if ventilation is inadequate

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for Spray Painting and Powder Coating (SWA, 2015) or relevant State or Territory Code of Practice

- 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 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 component of inks, overvarnishes and surface coatings for industrial use only, 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.

No additional secondary notification conditions are stipulated.

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

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: degree of purity, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: flash point, flammability and autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada, China, Europe, Japan, Korea, New Zealand, Taiwan and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Irgacure® TPO-L

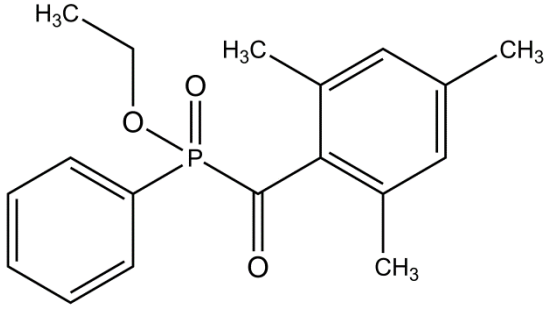
CAS NUMBER
84434-11-7

CHEMICAL NAME
Phosphinic acid, *P*-phenyl-*P*-(2,4,6-trimethylbenzoyl)-, ethyl ester

OTHER NAME(S)
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate
2,4,6-Trimethylbenzoylphenylphosphinic acid ethyl ester
Lucirin® TPO-L
Lucirin® LR 8893 X
Initiator 654

MOLECULAR FORMULA
$C_{18}H_{21}O_3P$

STRUCTURAL FORMULA



MOLECULAR WEIGHT

316.33 Da

ANALYTICAL DATA
Reference ^{1}H- and ^{31}P-NMR and GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
≥ 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear yellowish liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-12 °C	Measured
Boiling Point	257.4 °C at 101.3 kPa	Measured
Density	1,133 kg/m^3 at 20 °C	Measured
Vapour Pressure	2.1 × 10^{-7} kPa at 20 °C	Measured
Water Solubility	3.5 × 10^{-2} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{½}$ = 158 h at 70 °C at pH 4 $t_{½}$ = 114 h at 30 °C at pH 7 $t_{½}$ < 2.4 h at 50 °C at pH 9	Measured
Partition Coefficient (n-octanol/water)	log Pow = 2.91 at 25 °C	Measured
Adsorption/Desorption	log Koc = 3.37 at 26 °C	Measured
Dissociation Constant	Not determined	Contains no dissociable functionalities
Particle Size	Not determined	Liquid
Flash Point	144 °C (closed cup)	(M)SDS
Flammability	Not flammable	(M)SDS
Autoignition Temperature	423 °C	(M)SDS
Explosive Properties	Predicted negative	Contains no functional groups that would imply explosive properties
Oxidising Properties	Predicted negative	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 a photoinitiator and is expected to react during 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 be imported at 100% concentration and it will be imported in finished formulated ink, overvarnish or surface coating products at < 5% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

PORT OF ENTRY
Melbourne, Sydney

IDENTITY OF RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
The notified chemical (100%) will be imported by sea in 20 kg or 30 kg plastic jerry cans or 1,000 kg intermediate bulk containers. It will be transported by road from the wharf to the BASF contracted warehouse where it will be stored until required for delivery by road to customers.

It may also be imported in formulated ink, overvarnish or surface coating products at < 5% concentration in 5–20 L cans and pails.

USE
The notifier chemical is a liquid photoinitiator and is recommended for applications such as: opaque white printing inks for flexographic, gravure, lithographic, screen or digital applications, clear overprint varnishes, UV curing of coatings for can/oil, general industrial, floor, furniture, millwork or plastic component applications.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. It will be imported in bulk for reformulation, and in end-use products.

For reformulation into inks and coatings, at the site of reformulation the notified chemical (100% concentration) will be transferred from the container into the blending equipment. Samples will be collected from sampling port during and after blending for quality control. After blending, the end-use products containing the notified chemical will be transferred to 5 to 20 L containers via an automated process. The products will be supplied to Australian industrial customers.

During end-use of the products containing the notified chemical, they may be applied to substrates by spray, brush, roller or dispensers.

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 storage	4–8	50–100
Quality control chemists and technical service	0.5–4	20–50
Manufacturing operators	1–2	20–50
End users (printing/overprint varnishes/surface coatings)	8	200–240

EXPOSURE DETAILS
Transport and Storage
Transport and storage workers will handle the notified chemical at up to 100% concentration in bulk containers of various sizes. Exposure of these workers will be limited to events where there is a discharge, spill or leakage from damaged containers. If such an event occurs, a worker may be exposed to the notified chemical through dermal or ocular contact.

Reformulation
Reformulation and quality control workers may be exposed to the notified chemical at up to 100% concentration via the dermal and ocular route during the transfer of the chemical for reformulation, sampling for quality control and packaging of reformulated products. Cleaning and maintenance workers may also be exposed to the notified chemical during the cleaning and maintenance of blending equipment.

End-use

The final products containing the notified chemical at < 5% concentrations will be used in printing including flexographic printing and coatings.

Workers in the printing industry handling the inks containing the notified chemical < 5% concentration may be exposed via the dermal route and perhaps accidentally via ocular route during attending to substrate jams or during the cleaning and maintenance of printing machines. Inhalation exposure is not anticipated due to the process being carried out in enclosed system with local exhaust ventilation.

When used in coatings, the workers handing the products containing the notified chemical (< 5% concentration) may be exposed via the dermal, ocular or inhalation route during the application of the product on various surfaces. The products will be applied by spray, brush or roller. Spray application will normally be carried out in closed spray booths by manual or automated means.

Exposure to the notified chemical during handling, reformulation and end-use is proposed to be minimised by the use of engineering controls such as enclosed systems and exhaust ventilation and by personal protective equipment (PPE) including impervious gloves, coveralls, safety glasses and respiratory protection.

6.1.2. Public Exposure

The inks and coating containing the notified chemical at < 5% concentration will not be sold to the public. Contact with printed or coated products may occur. However, once the printing ink or coating is cured, the notified chemical is expected to remain bound within the cured film and will not 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*
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 was not reported
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOAEL male = 1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Cell Gene Mutation Test	non genotoxic

Toxicokinetics, metabolism and distribution

Based on the low molecular weight (316 Da) and partition coefficient (log Pow = 2.91) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur.

Acute toxicity

The notified chemical was found to have low acute oral and dermal toxicity in rats. In the acute inhalation toxicity study provided, the LC50 was not reported as the exposure was based on a calculated saturated vapour concentration; however, there were no mortalities in clinical and laboratory observations. Therefore, there is uncertainty as to the acute inhalation toxicity of the notified chemical.

Irritation

Based on studies conducted in rabbits, the notified chemical was considered to be non-irritating to the skin and slightly irritating to eyes.

Sensitisation

The notified chemical was a skin sensitiser in a local lymph node assay (LLNA) in mice, with reported stimulation indices of 1.5, 5.0 and 6.7 at 10, 25 and 50% concentration, respectively. An EC3 value of 16.4% was determined by the study authors.

Repeated dose toxicity

A 28 day repeat dose study by oral gavage was conducted in rats with the notified chemical at dose levels of 0, 50, 150 and 500 mg/kg bw/day. A range of clinical and laboratory observations were noted, for example, salivation appeared temporally in all animals of the high dose group and 4 female animals in the medium dose group, the mean absolute and/or relative weights of kidneys and liver were significantly increased with some values being statistically significant, 2 male and 3 female animals in the highest dose group showed dark discolouration of the liver and treatment related findings were observed in the liver of male and female animals in the highest dose group. The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1,000 mg/kg bw/day by the study authors based on no signs of systemic toxicity and changes with regard to the reproductive organs were observed up to the highest dose tested.

Mutagenicity/Genotoxicity
The notified chemical was not considered to be mutagenic in a bacterial reverse mutation study and was not considered to be clastogenic in an in vitro mammalian cell gene mutation test using the HPRT locus in V79 cells of the Chinese hamster.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin Sensitisation (Category 1B)	H317 – May cause an allergic skin reaction

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):
R43: May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The critical health effect of the notified chemical is as a skin sensitiser.

During reformulation workers may be exposed to the notified chemical at up to 100% concentration. At these concentrations, the potential risk of sensitising effects is expected to be minimised by the stated use of personal protective equipment including protective clothing, impervious gloves and goggles, and largely automated and enclosed processes minimising exposure by the dermal, ocular and inhalation routes.

During end-use workers may be exposed to the notified chemical at < 5% concentration. At these end-use concentrations, the potential risk of sensitising effects is also expected to be minimised by the use of PPE and engineering controls similar to those used during reformulation.

Given the stated controls in place to minimise exposure during reformulation and end use, the risk to the health of workers is not considered unreasonable.

6.3.2. Public Health
The notified chemical will be used in industrial settings only and will not be sold to the public. The public may come into contact with the printed or coated products containing the notified chemical. However, once the notified chemical is cured, it will be bound within the ink or coated matrix and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health 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 as a liquid photoinitiator for reformulation into commercial printing inks and industrial coatings, or as a component of finished commercial printing inks and industrial coatings. No significant release of the notified chemical is expected from transportation and storage, except in the unlikely event of accidental spills or leaks. It is estimated by the notifier that a maximum of 0.25% (or up to

25 kg) of the notified chemical may be released from accidental spills and leaks. In the event of spills, the notified chemical and products containing the notified chemical are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified chemical from this process to the environment is not expected. The process will be followed by automated filling of the formulated products into containers suitable for distribution. Wastes containing the notified chemical generated during reformulation include equipment wash water, empty import containers, and spilt materials. It is estimated by the notifier that a maximum of 0.75% (or up to 75 kg) of the notified chemical may be released through equipment wash water. Wastes are expected to be collected and recycled during subsequent blending.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical will be used as a photoinitiator in commercial printing inks for printing onto paper (60% of the total import volume, or 6,000 kg). A minor amount of the notified chemical in commercial printing inks or industrial coatings will be applied to non-recyclable substrates (40% of the total import volume, or 4,000 kg). The printing process will be largely automated, and the notified chemical is expected to be stable within an inert ink or coating matrix on printed and coated substrates once cured.

Industrial coatings containing the notified chemical are expected to be applied by spray, brush or roller techniques. Spray applications are expected to occur within spray booths with ventilation systems to collect particulate overspray. Residues containing the notified chemical in spray equipment and on brushes and rollers are expected to be rinsed into containers, and then allowed to cure before disposal as solid wastes to landfill. Therefore, environmental release of the notified chemical during use is expected to be limited to accidental spills and leaks, and cleaning of printing and application equipment. It is estimated by the notifier that up to 1% of the annual import volume (or 100 kg) may be released as a result of spills and equipment cleaning. Spilt material and solid wastes from cleaning will be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will be used in commercial printing inks and industrial coatings for application onto paper and non-recyclable substrates. The majority of the notified chemical is expected to share the fate of the printed and coated articles to which it is bound, and is expected to be disposed of to landfill at the end of their useful lives.

Of the 60% import volume of the notified chemical applied to paper, it is assumed that half of this amount is expected to be disposed of to landfill, and the remainder will undergo paper recycling processes (i.e. 30% of the total import volume, or 3,000 kg). Empty containers containing residues of the notified chemical will be disposed of to landfill in accordance with local government regulations. Hence, the majority of the notified chemical is expected to be disposed of to landfill, with a potential for some release to sewer through paper recycling processes. During paper recycling processes, waste paper is pulped using a variety of chemical treatments which, amongst other things, will enhance ink detachment from the fibres. Waste water containing the notified chemical will be released to sewer.

7.1.2. Environmental Fate

The majority of the notified chemical in commercial printing inks and industrial coatings will be bound within an inert matrix, and is expected to remain adhered to the printed and coated articles throughout its useful life. The notified chemical is not expected to be biodegradable, mobile, bioavailable or bioaccumulative in this form. Therefore, the majority of the notified chemical will share the fate of the printed and coated articles, and will involve eventual disposal to landfill or undergo paper recycling processes. Based on the results of a ready biodegradability study, the notified chemical is not considered readily biodegradable (6–9% in 28 days) (refer to Appendix C).

Potentially 60% of the notified chemical could be disposed of to landfill as part of printed waste paper. However, approximately half of the paper to which the inks containing the notified chemical are applied is expected to be recycled. During the de-inking process, the notified chemical has the potential to be released into the supernatant waters due to its low molecular weight. However, the notified chemical is not expected to be bioaccumulative due to its low partition coefficient (log P_{OW} = 2.91). During recycling processes, based on its low water solubility and high adsorption coefficient (log K_{OC} = 3.37), the majority of the notified chemical is expected to adsorb to sludge and sediment. Sewage sludge will eventually be disposed of to landfill, or re-used for soil remediation. In

landfill and in surface waters, the notified chemical is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and phosphorus.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with half of the paper substrates containing the notified chemical undergoing recycling (i.e. 10,000 kg import volume × 60% printed onto paper substrates × 50% = 3,000 kg). It is assumed that the notified chemical will be released into sewers during recycling, with no removal during recycling or STP processes. As the notified chemical bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	30%	
Annual quantity of chemical released to sewer	3,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	11.54	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:	2.551	µg/L
PEC - Ocean:	0.255	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 2.55 µg/L may potentially result in a soil concentration of approximately 17.01 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 85.04 µg/kg and 170.1 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 LC50 = 1.89 mg/L	Toxic to fish
Daphnia Toxicity	48 h EC50 = 2.69 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	72 h EC50 = 1.01 mg/L	Toxic to algae
Inhibition of Bacterial Respiration	3 h IC50 > 1,000 mg/L	Not inhibitory to microbial respiration

Based on the above acute ecotoxicological endpoints, the notified chemical is expected to be toxic to aquatic organisms. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is formally classified as 'Acute Category 2; Toxic to aquatic life'. Based on the acute toxicity and its lack of ready biodegradability, the notified chemical is formally classified as 'Chronic Category 2; Toxic to aquatic life with long lasting effects' under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 100 was used given acute ecotoxicological endpoints are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Algae, 72 h)	1.01	mg/L
Assessment Factor	100	

Mitigation Factor	1.00	
PNEC:	10.1	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	2.551	10.1	**0.253**
Q – Ocean	0.255	10.1	**0.025**

The Risk Quotients for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Although the notified chemical is not readily biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio and assessed use pattern in commercial printing inks and industrial coatings, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -12 ± 1 °C

Method Similar to EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks A simple manual technique with a low-temperature thermometer and a test tube was used.
Test Facility BASF (1994)

Boiling Point 257.4 °C at 101.33 kPa

Method Similar to EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks Dynamic method was used.
Test Facility BASF (1994)

Density 1,132.8 ± 2 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
Remarks The pycnometer method was used.
Test Facility BASF (2004)

Vapour Pressure 2.1×10^{-7} kPa at 20 °C
1.6×10^{-5} kPa at 50 °C

Method EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks The effusion method was used.
Test Facility BASF (2004)

Water Solubility 3.5×10^{-2} g/L at 20 °C

Method EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method
Test Facility BASF (1994)

Hydrolysis as a Function of pH $t_{½}$ = 158 h at 70 °C at pH 4
$t_{½}$ = 114 h at 30 °C at pH 7
$t_{½}$ < 2.4 h at 50 °C at pH 9

Method EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ (h)*
4	70	158
4	80	53
7	30	114
7	50	18
9	50	< 2.4

Remarks HPLC method. The test substance was weighed and dissolved in a stock solution of acetonitrile heated to the appropriate test temperature, and injected after definite time intervals into the HPLC system. Under accelerated conditions of 70 °C, the rate of hydrolysis was $t_{½}$ = 158 h at pH 4. The rate of hydrolysis at 30 °C at pH 7 was $t_{½}$ = 114 h. The rate of hydrolysis under accelerated conditions of 50 °C at pH 9 was $t_{½}$ < 2.4 h. Therefore, it can be concluded that under the conditions of the test, the notified chemical is expected to slowly hydrolyse under acidic and neutral conditions, and is expected to rapidly hydrolyse under basic conditions.
Test Facility BASF (2004)

Partition Coefficient (n-octanol/water) log Pow = 2.91 at 25 °C

Method	EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	HPLC Method
Test Facility	BASF (1994)

Adsorption/Desorption $\log K_{oc} = 3.37$ at 26 °C

Method	OECD TG 121 Estimation of the Adsorption Coefficient (K_{OC}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).
Remarks	HPLC screening method.
Test Facility	BASF (2004)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Wistar/Dr. Thomae
Vehicle	0.5% aqueous carboxymethyl cellulose
Remarks - Method	No protocol deviations. Date of original German report: 7 June 1982.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2,610	2 F
2	5 per sex	3,830	1 F
3	5 per sex	5,000	1 M, 2 F

LD50	> 5,000 mg/kg bw for male animals approx. 5,000 mg/kg bw for female animals
Signs of Toxicity	Signs and symptoms of male animals noted: dyspnea, apathy, abnormal position, staggering, twitching, tonus with bending, tonic-clonic convulsions, piloerection, salivation fasciculation, and poor general state. Signs and symptoms of female animals noted: dyspnea, apathy, abnormal position, staggering, paresis hind leg, twitching, spastic gait, tonus with bending, opisthotonos, tonic convulsions, clonic convulsions, tonic-clonic convulsions, piloerection, erythema, loss of hair, exsiccosis, salivation, fasciculation, cachexia and poor general state.
Effects in Organs	No abnormalities were detected in organs for sacrificed animals. For died female animals, bloody erosions in the region of the glandular stomach in one female animal were noted and greyish-white to clay-coloured periphery involving a minimum part of the acinus was noted in liver.
Remarks - Results	The mean body weight for female animals on dose of 2,610 mg/kg bw decreased in the first week and became normal after 13 days. The body weight gain for other animals was normal.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	BASF (1982a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar/Crl:Wl (Han) SPF
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	GLP Certificate. No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2,000	0

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	No local effects were noted.
Signs of Toxicity - Systemic	No systemic clinical signs were noted during clinical examination.
Effects in Organs	No macroscopic pathologic abnormalities were noted in all animals examined on the last day of observation.
Remarks - Results	The mean body weight of the male animals increased throughout the study period within the normal range. For female animals, the weight gain only slightly increased during the first week, but increased within the normal range in the second week. The study authors thought that this result was consistent with general knowledge for female animals.

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

TEST FACILITY Bioassay (2013)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 403 Acute Inhalation Toxicity – Limit Test.

Species/Strain	Rats/Sprague-Dawley
Vehicle	None
Method of Exposure	Whole-body exposure
Exposure Period	7 hours
Physical Form	Vapour
Remarks - Method	No protocol deviations. Date of original German report: 15 June 1982. The exposed concentration was not reported. The mixture of air and test substance was generated by a stream of compressed air (200 L/h) supplied to a fritted glass flask containing the substance maintained at 20 ± 1 °C. The apparatus was darkened to minimise light access to the substance. The saturated vapour concentration was calculated to be 2.7×10^{-5} mg/L.

RESULTS

LC50	Not provided
Signs of Toxicity	No abnormalities were observed.
Effects in Organs	No abnormalities in organs were noted.
Remarks - Results	No animals died during the observation period of 14 days.

CONCLUSION Insufficient information is available to make a conclusion.

TEST FACILITY BASF (1982b)

B.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/White Vienna
Number of Animals	1 M, 2 F
Vehicle	None
Observation Period	9 days
Type of Dressing	Occlusive
Remarks - Method	No protocol deviations. Date of original German report: 15 December 1981. Readings were reported at 24, 48 and 216 hours only.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	-	0
Oedema	0	0	0	0	-	0

* Calculated on the basis of the scores at 24, 48, and 216 hours for EACH animal.

Remarks - Results No erythema or oedema was observed during the observation period.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY BASF (1981a)

B.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 M, 3 F
Observation Period 8 days
Remarks - Method No protocol deviations. Date of original German report: 15 December 1981. Readings were reported at 24, 48, 72 and 192 hours only.

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: redness	1.3	1	0.3	0.3	0.3	2	2	< 8 days	0
Conjunctiva: chemosis	0	0	0		0	0.7	1	< 8 days	0
Conjunctiva: discharge	0	0	0	0	0	1	1	< 8 days	0
Corneal opacity	0	0	0	0	0	0.3	1	< 8 days	0
Iridial inflammation	0	0	0	0	0	0	0	-	0

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

Remarks - Results The primary irritation index was calculated to be 3.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY BASF (1981b)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain Mouse/CBA/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 cinnamaldehyde.
Remarks - Method GLP Certificate.
Minor deviations did not affect the validity of the study. The highest test

substance concentration which could be technically used was a 50% solution in the vehicle.

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	424.5 ± 137.0	1.0
10	5 F	634.9 ± 409.1	1.5
25	5 F	2123.1 ± 595.1	5.0
50	5 F	2837.7 ± 664.2	6.7
Positive Control	α-hexyl cinnamaldehyde		
0	not reported	303.8	1.0
5	not reported	448.6	1.5
10	not reported	585.0	1.9
25	not reported	1715.0	5.7

EC3 16.4 % (w/w)

Remarks - Results No deaths occurred. The body weight of animals was normal.

No signs of systemic toxicity were noted. Form day 3 to 5, the animals treated with a test substance concentration of 50% showed an erythema of the ear skin (score 1). Animals treated with lower concentrations did not show any local signs.

An outlier was identified in the high dose group. However, as taking out the outlier did not change the overall test result, the value in question was not taken out from calculation.

A statistically significant and biologically relevant increased in DPM value and also in lymph node weight and cell count was observed in the mid and high dose groups comparing with the vehicle control group confirming the positive response. In addition, the cut-off value of 1.55 for a positive response regarding the lymph node cell count index reported for BALB/c mice was exceeded for the mid and high dose groups (index 2.0 and 2.2 respectively).

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical. An EC3 value of 16.4% was determined by the study authors.

TEST FACILITY Harlan (2013a)

B.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain Rat/Crl:WI(Han)

Route of Administration Oral – gavage

Exposure Information Total exposure days: 28days
Dose regimen: 7 days per week
Post-exposure observation period: none

Vehicle Drinking water containing 1% carboxymethylcellulose

Remarks - Method GLP Certificate.
No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0
low dose	5 per sex	50	0
mid dose	5 per sex	150	0
high dose	5 per sex	500	0

Mortality and Time to Death
No animals died prematurely.

Clinical Observations
The temporary and short appearance of salivation in all animals of the high dose group and 4 female animals in the medium dose group immediately after dosing was consider to be induced by a bad taste of the test substance or local affection of the upper digestive tract.

No test substance-related changes were observed in food consumption, water consumption, body weight, body weight gain, functional observational battery, motor activity measurement and oestrous cycle.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment-related changes among haematological, clinical chemistry, urinalysis and sperm parameters were observed.

Effects in Organs
When compared to control group, the mean absolute and/or relative weights of kidneys and liver were significantly increased with some values being statistically significant.

In the highest dose group, 2 male and 3 female animals showed dark discolouration of the liver. However, no histopathological correlate was noted for this macroscopic finding.

In the highest dose group, treatment related findings were observed in the liver of male and female animals, including 5 of 5 male animals showing grade 2 centrilobular hepatocellular hypertrophy and 4 of 4 female animals showing grade 1 centrilobular hepatocellular hypertrophy.

No histopathological correlate was found for the absolute and/or relative kidney weight increase in all animals in the highest dose group.
Remarks – Results
The kidney weight increase of these animals, being not correlated to histopathological findings, was regarded as treatment related but not adverse. The liver weight increases for all animals in the highest dose group, correlated with histopathological findings, and were regarded treatment related. However, these effects were considered adaptive by study authors and, therefore, these were not regarded as adverse.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 500 mg/kg bw/day in this study, based on that no signs of systemic toxicity or no changes with regard to the reproductive organs was observed up to the highest dose tested.

TEST FACILITY BASF (2013)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure/Pre incubation procedure
Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA
Metabolic Activation System Aroclor-induced rat liver S-9 mix

Concentration Range in Main Test	a) Plate incorporation procedure for test 1: 0, 20, 100, 500, 2,500 and 5,000 µg/plate b) Pre incubation procedure for tests 2 and 4: 0, 4, 20, 100, 500 and 2,500 µg/plate or for test 3: 0, 0.4, 2, 10, 50 and 250 µg/plate
Vehicle	Acetone
Remarks - Method	GLP Certificate. No protocol deviations. No preliminary test was conducted. Only *S. typhimurium* TA100 was used in test 4.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 5,000	≥ 2,500	negative
Test 2	≥ 2,500	≥ 2,500	negative
Test 3	≥ 250	> 250	negative
Test 4	≥ 2,500	≥ 2,500	negative
Present			
Test 1	≥ 2,500	≥ 2,500	negative
Test 2	≥ 2,500	≥ 2,500	negative
Test 3	> 250	> 250	negative
Test 4	≥ 2,500	≥ 2,500	negative

Remarks - Results	An increase in the number of his^+ or trp^+ revertants was not observed in the plate incorporation procedure or in the pre incubation procedure either with or without S-9 mix. The positive and negative controls produced satisfactory responses, 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	BASF (2002)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 476 In vitro Mammalian Cell Gene Mutation Test. EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.
Cell Type/Cell Line	The HPRT locus in V79 cells of the Chinese hamster
Metabolic Activation System	Phenobarbital/β-naphthoflavone induced rat liver S9
Vehicle	DMSO
Remarks - Method	GLP Certificate. No protocol deviations. Due to severe cytotoxic effects, some cultures being treated with higher concentrations were not tested.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 6.3*, 12.5*, 25.0*, 50.0*, 75.0, 100.0	4 h	7 d
Test 2	0, 1.6, 3.2*, 6.3*, 12.5*, 25.0,* 37.5*	4 h	7 d
Present			
Test 1	0, 12.5*, 25.0*, 50.0*, 100.0*, 150.0, 200.0	4 h	7 d
Test 2	0, 12.5*, 25.0*, 50.0*, 100.0*, 125.0, 150.0	4 h	7 d

*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	≥ 51.6			
Test 1		≥ 50.0	> 100.0	negative
Test 2		≥ 37.5	> 37.5	negative
Present	> 103.1			
Test 1		≥ 100.0	> 200.0	negative
Test 2		≥ 125.0	> 150.0	negative

Remarks - Results

No relevant and reproducible increase in mutant colony numbers/10^6 cells was observed in the tests up to the highest concentration. The mutant frequency did not exceed the historical range of solvent controls.

Based on a linear regression analysis (least squares), no significant dose dependent trend of the mutation frequency indicated by a probability value of < 0.05 was determined in any of the test groups.

The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.

CONCLUSION

The notified chemical was not clastogenic to HPRT locus using V79 cells of the Chinese hamster treated in vitro under the conditions of the test.

TEST FACILITY

Harlan (2013b)

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 sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Oxygen Demand (ThOD)
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Test substance		*Toxicity control*		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
7	4-5	7	44	7	59
14	6-7	14	48	14	70
21	6-9	21	50	21	72
28	6-9	28	56	28	74

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 8 days (61%), and attained 74% degradation in 28 days. Therefore, the tests indicate the suitability of the inoculums. The percentage degradation of the toxicity control surpassed the threshold level of 25% by 4 days (33%; 56% in 28 days), showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 6–9%. Therefore, the test substance is not considered to be readily biodegradable according to the OECD (301 F) guideline.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	BASF (2003a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static.
Species	*Danio rerio* (zebrafish)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	146-188 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Due to the low water solubility and hydrolytic instability of the test substance, it was prepared by adding a nominal loading rate (150 mg) to water then stirred for 3 h. The suspension was filtered and analysed by HPLC. The resulting concentration was then diluted to the relevant nominal test concentrations. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*2 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	7	0	0	0	0	0
0.25	0.162	7	0	0	0	0	0
0.5	0.349	7	0	0	0	0	0
1	0.74	7	0	0	0	0	0
2	1.29	7	0	0	0	14.3	14.3
4	2.50	7	0	14.3	100	100	100
8	5.09	7	0	100	100	100	100

LC50	1.89 mg/L (95% CI 1.46-2.43 mg/L) at 96 hours.
NOEC	1.29 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were renewed every 24 hours during the 96 h test period. The actual concentrations of the test substance were measured at the start and after every 24 hours during the 96 h test period. The 96 h LC50 and NOEC for fish were determined to be 1.89 mg/L (95% CI 1.46–2.43 mg/L) and 1.29 mg/L, respectively, based on measured concentrations.

CONCLUSION The notified chemical is considered to be toxic to fish.

TEST FACILITY BMG (2014)

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	Acetone
Water Hardness	2.52 mmol/L Ca + Mg
Analytical Monitoring	HPLC
Remarks - Method	Due to the low water solubility of the test substance, a stock solution containing the nominal loading rates of the test substance was prepared. The solvent was allowed to evaporate completely before addition of aerated test medium, which was then stirred for a minimum of 24 h before filtration of any undissolved material. A total of 20 daphnids were used. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Cumulative Immobilised (%)*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
6.25	1.00	20	0	0
12.5	2.85	20	0	50–80
25.0	6.75	20	5–10	90–100
50.0	16.2	20	80–85	100
100	29.2	20	95–100	100

EC50	2.69 mg/L (95% CI 2.27–3.12 mg/L) at 48 hours
NOEC	Not determined
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The actual concentrations of the test substance were measured at the start and after every 24 hours during the

48 h test period. The 48 h EC50 for daphnids was determined to be 2.69 mg/L (95% CI 2.27–3.12 mg/L), based on geometric mean measured concentrations.

CONCLUSION The notified chemical is considered to be toxic to aquatic invertebrates.

TEST FACILITY BMG (2013a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test – Static.

Species	*Desmodesmus subspicatus* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 0.625-20.0 mg/L Actual: < 0.1–1.47 mg/L
Auxiliary Solvent	Acetone
Water Hardness	Not reported
Analytical Monitoring	HPLC
Remarks - Method	Due to the low water solubility of the test substance, a stock solution containing the nominal loading rates of the test substance (0.625, 1.25, 2.50, 5.00, 10.0, and 20.0 mg/L) was prepared. The solvent was allowed to evaporate completely before addition of aerated test medium, which was then stirred for a minimum of 24 h before filtration of any undissolved material. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L*	*E_rC50 mg/L at 72 h*	*NOEC mg/L*
0.239	Not determined	1.01	Not determined

Remarks - Results All validity criteria for the test were satisfied. The actual concentrations of the test substance were measured at the start and after every 24 hours during the 72 h test period. The 72 h E_rC50 was determined to be 1.01 mg/L (95% CI 0.383–222 mg/L), based on geometric mean measured concentrations.

CONCLUSION The notified chemical is considered to be toxic to algae.

TEST FACILITY BMG (2013b)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum	Activated sewage sludge
Exposure Period	3 hours
Concentration Range	Nominal: 1,000 mg/L Actual: Not determined
Remarks – Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. 3,5-Dichlorophenol was used as the reference control. The respiration rate was determined by measurement of Biological Oxygen Demand during the test after 3 hours of exposure.

RESULTS

IC50	> 1,000 mg/L at 3 hours
NOEC	1,000 mg/L at 3 hours
Remarks – Results	All validity criteria for the test were satisfied. No significant inhibition of respiration rates were observed at 1,000 mg/L. The 3 h IC50 was determined to be > 1,000 mg/L, based on nominal concentrations.

CONCLUSION The notified chemical is not inhibitory to microbial activity.

TEST FACILITY BASF (2003b)

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