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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

DMG 100

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.

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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/1626	Clariant (Australia) Pty. Ltd.	DMG 100	ND*	≤ 50 tonnes per annum	Component of water-based architectural paints

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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

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:
  - Local exhaust ventilation
  - Enclosed and automated systems where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid eye contact
  - Avoid generation 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:
  - Safety glasses or goggles
  - Respiratory protection if aerosol formation is expected

  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 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.

Public Health

- Safe use instructions of paint products containing the notified chemical should be provided for do-it-yourself (DIY) users.

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(1) of the Act; if
  - the notified chemical is intended to be introduced in powder form;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of water-based architectural paints, 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.

Safety Data Sheet
The SDS of the notified chemical (and products containing the notified chemical) provided by the notifier was reviewed by NICNAS. The accuracy of the information on the 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, Olympus Building
3 Acacia Place
296-324 Ferntree Gully Road
NOTTING HILL VIC 3168

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: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, residual impurities, use details, import volume and site of reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
The endpoints for which a variation of the scheduled data requirements is being claimed include: particle size, flash point, auto-ignition temperature, explosive properties, oxidative properties, acute inhalation toxicity and genotoxic damage *in vivo*.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2016)
EU (2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
DMG 100

MOLECULAR WEIGHT
< 500 g/mol

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

3. COMPOSITION

DEGREE OF PURITY
> 94%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White powder*

Property	Value	Data Source/Justification
Melting Point	90.3 °C	Measured
Boiling Point	260 – 360 °C (under decomposition)	Measured
Density	1,330 kg/m^3 at 20.2 °C	Measured
Vapour Pressure	6.6×10^{-7} kPa at 20 °C	Measured
Water Solubility	> 583 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Hydrolytically stable at pH 4, 7, 9 at 50 °C	Measured

Partition Coefficient (n-octanol/water)	log P_{ow} < -1.8 at 20 °C	Estimated based on the ratio of the individual solubilities in water and n-octanol[#]
Adsorption/Desorption	log K_{oc} = 0.7	Calculated using MCl method, KOCWIN v2.00 (US EPI, 2012)
Dissociation Constant	pKa = 9.2	Measured
Flash Point	Not determined	Imported in aqueous dispersion
Flammability	Not a highly flammable solid	Measured
Autoignition Temperature	Not determined	–
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Powder form of the notified chemical will not be imported.
# HPLC method or Flask method are not applicable due to predicted low log P_{ow}.

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. It will be imported in aqueous dispersion at ≤ 55% concentration as a raw material for further reformulation into water-based architectural paints. It will also be imported as a component in finished paints at ≤ 6% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 50	≤ 50	≤ 50	≤ 50	≤ 50

PORT OF ENTRY
Melbourne or Sydney

TRANSPORTATION AND PACKAGING
Products containing the notified chemical, including both the aqueous dispersion (≤ 55% concentration) and the finished paint products (≤ 6% concentration), will be imported in various sized containers, ranging from 1 L steel cans to 200 L steel drums and 1,000 kg intermediate bulk containers (IBCs), to be distributed to industrial customers by road or railway for reformulation and end use.

USE
The notified chemical will be used as a component of water-based architectural paints at a final use concentration of ≤ 6%. The paints may be used by both professional workers and do-it-yourself (DIY) painters for applications to commercial or residential buildings.

OPERATION DESCRIPTION
Manufacture of the notified chemical will not occur in Australia.

Reformulation/repackaging
The notified chemical will be imported in aqueous dispersion (at ≤ 55% concentration) to be used as a raw material for local reformulation into finished architectural paint products.

At reformulation sites, factory operators will be involved in transferring the aqueous dispersion containing the notified chemical from imported containers (25 kg cans, 200 kg drums or 1,000 kg IBCs) into open stainless-steel blending tanks (10,000 L capacity) under local exhaust ventilation. The transfer operation will involve manually measuring and pouring the aqueous dispersion. High speed mixing will be used to blend the paint components. During mixing, the tanks will be in an enclosed environment. Additional quantities of the aqueous dispersion may be added during this process to achieve the desired product specifications.

Quality assurance (QA) personnel will take samples and test the final paint formulations containing the notified chemical. Samples will be taken from open floor pots using cups and poured into sealable 500 mL steel containers for further examinations in a laboratory.

Filling line staff will operate and clean the automated filling equipment. The finished paint products containing the notified chemical (at ≤ 6% concentration) will be filled from the floor pots via hoppers into 1, 5, 10 or 20 L cans by gravity feed. Filling lines will be equipped with ventilation extraction systems.

Paint products will be stored in warehouses and further distributed to customers.

End-use operations
Final paint products containing the notified chemical (≤ 6% concentration) can be used for indoor or outdoor surface application, and applied by brush, roller or airless spray. Equipment used for applying the paint products can be cleaned using a cloth or newspaper to remove the majority of the residues and then rinsed with water.

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	10 – 20
Blending/formulation	2 – 8	210
Professional tradesmen	2 – 8	210

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers are not expected to be exposed to the notified chemical except in the unlikely event of an accident as the products containing the notified chemical will be sealed in containers during operations.

Reformulation
During reformulation operations, dermal and ocular exposure of workers to the notified chemical at ≤ 55% concentration is possible when weighing and transferring of the aqueous dispersion of the notified chemical from imported containers into blending tanks. The loading operation will be carried out under a fume extractor and blending will occur in a closed mixing tank under local exhaust ventilation. Inhalation of the notified chemical is not expected unless the chemical becomes airborne. The notifier stated that PPE, such as coveralls, gloves, suitable respirators, and eye protection, will be required when carrying out the activities. During filling operations, potential exposure of workers to the notified chemical in finished paint products (at ≤ 6% concentration) will likely be through dermal or ocular routes. The exposure is expected to be minimal due to the use of automated/enclosed systems and appropriate PPE.

Members of QA staff will wear laboratory coats, gloves and safety glasses to minimise exposure to the notified chemical in the samples during testing.

End Use
For professional workers using the finished paint products, dermal or ocular exposure to the notified chemical (≤ 6% concentration) will most likely occur during applications of the products to building surfaces using brushes or rollers. Dermal and ocular exposure can also occur from spills during opening, decanting and mixing

processes of the paint products, and during equipment cleaning. Inhalation exposure to the notified chemical at ≤ 6% concentration is also possible when spray applications are used. As advised by the notifier, airless spray equipment will be used for the majority of the spray applications to reduce the exposure to the aerosolised notified chemical. For indoor applications, the notifier has proposed the use of suitable respirators with windows and doors opened to improve general ventilation. Other PPE including protective clothing, safety boots, impervious gloves and safety goggles are also proposed.

6.1.2. Public Exposure

DIY users may come into contact with the notified chemical (at ≤ 6% concentration) when using the finished paint products. The exposure pattern of these DIY users is expected to be similar to that described above for professional workers, including the use of airless spray equipment for application. However, the frequency and extent of exposure is expected to be lower. Certain level of PPE may or may not be used by DIY users. By following the safe use instructions provided with the paint products, the potential for exposure to the notified chemical should be further reduced.

Members of the public may come into contact with building surfaces coated with the finished paint products containing the notified chemical. However, once dried the notified chemical is expected to be bound into the inert matrix of the paints 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 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 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.	NOAEL = 1,000 mg/kg bw/day (highest dose tested)
Mutagenicity – bacterial reverse mutation	Non-mutagenic
Genotoxicity – *in vitro* Mammalian Cell Gene Mutation Tests	Non-mutagenic
Genotoxicity – *in vitro* Mammalian Chromosome Aberration test	Non-clastogenic

Toxicokinetics, metabolism and distribution

A toxicokinetics, metabolism and distribution study of the notified chemical was conducted in rats. After oral (gavage) administration of the ^{14}C-labelled notified chemical at a dose level of 100 mg/kg bw, 99% of the notified chemical was excreted after 72 hours in conventional (non-cannulated) rats and 95% was excreted after 96 hours in bile-cannulated rats. The majority of the notified chemical was excreted via faeces (94% and 81% in conventional and bile-cannulated rats, respectively), with the remaining quantity of the notified chemical excreted via urine (5% and 13% in conventional and bile-cannulated rats, respectively).

After oral administration of the notified chemical, the plasma concentration increased rapidly. In 0.5 hours, the peak concentrations were reached at 1,390 and 2,560 ng/g in blood and plasma, respectively. No evidence was noted indicative of specific affinity to red blood cells. After absorption, the notified chemical was rapidly eliminated from blood and plasma.

For the total amount of radioactivity used, a 95% recovery of the notified chemical from bile-cannulated rats was noted by the study authors; however, the reason for the lower recovery rate was not determined.

Based on the results, the calculated oral absorption (total from urine, volatiles, bile and carcass recoveries) of the notified chemical was 5% in conventional rats and 13% in bile-cannulated rats.

Acute toxicity

The notified chemical was found to have low acute oral and dermal toxicity in rats with LD_{50} > 2,000 mg/kg bw in the studies.

No acute inhalation toxicity data were submitted for the notified chemical. Based on the analogue data provided and the high alkalinity of the notified chemical, it may have the potential to cause respiratory tract irritation effects if inhaled.

Irritation and sensitisation
In an acute dermal irritation/corrosion study conducted in rabbits, the notified chemical did not produce corrosive or irritating effects.

An acute eye irritation/corrosion study of the notified chemical in rabbits indicated slight eye irritation. A single ocular application of the notified chemical at a dose of 0.1 g produced irritation effects, including conjunctival redness, chemosis and hypersecretion in all 3 animals and iris lesion in 1 of the 3 animals. The effects were fully reversible within 72 hours for 2 of the 3 animals and within 14 days for the remaining animal. The iris lesion (score 1) observed in 1 animal was recovered within 24 hours.

A skin sensitisation study of the notified chemical was conducted in albino guinea pigs. The notified chemical was administered at 0.5% concentration for intradermal induction and 50% concentration for epidermal induction. No skin reactions were evident after the challenge at 50% concentration. The study authors concluded that the notified chemical was not a skin sensitiser in guinea pigs under the conditions of the study.

Repeated dose oral toxicity
A repeated dose oral (gavage) toxicity study on the notified chemical was conducted in rats. The notified chemical was administered at 100, 300 and 1,000 mg/kg bw/day for 28 consecutive days with a 14 day recovery period. No clinical signs of toxicity or mortality were observed throughout the treatment and recovery period. There were no treatment-related adverse effects on clinical chemistry, haematology or urinalysis. No treatment-related macroscopic and microscopic findings were noted during necropsy. The study authors concluded that the No Observed Adverse Effect Level (NOAEL) for the notified chemical was 1,000 mg/kg bw/day based on the highest dose tested.

Repeated dose inhalation toxicity (local effects)
No repeated dose inhalation toxicity data were submitted for the notified chemical. Based on the acute oral, acute dermal and repeated dose oral toxicity studies provided for the notified chemical, systemic toxicity via the inhalation route is expected to be limited; however, local effects on the respiratory tract cannot be ruled out.

Analogue data were provided by the applicant to evaluate the respiratory tract effects of the notified chemical. The proposed analogue was considered appropriate to assess the local effects as it has comparable physico-chemical properties to those of the notified chemical including alkalinity that was specifically considered by the applicant as having the potential to cause local toxic effects.

The toxic effects of the proposed analogue were determined in a 28-day repeat dose inhalation study conducted in rats. Exposure to the analogue chemical (at concentration levels of 20, 100 and 500 mg/m^3, 6 hours/day) resulted in toxic effects to the upper respiratory tract (URT), with concentration-dependent inflammation of the larynx epithelium observed in all test animals. Based on these results the study authors concluded the No Adverse Effect Concentration (NOAEC) of the analogue chemical was 14 mg/m^3, as minimal to slight laryngeal irritation was noted in 3 male animals exposed to the lowest dose (20 mg/m^3 of the analogue chemical). This value was used by the study authors to derive a 90-day NOAEC value of 4.7 mg/m^3 for the analogue chemical. No deep lung effects were reported ([Journal Article One] 2008).

Mutagenicity/Genotoxicity
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation assay and in an *in vitro* mammalian cell gene mutation test using Chinese hamster ovary cells. The notified chemical was also determined to be non-clastogenic in an *in vitro* mammalian chromosome aberration test using Chinese hamster ovary cells.

Health hazard classification
Based on the available toxicity data noting acute inhalation data was unavailable, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified chemical is slightly irritating to the eye and may cause respiratory tract irritation effects if inhaled.

Reformulation

Reformulation workers may be at risk of irritating effects to the eyes and respiratory tract when handling the notified chemical as introduced at ≤ 55% concentration. However, the risk is expected to be minimised by the use of appropriate PPE including eye and respiratory protection. In addition, the risk will be further minimised in cases where enclosed and automated processes are used during reformulation.

Provided control measures are in place to limit exposure, the risk to the health of reformulation workers is not considered to be unreasonable.

End-use

Professional painters exposed to the notified chemical at ≤ 6% concentration during application of paints by airless spray may be at risk of respiratory tract irritation. Eye irritation effects are not expected at the relatively low final use concentration. Given the expected use of respiratory protection during spray operations, the risk to the health of professional painters from the use of the notified chemical in finished paints is not considered to be unreasonable.

6.3.2. Public Health

Similar to professional painters, DIY users may be at risk of irritation to the respiratory tract when exposed to the notified chemical at ≤ 6% concentration during application of paints by airless spray. Given that the paints contain a relatively low concentration of the notified chemical and DIY users will have limited access to the paint products, the risk to the health of DIY users from the use of the notified chemical is not considered to be unreasonable.

Members of the public may come into contact with articles or surfaces which have been treated with paints containing the notified chemical. However, the notified chemical will be bound within an inert matrix after drying and will not be bioavailable for exposure.

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 either in end-use paints, or in aqueous dispersion for reformulation into end-use paints. The reformulation process will involve transferring the aqueous dispersion containing the notified chemical to stainless-steel blending tanks, where it will be mixed with other ingredients. High speed mixing will be used to blend the paint components in an enclosed environment under local exhaust ventilation. The finished paints will then be filled into end-use containers by automatic processes. Liquid waste from cleaning of the reformulation equipment will either be reused or disposed of in accordance with local government regulations. Release of the notified chemical to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. Empty import containers containing residues of the notified chemical will either be recycled or disposed of through an approved waste management facility.

RELEASE OF CHEMICAL FROM USE

The finished paints containing the notified chemical will be used by both professional workers and DIY painters for applications to commercial or residential buildings. During use, the paints will be applied by airless spray, roller or brush.

Any spills and drips during use are expected to be collected on a suitable absorbent material and disposed of in accordance with local government regulations. Cleaning paint application equipment will involve using a cloth or newspaper to remove the majority of paint residue, and then rinsing the equipment with water. The waste from cleaning the paint equipment will be reused or disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified chemical is expected to share the fate of the substrate to which it has been applied and to be disposed of to landfill at the end of its life cycle. Residual notified chemical in empty end-use containers is expected to be cured into an inert solid matrix and to be disposed of to landfill along with the empty containers.

As a worst case scenario, it is assumed that ≤ 6% of paints containing the notified chemical used by DIY users may be incorrectly disposed of into sewers, drains, or the ground from waste and washing of paint application equipment.

7.1.2. Environmental Fate

As a result of the use pattern, most of the notified chemical is expected to share the fate of the substrate to which it has been applied and to be disposed of to landfill at the end of its life cycle. In landfill, the notified chemical will be present as cured solids and will be neither bioavailable nor mobile. A small proportion of the paint used by DIY users may be incorrectly disposed of into sewers. Based on its ready biodegradability (81.2% degradation over 28 days in OECD 301F test), the notified chemical is expected to be removed effectively through biodegradation at sewage treatment plants (STPs) (Struijs, 1996). For details of the biodegradation study conducted on the notified chemical, refer to Appendix C.

Due to its high water solubility (> 583 g/L) and the estimated low log P_{ow} (log P_{ow} < -1.8), the notified chemical is not expected to absorb to sludge significantly at STPs (Struijs, 1996). For details of the water solubility study conducted on the notified chemical, refer to Appendix A. The notified chemical is not expected to bioaccumulate based on its ready biodegradability and estimated low log P_{ow}. In landfill and water, the notified chemical is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the reported use of the notified chemical in paints, a conservative release of 5% of the annual import volume to sewers on a nationwide basis over 365 days per year has been used for the notified chemical. It is also assumed under the worst case scenario that there is no removal of the notified chemical during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	5	%
Annual quantity of chemical released to sewer	2,500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	6.9	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.4	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River:	1.4	µg/L
PEC – Ocean:	0.1	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 at 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 1.4 µg/L may potentially result in a soil concentration of approximately 9.4 µg/kg.

7.2. Environmental Effects Assessment

The results from the ecotoxicological investigation 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	EC50 > 100 mg/L	Not harmful to fish
Daphnia Toxicity	EC50 > 100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	EC50 > 100 mg/L	Not harmful to alga
Inhibition of Bacterial Respiration	EC50 > 1,000 mg/L	Does not inhibit bacterial activity at STPs

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

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated based on the most sensitive endpoint for fish as shown in the table below. An assessment factor of 100 was used given the acute endpoint for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Fish EC50	100	mg/L
Assessment Factor	100	
Mitigation Factor	1	
PNEC:	1,000	µg/L

7.3. Environmental Risk Assessment

Based on the above predicted PEC and PNEC, the following Risk Quotient (Q = PEC/PNEC) has been calculated.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	1.4	1,000	0.001
Q – Ocean	0.1	1,000	0.000

The conservative risk quotient for discharge of effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity. Based on its ready biodegradability and estimated low log P_{ow}, the notified chemical is not expected to be bioaccumulative. Therefore, on the basis of the predicted PEC/PNEC ratio, the maximum annual importation volume, and the assessed use pattern as a component of water-based architectural paints, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 90.3 °C

Method	OECD TG 102 Melting Point/Melting Range EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks	Determined by differential scanning calorimetry (DSC)
Test Facility	Siemens AG (2016a)

Boiling Point 260 – 360 °C (under decomposition)

Method	OECD TG 103 Boiling Point EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Broad ambiguous endothermal signal with no clear indication for boiling was noted at 260 – 360 °C. No further endothermal or exothermal effects were observed up to 400 °C.
Test Facility	Siemens AG (2016a)

Density 1,330 kg/m^3 at 20.2 °C

Method	OECD TG 109 Density of Liquids and Solids EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	Determined using gas comparison pycnometer; D_4^R = 1.3
Test Facility	Siemens AG (2016b)

Vapour Pressure 6.6 × 10^{-7} kPa at 20 °C

Method	OECD TG 104 Vapour Pressure EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	Determined using a vapour pressure measuring device with Knudsen cell
Test Facility	Siemens AG (2016c)

Water Solubility > 583 g/L at 20 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask Method
Test Facility	Siemens AG (2016d)

Hydrolysis as a Function of pH

Method	OECD TG 111 Hydrolysis as a Function of pH EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH

pH	*T (°C)*	*$t_{½}$ <hours or days>*
4	50	> 1
7	50	> 1
9	50	> 1

Remarks	The test substance is hydrolytically stable at environmental pH range of 4 – 9
Test Facility	Noack Laboratorien GmbH (2017)

Dissociation Constant pKa = 9.2

Method	OECD TG 112 Dissociation Constants in Water
Remarks	Titration method
Test Facility	Siemens AG (2016e)

Flammability Not a highly flammable solid

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids)
Remarks	During the preliminary test the notified chemical could not be ignited with a flame and the chemical melted instead. The performance of the main test was not conducted.
Test Facility	Siemens AG (2016f)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical at a concentration of 71.2% in water
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/WISTAR Crl: WI(Han)
Vehicle	Purified water
Remarks - Method	No major deviations from the test guideline were reported. Oral administration was adjusted for the notified chemical based on the purity.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	6 (3M/3F)	2,000	0/6

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No clinical signs were observed
Effects in Organs	The mean body weight of all animals increased within the normal range throughout the study period. There were no macroscopic pathological findings in the animals sacrificed at the end of the observation period.
Remarks - Results	No mortalities occurred

CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	BSL (2015)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical at a concentration of 71.2% in water
METHOD	OECD TG 402 Acute Dermal Toxicity– Limit Test
Species/Strain	Rat/Sprague Dawley
Vehicle	None
Type of dressing	Semi-occlusive
Remarks - Method	No major deviations from the test guideline were reported. Dermal administration was adjusted for the notified chemical based on the purity.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	10 (5M/5F)	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	No signs of local toxicity were observed.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed.
Effects in Organs	The mean body weight of all animals increased within the normal range throughout the study period. There were no macroscopic pathological findings in the animals sacrificed at the end of the observation period.
Remarks - Results	No mortalities occurred.

CONCLUSION	The notified chemical is of low acute toxicity via the dermal route.
TEST FACILITY	Bioneeds (2016a)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical (neat form)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White Crl: KBL (NZW)
Number of Animals	3
Vehicle	Purified water
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No major deviations from the test guideline were reported.

RESULTS

Remarks - Results	Under the study conditions, a single dermal application dose of 0.5 g of the notified chemical to three male rabbits showed no clinical signs of corrosive or irritation effects. No mortalities or other significant clinical signs of toxicity were observed.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	BSL (2016a)

B.4. Irritation – eye

TEST SUBSTANCE	Notified chemical (neat form)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion
Species/Strain	Rabbit/ New Zealand White Crl: KBL (NZW)
Number of Animals	3
Observation Period	72 hours after dosing To determine reversibility observation period was extended to 14 days for 1 of the 3 animals.
Remarks - Method	No major deviations from the test guideline were reported.

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	1.3	2	< 14 days	0
Conjunctiva: chemosis	0	0	0.3	2	< 48 h	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	1	< 24 h	0

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

Remarks - Results	Under the study conditions, a single ocular application of the notified chemical to 3 male rabbits at a dose of 0.1 g produced irritation effects. Conjunctival (palpebral and bulbar) redness, chemosis (lids and/or nictitating membranes) and hypersecretion were observed in all 3 animals as well as iris lesion in 1 of the 3 animals. The conjunctival effects were fully reversible within 72 hours for 2 animals or within 14 days for the remaining animal. Recovery from the iris lesion (score 1) observed in 1 animal occurred within 24 hours. No mortalities or significant clinical signs of systemic toxicity were observed.
CONCLUSION	The notified chemical is slightly irritating to the eye.

TEST FACILITY BSL (2016b)

B.5. Skin sensitisation

TEST SUBSTANCE Notified chemical (neat form)

METHOD OECD TG 406 Skin Sensitisation Maximisation-Test

Species/Strain Albino Guinea pig (female)/Dunkin Hartley strain, (SPF-quality)

PRELIMINARY STUDY Maximum Non-irritating Concentration:

intradermal: 50%

topical: 50%

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

Vehicle Water

Positive control Sodium-dodecyl-sulfate (SDS)

INDUCTION PHASE Induction Concentration:

intradermal: 0.5%

topical: 50%

Signs of Irritation Slight erythema (barely perceptible)

CHALLENGE PHASE

1st challenge topical: 50%

Remarks - Method Maximisation test was selected since the local lymph node assay (LLNA) was not considered to be appropriate due to the structure of the notified chemical.

A 50% concentration of the notified chemical was considered the highest dose that could technically be injected.

No major deviations from the test guideline were reported.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after Challenge*	
		24 h	*48 h*
Test Group	0%	0/10	0/10
	50%	0/10	0/10
Control Group	0%	0/5	0/5
	50%	0/5	0/5

Remarks - Results There was no evidence that the notified chemical caused skin hypersensitivity in guinea pigs. When challenged with 50% topical concentration of the notified chemical in the challenge phase.

All control group animals did not show any signs of skin irritation during the induction phase.

Positive controls were not included in parallel with the study. The validity of the test method was confirmed by a satisfactory result for the positive control conducted historically.

CONCLUSION There is no evidence of reactions indicative of skin sensitisation to the notified chemical at 50% concentration under the conditions of the test.

TEST FACILITY Charles River Laboratories (2016)

B.6. Repeat dose oral toxicity

TEST SUBSTANCE Notified chemical at a concentration of 71.2% in water

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents

Species/Strain	Rat/Sprague Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Purified water
Remarks - Method	Dose levels were adjusted for the purity of the notified chemical during formulation preparations. A 14-day dose range finding study on the notified chemical was conducted prior to the main study (Bioneeds 2016b). The highest dose administered was 1,000 mg/kg bw/day and no clinical signs of toxicity were observed. Therefore, in the main study the test substance was administered at 100, 300 and 1,000 mg/kg bw/day. No major deviations from the test guideline were reported.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
control	10 (5M/5F)	0	0/10
low dose	10 (5M/5F)	100	0/10
mid dose	10 (5M/5F)	300	0/10
high dose	10 (5M/5F)	1,000	0/10
control recovery	10 (5M/5F)	0	0/10
high dose recovery	10 (5M/5F)	1,000	0/10

Mortality and Time to Death
All animals survived until scheduled necropsy.

Clinical Observations
No abnormality observed during the study and 14-day post exposure observation period

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no treatment related adverse effects on clinical chemistry, haematology or urinalysis reported.

Effects in Organs
No effects were reported.

Remarks – Results
There were no treatment related adverse effects observed during the study.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established by the study authors as 1,000 mg/kg bw/day, based on the absence of treatment related adverse effects at the highest dose tested.

TEST FACILITY Bioneeds (2017)

B.7. Pharmacokinetic/toxicokinetic

Test Substance	Notified chemical at a concentration of 71.2% in water (^{14}C-labelled notified chemical purity > 99%)
Method	OECD TG 417 Toxicokinetics

Study Design and Objective
The objective of this study was to obtain information on the absorption, distribution and excretion of the notified chemical after oral administration in male Sprague-Dawley rats. A radiolabelled form of the notified chemical was used to determine the toxicokinetic parameters.

No major deviations from the test guideline were reported.

Results
Two groups of test animals were administered the test substance orally (gavage) at a dosage of 100 mg/kg (with ^{14}C-radioactivity adjusted to 1 MBq/mg). In conventional rats (group 1) after 72 hours 99% of the notified chemical was excreted. In bile-cannulated rats (group 2) 95% of the notified chemical was excreted after 96 hours. In both test groups the majority of the notified chemical was excreted via faeces (94% and 81% in conventional and bile-cannulated rats, respectively), with the remaining quantity of the notified chemical excreted via urine (5% and 13% in conventional and bile-cannulated rats, respectively). Excretion via other routes such as bile and volatiles (< 0.2%) was considered negligible by the study authors.

The results indicated that after oral administration of the notified chemical the plasma concentration increased rapidly. In 0.5 hour, the peak concentrations were reached at 1,390 and 2,560 ng/g in blood and plasma, respectively. No evidence was noted indicative of specific affinity to red blood cells. After the absorption, the notified chemical was rapidly eliminated from blood and plasma.

A 95% recovery of the radiolabelled notified chemical in bile-cannulated rats was reported by the study authors. At the end of the study the average remaining radiolabelled notified chemical in carcass (including blood and tissues) was 0.3% in both conventional and bile-cannulated rats, indicating the notified chemical was not accumulated in the body. The study authors were uncertain as to the reason for the lower recovery rate. Based on these results, the study authors calculated the oral absorption (urine, volatiles, bile and carcass recoveries) of the notified chemical as 5% in conventional rats and 13% in bile-cannulated rats.

No mortalities or significant clinical signs of systemic toxicity were observed in treated rats.

Conclusion
The study authors concluded that, when the notified chemical is administered orally, minimal absorption occurs and the chemical is excreted primarily via faeces.

Test Facility	Charles River Laboratories (2017)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical at a concentration of 71.2% in water
METHOD	OECD TG 471 Bacterial Reverse Mutation Test Plate incorporation and pre-incubation procedures
Species/Strain	*Salmonella typhimurium*: TA1537,TA1535, TA100, TA98 *Escherichia coli*: WP2*uvr*A
Metabolic Activation System	Phenobarbital and β-naphthoflavone induced rat liver S9 mix
Concentration Range in Main Test	a) With metabolic activation: 31.6 – 5,000 µg/plate b) Without metabolic activation: 31.6 – 5,000 µg/plate
Vehicle	Purified water
Remarks - Method	Test concentrations were adjusted for the purity of the notified chemical. Concentrations for the main test were chosen based on the preliminary test results. The vehicle control and positive controls were run concurrently. Positive controls were: - With metabolic activation: 2-aminoanthracene (TA1537, TA1535, TA100, TA98 and WP2*uvr*A). - Without metabolic activation: sodium azide (TA1535 and TA100); 4-nitro-o-phenylene-diamine (TA1537 and TA98);

methylmethanesulfonate (WP2*uvr*A).

No major deviations from the test guideline were reported.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (plate incorporation)	> 5,000	> 5,000	> 5,000	negative
Test 2 (pre-incubation)	–	> 5,000	> 5,000	negative
Present				
Test 1 (plate incorporation)	> 5,000	> 5,000	> 5,000	negative
Test 2 (pre-incubation)	–	> 5,000	> 5,000	negative

Remarks - Results

No biologically relevant increases in revertant colony numbers of any of the tester strains were observed at any concentration of the notified chemical.

The positive and negative controls provided 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

Eurofins (2016)

B.9. Genotoxicity – *in vitro* mammalian cell gene mutation test

TEST SUBSTANCE

Notified chemical at a concentration of 71.2% in water

METHOD

OECD TG 476 *In vitro* Mammalian Cell Gene Mutation Test

Species/Strain

Chinese hamster ovary cells

Cell Type/Cell Line

CHO AA8 cells

Metabolic Activation System

Phenobarbital and β-naphthoflavone induced rat liver S9 mix

Vehicle

Purified water

Remarks - Method

Hypoxanthine-Guanine Phosphoribosyl Transferase (HPRT) method was used.

Test concentrations were adjusted for the purity of the notified chemical.

Based on precipitation and pH test, 2 mg/mL was selected as the highest dose for preliminary cytotoxicity test. Concentrations for the main test were chosen based on the preliminary cytotoxicity test. When compared with the respective controls, the relative survival, both in the presence and absence of metabolic activation, was > 20%. Hence, the concentrations of 0.25, 0.5, 1 and 2 mg/mL were selected.

No major deviations from the test guideline were reported.

Metabolic Activation	*Test Substance Concentration (mg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1 (preliminary)*	0, 0.125, 0.25, 0.5, 1, 2	4 h	7 d
Test 2 (main)	0, 0.25, 0.5, 1, 2	4 h 10 m	9 d
Present			
Test 1 (preliminary)*	0, 0.125, 0.25, 0.5, 1, 2	4 h	7 d
Test 2 (main)	0, 0.25, 0.5, 1, 2	4 h 10 m	9 d

* Preliminary cytotoxicity test only

RESULTS

Metabolic Activation	*Test Substance Concentration (mg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (preliminary)*	> 2	–	> 2	–
Test 2 (main)	–	> 2	> 2	negative
Present				
Test 1 (preliminary)*	> 2	–	> 2	–
Test 2 (main)	–	> 2	> 2	negative

* Preliminary cytotoxicity test only

Remarks - Results

The test substance did not result in a statistically significant and/or dose dependent increase in the frequency of cells with HPRT gene mutation compared to the vehicle control groups, both with or without metabolic activation.

The positive controls demonstrated the sensitivity of the assay and the metabolising activity of the rat liver S9 preparations.

CONCLUSION

The notified chemical was not mutagenic to Chinese Hamster ovary (CHO) AA8 cells treated *in vitro* under the conditions of the test.

TEST FACILITY

Bioneeds (2016c)

B.10. Genotoxicity – *in vitro* mammalian chromosome aberration test

TEST SUBSTANCE

Notified chemical at a concentration of 71.2% in water

METHOD

OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test

Species/Strain: Chinese hamster ovary cells

Cell Type/Cell Line: CHO-K1 cell line

Metabolic Activation System: Phenobarbital and β-naphthoflavone induced rat liver S9 mix

Vehicle: Purified water

Remarks - Method: Test concentrations were adjusted for the purity of the notified chemical.

Based on the solubility and precipitation tests, 2 mg/mL was selected as the highest dose for preliminary cytotoxicity test.

No major deviations from the test guideline were reported.

Metabolic Activation	*Test Substance Concentration (mg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 0.5, 1, 2	3 h	18 – 20 h
Test 2	0, 0.5, 1, 2	19 h 20 m	20 h
Present			
Test 3	0, 0.5, 1, 2	3 h	18 – 20 h

All cultures were selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (mg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 2	> 2	> 2	negative
Test 2	> 2	> 2	> 2	negative
Present				
Test 3	> 2	> 2	> 2	negative

Remarks - Results	The test substance did not result in a statistically significant and/or dose dependent increase in the frequency of cells with chromosome aberrations compared to the vehicle control group either with or without metabolic activation. The positive controls demonstrated the sensitivity of the assay and the metabolising activity of the rat liver S9 preparations.
CONCLUSION	The notified chemical was not clastogenic to Chinese hamster ovary CHO-K1 cells treated *in vitro* under the conditions of the test.
TEST FACILITY	Bioneeds (2016d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical at a concentration of 75.2% in water
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Activated sludge from a local sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand (BOD) by automatic respirometer
Remarks - Method	No major deviations from the test guideline were reported. A concentrated stock solution of 802 mg/L (corrected for the water content) was prepared by adding the test substance to the basal mineral salt medium (BSN). The test concentration of 50 mg/L was prepared from the stock solution and BSN.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
10	62.4	10	77.6
14	65.3	14	80.2
21	73.2	21	80.1
28	81.2	28	83.5

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate surpassed the threshold level of 60% within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance calculated from BOD after 28 days was 81.2%.
CONCLUSION	The test substance is ready biodegradable.
TEST FACILITY	PEAPC (2016a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical at a concentration of 75.2% in water
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static. The Guidelines for the Testing of Chemicals, HJ/T 153-2004, China. The Guidelines for the Testing of Chemicals – Effects on Biotic Systems, 2nd edition, 2013, Beijing: China Environment Press.
Species	*Gobiocypris rarus*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	174 – 181 mg $CaCO_3$/L
Analytical Monitoring	High Performance Liquid Chromatography – Tandem Mass Spectrometry (HPLC – MS/MS)
Remarks – Method	No major deviations from the test guideline were reported. The test substance was directly added to the dilution water to achieve a test concentration of 100 mg/L (corrected for the water content).

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	< LOQ*	21	0	0	0	0	0
100	102	21	0	0	0	0	0

* LOQ: Limit of Quantitation

LC50	> 100 mg/L at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. The analytical results showed that the concentration of the test substance was stable under the test condition (99.3 – 104% of nominal concentration).

CONCLUSION The test substance is not harmful to fish.

TEST FACILITY PEAPC (2016b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical at a concentration of 75.2% in water

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	258 mg $CaCO_3$/L
Analytical Monitoring	Liquid Chromatography – Tandem Mass Spectrometry (LC – MS/MS)
Remarks - Method	No major deviations from the test guideline were reported. The test substance was directly added to the dilution water to achieve a test concentration of 100 mg/L (corrected for the water content). The concentrations of the test substance were measured at the start and at the end of the exposure.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	< LOQ*	20	0	0
100	93	20	0	0

* LOQ: Limit of Quantitation

LC50	> 100 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The analytical results showed that the concentration of the test substance was stable under the test condition (91 – 95% of nominal concentration).

CONCLUSION The test substance is not harmful to aquatic invertebrates.

TEST FACILITY Noack Laboratorien GmbH (2016a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical at a concentration of 75.2% in water

METHOD OECD TG 201 Alga, Growth Inhibition Test
EC Council Regulation No 440/2008 C.3 Algal Inhibition Test

Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L

	Actual: 106 mg/L
Auxiliary Solvent	None
Water Hardness	0.24 mmol Ca + Mg/L
Analytical Monitoring	Liquid Chromatography – Tandem Mass Spectrometry (LC – MS/MS)
Remarks - Method	No major deviations from the test guideline were reported. The test substance was added directly to the dilution water to achieve a test concentration of 100 mg/L. The concentrations of the test substance were measured at the start and end of exposure.

RESULTS

Biomass		*Growth*	
EC50	*NOEC*	*EC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 100	≥ 100	> 100	≥ 100

Remarks - Results	All validity criteria for the test were satisfied. The analytical results showed that the concentration of the test substance was stable under the test conditions (106 – 109% of nominal concentration).

CONCLUSION The test substance is not harmful to alga.

TEST FACILITY Noack Laboratorien GmbH (2016b)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical at a concentration of 75.2% in water

METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test
Inoculum	Activated sludge from a local sewage treatment plant
Exposure Period	3 hours
Concentration Range	Nominal: 1,000 mg/L (corrected for the water content)
Remarks – Method	No major deviations from the test guideline were reported. The test substance was directly added to the dilution water to achieve a test concentration of 1,000 mg/L (corrected for the water content).

RESULTS

IC50	> 1,000 mg/L
NOEC	≥ 1,000 mg/L
Remarks – Results	All validity criteria for the test were satisfied.

CONCLUSION The test substance does not inhibit bacterial activity at STPs.

TEST FACILITY Noack Laboratorien GmbH (2016c)

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