File No: STD/1587

December 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Octene, hydroformylation products, high-boiling

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/1587	BASF Australia Ltd	Octene, hydroformylation products, high-boiling	No	< 5,000 tonnes per annum	A mineral processing aid in the mining industry

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

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the reported use pattern and low expected aquatic exposure, 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.

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:
  - Automated and enclosed processes, where possible
  - Good ventilation when processing occurs inside buildings

- Pumps, couplings and transfer lines should be selected to avoid spillage.

- 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 contact with skin and eyes
  - Do not breathe vapours

- 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:
  - Gloves
  - Coveralls
  - Eye and face protection

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, physical collection and subsequent safe disposal.

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
  - further information becomes available on the sensitisation potential of the notified chemical;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a mineral processing aid in the mining industry, 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: analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume and site of recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point, Boiling Point, Density, Hydrolysis as a Function of pH, Partition Coefficient (n-octanol/water), Dissociation Constant, Flash Point, Autoignition Temperature, Explosive Properties, Oxidising Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
None known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Oxooel 9N

CAS NUMBER
68526-89-6

CHEMICAL NAME
Octene, hydroformylation products, high-boiling

UVCB definition: a complex combination of hydrocarbons produced by the distillation of products from the hydrogenation of isononanal from the hydroformylation of octene. It consists predominantly of C9-10 primary aliphatic alcohols, C10-20 dimer alcohols, C>18 acetals and esters and C>18 acid sodium salts and boils in the range of approximately 200 °C to 400 °C (392 °F to 752 °F).

OTHER NAME(S)
Isononyl Alcohol Bottoms

MOLECULAR FORMULA
Unspecified

MOLECULAR WEIGHT
144–566 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 97%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellowish liquid with faint odour

Property	Value	Data Source/Justification
Melting Point	< -50 °C	Measured*
Boiling Point	294 °C at 101.3 kPa	Measured*
Density	861.1 kg/m^3 at 20 °C	Measured*
Vapour Pressure	0.41 kPa at 20 °C 1.81 kPa at 50 °C	Measured*
Water Solubility	0.038 g/L at 1 g/L loading rate at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	UVCB – expected to contain hydrolysable functionalities
Partition Coefficient (n-octanol/water)	log Pow ≥ 3.8 at 23 °C	Estimated based on the single solubilities in n-octanol and water
Adsorption/Desorption	log K_{oc} = 4.21 at 23 °C	Measured
Dissociation Constant	Not determined	UVCB – not expected to contain dissociable functionalities
Flash Point	131 °C (closed cup)	Measured*
Autoignition Temperature	240 °C	Measured*
Explosive Properties	Predicted negative	UVCB – not expected to contain functional groups that would imply explosive properties
Oxidising Properties	Predicted negative	UVCB – not expected to contain functional groups that would imply oxidising properties

* Summary data only was provided

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 be imported at 100% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 5,000	< 5,000	< 5,000	< 5,000	< 5,000

PORT OF ENTRY
Melbourne, Sydney, Brisbane, Fremantle

IDENTITY OF MANUFACTURER/RECIPIENTS
Mineral processing plants across Australia

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by sea in bulk in 20 tonne bulk isotainers and transported by road to a third party contacted warehouse for storage before it is transported to end-use sites by road in the original isotainers.

USE
The notified chemical will be used as a mineral processing aid in the mining industry.

OPERATION DESCRIPTION
The notified chemical will not be manufactured or reformulated within Australia.

At the mineral processing facility, the notified chemical will be pumped via a hose from isotainers into a fully earthed and enclosed storage tank and in some cases, to smaller tanks closer to the flotation cell. From these tanks the notified chemical is then pumped to the flotation cells through fixed lines and dosed automatically at pre-determined levels, typically at less than 100 g per tonne of mineral processed (< 0.01%). The flotation cells are partially open and may be located inside buildings or in covered areas open to the atmosphere.

Minerals being collected will partition into froth in the flotation cell. The mineral concentrate harvested from the first cell may then be further concentrated in subsequent 'cleaner' flotation cells. The final mineral concentrate will be dewatered and then carried by conveyor to an outdoor stockpile before distribution to users throughout Australia. The tailing stream will be filtered to remove excess water from waste or gangue and the filtered water will be reused within the flotation circuit. Settling ponds are part of the water recirculation loop, where depleted ore and wastes will be deposited.

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 Warehousing Personnel	1	200
Mineral Processing/Plant Operators	8	260
Quality Control	1	260
End use of processed mineral	8	260

EXPOSURE DETAILS

Transport and storage workers
Transport and warehousing personnel will only come into contact with the notified chemicals (up to 100% concentration) in the unlikely event of an accident. However exposure could occur when connecting and disconnecting hoses when bulk shipments are transferred.

Mineral processing
Dermal and ocular exposure to the notified chemical at up to 100% concentration may occur when plant operators are connecting and disconnecting isotainers to storage tanks or smaller tanks closer to the flotation cell. Dermal exposure to the notified chemical at < 0.01% concentration is also possible from splashes from the flotation cells, during quality control processes, regular cleaning and minor maintenance of the containers. Workers are expected to wear long sleeve shirts, long trousers, safety glasses with side shields and chemical resistant gloves as a minimum to further minimise exposure. A chemical resistant apron may be worn, if required.

During the flotation process, approximately 80% of the notified chemical is expected to adhere to the mineral surface and end up in the mineral concentrate stream. As most of the control of process is remote, production workers are not expected to be near the notified chemical during processing for extended periods of time. However there is also potential for exposure of maintenance workers. Inhalation exposure is also expected to be low given the relatively low vapour pressure of the notified chemical (0.41 kPa at 20 °C). In addition, potential for inhalation exposure will be minimised in plants that are open to the atmosphere, but may be higher when processing occurs within buildings. Potential exposure would be further reduced by personal protective equipment worn by workers.

End use
Worker exposure to the notified chemical in the processed mineral is expected to be low due to the low concentration of residual chemical in the mineral (< 0.01%). The notified chemical will be thermally decomposed during the final processing and end use of the mineral concentrate.

6.1.2. Public Exposure
The notified chemical will only be used by the mining industry and the potential for public exposure is expected to be very low.

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	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOAEL = 1,000 mg/kg bw/day for females NOAEL = 300 mg/kg bw/day for males
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian cell gene mutation test	non genotoxic
Genotoxicity – in vitro mammalian cell micronucleus test	non genotoxic

Toxicokinetics, metabolism and distribution
Based on the low molecular weight (144-566 Da) and partition coefficient (log Pow ≥ 3.8) 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. No information is available on inhalation toxicity.

Irritation
Based on studies conducted in rabbits, the notified chemical was considered to be slightly irritating to the skin and eyes. Information on irritation to the respiratory tract is not available.

Sensitisation
The notified chemical was not sensitising in a guinea pig maximisation test. It was a skin sensitiser in a local lymph node assay (LLNA) in mice, with reported stimulation indices of 2.41, 6.43 and 4.75 at 25, 50 and 100% concentration, respectively. An EC3 value was not determined by the study authors.

On the basis of the weight of evidence of the information currently available, the notified chemical is considered to meet the criteria for classification for this endpoint. However, further testing is being undertaken by the notifier regarding the sensitisation potential of the notified chemical.

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, 100, 300 and 1,000 mg/kg bw/day. The No Observed Adverse Effect Level (NOAEL) was established by the study authors as 1,000 mg/kg bw/day for females in this study and 300 mg/kg bw/day for males, based on incipient signs of toxicity in males at 1,000 mg/kg bw/day such as decreased body weight. Other changes in organs were noted but not considered adverse.

Mutagenicity/Genotoxicity
The notified chemical was not 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 Chinese Hamster V79 cells, or in an *in vitro* mammalian cell micronucleus test, also using Chinese hamster V79 cells.

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 notified chemical will be imported and used at up to 100% concentration. The notified chemical is a skin sensitiser, but is not expected to be a strong sensitiser. It is also a slight skin and eye irritant.

At mineral processing plants, the highest potential exposure and risk is for workers who are connecting or disconnecting transfer hoses, or during quality control, cleaning/maintenance operations, where dermal and ocular exposure to the notified chemical at 100% may occur. Exposure will be minimised by the use of automated processes where possible and PPE (long sleeve shirts, long trousers, safety glasses with side shields and chemical resistant gloves as a minimum).

Once added to the minerals, and during distribution to end-users, the concentration of the chemical and potential exposure will be greatly reduced. Inhalation exposure is also expected to be low, but may be higher in processing plants that are indoors.

Overall, provided exposure is minimised using automated processes where possible, safe work practices and appropriate PPE, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health
As the public is expected to have little or no exposure to the notified chemical, 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 neat for use as a mineral processing aid in onshore mining applications; no reformulation or repackaging will occur in Australia. Therefore, no environmental release is expected from manufacturing or reformulation in Australia. Environmental release of the notified chemical during importation, transport and storage is likely to be limited to accidental spills and leaks. In the event of spills, the product containing the notified chemical is expected to be collected with adsorbents, and disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
During mineral processing, the notified chemical will be pumped from import containers into earthed storage tanks, then automatically dosed through fixed lines to flotation cells. The mineral processing will occur in a closed-loop water recirculation system, and the notified chemical will be mixed with the mineral slurry to adsorb to the ore. The typical usage of the notified chemical in the closed-loop water recirculation system is < 0.01%. It is estimated by the notifier that approximately 80% of the notified chemical is expected to adsorb to the mineral

surface, with the remainder associating with the gangue material or remaining in solution. The mineral slurry containing the notified chemical will be collected and dewatered, with waste water recirculated for subsequent reuse. The mineral solids containing the notified chemical are further dried to produce the final mineral concentrate, which is then carried by conveyer to an outdoor stockpile before distribution to users throughout Australia.

Notified chemical that has not adsorbed to the mineral slurry will remain in the gangue material and waste waters, and be pumped out of the flotation cells into tailings pond. The solid wastes are allowed to settle with the aid of flocculants, and pumped into onsite tailings storage settling dams. Excess water from the pond will be recycled back into subsequent mineral processing. It is estimated that approximately half of the notified chemical that is not adsorbed to the minerals is expected to adsorb to solid wastes in the gangue material (i.e. 10% of the import volume of the notified chemical, or 500,000 kg). Therefore, it is expected that the remaining 10% will remain dissolved in waste waters to be reused in mineral processing. At a steady state, it is expected that 20% of the dosed amount of the notified chemical will remain in the tailings dam, which equates to 0.002% (20% × 0.01%).

Tailings storage settling dam walls are typically constructed using tailings and are designed to permit water to leach. It is, therefore, anticipated that some water will inevitably enter the groundwater. Based on the limited water solubility of the notified chemical, it is expected that only a small proportion of the total annual import volume will be mobile that could enter groundwater. However, given the very large quantities used, this release could be significant. Settling dam walls occasionally breach during periods of intense precipitation, releasing the contents of the dam. It is possible that in such an event, significant quantities of notified chemical may be released, and enter terrestrial waterways.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to adsorb to mineral solids during mineral processing, and will undergo thermal decomposition during the final processing and end use of the mineral concentrate.

Residues of the notified chemical in empty import containers are expected to be rinsed out, and the wash water re-used in mineral processing. Empty containers are expected to be collected and returned to the supplier for reuse. Residues of the notified chemical in processing equipment and pumps are expected to be flushed with water, and the wash water recycled back into subsequent mineral processing.

It is estimated approximately 20% of the import volume of the notified chemical will remain in tailings dams as residues in gangue material and waste waters. The notified chemical dissolved in waste waters is expected to eventually leach into the aquatic environment via groundwater.

7.1.2. Environmental Fate

Following its use as a mineral processing aid in mining applications, the majority of the notified chemical is expected to share the fate of the mineral solids to which it is adsorbed. The majority of mineral solids will be thermally decomposed during the final processing and end use of the mineral concentrate. A small proportion of the notified chemical adsorbed to gangue material is expected to share the fate of the solid wastes. These are expected to be released to onsite tailings dams. Based on the results of two ready biodegradability studies, the notified chemical is considered readily biodegradable (88% in 28 days; 100% in 42 days). For details of the environmental fate studies, please refer to Appendix C. Based on its limited water solubility and high adsorption coefficient (log K_{OC} = 4.21), the notified chemical is unlikely to partition to surface waters and is expected to adsorb to soil and sediment. The notified chemical has the potential to bioaccumulate based on its low molecular weight and high partition coefficient (log $P_{OW} \geq 3.8$). However, this is not expected, as the notified chemical is not expected to be bioavailable based on its high adsorption coefficient and ready biodegradability. Therefore, in surface waters and in tailings dams, the notified chemical is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

There is expected to be minimal release of the notified chemical to the environment from spills at mine sites during use. The majority of the notified chemical is expected to adsorb to the surface of mineral particles, and will be thermally decomposed during the final processing and end use of the mineral concentrate to water vapour and oxides of carbon. The most likely release to the environment is expected from seepage of waste waters containing the notified chemical in tailings dams.

A well designed and maintained clay liner in tailings dams is expected to have a permeability of 10^{-6} cm/s or less, and be 61-132 cm thick. Similarly, synthetic liners are expected to have a permeability of 10^{-9} to 10^{-14} cm/s, and have a thickness of 0.10-0.15 cm (US EPA, 1994).

The predicted environmental concentration (PEC) may be calculated assuming the maximum concentration of the notified chemical in the dam (0.002%), and the degradation of the notified chemical as it permeates through the tailings liner. The minimum time taken to permeate through the liners is the depth (61 cm) ÷ the highest permeability rate (1×10^{-6} cm/s), which results in 61×10^6 s, or 706 days. For synthetic liners, the time is 100×10^6 s, or approximately 1,157 days. Based on the results of the ready biodegradability studies, the notified chemical has a conservative half-life of 17 days. Accordingly, it will undergo approximately 41.5 half lives (706 ÷ 17) during its permeation through the liner. A worst case PEC at release from the tailings dam may be calculated as $0.002\% \times 0.5^{41.5} = 6.43 \times 10^{-9}$ µg/L.

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 ≥ 220 mg/L	Not harmful to fish
Daphnia Toxicity	48 h EL50 > 100 mg/L (WAF*)	Not harmful to aquatic invertebrates up to water solubility limit
Algal Toxicity	72 h E_L50 > 100 mg/L (WAF*)	Not harmful to algae up to water solubility limit
Inhibition of Bacterial Respiration	3 h IC50 > 1,000 mg/L	Not inhibitory to microbial respiration

*Water accommodated fraction

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

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated, since the notified chemical is not harmful to aquatic life up to the limit of its solubility in water. Based on the calculated PEC, it is also expected that there will be no significant release of the notified chemical to the aquatic environment.

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has not been calculated, since the PNEC is not available. The notified chemical is considered readily biodegradable, and is not expected to be bioavailable or harmful to aquatic life. On the basis of the assessed use pattern in mineral processing in mining applications, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Vapour Pressure 0.41 kPa at 20 °C
1.81 kPa at 50 °C

Method	OECD TG 104 Vapour Pressure.
Remarks	Dynamic Method
Test Facility	BASF (2009a)

Water Solubility 0.038 g/L at 1 g/L loading rate at 20 °C
0.153 g/L at 10 g/L loading rate at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method
Test Facility	BASF (2009b)

Partition Coefficient (n-octanol/water) log Pow ≥ 3.8 at 23 °C

Method	OECD TG 105 Water Solubility
Remarks	Estimated based on the single solubilities in n-octanol and water as determined by the shake flask method.
Test Facility	BASF (2009b)

Adsorption/Desorption – screening test log K_{oc} = 4.2117 at 23 °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 Method
Test Facility	BASF (2015a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	Olive oil DAB 9
Remarks - Method	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	There were no signs of toxicity.
Effects in Organs	There were no adverse macroscopic findings.
Remarks - Results	Weight gain was as expected.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	BASF (1990a)

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/Charles River
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No protocol deviations. The application site was rinsed with warm water at the end of the exposure period.

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	There were no local effects.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity or skin effects.
Effects in Organs	There were no macroscopic pathological abnormalities.
Remarks - Results	The mean body weight for male animals was within normal range throughout the study. The mean average body weight of female animals slightly decreased during the first week of the post-exposure observation and increased during the second week within the normal range,

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Bioassay (2009)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/White Vienna
Number of Animals 2 M, 1 F
Vehicle None
Observation Period 72 hours
Type of Dressing Semi-occlusive.
Remarks - Method No protocol deviations. The test substance was removed at the end of the exposure period.

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	1	0	0	2	< 72 h	0
Oedema	0	0	0	0	-	0

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

Remarks - Results The female animal showed well-defined erythema at the 4- and 24-hour observations post exposure and very slight erythema at the 48-hour observation. One male animal showed well-defined erythema and another male animal showed very slight erythema at the 4-hour observation post exposure. No effects remained at the 72 hour observation. No oedema was observed in any animal.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY BASF (1990b)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/White Vienna
Number of Animals 2 M, 1 F
Observation Period 8 days
Remarks - Method No protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	0	0	2	< 8 d	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	2	< 24 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results One male animal showed well-defined conjunctival redness at 1, 24, 48 and 72 hours post exposure, which had resolved by the next observation on day 8. At 1 hour post exposure the other male animal showed slight conjunctiva redness and discharge and the female animal showed well-defined conjunctiva redness and discharge. These effects had resolved at

24 hours.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY BASF (1990c)

B.5. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation - <Magnusson and Kligman>.

Species/Strain Guinea pig/Pirbright White, Dunkin Hartley Crl:(HA)BR[SPF]

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 5% (only concentration tested, some irritation seen)
topical: 100%

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

Vehicle Olive oil DAB 10

Positive control 1-Chloro-2,4-dinitrobenzene (test performed twice yearly)

INDUCTION PHASE Induction Concentration:
intradermal: 5%
topical: 100%

Signs of Irritation After the intradermal induction well-defined erythema and slight oedema could be observed at the injection sites of the control and test group animals at which only Freund's adjuvant/0.9% aqueous NaCl-solution (1:1) was applied. Injection of the test substance preparation caused well-defined erythema in all test animals and very slight oedema in 7 out of 20 test group animals. After injection of the test substance preparation in Freund's adjuvant/0.9% aqueous NaCl-solution (1:1) the test group animal showed well-defined erythema and slight oedema. The control group animals injected with the solvent showed well-defined erythema.

Incrustation, particularly open, caused by the intradermal induction could be noted in addition to well-defined erythema and slight oedema.

CHALLENGE PHASE

1st challenge topical: 100%

2nd challenge topical: 100%

Remarks - Method No protocol deviations. The study report provided was incomplete, in that results of only 18 of the 20 test animals were shown. At the challenge stage, readings were taken 24h and 48 h after removal of the patch he findings obtained 24 hours after the removal of the patch were used for the determination of the sensitisation rate.

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	4/20	2/20	0/20	0/20
Control Group	100%	0/10	0/10	0/10	0/10

RESULTS In the first challenge, 4/20 test animals showed very slight erythema at 24 h, and 2/20 after 48 h. At 48 h 1/20 test animal had scaling. No effects were seen in control animals.

In the second challenge, no effects were seen in test or control animals. The periodic test on the positive control performed as expected.

Based on these results (an incidence of erythema of < 30% in the first challenge and no adverse effects in the second challenge) the study authors did not consider the chemical to be a skin sensitiser.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	BASF (1994)

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

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (2002) EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA/Ca
Vehicle	Acetone/olive oil 4:1
Preliminary study	Yes
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde.
Remarks - Method	No protocol deviations. Concentrations were chosen on the basis of a preliminary test, which did not indicate systemic toxicity or excessive local irritation.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	4 F	748.88	-
25	4 F	1802.35	2.41
50	4 F	4819.02	6.43
100	4 F	3557.64	4.75
Positive Control			
15	5 (sex not reported)	not reported	10.91

EC3	Not reported, expected to be 25-50%
Remarks - Results	There were no deaths. No signs of systemic toxicity were observed in the test or control animals. Bodyweight gain was normal. A stimulation index of > 3 was recorded at 50% and 100% concentrations.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	SafePharm Laboratories (2008)

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
Vehicle	Olive Oil Ph. Eur
Remarks - Method	No protocol deviations. Dosages were chosen on the basis of a range-finding study. Urinalysis was included, and the level of T3, T4 and TSH hormones was measured.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0
low dose	5 per sex	100	0
mid dose	5 per sex	300	0
high dose	5 per sex	1,000	0

Mortality and Time to Death
There were no premature deaths.

Clinical Observations
Slight and moderate salivation after treatment was seen in all males and 4 females of the high dose group, in all males and females of the mid-dose group and in 2 males of the low dose group. The finding was noted from day 5 onwards for several days. Salivation was considered to be related to bad taste of the test substance or local effects on the upper digestive tract. Therefore the finding was not considered to be adverse or toxicologically relevant.

Mean body weight was lower, although not significantly, in males only of the high dose group compared to controls, with a maximum reduction of 7.15% on study day 21. Lower weight gains were also seen, with one value showing statistical significance. These changes were considered dose related.

No test substance-related effects on food consumption, water consumption, functional observational battery and motor activity measurement were noted.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment-related changes for haematological or clinical chemistry were observed. A dose-related increase in TSH was seen in males, but was not statistically significant.

In males of the high dose group the incidences of granulated and epithelial cell casts and transitional cells in urine sediment were increased, with an increase in casts also seen in mid-dose males. These changes were considered to be due to α2μ-globulin nephropathy syndrome, which is a species- and gender-specific effect in male rats, and is therefore not relevant to humans.

Lower urine volume and higher urinary specific gravity in all female dose groups was regarded an adaptive and not adverse.

Effects in Organs
Few gross lesions in organs occurred, and were considered incidental and not dose related.

When compared with the control group, the mean absolute heart weight was significantly decreased for females in the mid- and high dose groups, and absolute heart weight was reduced in the high dose group. There were no histopathological correlates, and the study authors considered the weight changes unlikely to be test-item related.

A statistical increase in absolute liver weights (mid and high dose females) and relative liver weights (high dose females and high and mid dose males) was considered dose related but adaptive. It was associated with central hepatocyte hypertrophy in two high dose females.

Reduced thymus size and weight in high dose males was consider to be related to reduced body weight, and was not accompanied by changes in the histological architecture.

Higher relative kidney weights in all male dose groups were not considered to be dose related. The occurrence of eosinophilic droplets in the cytoplasm of proximal convoluted tubules was considered related to α2μ-globulin nephropathy. However no tubular injury was found and the increase in droplets was not considered adverse.

In the thyroid gland, the number of animals with minimal or slight follicular hypertrophy/hyperplasia increased in males of the mid-dose group and in males and females in the high dose group. In affected animals the number of small follicles increased or the follicular epithelium was higher, varying in size from cuboidal cells to columnar cells. Although the thyroid weights did not increase, a test substance related effect could not be fully ruled out but was considered by the study authors as non-adverse.

Remarks – Results
The study authors based the NOAEL on reduced body weight and body weight gain in males, that was considered indicative of incipient toxicity.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day for females in this study and 300 mg/kg bw/day for males.

TEST FACILITY BASF (2010)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test (1983).
Plate incorporation procedure/Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Aroclor 1254 induced rat liver S-9 mix.
Concentration Range in Main Test	a) With metabolic activation: 0, 20, 100, 500, 2,500, 5,000 µg/plate b) Without metabolic activation: 0, 20, 100, 500, 2,500, 5,000 µg/plate
Vehicle	Acetone
Remarks - Method	There was no preliminary test. *E. coli* was not used.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Plate incorporation procedure	> 5,000	≥ 5,000	negative
Pre incubation procedure	> 5,000	> 5,000	negative
Present			
Plate incorporation procedure	> 2,500	> 5,000	negative
Pre incubation procedure	> 5,000	> 5,000	negative

Remarks - Results
An increase in mutations was not noted either in the standard plate test or in the pre incubation test in the presence or absence of a metabolising system.

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 (1995)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test (1997).
EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Species/Strain	Chinese hamster
Cell Type/Cell Line	HPRT locus in V79 cells
Metabolic Activation System	Phenobarbital/β-naphthoflavone induced rat liver S9
Vehicle	Acetone
Remarks - Method	Minor deviations did not affect the validity of the study. Detailed tables of results were incomplete. Due to extreme cytotoxicity in the absence of metabolic activation, the concentration originally chosen for Test 1 was reduced to the levels reported below.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	0, 0.08. 0.16*. 0.31*, 0.63*, 1.25*, 2.5*, 5.0, 10.0, 20.0, 40.0	4 h	7 d	8 d
Test 2	0, 0.6, 1.3*, 2.5*, 5.0*, 10.0*, 20.0*	24 h	7 d	8 d
Test 3	0, 2.5*, 5.0*, 10.0*, 20.0*, 30.0*, 40.0	24 h	7 d	8 d
Present				
Test 1	0, 39.1*, 78.1*, 156.3*, 312.5*, 625.0, 937.5, 1,250*	4 h	7 d	8 d
Test 2	0, 20.0, 40.0*, 80.0*, 160.0*, 320.0*, 640.0*, 1,280	4 h	7 d	8 d
Test 3	0, 20.0, 40.0*, 80.0*, 160.0*, 320.0*, 640.0*, 1,280	4 h	7 d	8 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	≥ 10			
Test 1		≥ 2.5	> 40.0	negative
Test 2		≥ 20.0	> 20.0	negative
Test 3		≥ 30.0	> 40.0	negative
Present	> 542.4			
Test 1		> 1,250	> 1,250	negative
Test 2		≥ 40.0	> 1,280	negative
Test 3		≥ 320	> 1,280	negative

Remarks - Results

Variations in cytotoxicity in the presence of metabolic activation were attributed to phase separation effects.

No relevant and reproducible increase in mutant colony frequency was observed in the tests up to the highest concentration.

The induction factor of 3 times the vehicle control was exceeded in test 3, culture 2 with metabolic activation at almost all of the concentrations. However, this effect was not considered biologically relevant by the study authors as it was not reproduced in the parallel culture conducted under the same conditions and was not dose dependent. The increase was attributed to the low corresponding solvent control.

An isolated substantial increase of mutation frequency in the second culture of the test 2 at 20 µg/mL was discounted as it did not occur in the parallel culture under the same conditions, and did not occur when the test was repeated.

Potential dose dependent increases in the mutant frequency identified through linear regression analysis (least squares) were also discounted by the study authors, as they were less than a threefold increase, were not

verified by a repeat study, or resulted in decreased incidence of mutant colonies.

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 (2010)

B.10. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 487 Genetic Toxicology: In Vitro Mammalian Cell Micronucleus Test (2010).

Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cells
Metabolic Activation System	Liver S9 mix from phenobarbital/β-naphthoflavone induced rats
Vehicle	Acetone
Remarks - Method	No protocol deviations. CytoB was used to block cytokinesis, and binucleated cells were used for scoring micronuclei.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 6.25, 12.5*, 25.0*. 50.0*, 100.0, 200.0	4	24
Test 2	0*, 1.56, 3.13*, 6.25*, 12.5*, 25.0, 50.0	24	24
Present			
Test 1	0*, 50.0*, 100.0*, 200.0*, 1,250.0, 2,500.0, 5,000.0	4	24
Test 2	0*, 25.0, 50.0*, 100.0*, 200.0*, 400.0*, 800.0	4	44
Test 3	0*, 25.0, 50.0, 100.0*, 200.0*, 400.0*, 800.0	4	24

*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	> 39.06			
Test 1		> 50.0	> 200.0	negative
Test 2		> 25.0	> 50.0	negative
Present	> 5,000.0			
Test 1		> 1,250.0	> 5,000.0	negative
Test 2		> 400.0	> 800.0	negative
Test 3		> 800.0	> 800.0	negative

Remarks - Results No biologically relevant increase in the number of micronucleated cells either without S9 mix or with S9 mix. The frequencies of micronuclei after test substance treatment were close to the range of concurrent vehicle control values and they were within the range of historical negative control data.

Growth inhibition was seen, at least at the highest dose, in the presence and absence of metabolic activation. In at some dose levels, slides could not be evaluated due to strongly reduced proliferation.

Osmolarity and pH values were not influenced by test substance treatment.

	The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.
CONCLUSION	The notified chemical was not clastogenic to V79 cells of the Chinese hamster treated in vitro under the conditions of the test.
TEST FACILITY	BASF (2014)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Carbon Dioxide ($ThCO_2$)
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	33	7	45	7	52
14	61	14	72	14	77
20	75	20	84	20	87
28	88	28	90	28	96

Remarks - Results

The dissolved inorganic carbon in the blank control was 0.5 mg/L at the start of the test, which exceeded the threshold value (< 0.5 mg/L). However, this was not deemed to have significantly impacted the integrity or validity of the study. All other validity criteria for the test were satisfied.
The percentage degradation of the reference compound surpassed the threshold level of 60% by 11 days (68%). Therefore, the tests indicate the suitability of the inoculum. The percentage degradation of the toxicity control surpassed the threshold level of 25% by 4 days (26%; 90% 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 88%. As the test substance is of unknown and variable composition, complex reaction mixtures and biological materials (UVCB), the 10-day window is not applicable. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 B) guideline.

CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	BASF (2008)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test
Inoculum	Activated sewage sludge
Exposure Period	60 days (terminated at 42 days after attaining 100% degradation)
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Carbon Dioxide ($ThCO_2$)
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	17	7	38	7	56
14	46	14	68	14	85
21	67	21	77	21	94
28	73	28	83	28	99
35	95	35	88	—	
42	104	42	92	—	

Remarks – Results

All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 11 days (70%). Therefore, the tests indicate the suitability of the inoculum. The percentage degradation of the toxicity control surpassed the threshold level of 25% by 7 days (38%; 92% 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 was 73% after 28 days and 100% after 42 days. As the test substance is of unknown and variable composition, complex reaction mixtures and biological materials (UVCB), the 10-day window is not applicable. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 B) guideline.

CONCLUSION

The notified chemical is readily biodegradable.

TEST FACILITY

BASF (2015b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE

Notified chemical

METHOD

DIN 38 412, Part L15 – Static.

Species: *Leucisus idus* L. (golden orfe)
Exposure Period: 96 hours
Auxiliary Solvent: None
Water Hardness: 2.5 mmol $CaCO_3$/L
Analytical Monitoring: GC
Remarks – Method: The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. The median lethal concentration (LC50) was calculated using Probit Analysis.

RESULTS

Nominal Concentration mg/L	*Number of Fish*	*Mortality (%)*				
		1 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0
100	10	0	0	0	0	0
215	10	0	0	0	0	0
464	10	90	100	100	100	100
1,000	10	100	100	100	100	100

LC50: ≥ 220 mg/L at 96 hours.
NOEC: 215 mg/L at 96 hours.
Remarks – Results: All validity criteria for the test were satisfied. Undissolved oily test substance was visible on the surface of the test media, increasing with increased concentration. The test solutions were not renewed during the 96 h test period. The actual concentrations of the test substance were not measured during the 96 h test period. The 96 h LC50 and NOEC for fish were determined to be ≥ 220 mg/L and 215 mg/L, respectively, based on nominal concentrations.

CONCLUSION The notified chemical is not considered to be harmful to fish.

TEST FACILITY BASF (1991)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

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

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	The test substance was prepared as water accommodated fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 100 mg/L was prepared by stirring the test substance in water for 24 h, and any undissolved material was removed by siphoning. Following the range finding test, as no effects were observed at the highest concentration tested, the definitive test was conducted at the nominal loading rate of 100 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Nominal Concentration mg/L	*Number of D. magna*	*Cumulative Immobilised (%)*	
		24 h	*48 h*
Control	20	0	0
100	20	0	0

EL50	> 100 mg/L (WAF) at 48 hours
NOEL	100 mg/L (WAF) at 48 hours
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 end of the 48 h test period. As measured concentrations were below the limit of quantitation, the nominal concentrations were used. The 48 h EL50 and NOEL for daphnids were determined to be > 100 mg/L and 100 mg/L (WAF), respectively, based on nominal concentrations.

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

TEST FACILITY Harlan (2009a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

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

Species	*Desmodesmus subspicatus* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: Below limit of quantitation
Auxiliary Solvent	None
Water Hardness	Not reported

Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	The test substance was prepared as water accommodated fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 100 mg/L was prepared by stirring the test substance in water for 24 h, and any undissolved material was removed by siphoning. Following the range finding test, as no effects were observed at the highest concentration tested, the definitive test was conducted at the nominal loading rate of 100 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Biomass		*Growth*	
EL50	*NOEL*	*EL50*	*NOEL*
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 test solutions were not renewed during the 72 h test period. The actual concentrations of the test substance were measured at the start and end of the 72 h test period. As measured concentrations were below the limit of quantitation, the nominal concentrations were used. The 72 h EL50 and NOEL for algae were determined to be > 100 mg/L and 100 mg/L (WAF), respectively, based on nominal concentrations.
CONCLUSION	The notified chemical is not considered to be harmful to algae up to the limit of its water solubility.
TEST FACILITY	Harlan (2009b)

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