File No: STD/1463

July 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Bruggolite FF6

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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/1463	Nuplex Industries (Aust) Pty Ltd	Bruggolite FF6	No	≤ 20 tonnes per annum	Agent for polymer manufacture

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Enclosed, automated processes, 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 as introduced:
  - Avoid eye contact
  - Avoid inhaling dust

- 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 as introduced:
  - Goggles
  - Respiratory protection where dust may occur

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the 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

- The notified chemical should be disposed of to landfill.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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/polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an agent for polymer manufacture, 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)
Nuplex Industries (Aust) Pty Limited (ABN: 25 000 045 572)
49-61 Stephen Road
BOTANY NSW 2019

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, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, use details, import volume and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: boiling point, hydrolysis as a function of pH, adsorption/desorption, flash point, oxidising properties and acute inhalation toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
ECHA (2010) and New Zealand (2010)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Bruggolite FF6

OTHER NAME(S)
Bruggolite FF6 M
Brüggolit FF6 M
Bruggolite FF7
Brüggolit FF7

MOLECULAR WEIGHT
< 500 Da

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

3. COMPOSITION

DEGREE OF PURITY 60-80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White powder

Property	Value	Data Source/Justification
Melting Point	Decomposes without melting at > 200 °C	Measured
Boiling Point	Not determined	Decomposes before boiling based on melting point determination
Density	1840 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 1x10^{-10} kPa at 25 °C	Calculated
Water Solubility	≥ 125.76 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Expected to react with other ingredients in water to initiate polymerisation
Partition Coefficient (n-octanol/water)	log Pow < -2.4 at 20 °C	Measured
Adsorption/Desorption	Not determined	Not expected to absorb to soil/sediment strongly based on the reported high water solubility
Dissociation Constant	pKa = 7.00 at 20°C	Measured
Particle Size	Inhalable fraction (< 100 μm):	Measured

	99% Respirable fraction (< 10 μm): 28% MMAD* = 17.52 μm	
Flash Point	Not determined	The notified chemical is a solid.
Flammability	Not highly flammable	Measured
Autoignition Temperature	> 400 °C	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

* MMAD = Mass Median Aerodynamic Diameter

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 for the 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 as a powder at up to 80% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 20	≤ 20	≤ 20	≤ 20	≤ 20

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be manufactured overseas and imported by the notifier.

TRANSPORTATION AND PACKAGING
The notified chemical (at ≤ 80% concentration) will be imported by sea in 25 kg PE bags and distributed by road.

USE
The notified chemical will be used in the manufacture of polymers.

OPERATION DESCRIPTION
The notified chemical will be imported into Australia at up to 80% concentration for use in the manufacture of polymers. The notified chemical is consumed during this process and will not be present in the end product polymers.

End-use/ Polymer manufacture
The notified chemical in powder form will be added to a reactor vessel and dissolved in water in the sealed vessel. The resulting solution will be added to the polymerisation process using dedicated lines and a fully automated process. The notified chemical will be consumed during the reaction process.

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)*
Transportation	8	200
Storage	8	200
Synthesis of polymers	8	200

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified chemical (at ≤ 80% concentration) only in the event of accidental rupture of containers.

End use/ Polymer manufacture

Dermal and ocular exposure of workers to the notified chemical (at ≤ 80% concentration) may occur during formulation when charging the mixing tanks and while performing maintenance and cleaning of equipment. Inhalation of the powdered notified chemical is also possible when adding the notified chemical to the mixing tank. Exposure is expected to be minimised through the use of mechanical ventilation and enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves.

6.1.2. Public Exposure

The notified chemical will only be used by industry in the production of polymers and will not be available to the public. In addition, the notified chemical will be consumed in the manufacture process and will not be available for exposure in finished products.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000; low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg bw/day
Rat, repeat dose oral toxicity – 90 days.	NOAEL = 250 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian chromosome aberration	genotoxic
Genotoxicity – in vivo Mammalian erythrocyte micronucleus	non genotoxic
Rat, developmental toxicity	NOAEL = 1000 mg/kg bw/day

Toxicokinetics.

The notified chemical is highly hydrophilic (log Pow < -2.4 at 20° C), hence dermal absorption is not expected. Given the low molecular weight of the notified chemical (< 500 Da) absorption across the respiratory or GI tract may occur. This is supported by evidence of systemic toxicity at high doses in an acute oral toxicity study and in a 90-day repeated dose oral toxicity study.

Acute toxicity.

There are two studies on the acute oral toxicity of the notified chemical. The data indicate that the notified chemical is of low acute oral toxicity. One study reported hunched posture and apathy in animals treated at 2000 mg/kg bw. The second study reported no signs of toxicity at 2000 mg/kg bw but observed lethargy, decreased reaction to stimuli, coma and death in groups treated with 4000 mg/kg bw notified chemical.

An acute dermal toxicity test was conducted on the notified chemical with no signs of toxicity observed at the

highest dose tested, giving an LD50 > 2000 mg/kg bw.

No acute inhalation toxicity data was submitted for the notified chemical. Although the notified chemical has a low vapour pressure, it is a powder that contains a high proportion of respirable particles; hence, inhalation exposure may occur when handling the powdered form of the notified chemical. Given the low molecular weight, absorption across the respiratory tract may occur. The notified chemical has been found to be of low toxicity by the oral route in both acute and repeated dose studies with the only signs of toxicity occurring at high doses. Furthermore, no health effects have been reported in workers who have been exposed to the notified chemical, including any effects to the respiratory tract and mucous membranes (Reischle, 2010). Based on the weight of evidence, the notified chemical is not expected to have significant toxic effects by the inhalation route.

Irritation and sensitisation.
A slight erythema was noted in two of three animals one hour after patch removal in a skin irritation test. These effects were resolved prior to the 24 hour observation time point. The notified chemical was found to be non-irritating to the skin.

An eye irritation study in rabbits reported serous lacrimation in all animals one hour after test substance instillation. Corneal opacity was also observed in one animal after one hour. The conjunctivae were red in all three animals after 24 hours with the redness fading in all animals by day 7. The notified chemical is slightly irritating to the eyes.

There was no evidence of sensitisation in a guinea pig maximisation test.

Repeated Dose Toxicity.
In a 28 day repeated oral dose toxicity study on the notified chemical, the NOAEL was determined to be 1000 mg/kg bw/day. A statistically significant decrease was observed in aspartate aminotransferase in the high dose group males and females. However, the study authors noted that the toxicological significance of this could not be determined as there was no associated liver cell damage. In addition, statistically significant differences in the absolute and relative weights of organs were observed; however, these were within the historical ranges of the laboratory. These effects were observed predominantly in the high-dose group suggesting that there may be a dose-related response.

In a 90 day repeated dose oral toxicity study on the notified chemical, the NOAEL was determined to be 250 mg/kg bw/day based on toxicity observed at 1000 mg/kg bw/day. Four animals were found dead, believed to be due to gavage error, before the completion of the study. The cause of death of the fourth female was not determined. A number of signs of toxicity were observed in animals of both sexes treated at 1000 mg/kg bw/day. These included decreased activity, piloerection and soft faeces. Statistically significant changes were noted in males receiving 1000 mg/kg bw/day including decreased alkaline phosphatase, γ-glutamyl transferase, creatinine, protein, albumin and globulin and increases in alanine aminotransferase and phosphorus. In females treated at 1000 mg/kg bw/day, a statistically significant increase was observed on urea levels and a significant decrease observed in bilirubin, chloride, potassium and sodium levels. Dose-related increases were also observed in triglycerides of all treated females, and were statistically significant in those receiving 1000 mg/kg bw/day.

An increase in the incidence of depressed and/or pale areas was observed in the kidneys of animals of both sexes. An increase in the incidence of thickened limiting ridge of the stomach (the non-glandular transition line of the fore stomach, close to the glandular stomach) was observed in animals of both sexes.

Mutagenicity/Genotoxicity.
The notified chemical was negative in a bacterial reverse mutation assay and an in vivo erythrocyte micronucleus test. The notified chemical was positive in a mammalian cell chromosome aberration test. Based on these data the notified chemical is not expected to be genotoxic.

Toxicity for development.
A preliminary prenatal developmental toxicity study in rats was conducted on the notified chemical at a single dose of 1000 mg/kg bw/day. One out of 80 foetuses was found to be small in the control group and three out of 74 were small in the treatment group, relative to historical data. This was not deemed to be statistically significant. Litter data and sex ratios were not affected by treatment with the notified chemical. The data indicate that the notified chemical is neither teratogenic nor toxic to pregnant female rats. Based on this study the NOAEL was established as 1000 mg/kg bw/day.

Observations on Human Exposure.
No health effects have been observed in 33 workers exposed to the notified chemical between 2006 and 2009. In particular, no indication of increased skin problems, or reductions in pulmonary functions was reported (Reischle, 2010).

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical is slightly irritating to the eyes. It has the potential to cause systemic toxicity (NOAEL 250 mg/kg bw/day) if absorbed, however absorption by the dermal route is not expected. The notified chemical contains a considerable proportion of respirable particles. The acute inhalation toxicity of the notified chemical is not known. The notified chemical has been found to be of low toxicity by the oral route in both acute and repeated dose studies with the only signs of toxicity occurring at high doses. Furthermore, no health effects have been reported in workers who have been exposed to the notified chemical, including any effects to the respiratory tract and mucous membranes (Reischle, 2010). Based on the weight of evidence, the notified chemical is not expected to have significant toxic effects by the inhalation route.

Polymer manufacture workers will be exposed to the notified chemical at ≤ 80% concentration. These workers are expected to wear adequate PPE, such as goggles and respiratory protection where dust formation may occur. The presence of engineering controls will further limit exposure. Therefore, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health
The public is not expected to be exposed to the notified chemical; hence, the risk to public health is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported for use as a component in the manufacture of polymers. No reformulation of the notified chemical in Australia is expected. Therefore, no release is expected from these activities. Accidental spills during transport are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be consumed (decomposed) as a reagent in the manufacture of polymer products. The breakdown products of the notified chemical are expected to partially remain in the polymer matrix as part of the polymer generated and partially remain in the reaction medium. The release of the unreacted notified chemical from use is expected to be minimal. Only a small amount of waste is expected to be generated during this process. The majority of the waste containing the notified chemical is a result of residues in empty import containers. These containers are expected to be either sent to a landfill, or recycled. During the recycling process, the residual notified chemical is expected to be thermally decomposed into water, salts, and oxides of carbon and sulphur.

RELEASE OF CHEMICAL FROM DISPOSAL
Most of the notified chemical is expected to be consumed (decomposed) during the polymerisation for manufacture of polymer products. The releases to the aquatic environment are expected to be mainly from the residues in the empty containers, which may be either sent to landfill or thermally recycled. Therefore, the release of the notified chemical into the environment from disposal is expected to be minimal.

7.1.2. Environmental Fate

A study provided by the notifier indicates that the notified chemical is rapidly biodegradable. For the details of the biodegradation study please refer to Appendix C. Based on the rapid biodegradability, and the high water solubility, the notified chemical is not expected to be bioaccumulative.

The majority of the notified chemical will be reacted during the polymerisation and be decomposed, with some of the breakdown products remaining in the polymer matrix. A small amount of the notified chemical is expected to end up in landfill in the form of residues in empty containers, or to be thermally decomposed during the recycling of the containers. Either in landfill or being thermally decomposed, the notified chemical is expected to eventually decompose into water, inorganic salts, and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

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)	EC50 > 7400 mg/L	Not harmful to fish
Daphnia Toxicity (48 h)	EC50 = 4400 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity (72 h)	EC50 = 315 mg/L	Not harmful to algae
Inhibition of Bacterial Respiration (3 h)	EC50 > 2000 mg/L	Not expected to be inhibitive to sludge bacteria respiration

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is not considered to harmful to aquatic organisms. Based on the toxicity to aquatic organisms the notified chemical is not formally classified under the GHS for acute and long term hazard.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was not calculated as no significant release of the notified chemical to aquatic environment is expected and the notified chemical is expected to pose a low hazard to aquatic organisms.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not calculated. Neither PEC nor PNEC have been calculated due to the expected limited release of the notified chemical to the environment. In addition, the notified chemical is not considered harmful to aquatic organisms, is rapidly biodegradable and is not expected to bioaccumulative. Therefore, the notified chemical is not expected to pose unreasonable risk to the environment based on its assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Decomposes without melting at > 200 °C

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	Determined using the capillary method. No melting was observed below 280 °C. However the colour of the test substance changed from white to slight grey-brown at ~207 °C indicative of decomposition.
Test Facility	GAB (2000)

Density 1841 kg/m^3 at 20 °C

Method	EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Pycnometer method
Test Facility	ToxLabs (1998a)

Water Solubility ≥ 125.76 g/L at 20 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method. Approximately 4 g of the notified chemicals were mixed with 5 mL of water, followed by agitation 24 hours at 30°C, and another period of 24 hours at 20°C. After this the pH was determined to be 9.65 – 9.78. Samples were collected and centrifuged for HPLC analysis. The mean water solubility for three components of the notified chemicals were reported to be 727.41 g/L, 317.14 g/L, and 125.76 g//L Therefore, the water solubility of the notified chemicals has been determined to be ≥ 125.76 g//L at 20°C.
Test Facility	GAB (1998a)

Partition Coefficient (n-octanol/water) log Pow < -2.4 at 20 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	Flask Method was used in a preliminary test that determined a log P_{OW} value of < -2.4.
Test Facility	GAB (1998b)

Dissociation Constant pKa = 7.0 at 20°C

Method	OECD TG 112 Dissociation Constants in Water.
Remarks	Titration was performed using HCl at concentration of 0.1 mol/L. The equivalent point was detected electrometrically. The measurements were taken in triplicate. The mean pKa was determined to be 7.00 ± 0.04.
Test Facility	LAUS GmbH (2009)

Particle Size Inhalable fraction (< 100 μm): 99%
Respirable fraction (< 10 μm): 28%

Method	Similar to OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.
Remarks	Non-GLP study. Determined using a particle size analyser.
Test Facility	Malvern Instruments (2000)

Flammability Not highly flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks	Determined by ignition
Test Facility	GAB (1998c)

Autoignition Temperature > 400 °C

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	The notified chemical (4 g) was placed into a quartz vessel and into a furnace which was heated from 50-400 °C. The test article showed no self-ignition in this range.
Test Facility	ToxLabs (1999b)

Explosive Properties Not explosive

Method	Non-GLP study
Remarks	Several concentrations of dust were dispersed in the air in an autoclave of 20 L volume. The dispersions were exposed to an ignition source. If an excess of 0.2 bars is reached or exceeded, the substance is classified as explosive.
Test Facility	Inburex (2000)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity. Non-GLP study.
Species/Strain	Rat/Wistar (strain Winkelmann Paderborn)
Vehicle	Carboxyl-methylcellulose
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5M/5F	2000	0/10
II	5M/5F	4000	5/10

LD50	4000 mg/kg bw
Signs of Toxicity	No signs were observed in the lower dose group. At 4000 mg/kg bw signs included lethargy, decreased reaction to stimuli, coma and death.
Effects in Organs	No effects in organs were observed at necrospy.
Remarks - Results	The notified chemical can be considered to be of low toxicity as no deaths or signs of toxicity were observed at a dose of 2000 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Pharmatox (1997)

B.2. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity-Limit test.
Species/Strain	Rat/ Wistar Crl:WR BR
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5M/5F	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity	Signs included slight apathy and hunched posture. Body weight gain was not affected.
Effects in Organs	No effects in organs were observed at necropsy.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	ToxLabs (1998a)

B.3. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/ Wistar Crl:WR BR
Vehicle	None
Type of dressing	Occlusive

Remarks - Method No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5M/5F	2000	0/10

LD50 > 2000 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 No effects in organs were noted.

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

TEST FACILITY ToxLabs (1999b)

B.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White (SPF Crl:NZW)
Number of Animals 3
Vehicle None
Observation Period 14 days
Type of Dressing Occlusive.
Remarks - Method No significant protocol deviations

RESULTS
Remarks - Results A slight erythema was observed in two animals one hour after patch removal. There were no signs of irritation noted at any other time point.

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

TEST FACILITY ToxLabs (1998c)

B.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 7 days
Remarks - Method No significant protocol deviations. Observations were made at 1, 24, 48 and 72 hours, and 4, 5, 6 and 7 days after instillation.

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	1.7	1.7	1.7	2	< 7 days	0
Conjunctiva: chemosis	0.7	0	0	2	< 48 h	0
Conjunctiva: discharge	0	0	0	0	-	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 A serous lacrimation was observed in all animals one hour after test

substance instillation.
The cornea showed a slight opacity in one animal one hour after instillation.
The conjunctivae were slightly red in one animal and clearly red in the other two animals one hour after instillation and clearly red after 24 hours in all animals. The redness had faded in all animals by day 7.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY ToxLabs (1998d)

B.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation - Maximisation Test.
Species/Strain Guinea pig/Dunkin Hartley, Crl(HA)BR
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 5%
topical: 75%
MAIN STUDY
Number of Animals Test Group: 10 males Control Group: 5 males
INDUCTION PHASE Induction Concentration:
intradermal: 10%
topical: 75%
Signs of Irritation
CHALLENGE PHASE
1st challenge topical: 75%
Remarks - Method Signs of irritation were observed after intradermal induction but there were no signs of irritation after topical induction.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	75%	0/10	0/10	-	-
Control Group	75%	0/5	0/5	-	-

Remarks - Results No skin reactions were noted in either the control or test group.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY ToxLabs (1998e)

B.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain Rat/ Wistar Crl:WI BR
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 Distilled water
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5M/5F	0	0/20
low dose	5M/5F	100	0/20
mid dose	5M/5F	300	0/20
high dose	5M/5F	1000	0/20
control recovery	5M/5F	0	0/5
high dose recovery	5M/5F	1000	0/5

Mortality and Time to Death
No unscheduled deaths occurred during the course of this study.

Clinical Observations
A statistically significant decrease was observed in aspartate aminotransferase in the high dose group males and in the low and high dose females. Levels did not return to normal during the recovery period. The study authors noted that the toxicological significance of this could not be determined as there was no associated liver cell damage.

Body weights and food consumption were normal.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No substance-dependent findings were observed.

Effects in Organs
Statistically significant differences in the absolute and relative weights of organs was observed, however these were within the historical ranges of the laboratory. These effects were observed predominantly in the high-dose group suggesting that there may be a dose-related response.

Remarks – Results
A number of effects were observed in enzymes and organ weights, however, these were not conclusively attributed to dose-related effects.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study.

TEST FACILITY Kesla (2000)

B.8. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
EC Directive 88/302/EEC B.26 Sub-Chronic Oral Toxicity Test: 90-Day.

Species/Strain	Rat/ Wistar Crl:WI BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 13 weeks Dose regimen: 7 days per week Post-exposure observation period: 4 weeks
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10M/10F	0	1/20
low dose	10M/10F	50	1/20

mid dose	10M/10F	250	0/20
high dose	10M/10F	1000	3/20
control recovery	5M/5F	1000	0/5
high dose recovery	5M/5F	0	0/5

Mortality and Time to Death

One control male was found dead on day 29 due to a gavage error. Four females (3 receiving 1000 mg/kg bw/day and one receiving 50 mg/kg bw/day) were found dead, three of these animals were believed to have died due to a gavage error on days 5 and 6. The cause of death of the fourth female was not determined, though it was noted that multiple organs were cannibalised.

Clinical Observations

Clinical signs were observed for a number of days in animals of both sexes receiving 1000 mg/kg bw/day including decreased activity, piloerection and soft faeces (from day 37 in males and day 52 in females until day 66). Hunched posture and piloerection was also observed in females receiving 50 mg/kg bw/day.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Some statistically significant changes were noted in males receiving 1000 mg/kg/day including decreased alkaline phosphatase, γ-glutamyl transferase, creatinine, protein, albumin and globulin and increases in alanine aminotransferase and phosphorus. In females treated at 1000 mg/kg bw/day, a statistically significant increase was observed on urea levels and a significant decrease observed in bilirubin, chloride, potassium and sodium levels. Dose-related increases were also observed in triglycerides of all treated females, and were statistically significant in those receiving 1000 mg/kg bw/day test substance.

Effects in Organs

An increase in the incidence of depressed and/or pale areas was observed in the kidneys of animals of both sexes. An increase in the incidence of thickened limiting ridge of the stomach (the non-glandular transition line of the fore stomach, close to the glandular stomach) was observed in animals of both sexes.

Remarks – Results

Treatment-related microscopic findings were noted in the kidneys and stomachs of females and in the urinary bladder of males dosed at 1000 mg/kg bw/day. The changes consisted of an increase of incidence and severity of nephropathy (more frequent and severe in males), subchronic inflammation in the interstitium and presence of crystal like unstained aggregates in the tubular lumen or in the pelvic cavity. In addition, mild focal hyperplasia of the limiting ridge was noted in the forestomach and minimal to mild epithelial hyperplasia was observed in the urinary bladder of males only.

Treated males and females in the recovery group still showed nephropathy in the kidneys with interstitial inflammatory cell infiltration and fibroblastic reaction after sacrifice. Pelvic epithelial hyperplasia was observed in the kidneys of one female as well as epithelial hyperplasia in the urinary bladder in one male. Taken together these data indicate a trend toward recovery when compared to the severity of effects observed in the high dose group sacrificed without a recovery period.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 250 mg/kg bw/day in this study, based on adverse effects observed at 1000 mg/kg bw/day.

TEST FACILITY RTC (2012a)

B.9. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Liver preparations (S9 mix) from rats treated with phenobarbital and ß-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 50- 5000 µg/plate b) Without metabolic activation: 50- 5000 µg/plate

Vehicle	Distilled water
Remarks - Method	No significant protocol deviations

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2		> 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2		> 5000	> 5000	Negative

Remarks - Results

The test substance was tested up to the maximum recommended dose level of 5000 µg/plate. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies 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

ToxLabs (1998f)

B.10. Genotoxicity – in vitro

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain	Chinese Hamster
Cell Type/Cell Line	Chinese Hamster /V79
Metabolic Activation System	Liver preparations (S9 mix) from rats treated with phenobarbital and ß-naphthoflavone
Vehicle	Water
Remarks - Method	No significant protocol deviations

Metabolic Activation	*Test Substance Concentration (µg/mL)**	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 1250, 2500, 5000	4 h	18 h
Test 2a	0, 625, 1250, 2500, 5000	18 h	18 h
Test 2b	0, 1250, 2500, 5000	26 h	26 h
Present			
Test 1	0, 1250, 2500, 5000	4 h	18 h
Test 2a	0, 1250, 2500, 5000	4 h	18 h
Test 2b	0, 5000	4 h	26 h

* All cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				

Test 1	> 5000	≥ 5000	> 5000	Negative
Test 2a	≥ 1481	> 1250	> 5000	Positive
Test 2b	≥ 658	> 625	> 5000	Negative
Present				
Test 1		≥ 5000	> 5000	Positive
Test 2a		> 5000	> 5000	Positive
Test 2b		> 5000	> 5000	Negative

Remarks - Results

In Test 1 the test substance induced an increased incidence of structural chromosomal aberrations (number of aberrant phases was 13.0%) at the highest dose of 5000 µg/mL in the presence of metabolic activation.

In Test 2a in the absence of metabolic activation in one of the duplicate cultures and in both cultures in the presence of metabolic activation a slight increase in the aberration rate (number of aberrant phases ranged from 5-9% for the individual cultures) was found at a dose of 5000 µg/mL.

There was no increase in the aberration rate observed in Test 2b.

The positive substances induced sufficient aberrations to confirm the effectiveness of the test.

CONCLUSION

The notified chemical was clastogenic to Chinese Hamster cells treated in vitro under the conditions of the test.

TEST FACILITY

ToxLabs (1999c)

B.11. Genotoxicity – in vivo

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test- Limit test

Species/Strain: Mouse/ NMRI

Route of Administration: Oral – gavage

Vehicle: Deionised water

Remarks - Method: No significant protocol deviations

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5M/5F	0	24
II (test group)	5M/5F	2000	12
III (test group)	5M/5F	2000	24
IV (test group)	5M/5F	2000	48
V (positive control, CP)	5M/5F	40	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity: No signs of toxicity were observed.

Genotoxic Effects: No genotoxic effects were observed.

There was a statistically significant increase in the number of micronucleated cells in the positive control group, as compared to the vehicle control group, thus validating the conduct of assay.

Remarks - Results: Statistical analysis of micronucleated polychromatic erythrocytes (MPCEs) revealed that the frequency of MCPEs were in the same range in the vehicle control and test groups.

CONCLUSION

The notified chemical was not clastogenic under the conditions of this *in*

vivo mouse micronucleus test.

TEST FACILITY Kesla (2001)

B.12. Developmental toxicity

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD 414 preliminary prenatal developmental toxicity study-Limit test

Species/Strain	Rat/ Wistar Hannover
Route of Administration	Oral – gavage
Exposure Information	Exposure days: 14 days Post-exposure observation period: 1 day
Vehicle	Water
Remarks - Method	All animals were dosed once a day from Day 6 (*post coitum*) through to day 19. Clinical signs were recorded for individual animals as were body weight and food consumption. All animals were sacrificed on day 20 *post coitum*.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
I	6	0	0/6
II	6	1000	0/6

Mortality and Time to Death

There were no unscheduled deaths during this study.

Effects on Dams

No signs of toxicity were observed in dams.

Effects on Foetus

Foetuses were only examined externally. A total of 1out of 80 foetuses were found to be small in the control group and 3 out of 74 were small in the treatment group, relative to historical data. Litter data and sex ratios were not affected by treatment with the notified chemical.

Remarks – Results

The data indicate that the notified chemical is neither teratogenic nor toxic to pregnant female rats.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on no adverse effects at this dose.

TEST FACILITY RTC (2012b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Not applied
Analytical Monitoring	Respirometric biochemical oxygen demand (BOD)-determination with CO_2-absorption on soda lime. The biodegradability is expressed as the percentage oxygen uptake of the theoretical oxygen demand (ThOD) or the chemical oxygen demand (COD).
Remarks - Method	The test was performed in a closed system with electrolytic oxygen supply at concentration of 300 mg/L. Sodium benzoate in mineral medium at 100 mg/L was used in the reference test (one replicate).

RESULTS

Notified chemicals		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
28	70.9	14	88.4
		28	90.8

Remarks - Results	All relevant test validity criteria met. Good laboratory Practice (GLP) principles were followed. The BOD in the abiotic control vessel was determined to be 0 mg O_2/L. The overall biodegradation degree of the notified chemicals was reported at 70.9% at day 28. The 10 day window biodegradation results were not reported. Therefore, the readily biodegradability of the notified chemical cannot be established. However, the chemical is considered to be rapidly biodegradable given the final high percentage of biodegradability.
CONCLUSION	The notified chemical is rapidly biodegradable.
TEST FACILITY	STZ Angewandte u. Umwelt-Chemie (1998a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static.
Species	Teleostei, Cyprinidae, Hamilton-Buchanan
Exposure Period	96 hours
Auxiliary Solvent	Not applied
Water Hardness	143 mg/L (8 °dH) carbonate
Analytical Monitoring	TOC (total organic carbon) measurements were conducted for analysis of the actual concentrations for the nominal levels 2500 and 10000 mg/mL.
Remarks – Method	A stock solution of 10000 mg/L (oxygen saturation maintained at ≥ 80%) was prepared and used for preparation of test solutions at 0.6, 1.25, 2.5, 5.0, 10000 mg/L. The test was conducted at 23 ± 2°C.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*			
Nominal	*Actual (96 hour)*		*24 h*	*48 h*	*72 h*	*96 h*
0	Not supplied	7	0	0	0	0
600	Not supplied	7	0	0	0	0
1250	Not supplied	7	0	0	0	0
2500	2150	7	0	0	0	0
5000	Not supplied	7	0	0	0	0
10000	7410	7	0	0	14.3	14.3

LC50	> 7400 mg/L at 96 hours (measured concentration)
NOEC	5000 mg/L at 96 hours (measured concentration)
Remarks – Results	All the test validity criteria were met. GLP principles were followed. Based on the reported test results, the notified chemical is not considered to be harmful to fish. Considering the high level of test concentration, and the consistent dose response observed the test result is considered reliable.

CONCLUSION The notified chemicals are considered not harmful to fish.

TEST FACILITY STZ Angewandte u. Umwelt-Chemie (1998b)

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	Not applied
Water Hardness	Not provided
Analytical Monitoring	The actual concentrations were not determined.
Remarks - Method	The test substance is a soluble powder with strongly reducing properties. This would lead to total oxygen depletion in the test solutions. A stock solution of 10000 mg/L was prepared and aerated with clean compressed air until complete oxidation (24 hours at 20 °C). The stock solution prepared was used for preparation of test solutions at 625, 1250, 2500, 5000, 10000 mg/L.

RESULTS

Concentration mg/L	*Number of D. magna*	*Immobilisation (%)*	
Nominal		*24 h*	*48 h*
0	20	0	0
625	20	0	0
1250	20	0	0
2500	20	0	0
5000	20	0	85
10000	20	60	90

EC50	4400 mg/L at 48 hours (nominal)
NOEC	2500 mg/L at 48 hours (nominal)
Remarks - Results	All the test validity criteria were met. GLP principles were followed. Based on the reported test results, the notified chemical is not considered to be harmful to daphnia.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates.

TEST FACILITY STZ Angewandte u. Umwelt-Chemie (1998c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 0, 50, 100, 1250, 2500, 5000, 10000 mg/L
Auxiliary Solvent	Not applied
Water Hardness	Not provided
Analytical Monitoring	TOC (total organic carbon) measurements were conducted for analysis of the actual concentrations for the nominal levels 50, 1250 and 10000 mg/mL
Remarks - Method	The test substance is a well soluble powder with strongly reducing properties. This would lead to total oxygen depletion in the test solutions. A stock solution was prepared and aerated with clean compressed air until complete oxidation (24 hours at 20°C). The stock solution was used for preparation of test solutions with further dilution. The EC50 values were ascertained using the plot method.

RESULTS

Biomass (nominal) E_bC50 *(mg/L at 72 h)*	*Growth (nominal)* E_rC50 *(mg/L at 72h)*
300	315

Remarks - Results	All the test validity criteria were met. GLP principles were followed. The 72 h concentration was determined to be 25, 768, and 5914 mg/L, respectively for the nominal 50, 1250, and 10000 mg/L levels. The 72h E_bC50 and E_rC50 was determined to be 300 and 315 mg/L, respectively. The 72 NOEC was not established since inhibition was observed at all the test concentrations. The notified chemicals are considered not harmful to algae based on the test results.
CONCLUSION	The notified chemical is not harmful to algae.
TEST FACILITY	STZ Angewandte u. Umwelt-Chemie (1998d)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 125, 250, 500, 1000, and 2000 g/L. Actual: Not determined
Remarks – Method	Following a limit-test at 1000 mg/L, the main test was conducted over three hours at concentrations ranging 125 – 2000 mg/L. In the reference test 3,5-dochlorophenole was used as the reference item. The activated sludge was 1.72 g dry weight of suspended solids/L in the test.
RESULTS	
IC50	> 2000 mg/L
NOEC	< 125 mg/L

Remarks – Results	All the test validity criteria are met. GLP principles were followed. The 3 h IC50 was determined to be > 2000 g/L. The NOEC (no observed effect concentration) was determined to be < 125 g/L. The notified chemical mixture is therefore not expected to be inhibitory to microbial activity.
CONCLUSION	The notified chemical is not be inhibitory to microbial activity.
TEST FACILITY	LAUS GmbH (2008)

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