File No: STD/1592

May 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ester in Emgard® XFE 75W-90

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

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/1592	BASF Australia Ltd	Ester in Emgard® XFE 75W-90	ND	≤ 250 tonnes per annum	Component of synthetic automotive lubricants

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, 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.

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

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

Environmental risk assessment
On the basis of the low expected aquatic release and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during repackaging and/or end use processes:
  - Avoid contact with skin

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during repackaging and/or end use processes where practicable:
  - Gloves
  - Coveralls

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

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

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

Disposal

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

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent 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;
- the chemical is imported and used at > 30% concentration;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of synthetic automotive lubricants, 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.

Safety Data Sheet
The SDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
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: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, degree of purity, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, dissociation constant, induction of germ cell damage and bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2010), Canada (2015), EU REACH (2015), Switzerland (2015), China (2016), Taiwan (2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Emgard® XFE 75W-90 (product containing the notified chemical)

OTHER NAME(S)
Ester in XPB 115

MOLECULAR WEIGHT
< 500 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -100 °C	Measured
Boiling Point	377–388 °C at 101.3 kPa	Measured
Density	910 kg/m^3 at 20 °C 900 kg/m^3 at 40 °C	Measured
Vapour Pressure	1.1 × 10^{-8} kPa at 20 °C 2.3 × 10^{-8} kPa at 25 °C 6.5 × 10^{-7} kPa at 50 °C	Measured
Water Solubility	< 6×10^{-5} g/L at 20 °C	Measured
Hydrolysis as a Function of	Not determined	Contains hydrolysable functionalities but no

pH		significant hydrolysis is expected at environmental conditions
Partition Coefficient (n-octanol/water)	log Pow > 6.5 at 25 °C	Measured
Adsorption/Desorption	log Koc > 5.6 at 25 °C	Measured
Dissociation Constant	Not determined	Does not contain dissociable functionalities
Particle Size	Not determined	Liquid
Flash Point	208.5 °C (pressure unknown)	Measured
Flammability	Not considered pyrophoric	Measured
Autoignition Temperature	334 °C	Measured
Explosive Properties	Not determined	The exothermic decomposition energy, determined by DSC, is less than 500 J/g.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties.

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

Reactivity
The notified chemical is 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 as a component of synthetic lubricant for automotive at ≤ 30% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	50–100	50–100	100–150	150–200	200–250

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 175 kg closed head steel drums and 1,000 L intermediate bulk containers (IBCs). The drums will be packed on pallets and the drums and IBCs will be transported in a shipping container from the wharf to contracted warehouses in Melbourne and Sydney by road.

USE
The notified chemical will be as a component of synthetic lubricants for industrial automotive use (at ≤ 30% concentration).

OPERATION DESCRIPTION
The notified chemical will not be manufactured or reformulated in Australia. It will be supplied to customers for either rebranding or repacking into smaller containers (e.g. 10 L) as required. The notified chemical will be repackaged using automated processes. The product containing the notified chemical at ≤ 30% concentration will be used by industry only as transmission fluids in automotive applications, such as heavy industrial trucks.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	1	30–60
Production / packaging operators	2	50–100
Quality technicians	1	50–100
End use	1–2	100–200

EXPOSURE DETAILS

Storage and transportation

Waterside workers, transport drivers and warehouse workers may come into contact with the notified chemical (at ≤ 30% concentration) only in the unlikely event of an accident.

Repacking

Dermal and ocular exposure to the notified chemical at ≤ 30% concentration is possible when operators are connecting and disconnecting pump lines to transfer product from imported containers (e.g. from IBC to a smaller package of 10 L). It is expected that minimal exposure will occur during the repackaging process. Dermal exposure to the notified chemical at ≤ 30% concentration is possible when workers clean up spills or leaks during maintenance of the pump transfer equipment. Workers involved in the transfer process are expected to wear personal protective equipment (PPE) including impermeable gloves, goggles or face shield and protective clothing to minimise exposure.

End use

There is potential for dermal and ocular exposure to the notified chemical at ≤ 30% concentration during the transfer of the lubricant into, and maintenance of, industrial vehicles. Exposure is expected to be minimised by the use of PPE such as gloves, goggles and protective clothing.

6.1.2. Public Exposure

The notified chemical will only be used by the industry and the potential for public exposure is expected to be 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 > 5,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	non-irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of weak sensitisation
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days.	NOAEL = 209 mg/kg bw/day for males and 244 mg/kg bw/day for females
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo micronucleus test	non genotoxic
Rat, reproductive and developmental toxicity	NOAEL = 200 mg/kg bw/day

Toxicokinetics, metabolism and distribution

Based on the low molecular weight (< 500 Da) and partition coefficient (log Pow > 6.5) 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 non-irritating to eyes. Information on irritation to the respiratory tract is not available.

Sensitisation
The notified chemical was a skin sensitiser in a local lymph node assay (LLNA) in mice, with reported stimulation indices of 0.84, 2. 80 and 3.70 at 10, 25 and 50% concentration, respectively. An EC3 value of 39.2% was determined by the study authors. However, chemicals with skin irritating properties tested in the LLNA study using acetone/olive oil may show false positive results (Anderson *et al.* 2011 and Basketter *et al.* 2009).

The notified chemical was not a skin sensitiser in a guinea pig maximisation test using the Magnusson and Kligman method. Slight skin irritation was observed in animals during the study.

QSAR modelling (QSAR 2017) showed negative results for skin sensitisation, consistent with the observation that no structural alert related to skin sensitisation was presented in the structure of components of the notified chemical. In addition, three analogue chemicals with structures similar to the main component of the notified chemical provided by the notifier indicate negative results for skin sensitisation.

Based on the information available and using weight of evidence, the notified chemical is not classified for skin sensitisation.

Repeated dose toxicity
A 90 day repeat dose study was conducted in rats, with the notified chemical administered through the diet at dose levels of 0, 71 (male) and 85 (female), 209 (male) and 244 (female) and 875 (male) and 1,361 (female) mg/kg bw/day. The No Observed (Adverse) Effect Level (NO(A)EL) was established as 209 mg/kg bw/day for males and 244 mg/kg bw/day for females in this study, based on the test substance-related adverse signs of systemic toxicity noted at the highest dose, also considering clinical pathology and pathology parameters.

Mutagenicity/Genotoxicity
The notified chemical was not mutagenic in a bacterial reverse mutation study and was not considered to be genotoxic in an in vivo micronucleus test.

Toxicity for reproduction
A prenatal developmental toxicity study was conducted in rats, with the notified chemical administered by oral gavage at dose levels of 0, 60, 200 and 600 mg/kg bw/day. The No Observed Adverse Effect Level (NOAEL) was established as 200 mg/kg bw/day in the study, based on that no developmental toxicity was observed in the 60 and 200 mg/kg bw/day groups.

Health hazard classification
Based on the available information, 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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on toxicological studies on the notified chemical it is expected that the chemical is of low toxicity, with slight skin irritation. Based on the weight of evidence, the notified chemical is not classified for skin sensitisation; however, the potential of the notified chemical to act as a weak skin sensitiser at high concentrations cannot be ruled out.

During repackaging, workers may be exposed to the notified chemical at ≤ 30% concentration. During end-use professional workers may be exposed to the notified chemical at ≤ 30% concentration when manually decanting

product containing the notified chemical into industrial vehicles. Appropriate PPE (coveralls, impervious gloves, eye protection) will be used to limit workers' exposure. Even if the chemical is a weak skin sensitiser (EC3 = 39.2 in the LLNA), workers will not have exposure to the chemical at > 30% concentration.

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

6.3.2. Public Health

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 manufactured and formulated overseas. The notified chemical will be imported into Australia as a component of synthetic lubricant for industrial application in automotive transmission fluids at ≤ 30% concentration. No significant release of the notified chemical is expected from transportation and storage except in the unlikely event of accidental spills or leaks. Accidental spills and leaks during packaging procedures will be contained and collected for recycling where appropriate, or disposed of in accordance with local government regulations, most likely to landfill.

RELEASE OF CHEMICAL FROM USE

The finished products containing the notified chemical will be used as a component of automotive transmission fluids in industrial settings only. No 'do-it-yourself' (DIY) applications of automotive transmission fluids containing the notified chemical are intended. Release during use may arise from spills when pouring lubricants into automotive vehicles or from vehicle leaks. It is expected that these wastes are disposed of as waste fluids according to State/Territory regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty import containers containing residues of the notified chemical (< 1% as indicated by the notifier) will be collected for disposal to landfill in accordance with local government regulations. The used lubricant containing the notified chemical is expected to be recycled, re-refined or used as low grade burner fuel. It is likely that the notified chemical will be degraded into simpler compounds during re-refining with any residue partitioning to the heavy fractions such as lubricating oils or asphalt.

7.1.2. Environmental Fate

Based on the results of a biodegradability study provided by the notifier, the notified chemical is expected to be readily biodegradable (90–100% CO_2/$ThCO_2$). Details of the environmental fate studies can be found in Appendix C. Generally, the notified chemical is expected to show low bioavailability and bioaccumulation due to its low water solubility and anticipated limited release to the aquatic environment. In landfill the notified chemicals is expected to partition to soil due to its high adsorption coefficient (log KOC > 5.6) and low water solubility, and undergo biotic degradation. Most of the notified chemical will be thermally decomposed during use, recycling and refinement. The notified chemical is expected to be degraded into water and oxides of carbon by thermal decomposition in industrial facilities and via biotic and abiotic pathways in landfill.

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical is not anticipated to be released to surface waters. Therefore, the predicted environmental concentration (PEC) in aquatic environment has not been calculated.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LL50 > 100 mg/L (WAF*)	Not harmful to fish up to its water solubility limit

Daphnia Toxicity	48 h EL50 > 100 mg/L (WAF*)	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	72 h EC50 > 100 mg/L (WAF*)	Not harmful to algae up to its water solubility limit

*Water accommodated fraction

Based on the above ecotoxicological endpoints, the notified chemical is not expected to be harmful to aquatic life up to the limit of its 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 considered to be harmful to aquatic organisms up to the limit of its solubility in water and no significant aquatic exposure is expected based on the reported use pattern.

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) of the notified chemical has not been calculated as a PNEC is not available due to low water solubility and the low potential for release to the aquatic compartment based on its assessed use pattern in automotive transmission fluids. The majority of the notified chemical will be thermally decomposed during its use. Automotive transmission fluids containing the notified chemical, after their useful life, are expected to be disposed of according to State/Territory regulations. Exposure of the notified chemical to the aquatic compartment is unlikely based on the reported use pattern and low water solubility. On the basis of its limited aquatic exposure and assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -100 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Differential scanning calorimetry was used.
Test Facility	Siemens AG (2013a)

Boiling Point 377–387 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Differential scanning calorimetry was used.
Test Facility	Siemens AG (2013a)

Density 910 ± 10 kg/m^3 at 20 °C
900 ± 10 kg/m^3 at 40 °C

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	The oscillating densitometer was used.
Test Facility	Siemens AG (2013b)

Vapour Pressure 1.1×10^{-8} kPa at 20 °C
2.3×10^{-8} kPa at 25 °C
6.5×10^{-7} kPa at 50 °C

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Vapour pressure balance and effusion method were used.
Test Facility	Siemens AG (2013c)

Water Solubility < 6×10^{-5}g/L at 20 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method
Test Facility	Siemens AG (2013d)

Partition Coefficient (n-octanol/water) log Pow > 6.5 at 25 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water). HPLC method. EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	The log Pow of the notified chemical was above the highest log Pow value of the calibration substance (DDT). Therefore, the log Pow was outside the calibration range and reported as > 6.5.
Test Facility	Siemens AG (2013e)

Adsorption/Desorption – screening test log K_{oc} > 5.6 at 25 °C

Method	OECD TG 121 Estimation of the adsorption coefficient on soil and sewage sludge using HPLC.
Remarks	The adsorption coefficient of the notified chemical was found to be above the highest log Koc value of the calibration substance (DDT). Therefore, the log Koc was outside the calibration range, and reported as > 5.6.
Test Facility	Siemens AG (2014)

Flash Point 208.5 °C (pressure unknown)

Method	EC Council Regulation No 440/2008 A.9 Flash Point.
Test Facility	BASF (2013)

Flammability Not considered pyrophoric

Method	EC Council Regulation No 440/2008 A.13 Pyrophoric Properties of Solids and Liquids.
Test Facility	BASF (2013)

Autoignition Temperature 334 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	The tests were performed at an atmospheric pressure of 98.9–100.3 kPa. During the complete measurement the sample was held under nitrogen.
Test Facility	BASF (2013)

Explosive Properties Not determined

Remarks	The exothermic decomposition energy, determined by DSC, is less than 500 J/g. Hence EC Council Regulation No 440/2008 A.14 Explosive Properties Test was not carried out.
Test Facility	BASF (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (2001).
Species/Strain	Rat/Wistar/Crl:WI (Han)
Vehicle	None
Remarks - Method	GLP Certificate. No protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2,000	0
2	3 F	2,000	0
3	1 F	5,000	0
4	2 F	5,000	0

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No clinical signs were noted during the study.
Effects in Organs	No macroscopic pathological findings were noted in the animals sacrificed at the end of observation period.
Remarks - Results	The mean body weight increase during the study was within the normal range.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Bioassay (2013)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test (1987).
Species/Strain	Rat/Wistar
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	GLP Certificate. No protocol deviations

RESULTS

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

LD50	> 5,000 mg/kg bw
Signs of Toxicity - Local	No local effects were noted.
Signs of Toxicity - Systemic	No systemic clinical signs were noted during clinical examination.
Effects in Organs	No macroscopic pathological abnormalities were observed in the animals examined on the last day of observation.
Remarks - Results	The mean body weight of male animals increased within the normal range. The body weight of some female animals stagnated during the study. This effect was considered to not be test substance related as in the required age range the female animals have already reached the phase of slow growth.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Bioassay (2014a)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion (2002).
EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 F
Vehicle	None
Observation Period	7 days
Type of Dressing	Semi-occlusive
Remarks - Method	GLP Certificate. 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			
Erythema/Eschar	0.3	2	1.7	2	< 7 d	0
Oedema	0	0.7	0	1	< 7 d	0

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

Remarks - Results Erythema extended beyond the application area in one animal. The cutaneous reactions were reversible in one animal within 48 hours and in two animals within 7 days after removal of the patch.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Bioassay (2014b)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion (2012).
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 F
Observation Period	None
Remarks - Method	GLP Certificate. 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	0	0	0	1	< 24 h	0
Conjunctiva: chemosis	0	0	0	1	< 24 h	0
Conjunctiva: discharge	0	0	0	3	< 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 A slight conjunctival redness in two animals and a slight conjunctival

chemosis in one animal were noted at 1 hour after application. A severe discharge was noted in all animals at 1 hour after application. The ocular reactions were reversible in all animals within 24 h hours after application.

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

TEST FACILITY Bioassay (2014c)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (2010)
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Acetone:olive oil (4+1, v/v)
Preliminary study	Yes
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexyl cinnamaldehyde.
Remarks - Method	GLP Certificate. Minor deviation did not affect the validity of the study. The highest concentration tested (50%) was the highest level that could be achieved whilst avoiding systemic toxicity and excessive local skin irritation as confirmed in the pre-experiment. The periodic positive control experiment was conducted in October 2012.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	5 F	358.6 ± 146.5	1.00
10	5 F	301.0 ± 96.2	0.84
25	5 F	745.2 ± 183.5	2.08
50	5 F	1327.2 ± 638.0	3.70
Positive Control			
0	not stated	303.8	1.0
5	not stated	448.6	1.5
10	not stated	585.0	1.9
25	not stated	1715.0	5.7

EC3	39.2%
Remarks - Results	No deaths or no signs of systemic toxicity were noted during the study. The body weight was within the expected range.

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY Harlan (2013)

B.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Magnusson and Kligman

Species/Strain	Guinea pig/SPF albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: 100% intradermal: 0, 2.5%, 5%

	topical: 25%, 50%, 75%, 100%
MAIN STUDY	
Number of Animals	Study 1 & 2 Test Group: 10 F Study 1 & 2 Control Group: 5 F
Vehicle	Olive oil in both studies (100% or 50% with adjuvant solution)
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde.
INDUCTION PHASE	Induction Concentration Study 1: intradermal: 5% test substance in olive oil and adjuvant solution (1:1 mixture of Freund's Complete Adjuvant and NaCl 0.9%) topical: 100% occlusive for 48 hours
Signs of Irritation	Study 1 All 15 animals showed skin reactions (erythema of grade 0-3) on injection sites. The intradermal injections with FCA-involvement caused skin irritations (grades 2 to 3) and partial necrosis or beginning necrosis in the test and control groups. The sites of injections of the test substance and vehicle showed none or a discrete or patchy erythema only. Erythema and necrosis were also noted on the cranial and caudal injection sites in both groups during the dermal induction phase. The injection sites of the animals of the control and test group without FCA-involvement had no discernible erythema during the dermal induction phase. Study 2 All 15 animals showed skin reactions (erythema of grade 0-2) on injection sites. The intradermal injections with FCA-involvement caused skin reaction (grade 2) and partially open necrosis in the test and control groups. The sites of injections of the test substance and vehicle showed none to moderate erythema. Erythema and partially open necrosis were also observed on the cranial and caudal injections sites on both groups during the dermal; induction phase. The injection sites of the animals of the control group and test group without FCA-involvement had no discernible erythema during the dermal induction phase.
CHALLENGE PHASE	
1st challenge (3 weeks after first induction)	topical: 100% test substance on posterior right flank and vehicle on posterior left flank for study 1 (3 weeks after first induction) and 75% test substance on posterior right flank and vehicle on posterior left flank for study 2
2nd challenge (one week after first challenge)	topical: 75% test substance on anterior right flank and vehicle on anterior left flank for study 1 and 50% test substance on anterior left flank and vehicle on anterior right flank for study 2
Remarks - Method	GLP Certificate. Study 1: Due to ambiguous findings, caused by reactions of the control animals to the test substance as well as to the vehicle, the sponsor required the accomplishment of a rechallenge with a reduced test concentration of 75%. Study 2: The sponsor required the accomplishment of a rechallenge with a reduced test concentration of 50%.

RESULTS

Study 1

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% for challenge and 75% for rechallenge	0/10	0/10	0/10	0/10
Control Group	100% for challenge and 75% for rechallenge	0/5	0/5	0/5	0/5

*Only grade 2 (moderate and confluent erythema) and grade 3 (intense erythema and swelling) reactions are reported.

Study 2

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% for challenge and 50% for rechallenge	0/10	0/10	0/10	0/10
Control Group	75% for challenge and 50% for rechallenge	0/5	0/5	0/5	0/5

*Only grade 2 (moderate and confluent erythema) and grade 3 (intense erythema and swelling) reactions are reported.

Remarks - Results: Only discrete or patchy erythema was observed in some animals during challenge phase of Study 1.

The animals showed no signs of illness and normal development of body weight.

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

TEST FACILITY: Frey-Tox (2014)

B.7. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents (1998).

Species/Strain: Rats/Crl:WI(Han)
Route of Administration: Oral –diet
Exposure Information: Total exposure days: 90 days
Dose regimen: 7 days per week
Vehicle: None
Remarks - Method: GLP Certificate.
Minor deviation did not affect the validity of the study.

RESULTS

Group	*Number and Sex of Animals*	*Dose ppm*	*Dose mg/kg bw/day*	*Mortality*
control	10 per sex	0	0	0
low dose	10 per sex	1,000	71 (M), 85 (F)	0
mid dose	10 per sex	3,000	209 (M) 244 (F)	0
high dose	10 per sex	12,000 (M), 15,000 (F)	875 (M) 1,361 (F)	0

Mortality and Time to Death
No animals died prematurely in the study.

Clinical Observations
No test substance-related adverse findings were noted for clinical examinations, detailed clinical observations, food and water consumption, body weight data, functional observational battery, motor activity measurement and ophthalmological examinations.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
In high-dose group male animals, slight increases in alkaline phosphatase (ALP) activities were noted. In high-dose group female animals, slight increases in γ–glutamyl-transferase (GGT) activities were noted.

In high-dose group male animals urea and potassium levels were increased. In high-dose group female animals

total protein and albumin levels decreased. No treatment-related changes for haematological parameters were observed.

In high-dose group male animals higher incidences of granulated and epithelial casts were found in the urine sediment.

Effects in Organs
Target organs were the liver and the thyroid glands in pathological investigations.

The absolute and relative liver weights significantly increased in males (absolute 16% and relative 25%) and females (absolute 26% and relative 28%) in the high-dose group. These effects correlated with a minimal diffuse hepatocellular hypertrophy being observed in 6 out 10 males and in 7 out 10 females in the high-dose group. These were considered to be a correlate for a microsomal enzyme induction in the liver and they were regarded by the study authors to be treatment-related and adverse (when also considering the changes in clinical pathology parameters).

The incidence of follicular hypertrophy/hyperplasia and of altered colloid in the thyroid glands slightly increased in males of the high-dose group. These findings were regarded to be secondary to an induced UDP-glucuronyl transferase activity in hepatocellular hypertrophy. The well-known phenomenon is characteristic for rodents and leads to accelerated degradation of T4 with a compensatory increase of TSH, causing thyroid gland hypertrophy/hyperplasia of follicular cells. These findings were regarded by study authors to be treatment-related but not relevant for humans.

Remarks – Results
All other findings occurred individually or were biologically equally distributed over control and treatment groups. They were considered by study authors to be incidental or spontaneous in origin and without any relation to treatment.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 209 mg/kg bw/day for males and 244 mg/kg bw/day for females in this study, based on test substance-related adverse signs of systemic toxicity observed at the high dose.

TEST FACILITY BASF SE (2015a)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test (1997).
Plate incorporation procedure/Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Liver S9 mix from induced rats
Concentration Range in Main Test	With metabolic activation: 0, 33,100, 333, 1,000, 2,800 and 5,600 µg/plate Without metabolic activation: 0, 33,100, 333, 1,000, 2,800 and 5,600 µg/plate
Vehicle	Acetone
Remarks - Method	GLP Certificate. No protocol deviations. There was no preliminary test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 5,600	≥ 1,000	Negative
Test 2	> 5,600	≥ 1,000	Negative
Test 3	> 5,600	≥ 1,000	Negative
Present			

Test 1	> 5,600	≥ 1,000	Negative
Test 2	> 5,600	≥ 1,000	Negative
Test 3	> 5,600	≥ 1,000	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 metabolic activation.

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 SE (2013)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test (1997).
Species/Strain: Mice/NMRI
Route of Administration: Oral – gavage
Vehicle: Corn oil
Remarks - Method: GLP Certificate.
No protocol deviations

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 M	0	24
I (vehicle control)	5 M	0	48
II (low dose)	5 M	500	24
III (mid dose)	5 M	1,000	24
IV (high dose)	5 M	2,000	24
IV (high dose)	5 M	2,000	48
V (positive control, CP)	5 M	20	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity: The administration of the test substance led to weak clinical signs of toxicity at the top dose of 2,000 mg/kg body weight within the first day of exposure (piloerection).

A clear inhibition of erythropoiesis determined from the ratio of polymchromatic to normachromatic erythrocytes were detected at the highest recommended test substance dose of 2,000 mg/kg bw at the 48 hours sacrifice interval. Thus, bioavailability of the test substance in the target organ after oral administration was confirmed.

Genotoxic Effects: The number of normochromatic erythrocytes containing micronuclei did not differ to any appreciable extent in the vehicle control group or in the various dose groups at any of the sacrifice intervals. The number of normochromatic or polychromatic erythrocytes containing small micronuclei (d< D/4) or large micronuclei (d ≥ D4) did not deviate from the vehicle control values at any of the sacrifice intervals and was within the historical vehicle control data range.

Remarks - Results: The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.

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

vivo micronucleus test.

TEST FACILITY BASF SE (2014a)

B.10. Developmental toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 414 Prental Developmental Toxicity Study (2001).
Species/Strain Rat/Wistar Han
Route of Administration Oral – gavage
Exposure Information Exposure days: from day 6 to day 20 post-coitum, inclusive.
Post-exposure observation period: 1 day
Vehicle Corn oil
Remarks - Method Minor deviation did not affect the validity of the study.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
1	22 F	0	0
2 (low)	22 F	60	1
3 (mid)	22 F	200	0
4 (high)	22 F	600	0

Mortality and Time to Death
No mortality occurred that was considered to be related to treatment with the test substance.

Effects on Dams
No clinical signs or necropsy findings noted were considered to be related to treatment with the test substance. Mean body weights, body weight gain, weight gain corrected for uterus weight and food consumption for treated animals were similar to control animals.

Lower total protein and higher urea levels were noted in clinical biochemistry parameters in the high-dose group and these changes were statistically significant. The statistically significant lower alkaline phosphatase activity (ALP) and higher potassium value in the high-dose group were considered minor in nature by study authors.

Higher liver weights (after correction for body weight) were noted for the low- (7% increase) and high-dose (22% increase) groups and absolute liver weights were higher in the high-dose group. Spleen weights were unaffected.

There were no effects on the number of pregnant females, corpora lutea, implantation sites or pre- or post-implantation loss with the treatment. Examination of cage debris of pregnant females revealed no signs of abortion or premature birth. All females were pregnant with viable foetuses. The female that was euthanised on day 6 post coitum (due to accidental ingestion of part of the feeding tube) was also gravid.

Effects on Foetus
There were no treatment-related effects on litter size, male-female ratio, placenta weights, external foetal morphology and foetal visceral morphology.

In the high-dose group, foetal body weights (per sex, and combined for both sexes) were slightly lower than the control group. There were also treatment related effects on foetal skeletal variations. There were no test substance related effects on foetal skeletal malformation.

Total skeletal variations were observed in 35.2%, 51.4%, 46.9% and 81.7% of foetuses per litter in the control, low-, mid- and high-dose groups respectively. There was a statistically significant increase in total skeletal variations observed in the low- and high-dose groups.

An increased incidence of various skeletal variations was noted in the high-dose group, in particular, an increase in unossified metacarpal(s) and/or metatarsal(s) was reordered (45.5% at highest dose versus 3.37% in the control group). Other skeletal variations were seen at a higher incidence (statistically significant) in the high-dose group compared with controls, but to a lesser degree, than observed for the unossified metacarpal(s) and or metatarsal(s) included 14th rudimentary rib(s), 14th full rib(s), pelvic girdle-caudal shift, 7th cervical rudimentary rib(s) and reduced ossification of the skull.

Remaining skeletal variations seen in treated groups, including the increased incidence of total skeletal variations in the low-dose group, were not considered treatment related as they occurred infrequently, occurred in the absence of a dose-related incidence trend, and/or were observed at same frequencies as in the concurrent control group and historical controls.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 200 mg/kg bw/day in this study, based on that no developmental toxicity was observed in the 60 and 200 mg/kg bw/day groups.

TEST FACILITY WIL Research (2015)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The percentage degradation was calculated based on the production of CO_2 normalised by maximal theoretical CO_2 production ($ThCO_2$).
Remarks - Method	The notified chemical was directly added into the test medium and ultrasound for 10 min before further dilution. The notified chemical was tested in duplicate at average concentration of 15.0 mg/L.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
6	5.5	6	23
12	34.5	12	41
22	97.5	22	70
28	101.5	28	90

Remarks - Results	All validity criteria were satisfied. The degradation in the control containing the notified polymer and reference substance (sodium benzoate) achieved 49% by day 28. Therefore, the notified polymer is not considered to be toxic to the micro-organisms. The degree of degradation of the test substance after 28 days was 102%. As the 10 day window was achieved, 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	Bioassay and safety assessment lab, APM (2015)

C.1.2. Ready biodegradability (2nd test)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	TIC and DOC analyses were detected using a TOC analyser. The percentage degradation was calculated based on the production of CO_2 normalised by maximal theoretical CO_2 production.
Remarks - Method	All validity criteria were satisfied and no deviations from the test guidelines occurred during the course of the test.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
6	44.5	6	61

14	85.0	14	84
22	96.0	22	89
28	98.5	28	92

Remarks - Results: No toxic effects to microorganisms were observed in an inhibition control test assay. The required pass level for ready biodegradability within a ten days window was reached, and the degree of biodegradability was 90-100% after an exposure period of 28 days.

CONCLUSION: The notified chemical is readily biodegradable.

TEST FACILITY: BASF SE (2014b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test -96 hours- semi-static.
EC Council Regulation No 440/2008 C.1 Acute Toxicity for Fish.

Species	Zebra fish (*Danio rerio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	The analytical method was not sufficiently sensitive for determining concentrations of the notified chemical in test media up to its saturation limit.
Remarks – Method	The fish ecotoxicity test was conducted in a water accommodated fraction (WAF) of the notified chemical. A WAF of the nominal loading rate of 100 mg/L was prepared by stirring the notified chemical for approximately one day. The required volume of the saturated solution was siphoned from the bottom of the bottle.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control (0)	Control	7	0	0	0	0
100	Unknown	7	0	0	0	0

LL50	> 100 mg/L at 96 h (WAF)
NOEL	100 mg/L at 96 h (WAF)
Remarks – Results	Validity criteria were met. The 96 h LL50 was reported as > 100 mg/L based on the nominal concentration of the test substance in the media.

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

TEST FACILITY: BASF SE (2015b)

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-renewal.
EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia.

Species	*Daphnia magna Straus*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	The analytical method was not sufficiently sensitive for determining concentrations of the notified chemical in test media up to its saturation limit.
Remarks - Method	The test was conducted in a water accommodated fraction (WAF) of the notified chemical. A WAF of the nominal loading rate of 100 mg/L was prepared by stirring the notified chemical for approximately one day. The required volume of the saturated solution was siphoned from the bottom of the bottle.

RESULTS

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

EL50	> 100 mg/L at 48 h
NOEL	100 mg/L at 48 h

Remarks - Results The test was fully compliant with all the validity criteria required by the corresponding test guidelines. The 48 h EL50 was reported as > 100 mg/L based on the nominal concentration of the notified chemical.

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

TEST FACILITY BASF SE (2015c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

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

Species	*Pseudokirchneriella subcapitata* (*Raphidocelis subcapitata* KORSHIKOV).
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: unknown mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	The analytical method was not sufficiently sensitive for determining concentrations of the notified chemical in test media up to its saturation limit.
Remarks - Method	The test was conducted in a water accommodated fraction (WAF) of the notified chemical. A WAF of the nominal loading rate of 100 mg/L was prepared by stirring the notified chemical for approximately one day. The required volume of the saturated solution was siphoned from the bottom of the bottle.

RESULTS

Biomass		*Growth*	
EL50	*NOEL*	*EL50*	*NOEL*
mg/L at 0-72 h	*mg/L*	*mg/L at 72 h*	*mg/L*

> 100	100	>100	100

REMARKS – RESULTS	The results of this study were consistent with all validity criteria. The 72 h EL50 values were reported as > 100 mg/L based on the nominal concentration of the notified chemical.
CONCLUSION	The notified chemical is not considered to be harmful to algae up to the limit of its solubility in water.
TEST FACILITY	BASF SE (2015d)

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