File No: STD/1623

October 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in EFKA FA 4665 and EFKA FA 4666

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

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1623	BASF Australia Ltd	Chemical in EFKA FA 4665 and EFKA FA 4666	Yes	< 120 tonnes per annum	Component of industrial and automotive paints and coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Hazard classification	*Hazard statement*
Serious eye damage/eye irritation (Category 2A)	H319 – Causes serious eye irritation
Skin corrosion/irritation (Category 2)	H315 – Causes skin irritation
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

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

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

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Serious eye damage/eye irritation (Category 2A): H319 – Causes serious eye irritation
  - Skin corrosion/irritation (Category 2): H315 – Causes skin irritation
  - Skin Sensitisation (Category 1): H317 – May cause an allergic skin reaction

Health Surveillance

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

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation:
  - Enclosed, automated processes, where possible
  - Adequate ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosol

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation:
  - Protective clothing
  - Impervious gloves
  - Safety glasses
  - Respiratory protection, if inhalation exposure may occur

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

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

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

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

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.

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 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 a component industrial and automotive paints and coatings, 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 products containing the notified chemical provided by the notifier were 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, analytical data, impurities, additives/adjuvants, use details, import volume, and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point, boiling point, hydrolysis as a function of pH, partition coefficient, dissociation constant, and flammability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

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

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
EFKA FA 4665 (product containing the notified chemical at <50% concentration)
EFKA FA 4666 (product containing the notified chemical at <50% concentration)

MOLECULAR WEIGHT
> 400 g/mol

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

3. COMPOSITION

DEGREE OF PURITY
The notified chemical is a UVCB substance.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Highly viscous, dull yellow liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified chemical is imported only in solution at < 50% concentration
Boiling Point	Not determined	A normal boiling point temperature could not be determined due to the limited stability of the test substance
Relative Density	1051.5 kg/m^3 at 20°C	Measured
Vapour Pressure	0.02 kPa at 20 °C	Measured
Water Solubility	< 10 mg/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable functionalities, however, due to its limited water solubility, it is expected to hydrolyse slowly in the

		environmental pH range (4-9) at ambient temperature
Partition Coefficient (n-octanol/water)	log P_{ow} > 5 at 20°C	Estimated from single solubility in n-octanol and in water
Surface Tension	63 mN/m	Measured
Adsorption/Desorption	log K_{oc} = 5.23 at 25°C	Measured
Dissociation Constant	Not determined	The notified chemical contains potential anionic functionalities with a typical pKa ~4. It is expected to be ionised in the environmental pH range (4 - 9)
Flash Point	138.5 °C at 101.3 kPa	Measured
Flammability	Not determined	Not highly flammable based on measured flash point
Autoignition Temperature	374 °C	Measured
Explosive Properties	Not determined	Could not be determined due to the exothermic decomposition energy determined by the DSC test (< 500 J/g). However, the notified chemical is not expected to have explosive properties based on the chemical structure
Oxidising Properties	Not determined	Not expected to have oxidising properties based on the chemical structure

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 introduced into Australia at < 50% concentration in 18 kg plastic Jerri cans and 180 kg lined steel tight head drum containers. Paint products containing the notified chemical at < 5% concentration will be imported in 1L, 4L, 10L lined steel cans and 210 kg drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 20	< 60	< 120	< 120	< 120

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The imported products containing the notified chemical at < 50% concentration will be transported from the port wharf to the notifier contracted warehouse, then to the paint manufacturers' sites by road.

USE
The notified chemical will be used as a component of industrial and automotive paints and coatings at < 5% concentration. The paints will be applied by spray (50%), brush and roller.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. The notified chemical will be imported at < 50% concentration.

Reformulation of paints
At the reformulation site, the imported products containing the notified chemical at < 50% concentration will be transferred to the mixing tank by gravity feed or by low pressure pumps. Solvent, resin and pigments will be added to the mixing tank. Mixing process is expected to be equipped with local exhaust ventilation. Once mixing is complete sampling for quality control purposes will take place and the finished industrial and automotive paints and coatings will be pumped to filling machines where it will be transferred to a variety of containers (1 L, 4 L and 10 L cans and 210 kg lined steel drums) through gravity feed or low pressure pumps.

End-use
Industrial and automotive paints and coatings containing the notified chemical at < 5% concentration will be used by professional workers in industrial settings and are expected to be applied by spray, roller or brush. It is not anticipated that finished paints containing the notified chemical will be sold in general retail paint outlets and hardware stores.

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	4
Warehouse	1	4
Process operator	2.5	40
Quality control	0.5	40
Packaging	2	40
End use	1	60

EXPOSURE DETAILS

Transport and storage
Transport and storage workers are expected to only come into contact with the notified chemical (at < 50% concentration) in the unlikely event of an accident.

Reformulation
Dermal and ocular exposure may occur when workers manually weigh and pour the imported products containing the notified chemical (at < 50% concentration) into the mixing equipment, or when connecting and disconnecting transfer hoses, and during quality control, and cleaning and maintenance operations. Inhalation exposure is not expected based on the measured low vapour pressure of the notified chemical and the largely enclosed automated processes used during reformulation and packaging.

End-use
Dermal and ocular exposure of workers to the notified chemical (at < 5% concentration) may occur when workers apply industrial and automotive paints and coatings. There is also some potential for inhalation exposure when applying products containing the notified chemical by low pressure spraying methods. Personal protective equipment (PPE) is expected to be worn, including protective clothing, gloves, safety glasses and air fed respirators when aerosols may be present.

6.1.2. Public Exposure
Products containing the notified chemical will not be sold to the general public. Therefore, direct public exposure to the notified chemical is not expected. The general public may come into contact with the cured paint or coating on automotive bodies, where the notified chemical will be trapped within the matrix and will not be available for exposure.

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 mg/kg bw, low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation –non-adjuvant test.	evidence of sensitisation
Rat, combined oral repeated dose toxicity study with the reproductive/developmental screening toxicity test	NOAEL > 1000 mg/kg bw/day (systemic and reproduction/developmental toxicity)
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosome aberration test in Chinese hamster V79 cells	non genotoxic
Genotoxicity – *in vivo* mammalian erythrocyte micronucleus test	non genotoxic

Toxicokinetics
Based on the molecular weight (> 400 Da), low water solubility (< 10 mg/L at 20 °C) and high lipophilicity (Log P_{ow} > 5) of the notified chemical, dermal absorption is expected to be limited.

Acute toxicity
The notified chemical was found to have low acute oral and dermal toxicity in rats. Inhalation acute toxicity was not determined due to the high viscosity of the notified chemical (refer to appendix B).

Irritation and sensitisation
Based on studies conducted in rabbits, the notified chemical was considered to be irritating to the skin and eyes.

The notified chemical was a skin sensitiser in guinea pigs using the Buehler test.

Repeated dose toxicity
In a repeated dose oral (gavage) toxicity study combined with the reproduction/developmental toxicity screening test, the notified chemical was administered to rats at 0, 100, 300 and 1000 mg/kg bw/day.

No mortality was noted during the treatment period of the study. At dose level of 1,000 mg/kg bw/day, adverse effects observed included clinical signs, chemistry and microscopic finding but with no toxicological relevance. No abnormal findings of pups or fertility and implantation effects were noted. The No Observed Adverse Effect Level (NOAEL) for systemic and reproduction/developmental toxicity was considered to be 1000 mg/kg bw/day.

Mutagenicity/Genotoxicity
The notified chemical tested negative in a bacterial reverse mutation assay and an *in vitro* chromosome aberration test using Chinese Hamster V79 cells. The notified chemical also tested negative in an *in vivo* mouse bone marrow micronucleus test via the oral route.

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

Hazard classification	***Hazard statement***
Serious eye damage/eye irritation (Category 2A)	H319 – Causes serious eye irritation
Skin corrosion/irritation (Category 2)	H315 – Causes skin irritation
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical is irritating to the skin and eye, and is a skin sensitiser.

Reformulation
Reformulation workers may be at risk of irritating and skin sensitising effects when handling the notified chemical as introduced at < 50% concentration. However, the risk is expected to be minimised by the use of appropriate PPE including coveralls, impervious gloves, eye protection, and respiratory protection. In addition, the risk will be further minimised in cases where enclosed and automated processes are used during reformulation.

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

End-use
Professional painters may be exposed to the notified chemical at < 5% concentration during application of paints by brush, roller and spray. However, given the relatively low concentration of the notified chemical in paint products and the expected use of PPE including respiratory protection during spray operations, the risk to the health of professional painters from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
Although the public will come into contact with articles or surfaces which have been treated with paints or coatings containing the notified chemical, the notified chemical will be bound within an inert matrix and as such direct public exposure to the chemical is expected to be negligible.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported into Australia as a pigment dispersant in automotive and industrial paints and coatings. The reformulation process will involve adding the imported products containing the notified chemical to the paint mixing tank by gravity feed or low pressure pumps, where it will be blended with other ingredients, and then filled into end use containers. Blending equipment will be cleaned with solvents and the waste liquids containing the notified chemical will be disposed of in accordance with local government regulations. Release of the products containing the notified chemical to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. Empty containers will be collected by a licensed waste contractor for safe disposal.

RELEASE OF CHEMICAL FROM USE
The finished paints containing the notified chemical will be for industrial and commercial use. During use, the paints will be applied primarily by spray, and by brush and roller.

The main release of the notified chemical is likely from overspray during use. The overspray is expected to be collected using standard engineering controls such as spray booths before disposal to landfill. The solvent waste from cleaning of the application equipment is expected to be collected by a licensed waste contractor, and be disposed of in accordance with local government regulations.

During use, the notified chemical may also be released to the environment as accidental spills. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL
Most of the notified chemical is expected to share the fate of the substrate to which it has been applied, to be either disposed of to landfill or recycled for metals reclamation. Residual notified chemical in empty end-use containers is expected to be cured into an inert solid matrix and be disposed of to landfill.

7.1.2. Environmental Fate

Results of biodegradation tests conducted on the notified chemical shows that it is not readily biodegradable (15.0% degradation over 28 days in OECD 301B test) but inherently biodegradable in aquatic environment (60.8% degradation over 28 days in OECD 302C test). The notified chemical is not considered to bioaccumulate (BMF = 0.0106) as demonstrated in a bioaccumulation test conducted on fish. For details of the biodegradation and bioaccumulative studies, please refer to Appendix C.

As a result of its use pattern, most of the notified chemical is expected to share the fate of the substrate to which it has been applied, to be either disposed of to landfill or recycled for metals reclamation. In landfill, the notified chemical will be present as cured solids and will be neither bioavailable nor mobile. During metal reclamation, the notified chemical will thermally decompose to form water vapour and oxides of carbon. In landfill, soil, sludge and water, the notified chemical is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present at significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters when used in coatings. Therefore, the predicted environmental concentration (PEC) has not been calculated for the notified polymer.

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	96h EC50 > 100 mg/L	Not harmful to fish up to its water solubility limit
Daphnia Toxicity	48h EC50 > 100 mg/L	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	72h EC50 > 525 mg/L	Not harmful to alga up to its water solubility limit
Inhibition of Bacterial Respiration	3h EC50 > 1000 mg/L	Not expected to inhibit bacterial respiration
Earthworm	14d EC50 > 1000 mg/kg	Not harmful to Earthworm

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

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) 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.

7.3. Environmental Risk Assessment

The risk quotients (Q = PEC/PNEC) for the notified polymer have not been calculated as PNEC was not calculated and release to the aquatic environment in ecotoxicologically significant concentrations is not expected based on its reported use pattern as a component in industrial and automotive paints. Moreover, after curing, the majority of the imported quantity of the notified polymer will be irreversibly incorporated into an inert matrix and it is not expected to be mobile, bioavailable or bioaccumulative. On the basis of the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point Not determined

Method	OECD TG 103 Boiling Point
Remarks	The upper temperature of the static vapour pressure measurement is limited by the equipment to 180 °C. At a temperature of 159.5 °C a continuously increasing pressure was observed caused by a limited stability and thermal change of the liquid test item. A normal boiling temperature could not be obtained.
Test Facility	BASF (2012a)

Density 1.0516 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids
Remarks	The density was measured by an oscillating densitometer.
Test Facility	BASF (2012a)

Vapour Pressure 0.02 kPa at 20 °C

Method	OECD TG 104 Vapour Pressure
Remarks	The vapour pressure at 20, 25 and 50 °C was calculated from the regression equation 0.02 kPa at 20 °C, 0.03 kPa at 25 °C and 0.1 kPa at 50 °C (these values were extrapolated as the upper temperature of the static vapour pressure measurement was limited by the equipment to 180 °C). The regression of the results leads with a mean deviation of 0.12% to the regression equation.
Test Facility	BASF (2012a)

Water Solubility < 10 mg/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	BMG Engineering Ltd (2013a)

Surface Tension 63 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions
Remarks	The test solution was 90% saturation concentration
Test Facility	BASF (2012b)

Adsorption/Desorption log K_{oc} = 5.23 at 25 °C

Method	OECD TG 121 Adsorption - Desorption.
Remarks	HPLC Method
Test Facility	BASF (2012c)

Flash Point 138.5 °C at 101.3 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	Closed cup method
Test Facility	BASF (2012d)

Autoignition Temperature 374 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)
Remarks	Open vessel (isobaric conditions) method - EN 14522
Test Facility	BASF (2012d)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/Wistar/Crl:WI (Han)
Vehicle	1, 2 Propanediol
Remarks - Method	No deviations from protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3F	2000	0/3
2	3F	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs were observed
Effects in Organs	The mean body weight of all animals increased within the normal range throughout the study period. There were no macroscopic pathological findings in the animals sacrificed at the end of the observation period.
Remarks - Results	No mortalities occurred.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Bioassay (2012a)

B.2. Acute toxicity – dermal

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

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5M	2000	0/5
2	5F	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Very slight to moderate erythema and very slight to slight oedema were observed in addition to scaling and incrustations.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed
Effects in Organs	The female animal gained weight during the second week within the normal range. Another female showed stagnation of body weight during the whole observation period. No macroscopic pathologic abnormalities were noted in the animals examined at the end of the study.

Remarks - Results	The mean body weight of the male and female animals increased within the normal range throughout the study period, with the exception of one male and female animal which showed stagnation of body weight during the second post-exposure week.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Bioassay (2012b)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 403 Acute Inhalation Toxicity
Species/Strain	Not stated
Vehicle	Ethanol
Method of Exposure	Whole-body exposure.
Exposure Period	4 hours
Physical Form	Liquid aerosol.
Particle Size	Mass Median Aerodynamic Diameters (MMAD) = 1.67 μm, Geometric Standard Deviations (GSD) = 1.95
Remarks - Method	The test item remained highly viscous even after heating at 80-100 °C. A Hudson nebulizer was used to attempt to generate aerosols, but blocked at concentrations down to 12.5%. A sprayer apparatus was then used but blocked at 50%, with only small percentage of the test item arriving in the inhalation tower at concentration 40% and 30%. Using the sprayer the highest technically achievable aerosol concentration after dilution with ethanol to 20% was 0.24 ± 0.06 mg/L, at higher concentrations the ethanol concentration in the respirable aerosol is in a range were toxic effects due to the ethanol exposure are likely.
LC50	Not determined
Signs of Toxicity	Not mentioned in the test study
Effects in Organs	No information on effects were stated in the test study
Remarks - Results	The study author stated that the aerosol generation properties of Fatty Acids, sunflower oil, conjugated, maleated were shown to be low, it was therefore considered not to be possible to generate a suitable test atmosphere from the test item in its original form for use in an inhalation study.
CONCLUSION	The test could not be performed due to the high viscosity of the notified substance
TEST FACILITY	Harlan (2013a)

B.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No deviations from protocol.

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	3	3	3	3	14 days	2 (14 days)
Oedema	3.3	2.3	2.3	4	14 days	3 (14 days)

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

Remarks – Results: Very slight to moderate to severe erythema and very slight to moderate oedema were observed in all animals, with effects lasting to the end of the 14 day observation period. Scaling was observed in all animals at the end of the observation period and yellowish discolouration at the application site occurred in two animals.

CONCLUSION: The notified chemical is irritating to the skin.

TEST FACILITY: Bioassay (2012c)

B.5. Irritation – eye

TEST SUBSTANCE: Notified chemical

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

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3
Observation Period: 21 days
Remarks - Method: No deviations from protocol.

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	2	2	2	< 21 days	0
Conjunctiva: chemosis	2	2.3	2.7	4	< 21 days	0
Conjunctiva: discharge	1	2	2.3	3	< 7 days	0
Corneal opacity	2	1	1.3	2	< 7 days	0
Iridial inflammation	1	0.7	1	1	< 7 days	0

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

Remarks - Results: The following effects were noted during the observation period: slight to moderate corneal opacity, moderate iritis, slight to severe conjunctival chemosis, slight to severe discharge, slight to obvious conjunctival redness, small retraction in the eyelid, a small retraction in the eyelid, contracted pupil, and injected scleral vessels in a circumscribed or circular area were also noted in the animals during observation period.

In two animals the ocular reactions were reversible within 14 days, and in one animal reversible within 21 days after application.

CONCLUSION: The notified chemical is irritating to the eye.

TEST FACILITY: Bioassay (2012d)

B.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD	OECD TG 406 Skin Sensitisation - Buehler test/non adjuvant test
Species/Strain	Guinea pig/SPF albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: 10% topical (induction): 50% topical (challenge): 10%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
Vehicle	PEG E 400
Positive control	Not conducted in parallel with the test substance, but conducted previously in the test laboratory using α-Hexylcinnamaldehyde
INDUCTION PHASE	Induction Concentration: topical: 50% (three inductions)
Signs of Irritation	Discrete or patchy erythema to moderate to confluent erythema was observed in 16/20 animals in the test group.
CHALLENGE PHASE	
Challenge	topical: 10%
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge*	
		24 h	*48 h*
Test Group	0%	0/10	0/10
	10%	0/10	0/10
Control Group	0%	0/20	0/20
	10%	0/20	0/20

Remarks - Results	All control group animals did not show any signs of skin irritation during the induction phase. The validity of the test method was confirmed by the satisfactory result with the positive control conducted prior to the test. Due to the frequency of positive skin reactions in the test group (55 %) compared to the control group (0%), the sensitisation potential of the test item has been sufficiently shown in the first challenge and a second challenge was waived.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Frey-tox (2012)

B.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test
Species/Strain	Rat / HanRcc:WIST
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days to Male rats; 14 days to female rats prior to pairing and then until the F1 generation reached day 4 post partum. Dose regimen: 7 days per week
Vehicle	PEG 300
Remarks - Method	No deviations from protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
control	11 per sex	0	0/22
low dose	11 per sex	100	0/22
mid dose	11 per sex	300	0/22
high dose	11 per sex	1000	0/22

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

Clinical Observations
Bedding in the mouth was noted at the 300 and 1000 mg/kg bw/day. This finding was considered by the study authors to be a sign of discomfort and without toxicological relevance.

One male rat at 300 mg/kg bw/day showed slight breathing noises towards the end of the pre-pairing period. Similar findings were noted at functional observational battery in 5 male rats, treated at 1000 mg/kg bw/day. In the absence of correlated findings in the respiratory system at histopathology, the study authors considered this finding to be not adverse. No findings at detailed weekly clinical observation were noted in female rats at any dose level and in male rats treated at 0, 100 and 300 mg/kg bw/day.

There were no effects on mean food consumption, mean body weight gain or mean body weights at any dose level and in any period.

Locomotor activity was not affected by the treatment with the test item at any dose level.

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

Effects in Organs
No effects on organ weights were noted in any group.

There were no test item-related macroscopic findings in any group.

Microscopically, minimal hepatocellular hypertrophy in the liver at ≥ 300 mg/kg bw/day and minimal diffuse follicular cell hypertrophy in the thyroid gland at 1000 mg/kg bw/day were noted in individual male rats. These changes were considered to reflect an adaptive response of the liver to increased metabolic load and subsequent activation of the hypothalamic-pituitary-thyroid axis due to increased thyroid hormone turnover, the latter being rat-specific with no relevance to humans. Some male and female rats at 1000 mg/kg bw/day showed hypertrophy and/or vacuolation in the adrenal glands, likely related to stress and therefore considered not to be toxicologically relevant.

Reproductive and developmental effects
There were no treatment related adverse effects on any reproductive or developmental parameters at any dose level.

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

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established by the study author as 1000 mg/kg bw/day in this study, based on the absence of treatment related adverse effects.

TEST FACILITY Harlan (2013b)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria

	Standard plate test (SPT) procedure and Pre incubation procedure (PIT)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA,
Metabolic Activation System	S9 fraction from phenobarbital/beta-naphthoflavone induced (Aroclor 1254) rat liver
Concentration Range in Main Test	Standard plate test a) With metabolic activation: 33 to 5500 µg/plate b) Without metabolic activation: 33 to 5500 µg/plate Pre incubation procedure a) With metabolic activation: 10 to 2750 µg/plate b) Without metabolic activation: 10 to 2750 µg/plate
Vehicle	Dimethylsulfoxide (DMSO)
Remarks - Method	No significant protocol deviations Due to limited solubility of the test substance in ultrapure water, DMSO was used as a vehicle.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 5500			
Test 1		> 5500	> 5500	Negative
Test 2		> 2750	> 2750	Negative
Present	> 5500			
Test 1		> 5500	> 5500	Negative
Test 2		> 2750	> 2750	Negative

Remarks - Results	No relevant increase in the number of revertant colonies of any of the tested strains were observed following treatment with the notified chemical at any dose level, with and without metabolic activation, in either mutation test. A bacteriotoxic effect was observed in the PIT from 333 µg/plate onwards.
CONCLUSION	The notified chemical not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF (2012e)

B.9. 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	V79
Metabolic Activation System	S9 Microsomal fraction from male rats induced with Phenobarbital/β-Naphthoflavone
Vehicle	DMSO
Remarks - Method	No significant deviations from protocol

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Selection Time*
Absent			
Test 1	0, 0.5, 0.9, 1.9, 3.8, 7.6, 15.1, 30.2*, 60.5*, 120.9*, 241.9, 483.8, 967.5	4 hours	18 hours
Test 2B	0, 2.0, 3.9, 7.8, 15.6, 31.3*, 62.5*, 125.0*, 250.0*, 500.0	18 hours	18 hours

Test 2B	0, 2.0, 3.9, 7.8, 15.6*, 31.3*, 62.5*, 125.0, 250.0, 500.0	28 hours	28 hours
Test 2D	0, 12.5, 25.0, 50.0, 75.0, 100.0*, 125.0*, 150.0*, 175.0*, 300.0	28 hours	28 hours
Present			
Test 1	0, 1.9, 3.8, 7.6, 15.1, 30.2, 60.5, 120.9*, 241.9*, 483.8*, 967.5, 1935.0*, 3870.0	4 hours	18 hours
Test 2A	15.1, 30.2*, 60.5*, 120.9*, 241.9*, 483.8, 967.5, 1935.0, 3870.0	4 hours	28 hours
Test 2C	0, 25.0, 50.0, 100.0*, 150.0*, 200.0*, 250.0*, 300.0*, 400.0, 500.0	4 hours	28 hours

*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	120.9	≥ 120.9	≥ 120.9	Negative
Test 2B		≥ 500.0	≥ 62.5	Negative
Test 2B		-	≥ 62.5	Negative
Test 2D		≥ 300.0	≥ 125.0	Negative
Present				
Test 1	1935.0	≥ 1935.0	≥ 241.9	Negative
Test 2A		≥ 241.9	≥ 60.5	Positive
Test 2C		≥ 200.0	≥ 150	Positive

Remarks - Results

Cytotoxicity was observed in all of the tests with the exception of 2B with a 28 hour exposure period, although this may be due to the higher concentrations in this test not being evaluable.

No biologically relevant increases in the rate of polyploid or endomitotic metaphases. An increase to 1.5% endomitotic cells in test 2C at 200.0 µg/mL was considered by the study authors to be due to the cytotoxicity at this dose.

There were statistically significant increases in the number of chromosomal aberrations observed in experiment 2A at 60.5, 120.9, and 241.9 µg/mL and also in experiment 2C at 250.0 µg/mL. The study authors regarded the increases as biologically irrelevant due to cytotoxicity at 241.9 and 250.0 µg/mL in tests 2A and 2C respectively, the precipitation and the lack of a dose response in test 2C.

CONCLUSION

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

TEST FACILITY

Harlan CCR (2013a)

B.10. Genotoxicity – in vivo

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test

Species/Strain: NMRI Mouse

Route of Administration: Oral

Vehicle: DMSO 30 %/ 70 % PEG 400

Remarks - Method: Slight deviation in the study plan of the relative humidity in the animal rooms ranged between 45 – 78 % instead of 45 – 65 %.
The high dose group and control group were repeated as the formulation

had not reached 2000 mg/kg bw.
Positive control: Cyclophosphamide

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Sacrifice Time (hours)*
I (vehicle control)	5M	0	24 & 48
II (low dose)	7M	397	24
III (mid dose)	7M	889	24
IV (high dose I)	7M	1662	24 & 48
V (high dose II)	7M	2000	24 & 48
VI (positive control, CP)	5M	40	24

CP = cyclophosphamide.

RESULTS

Doses Producing Toxicity	The high dose (2000 mg/kg bw) reached the limit dose for a non-toxic test substance. There were no deaths or test substance-related clinical findings or remarkable bodyweight changes during the study.
Genotoxic Effects	The test substance is considered negative in this micronucleus assay. There was no statistically significant decrease in the PCE/NCE ratio, demonstrating that the test substance was not cytotoxic to the bone marrow. The test substance did not induce a statistically significant increase in the frequency of micronucleated PCE over the levels observed in the vehicle control.
Remarks - Results	The frequency of micronucleated PCE in the positive control was significantly higher than the vehicle control, 1.41% and 0.06%, respectively.

CONCLUSION The notified chemical was not clastogenic under the conditions of this *in vivo* mammalian erythrocyte micronucleus test.

TEST FACILITY Harlan CCR (2013b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
- Inoculum: Activated sludge
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring: Carbon dioxide
- Remarks - Method: No significant deviations from the test guidelines were reported. The test substance was weighed onto small glass plates to reach 20 mg/L Total Organic Carbon (TOC) corresponding to approximately 31 mg/L test substance. Because of the poor water solubility of the test substance, these glass plates were treated for few minutes in an ultrasonic bath to ensure an evenly distribution of the test substance in the test medium. The vessel for reference substance aniline was also prepared at 20 mg/L TOC.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*[a]	*Day*	*% Degradation*
4	2	4	33
7	4	7	61
11	7	11	76
14	10	14	76
21	13	21	73
28	15	28	78

[a]Mean value of two replicates

- Remarks - Results: All validity criteria for the test were satisfied. The percentage degradation of the reference compound, aniline surpassed the threshold level of 60 % within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the notified chemical after 28 days was 15%.

CONCLUSION: The notified chemical is not readily biodegradable.

TEST FACILITY: BASF, 2012f

C.1.2. Bioaccumulation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 305 Bioconcentration: Flow-through Fish Test.
- Species: *Oncorhynchus mykiss*
- Exposure Period: Exposure: 14 days Depuration: 8 days
- Auxiliary Solvent: Acetone
- Concentration Range: Nominal: mixture of 1 part [^{14}C] notified chemical and 24 parts unlabelled notified chemical at 500 mg /kg food
  Actual: 485 mg/kg food
- Analytical Monitoring: Liquid Scintillation Counter (LSC)
- Remarks - Method: No significant deviations from the test guidelines were reported. Due to the limited water solubility of the test substance, the dietary exposure test was conducted as recommended by the OECD guidelines. The [^{14}C] radiolabelled test substance was dissolved in tert-butyl acetate. 2.7 mg of

	the [^{14}C] test substance in 0.0432 g tert-butyl acetate was weighed into a glass vial. The tert-butyl acetate was completely evaporated. The [^{14}C] test substance was re-dissolved in 10 mL acetone. A 24-fold amount of unlabelled test substance was weighed in a beaker and dissolved in 10 mL acetone. The unlabeled stock solution was added to the labeled stock solution. The acetone stock solution was then pipetted onto 135 g fish diet and mixed completely. The acetone was completely evaporated from the diet.
RESULTS	
Biomagnification Factor (BMF)	The lipid- and growth-corrected BMF = 0.0106
Remarks - Results	All validity criteria for the test were satisfied.
CONCLUSION	The test substance is not considered to be bioaccumulative.
TEST FACILITY	BASF, 2014

C.1.3. Inherent biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 302 C Inherent Biodegradability: Modified MITI Test (II) The Guidelines for Testing of Chemicals HJ/T 153-2004 Chemical Inherent Biodegradation: Modified MITI Test (II) GB/T 21818-2008
Inoculum	A mixture of microorganisms from activated sludge, surface soil and surface water samples collected from ten local sites
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biological Oxygen Demand (BOD)
Remarks – Method	No significant deviations from the test guidelines were reported. Appropriate amount of the test substance was directly added into each bottle to reach a concentration of 35 mg/L in the bottles.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*[b]	*Day*	*% Degradation*
4	16	4	85
7	22	7	86
11	29	11	88
14	38	14	90
21	50	21	92
28	61	28	93

[b]Mean value of three replicates

Remarks – Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate surpassed the threshold level of 40 % within 7 days and 65% within 14 days, indicating the suitability of the inoculums. The recovery rate of residual amount of the test compound in the "abiotic" test was found to be more than 10% after 28 days. The degree of degradation of the notified chemical after 28 days was 60.8%.
CONCLUSION	The notified chemical is inherently biodegradable.
TEST FACILITY	PEAPC, 2014a

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	*Danio rerio*
Exposure Period	96 hours
Auxiliary Solvent	Acetone
Water Hardness	146-188 mg $CaCO_3$/L
Analytical Monitoring	High Performance Liquid Chromatography (HPLC)
Remarks – Method	No significant deviations from the test guidelines were reported. The test loading was prepared by adding the respective amount of an acetonic stock solution to an empty glass vessel. After complete evaporation of the solvent, the natural water was added, moderately stirred for 72 h, followed by filtration. The resulting water soluble fraction (WSF) was used in the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*2 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	7	0	0	1	1	1
100	<LOQ[c]	7	0	0	0	0	0

[c] *LOQ: Limit of quantitation is 10 mg/L*

LC50	>100 mg/L at 96 hours
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to fish up to its water solubility limit
TEST FACILITY	BMG Engineering Ltd, 2013b

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Acetone
Water Hardness	32 mg $CaCO_3$/L
Analytical Monitoring	High Performance Liquid Chromatography (HPLC)
Remarks - Method	No significant deviations from the test guidelines were reported. The test loading was prepared by adding the respective amount of stock solution in acetone to an empty glass vessel. After complete evaporation of the solvent, the aerated *Daphnia* medium was added, moderately stirred for 96 h, followed by filtration. The resulting water soluble fraction (WSF) was used in the test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	3	2
100	<LOQ[c]	20	0	0

[c] *LOQ: Limit of quantitation is 10 mg/L*

LC50	>100 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates up to its water solubility limit
TEST FACILITY	BMG Engineering Ltd, 2013c

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	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 50, 90, 162, 292, 525 mg/L Actual: < LOQ of 10 mg/L
Auxiliary Solvent	Acetone
Water Hardness	Not determined
Analytical Monitoring	High Performance Liquid Chromatography (HPLC)
Remarks - Method	No significant deviations from the test guidelines were reported. The test loading was prepared by adding the respective amount of stock solution in acetone to an empty glass vessel. After complete evaporation of the solvent, the aerated algal medium was added, moderately stirred for 96 h, followed by filtration. The resulting water soluble fraction (WSF) was used in the test.

RESULTS

Biomass		*Growth*	
EC50 *mg/L at 72 h*	*NOEC* *mg/L*	*EC50* *mg/L at 72 h*	*NOEC* *mg/L*
> 525	525	> 525	525

Remarks - Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to alga up to its water solubility limit
TEST FACILITY	BMG Engineering Ltd, 2013d

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 from a local municipal STP
Exposure Period	3 hours
Concentration Range	Nominal: 62.5, 125, 250, 500, 1000 mg/L Actual: Not determined
Remarks – Method	No significant deviations from the test guidelines were reported. The test substance was directly weighted into the test flasks.
RESULTS	
IC50	>1000 mg/L
NOEC	Not determined

Remarks – Results	All validity criteria for the test were satisfied
CONCLUSION	The notified chemical is not expected to inhibit bacterial respiration.
TEST FACILITY	BASF, 2012g

C.2.5. Acute toxicity in earthworm

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 207 Earthworms, Acute Toxicity Tests
Species	*Eisenia foetida*
Auxiliary solvent	Acetone
Exposure Period	14 days
Remarks – Method	No significant deviations from the test guidelines were reported. The test substance dissolved in 5 ml acetone was added into quartz sand and mixed completely. The solvent was removed by volatilation before the earthworms were introduced.

RESULTS

Concentration mg/kg		*Number of Earthworms*	*Mortality (%)*
Nominal(mg/kg)	*Actual*		*14 days*
Control	Control	10	0
11.1	Not determined	10	0
101	Not determined	10	0
1001	Not determined	10	0

LC50	> 1000 mg/kg at 14 days
NOEC	1000 mg/kg at 14 days
Remarks – Results	All validity criteria for the test are satisfied.
CONCLUSION	The notified chemical is not harmful to earthworm
TEST FACILITY	PEAPC, 2014b

BIBLIOGRAPHY

BASF (2012a) Final Report – Physico-Chemical Properties of the test substance, Study Code No. 12L00157, BASF SE, Competence Center Analytics, BASF SE, D-67056 Ludwigshafen (FRG). 15 October 2012, Page1 to 37.

BASF (2012b) Final Report – Physico-Chemical Properties of the test substance, Study Code No. 12L00157, Competence Center Analytics, BASF SE, D-67056 Ludwigshafen (FRG). 15 October 2012, Page 5 to 9.

BASF (2012c) Final Report – Physico-Chemical Properties of the test substance, Study Code No. 12L00157, Competence Center Analytics, BASF SE, D-67056 Ludwigshafen (FRG). 15 October 2012, Page 12 to 16.

BASF (2012d) Evaluation of Physical and Chemical Properties according to Regulation (EC) No 440/2008, Laboratory Study Code SIK-Nr. 12/0777, BASF SE, GCP/RS-L511 D-67056 Ludwigshafen (FRG). 15 October 2012, Safety Engineering Page1 to 11.

BASF (2012e) Test substance Salmonella Typhimurium/Escherichia Coli Reverse Mutation Assay, Project No.: 40M0113/12M062, BASF SE Experimental Toxicology and Ecology 67056 Ludwigshafen, Germany. 25 October 2012.

BASF (2012f) Test substance – Determination of the Ready Biodegradability in the CO_2 Evolution Test, Report No. 22G0113/12G135, Experimental Toxicology and Ecology, BASF SE, D-67056 Ludwigshafen (FRG). 05 October 2012.

BASF (2012g) Test substance – Determination of the Inhibition of Oxygen Consumption in the Activated Sludge, Report No. 08G0113/12G061, Experimental Toxicology and Ecology, BASF SE, D-67056 Ludwigshafen (FRG). 04 October 2012.

BASF (2014) [^{14}C] Test substance – Dietary Exposure Bioaccumulation (Biomagnification) Study in the Rainbow Trout (*Oncorhynchus mykiss*), Report No. 34F0533/13E014, Experimental Toxicology and Ecology, BASF SE, D-67056 Ludwigshafen (FRG). 02 October 2014.

Bioassay (2012a) [Notified Chemical] Acute oral toxicity study in rats, Project No.: 12-BF-OT080, Bioassay Labor für biologische Analytik GmbH 69120 Heidelberg, Germany. 15 November 2012.

Bioassay (2012b) [Notified Chemical] Acute dermal toxicity study in rats, Project No.: 12-BF-DT081, Bioassay Labor für biologische Analytik GmbH 69120 Heidelberg, Germany. 15 November 2012.

Bioassay (2012c) [Notified Chemical] Acute dermal irritation / corrosion in rabbits, Project No.: 12-BF-DI083, Bioassay Labor für biologische Analytik GmbH 69120 Heidelberg, Germany. 15 November 2012.

Bioassay (2012d) [Notified Chemical] Acute eye irritation in rabbits, Project No.: 12-BF-EI082, Bioassay Labor für biologische Analytik GmbH 69120 Heidelberg, Germany. 15 November 2012.

BMG Engineering Ltd (2013a), Test substance – Determination of the water solubility by the flask method (Study No. A12-01286, May 2013), BMG Engineering Ltd, Ifangstrasse 11, CH-8952 Schlieren, Zürich, Switzerland (Unpublished report submitted by the notifier).

BMG Engineering Ltd (2013b), Test substance – 96 hour Acute Toxicity to *Danio rerio* (Zebrafish) (Study No. A12-01287, May 2013), BMG Engineering Ltd, Ifangstrasse 11, CH-8952 Schlieren, Zürich, Switzerland (Unpublished report submitted by the notifier).

BMG Engineering Ltd (2013c), Test substance – 48 hour Acute Toxicity to *Daphnia magna* (Study No. A12-01289, April 2013), BMG Engineering Ltd, Ifangstrasse 11, CH-8952 Schlieren, Zürich, Switzerland (Unpublished report submitted by the notifier).

BMG Engineering Ltd (2013d), Test substance – Fresh Water Algal Growth Inhibition Test with *Desmodesmus subspicatus* (Study No. A12-01288, April 2013), BMG Engineering Ltd, Ifangstrasse 11, CH-8952 Schlieren, Zürich, Switzerland (Unpublished report submitted by the notifier).

Frey-tox (2012) [Notified Chemical] - Test for Delayed Contact Hypersensitivity in the Guinea pig Using the Buehler Test, Project Number 32H0113/12X070, Lab. No.03578 Original II of Ill Final completion date: 11 1 h Dec 2012 page 1 of 21.

Harlan (2013a) [Notified Chemical] 4-Hour Acute Inhalation Toxicity Study in the Rat, Study No.: D68271, Harlan Laboratories Ltd. Zelgliweg 1 4452 Itingen / Switzerland. 14 March 2013.

Harlan (2013b) [Notified Chemical] Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test in the Han Wistar Rat, Study No.: D55028, Harlan Laboratories Ltd. Wölferstrasse 4 4414 Füllinsdorf / Switzerland. 5 April 2013.

Harlan CCR (2013a) In vitro Chromosome Aberration Test in Chinese hamster V79 Cells with [Notified Chemical], Harlan CCR Study: 1487001, BASF Project No.: 32M0113/12X107, Harlan Cytotest Cell Research GmbH (Harlan CCR) In den Leppsteinswiesen 19 64380 Rossdorf, Germany. 18 March 2013.

Harlan CCR (2013b) [Notified Chemical] Micronucleus Assay in Bone Marrow Cells of the Mouse Oral Administration, Harlan CCR Study: 1487301, BASF Project No.: 26M0113/12X123, Harlan Cytotest Cell Research GmbH (Harlan CCR) In den Leppsteinswiesen 19 64380 Rossdorf, Germany. 16 May 2013.

PEAPC (2014a), Test substance – Report for Inherent Biodegradation Test, Study No. S2014NC009-01, Key Lab of Pesticide Environmental Assessment and Pollution Control (PEAPC), Nanjing Institute of Environmental Sciences, MEP, 8 Jiang-wangMiao street, Nanjing 210042, China. 11 September 2014.

PEAPC (2014b), Test substance – Report for Acute Toxicity Test to Earthworm, Study No. S2014NC009-02, Key Lab of Pesticide Environmental Assessment and Pollution Control (PEAPC), Nanjing Institute of Environmental Sciences, MEP, 8 Jiang-wangMiao street, Nanjing 210042, China. 11 September 2014.

SWA (2015) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating.

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.