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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME  
(NICNAS)**

**PUBLIC REPORT**

**Chemical in Irgalube® 355**

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  
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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/1682	BASF Australia Ltd	Chemical in Irgalube® 355	Yes	< 10 tonnes per annum	Component of hydraulic/compressor fluids and bearing/circulating oils

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard Classification

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

<i>Hazard Classification</i>	<i>Hazard Statement</i>
Skin corrosion/irritation (Category 2)	H315 – Causes skin irritation
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction
Specific target organ toxicity, repeated exposure (Category 2)	H373 – Causes damage to organs through prolonged or repeated exposure

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

<i>Hazard Classification</i>	<i>Hazard Statement</i>
Acute Category 3	H402 – Harmful to aquatic life
Chronic Category 3	H412 – Harmful to aquatic life with long lasting effects

### Human Health Risk Assessment

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

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

### Environmental Risk Assessment

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

### Recommendations

#### REGULATORY CONTROLS

#### Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Skin corrosion/irritation (Category 2): H315 – Causes skin irritation
  - Skin sensitisation (Category 1): H317 – May cause an allergic skin reaction

- Specific target organ toxicity, repeated exposure (Category 2): H373 – Causes damage to organs through prolonged or repeated exposure

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

#### Health Surveillance

- As the notified chemical is a skin sensitizer, 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 during handling of the notified chemical:
  - Enclosed and automated systems, where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with skin and eyes
  - Avoid inhalation if aerosols may be generated
- 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:
  - Protective clothing
  - Goggles
  - Impervious gloves

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

- 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.

##### 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.

##### 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.

## 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 of hydraulic/compressor fluids and bearing/circulating oils, or is likely to change significantly;
  - the amount of chemical being introduced has increased, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

### *Safety Data Sheet*

The SDS of a 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 exempt from publication include: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, use details, import volume, and identity of manufacturer.

#### VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Schedule data requirements are varied for adsorption/desorption, dissociation constant, flammability, acute inhalation toxicity, bioaccumulation and inhibition of bacterial respiration.

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

#### NOTIFICATION IN OTHER COUNTRIES

China, EU, Japan, New Zealand, Switzerland and USA

### 2. IDENTITY OF CHEMICAL

#### MARKETING NAME(S)

Irgalube® 355 (product containing < 50% notified chemical)

#### MOLECULAR WEIGHT

> 500 g/mol

#### ANALYTICAL DATA

Reference NMR, IR, GC, GC-MS, UV-Vis spectra were provided.

### 3. COMPOSITION

#### DEGREE OF PURITY

> 95%

### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow liquid

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Melting Point/Freezing Point	No melting point, glass transition at -65 °C	Measured
Boiling Point	Could not be determined	Measured
Density	949.3 kg/m <sup>3</sup> at 20 °C	Measured
Viscosity	863 mPa*s at 20 °C 204 mPa*s at 40 °C	Measured
Vapour Pressure	< 1 × 10 <sup>-7</sup> kPa at 20 or 25 °C (extrapolated) 7.6 × 10 <sup>-7</sup> kPa at 50 °C	Measured
Water Solubility	0.006 – 0.032 g/L at 20 °C	Measured
Fat/n-octanol Solubility	Miscible in any ratio with, n-octanol, at 20 °C and 23 °C	Measured

<b>Property</b>	<b>Value</b>	<b>Data Source/Justification</b>
Hydrolysis as a Function of pH	Could not be determined	Measured
Partition Coefficient (n-octanol/water)	$\log P_{ow} \geq 4.4$ at 20 °C	Estimated from individual solubility in n-octanol and in water
Surface tension	22 mN/m at 20 °C	Measured
Adsorption/Desorption	Could not be determined	Measured
Dissociation Constant	Not determined	Not expected to dissociate significantly due to low water solubility
Flash Point	153.5 °C at 101.3 kPa	Measured
Flammability	Not determined	Not expected to be highly flammable based on the measured flash point
Autoignition Temperature	336 °C	Measured
Explosive Properties	Not feasible as exothermic energy by DSC < 500 J/g	Measured
Oxidising Properties	Not oxidising	Measured

#### 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.

The notified chemical has a flash point of 153.5 °C which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the notified chemical may be considered as a Class C2 combustible liquid.

## 5. INTRODUCTION AND USE INFORMATION

#### MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified chemical will not be manufactured in Australia. It will be imported either in the product Irgalube® 355 at < 50% concentration for reformulation into finished products (hydraulic/compressor fluids and bearing/circulating oils) or in finished products at ≤ 5% concentration.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 10	< 10	< 10	< 10	< 10

#### PORT OF ENTRY

Melbourne, Sydney and Brisbane

#### TRANSPORTATION AND PACKAGING

The product Irgalube® 355 will be imported in 50 kg and 200 kg steel drums and transported by road or rail within Australia.

#### USE

The notified chemical will be used as a component of hydraulic/compressor fluids and bearing/circulating oils which will be used for industrial applications.

#### OPERATION DESCRIPTION

#### Reformulation

The imported product containing the notified chemical (at < 50% concentration) will be formulated into end-use products. The reformulation procedure will likely vary depending on the nature of the formulated products, and

may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and use closed systems with adequate ventilation, followed by automated filling of the reformulated products into containers of various sizes.

#### *End use*

The finished products (hydraulic/compressor fluids and bearing/circulating oils) containing the notified chemical at up to 5% concentration will be added to equipment at OEM and during the use. The finished products are expected to be added to the equipment through closed systems.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

##### CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehousing	2 - 4	20 - 30
Blending plant operators	3 - 5	10 - 20
Blending QA staff	1 - 3	10 - 20
End-use plant operators	4 - 12	200
End-use maintenance workers	6 - 8	200

##### EXPOSURE DETAILS

#### *Transport and warehousing*

Transport and storage workers may come into contact with the notified chemical as a component of lubricant additives (at < 50% concentration) or as a component of end-use products (at concentrations < 5%) only in the event of accidental rupture of packages.

#### *Reformulation*

During reformulation, dermal, ocular exposure of workers to the notified chemical at < 50% concentration may occur during the blending and filling operations, quality control analysis, packaging of materials and cleaning and maintenance of equipment. Exposure should be mitigated by the use of enclosed, automated systems and personal protective equipment (PPE: goggles, impervious gloves, protective clothing and hard hats), as anticipated by the notifier. Given the low vapour pressure (<  $1 \times 10^{-7}$  kPa at 20 or 25 °C) of the notified chemical inhalation exposure is not expected unless aerosols are generated.

#### *End-use*

Dermal and ocular exposure to the notified chemical at  $\leq 5\%$  concentration may occur during transfer of the finished lubricant products from the storage containers into the machinery reservoirs, and during cleaning and maintenance of equipment. Exposure should be limited by the use of ventilated environments and PPE (goggles, impervious gloves, protective clothing and hard hats), as anticipated by the notifier.

### 6.1.2. Public Exposure

Finished products (hydraulic/compressor fluids and bearing/circulating oils) containing the notified chemical at  $\leq 5\%$  concentration are intended for industrial use and will not be available to the public.

## 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.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Acute oral toxicity – rat	LD50 > 2000 mg/kg bw; low toxicity
Acute dermal toxicity – rat	LD50 > 2000 mg/kg bw; low toxicity
Skin irritation – rabbit	irritating
Eye irritation – rabbit	slightly irritating
Skin sensitisation – guinea pig maximisation test	evidence of sensitisation
Repeat dose oral toxicity – rat, 28 days	NOAEL < 50 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Genotoxicity – <i>in vitro</i> chromosome aberration test	non genotoxic

#### *Toxicokinetics*

No information on toxicokinetics of the notified chemical was provided. Based on the water solubility ( $5 - 34 \times 10^{-3}$  g/L at 20 °C), partition coefficient ( $\log Pow \geq 4.4$  at 23 °C) and relatively high molecular weight ( $> 500$  g/mol) of the notified chemical, passive diffusion of the notified chemical across the skin is expected to be limited.

#### *Acute Toxicity*

The notified chemical was of low acute oral and dermal toxicity when tested in rats.

#### *Irritation*

The notified chemical was found to be irritating to the skin when tested in rabbits, requiring hazard classification (GHS Category 2). The irritation reactions were not reversible in all three animals during the 14-day observation period.

The notified chemical was found to be slightly irritating to eyes when tested in rabbits. The slight irritation reactions were reversible in two out of three animals within 48 hours and in the remaining animal within 7 days after application.

#### *Sensitisation*

The notified chemical was a skin sensitizer in guinea pigs when tested in a maximisation test (induction by intradermal administration at 5% concentration and topical administration at 100% concentration, followed by challenge by topical administration at 50% concentration).

#### *Repeated Dose Toxicity*

In a repeated dose oral (gavage) toxicity study the notified chemical was administered to rats at 50, 150 and 450 mg/kg bw/day for 28 days. The No Observed Adverse Effect Level (NOAEL) was established as  $< 50$  mg/kg bw/day in this study, based on test substance-related adverse findings at each of the doses tested.

#### *Mutagenicity/Genotoxicity*

The notified chemical showed negative results in a bacterial reverse mutation assay and an *in vitro* chromosomal aberration test using Chinese hamster V79 cells.

#### **Health Hazard Classification**

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

<i>Hazard Classification</i>	<i>Hazard Statement</i>
Skin corrosion/irritation (Category 2)	H315 – Causes skin irritation
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction
Specific target organ toxicity, repeated exposure (Category 2)	H373 – Causes damage to organs through prolonged or repeated exposure

### **6.3. Human Health Risk Characterisation**

#### **6.3.1. Occupational Health and Safety**

Based on available toxicological studies on the notified chemical, the notified chemical is expected to be a skin irritant and a skin sensitizer, with specific target organ toxicity through prolonged or repeated exposure.

Workers handling the industrial lubricants containing the notified chemical may come into contact with the chemical at  $< 50\%$  concentration during reformulation or equipment servicing. However, the exposure is expected to be limited by the use of enclosed, automated systems (during reformulation) and PPE (goggles, impervious gloves, protective clothing and hard hats).

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.

### 6.3.2. Public Health

The notified chemical will be used in industrial settings only and will not be made available to the public. 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 either in finished products (hydraulic/compressor fluids and bearing/circulating oils) or in the product Irgalube® 355 for reformulation into the finished products. In general, the reformulation process involves automatic blending operations in closed systems, followed by automatic filling of the reformulated products into end-use containers. Any waste containing the notified chemical generated from the reformulation process is expected to be sent to on-site treatment facilities. Accidental spills of the products containing the notified chemical during import, transport, reformulation or storage are expected to be collected for recycling or treating at on-site treatment facilities in accordance with local government regulations. As estimated by the notifier, empty import containers may contain up to 0.1% of the import volume of the notified chemical (corresponding to 10 kg/annum). The empty containers will be steamed clean and the residual waste containing the notified chemical are expected to be sent to on-site treatment facilities. According to the notifier, more than 90% of the notified chemical is expected to be removed through on-site treatment facilities.

##### RELEASE OF CHEMICAL FROM USE

The finished products (hydraulic/compressor fluids and bearing/circulating oils) containing the notified chemical will be added to equipment at OEM and during use through a closed system. Releases during use may come from spills when pouring lubricants into the machinery reservoirs or leaks from the machinery, however these are expected to be negligible.

##### RELEASE OF CHEMICAL FROM DISPOSAL

At the end of their useful lives, the products containing the notified chemical will be drained from the machinery for disposal. The main method of disposal will be by recycling or thermal decomposition. Some of the residual fluid within the machinery will have the same fate as the machinery which may be recycled as scrap metal or disposed of to landfill.

#### 7.1.2. Environmental Fate

A biodegradability test conducted on the notified chemical shows that it is not readily biodegradable (1% degraded over 28 days in an OECD 301 B test). For the details of the biodegradability study, refer to Appendix C.

The used lubricant oils and fluids containing the notified chemical is expected to be recycled, re-refined or disposed of by approved waste management facilities. It is likely that the notified chemical will be degraded into simpler compounds during refining. According to the notifier, up to 10 kg/annum of residual notified chemical from empty drums may be released to on-site wastewater treatment facilities where more than 90% of the notified chemical is expected to be removed by adsorption to sludge. Minor amounts of the notified chemical may also be disposed of to on-site wastewater treatment facilities as collected spills. A very small proportion of the notified chemical may be applied to land when sludge from wastewater treatment facilities is used for soil remediation, or disposed of to landfill. Based on its low water solubility and high log  $P_{ow}$  (> 4.4), the notified chemical is expected to have low mobility in soil. The notified chemical in the environment is expected to eventually degrade into water, oxides of carbon, sulfur, phosphorous and nitrogen via biotic and abiotic pathways.

#### 7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified chemical to the aquatic environment will be limited based on its reported use pattern.

## 7.2. Environmental Effects Assessment

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

	<i>Result</i>	<i>Assessment Conclusion</i>
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 ErL50 = 34 mg/L (WAF)	Harmful to algae

WAF: Water Accommodated Fraction

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), the notified chemical is expected to be harmful to alga. Therefore, the notified chemical is formally classified as “Acute Category 3; Harmful to aquatic life” under the GHS. Based on the acute toxicity and lack of ready biodegradation, the notified chemical is formally classified as “Chronic Category 3; Harmful to aquatic life with long lasting effects” under the GHS (United Nations, 2009).

### 7.2.1. Predicted No-Effect Concentration

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

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
72 h Algal ErL50	34 mg/L
Assessment Factor	100
Mitigation Factor	1
PNEC	0.34 mg/L

## 7.3. Environmental Risk Assessment

The risk quotient ( $Q = PEC/PNEC$ ) for the notified chemical has not been calculated as release of the notified chemical to the aquatic environment in ecotoxicologically significant concentration is not expected based on its reported use pattern. Therefore, on the basis of this assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

<b>Melting Point/Freezing Point</b>	No melting temperature between -100 and 50 °C Glass transition temperature at -65 °C
Method	OECD TG 102 Melting Point/Melting Range
Remarks	Determined by differential scanning calorimetry
Test Facility	BASF (2015a)
<b>Boiling Point</b>	Not determined
Method	OECD TG 103 Boiling Point
Remarks	Determined by dynamic vapour pressure. The test item decomposed prior to boiling.
Test Facility	BASF (2015a)
<b>Density</b>	949.3 kg/m <sup>3</sup> at 20 °C
Method	OECD TG 109 Density of Liquids and Solids
Remarks	Determined by a oscillating density meter
Test Facility	BASF (2015a)
<b>Viscosity</b>	863 mPa*s at 20 °C 204 mPa*s at 40 °C
Method	OECD TG 114 Viscosity of Liquids
Remarks	Determined by a capillary viscometer
Test Facility	BASF (2015a)
<b>Vapour Pressure</b>	< 1 × 10 <sup>-7</sup> kPa at 20 and 25 °C (extrapolated) 7.6 × 10 <sup>-7</sup> kPa at 50 °C
Method	OECD TG 104 Vapour Pressure
Remarks	Effusion method
Test Facility	BASF (2015a)
<b>Water Solubility</b>	0.006 – 0.032 g/L at 20 °C
Method	OECD TG 105 Water Solubility
Remarks	Flask Method; the test item is a mixture of homologues and is surface active; the solubility in water increased with the mass of test item applied in the experiment.
Test Facility	BASF (2014a)
<b>Hydrolysis as a Function of pH</b>	
Remarks	Due to the low solubility in the buffer solutions and its behaviour in water, the determination of the hydrolysis as a function of pH according to OECD TG 111 is not feasible and sensible.
Test Facility	BASF (2015b)
<b>Surface Tension</b>	22 mN/m at 20 °C
Method	OECD TG 115 Surface Tension of Aqueous Solutions
Remarks	Concentration: 90% of the saturation concentration
Test Facility	BASF (2015a)
<b>Adsorption/Desorption</b>	Could not be determined
Method	OECD TG 121 Estimation of Adsorption Coefficient on Soil and Sewage Sludge using HPLC

Remarks The method is not suitable because the test item is a mixture of homologues and could not be chromatographed under the prescribed conditions.  
Test Facility BASF (2015b)

**Flash Point** 153.5 °C at 101.3 kPa

Method EC Council Regulation No 440/2008 A.9 Flash Point  
Test Facility BASF (2014b)

**Autoignition Temperature** 336 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)  
Remarks Test was performed at 100 – 100.8 kPa  
Test Facility BASF (2014b)

**Explosive Properties** Not feasible as exothermic energy by DSC < 500 J/g

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.  
Remarks Determined by differential scanning calorimetry  
Test Facility BASF (2014b)

**Oxidizing Properties** Not oxidising

Method Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 5<sup>th</sup> revised version, Test O.2  
Remarks The mean pressure rise time of the test substance was higher than that of a reference mixture.  
Test Facility BASF (2016a)

**APPENDIX B: TOXICOLOGICAL INVESTIGATIONS****B.1. Acute Oral Toxicity – Rat**

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

## RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs were noted during clinical examination.
Effects in Organs	There were no macroscopic pathological findings in the treated animals.
Remarks – Results	The mean body weight of 3 treated animals increased within the normal range throughout the study. In the other 3 animals, body weights increased within the normal range during the first week but revealed a stagnation of body weight during the second week. The study authors stated that this effect was observed occasionally in the rat strain used, because in the required age range the female animals had already reached the phase of slow growth.

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

TEST FACILITY Bioassay (2015a)

**B.2. Acute Dermal Toxicity – Rat**

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test
Species/Strain	Rat/Wistar Crl:WI (Han) SPF
Vehicle	None
Type of dressing	Semi-occlusive
Remarks – Method	No significant protocol deviations

## RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose (mg/kg bw)</i>	<i>Mortality</i>
1	5 per sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity – Local	Male animals Well-defined erythema was noted in 4/5 animals on Day 1 and persisted in 3/5 animals until Day 2 or 3. Thereafter, very slight erythema was noted in 1/5 animals on Day 6 and moderate erythema was noted in 2/5 animals on Day 3 with one of these animals showing very slight erythema on Day 6. The remaining animal showed very slight erythema on Day 1 which increased to well-defined erythema from Day 2 until Day 3.  In all animals very slight oedema was noted on Day 1 or 2 and persisted in one animal until Day 3. Oedema increased to well-defined oedema on Day 3 in one animal. Well-defined oedema was noted in 2/5 animals on Day 2 and increased to moderate oedema on Day 3.

Scaling was noted from Day 3 until Day 10 in all animals and incrustations were noted in 3/5 animals on Day 3.

#### Female animals

Well-defined erythema was noted in all animals on Day 1 and persisted in 1/5 animals until Day 2. In this animal moderate erythema was noted on Day 3, which decreased to very slight erythema from Day 6 until Day 7. Well-defined erythema decreased to very slight erythema in another animal which persisted from Day 2 to Day 6. In the remaining 3/5 animals moderate erythema was noted from Day 2 until Day 3. Among them, one animal showed very slight erythema from Day 6 until day 7, another one showed well-defined erythema on Day 6 and slight erythema on Day 7 and the third one showed well-defined erythema (grade 2) from Day 6 until Day 10.

In 2/5 animals very slight oedema was noted on Day 1 and persisted in one until Day 2. Thereafter, this animal showed moderate erythema on Day 3. Slight oedema was noted in the remaining 3/5 animals on Day 2 and increased to moderate oedema on Day 3. Slight oedema was noted in two of these animals on Day 6 which decreased to very slight oedema on Day 7. The third animal showed very slight oedema on Day 6.

Scaling was noted in all animals from Day 3 until Day 10 and incrustations were noted in 2/5 animals from Day 3 or 6 until Day 7 or 10.

Signs of Toxicity – Systemic  
Effects in Organs  
Remarks – Results

No signs of systemic toxicity were noted.  
No abnormalities were noted at necropsy.  
One female animal showed body weight loss in the first week and expected weight gain in the second week. The remaining animals showed expected body weight gains over the study period.

CONCLUSION

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

TEST FACILITY

Bioassay (2015b)

### B.3. Skin Irritation – Rabbit

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 404 Acute Dermal Irritation/Corrosion

Species/Strain

Rabbit/New Zealand White: Hsdlf: NZW – Harlan (SPF)

Number of Animals

3

Vehicle

None

Observation Period

14 days

Type of Dressing

Semi-occlusive

Remarks – Method

No significant protocol deviations

RESULTS

Lesion	Mean Score*			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Erythema/Eschar	3.0	3.3	3.3	4	> 14 days	4
Oedema	2.7	2.3	2.3	4	> 14 days	3

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

Remarks – Results

The first animal showed well-defined erythema immediately after patch removal which increased to moderate erythema after 24 hours, followed by severe erythema from Day 7 until Day 14. Very slight oedema was noted

after 1 hour and increased to slight oedema after 24 hours. Moderate oedema was noted after 48 hours, followed by severe oedema on Day 7 with regressed to slight oedema on Day 14. Erythema and oedema were noted beyond the application area after 48 hours and until Day 14. A yellowish discoloration was noted on the application area on Day 7 and strong scaling and plaque-like incrustations were noted on Day 14.

The second animal showed very slight erythema immediately after patch which increased to well-defined erythema. Moderate erythema was noted after 24 hours, followed by severe erythema after 72 hours and until Day 7 which regressed to moderate erythema on Day 14. Very slight oedema was noted after 24 hours which increased to slight oedema after 48 hours, followed by severe oedema after 72 hours and until Day 7 which regressed to moderate oedema on Day 14. Erythema beyond the application area was noted after 1 hour and until Day 14. Oedema beyond the application area was noted after 48 hours and until Day 14. A yellowish to brownish discoloration was noted on the application area on Day 7 and scaling was noted at the Day 7 and Day 14 observations.

The third animal showed well-defined erythema immediately after patch removal which increased to moderate erythema after 1 hour and until 48 hours. Severe erythema was noted in this animal after 72 hours and until Day 7 which decreased to moderate erythema on Day 14. Very slight oedema was noted immediately after patch removal which increased to slight oedema after 24 hours. Moderate oedema was then noted after 72 hours which increased to severe oedema on Day 7, before decreased to moderate oedema on Day 14. Erythema and oedema were noted beyond the application area after 24 hours and until Day 14 and scaling was noted on Day 14.

The cutaneous reactions were not reversible in all three animals during the 14-day observation period.

CONCLUSION The notified chemical is irritating to the skin.

TEST FACILITY Bioassay (2015c)

#### B.4. Eye Irritation – Rabbit

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion  
 Species/Strain Rabbit/New Zealand White: Hsdlf: NZW – Harlan (SPF) and Crl:KBL(NZW)-Charles River (SPF)  
 Number of Animals 3  
 Vehicle None  
 Observation Period 7 days  
 Remarks – Method No significant protocol deviations

#### RESULTS

Lesion	Mean Score*			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	Animal No.					
	1	2	3			
Conjunctiva – Redness	0.3	0.3	1	1	72 h	0
Conjunctiva – Chemosis	0	0	0.3	1	24 h	0
Conjunctiva – Discharge	0	0	0	0	n/a	0
Corneal Opacity	0	0	0	0	n/a	0
Iridial Inflammation	0	0	0	0	n/a	0

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

Remarks – Results

Slight conjunctival redness was noted in all animals 1 hour after application and persisted in one animal at the 72-hour observation.

Slight conjunctival chemosis was noted in all animals 1 hour after application and persisted in one animal at the 24-hour observation.

Slight discharge in 2/3 animals and obvious discharge in 1/3 animal were noted 1 hour after application.

Circular injected scleral vessels were noted in all animals 1 hour after application. Injected scleral vessels in a circumscribed area were noted in 2/3 animals after 24 hours and until 48 hours.

The ocular reactions were reversible in 2/3 animals within 48 hours and in 1/3 animal within 7 days after application.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Bioassay (2015d)

### B.5. Skin Sensitisation – Guinea Pig Maximisation Test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Magnusson and Kligman guinea pig maximisation test

Species/Strain Guinea pig/Dunkin Hartley  
 PRELIMINARY STUDY Mild-moderate irritating concentration:  
 Intradermal: 5%  
 Topical: 100%

MAIN STUDY

Number of Animals Test Group: 10 F Control Group: 5 F  
 Vehicle Paraffin subliquidum  
 Positive Control Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using  $\alpha$ -hexylcinnamaldehyde.

INDUCTION PHASE

Induction concentration:  
 Intradermal: 5%  
 Topical: 100%

Signs of Irritation Moderate and confluent erythema were noted in all animals of both treatment and control groups at intradermal induction with FCA-involvement, with some also showing open necrosis. The sites of injections of the test substance and vehicle showed discreet or patchy to moderate and confluent erythema at intradermal induction. Moderate and confluent erythema and open necrosis were noted in both treatment and control groups during the topical induction phase. The injection sites of the animals in the control group and treatment group without FCA-involvement showed no erythema or discreet or patchy erythema respectively during the topical induction phase.

CHALLENGE PHASE

Challenge Topical: 50%  
 Remarks – Method No significant protocol deviations

### RESULTS

Animal	Challenge Concentration	Number of Animals Showing Skin Reactions after Challenge	
		24 h	48 h
Test Group	50%	3/10	4/10
Control Group	50%	0	0

Remarks – Results	None of the animals of the control group or the skin areas treated with the vehicle in the treatment group showed skin reactions following challenge.  Discreet or patchy to moderate and confluent erythema were noted in 4/10 animals of the treatment group following challenge.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Frey-Tox (2015)

### B.6. Repeat Dose Oral Toxicity – Rat

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents Toxicity (Inhalation)
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: none
Vehicle	Corn oil
Remarks – Method	No significant protocol deviations

### RESULTS

Group	Number and Sex of Animals	Dose (mg/kg bw/day)	Mortality
Control	5 per sex	0	0/5
Low Dose	5 per sex	50	0/5
Mid Dose	5 per sex	150	0/5
High Dose	5 per sex	450	0/5

#### *Mortality and Time to Death*

There were no premature deaths.

#### *Clinical Observations*

No signs of general systemic toxicity were noted in any treatment group. Four out of five male and all female animals ploughed nose into bedding shortly after treatment at 450 mg/kg bw/day and all animals of this group showed slight to moderate salivation directly after treatment on several days of the study. These findings were considered by the study authors to be induced by a bad taste of the test substance or local affection of the upper digestive tract and to be non-adverse.

#### *Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*

In the group treated at 450 mg/kg bw/day, increased total white blood cell, absolute and relative neutrophil and absolute monocyte counts and decreased relative lymphocyte counts were noted in both male and female animals. Increased relative monocyte counts, alanine aminotransferase and aspartate aminotransferase activities were noted in female animals.

In the group treated at 150 mg/kg bw/day, increased absolute and relative neutrophil counts and decreased relative lymphocyte counts were noted in both male and female animals.

No test substance-related adverse changes in haematological and clinical chemistry parameters were noted in the group treated at 50 mg/kg bw/day.

No test substance-related adverse changes in urinalysis parameters were noted in any treatment group.

#### *Effects in Organs*

Pathological findings in the group treated at 450 mg/kg bw/day included statistically significant increase in



<i>Present</i>				
Test 1	> 5000	> 5000	≥ 5000	negative
Test 2		> 5000	> 5000	negative
Remarks – Results	No significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.			
	The positive and negative controls gave a satisfactory response confirming the validity of the test system.			
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.			
TEST FACILITY	Harlan (2015a)			

### B.8. Genotoxicity – *In Vitro* Mammalian Chromosome Aberration Test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 <i>In vitro</i> Mammalian Chromosome Aberration Test
Species/Strain	Chinese hamster
Cell Type/Cell Line	V79
Metabolic Activation System	S9 mix from phenobarbitone/β-naphthoflavone induced rat livers
Vehicle	Ethanol
Remarks – Method	The dose selection for the main experiments was based on toxicity noted in a preliminary test carried out at 20.3 µg/mL – 5.2 µL/mL.
	Vehicle and positive controls (ethylmethane sulfonate and cyclophosphamide) were run concurrently with the test substance.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	0.3, 0.7*, 1.6*, 4.1*, 10.2, 25.6, 64, 160, 400	4h	18h
Test 2	0.1, 0.3*, 0.7*, 1.6*, 4.1, 10.2, 25.6, 64, 160	18h	18h
Test 3	0.1*, 0.3*, 0.7*, 1.6, 4.1, 10.2, 25.6, 64, 160	28h	28h
<i>Present</i>			
Test 1	0.3, 0.7, 1.6, 4.1, 10.2*, 25.6*, 64*, 160, 400	4h	18h
Test 2	0.3, 0.7, 1.6, 4.1*, 10.2*, 25.6*, 64, 160, 320	4h	28h

\*Cultures selected for metaphase analysis.

#### RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	not reported*	≥ 10.2	> 400 <sup>^</sup>	negative
Test 2		≥ 4.1	> 160 <sup>^</sup>	negative
Test 3		≥ 1.6	> 160 <sup>^</sup>	negative
<i>Present</i>				
Test 1	not reported*	≥ 160	> 400 <sup>^</sup>	negative
Test 2		≥ 64	> 320 <sup>^</sup>	negative

\* The study authors stated that “since the cultures did not fulfil the requirements for cytogenetic evaluation, due to strong test item-induced toxic effects, this preliminary test was repeated with a top dose of 400.0 µg/mL (with and without S9 mix) and designated Experiment I”.

<sup>^</sup> No visible precipitation of the test substance in the culture medium was noted. Phase separation was observed at ≥ 160 µg/mL in Test 1 in the absence and presence of metabolic activation, at ≥ 25.6 µg/mL in Test 3 and at ≥ 64 µg/mL in Test 2 in the presence of metabolic activation.

Remarks – Results	<p>In both main tests, no statistically significant increases in the frequency of cells with structural chromosome aberrations were observed in the presence or absence of metabolic activation.</p> <p>The positive and negative controls gave a satisfactory response confirming the validity of the test system.</p>
CONCLUSION	<p>The notified chemical was not clastogenic to Chinese hamster V79 cells treated <i>in vitro</i> under the conditions of the test.</p>
TEST FACILITY	<p>Harlan (2015b)</p>

## 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 <sub>2</sub> Evolution Test
Inoculum	Activated sludge from a STP
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	TOC
Remarks – Method	No major deviations from the test guidelines were reported. The test substance was directly added to the test medium. A toxicity control was run.

#### RESULTS

<i>Test Substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
4	0.2	4	33.7
11	-7.0	11	58.1
25	-4.7	25	70.4
28	1.1	28	75.0

Remarks – Results All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 1%.

CONCLUSION The test substance is not readily biodegradable.

TEST FACILITY Guangdong (2015)

### C.2. Ecotoxicological Investigations

#### C.2.1. Acute Toxicity to Fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static EC Council Regulation No 440/2008 C.1 Acute Toxicity for Fish - Static
Species	Zebrafish ( <i>Danio rerio</i> )
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg CaCO <sub>3</sub> /L
Analytical Monitoring	None
Remarks – Method	A limit test was run with no major deviations from the test guidelines. A loading rate of 100 mg/L was prepared in a glass bottle and stirred for 1 day before the Water Accommodated Fraction (WAF) was removed from the bottom port for testing.

#### RESULTS

<i>Nominal Loading (mg/L WAF)</i>	<i>Number of Fish</i>	<i>Mortality 96 h</i>
Control	7	0
100	7	0

LL50 > 100 mg/L (WAF) at 96 hours (nominal concentration)  
 Remarks – Results All validity criteria for the test were satisfied. The dissolved oxygen (DO) concentration was  $\geq 8.2$  mg/L at 23°C ( $\geq 97\%$ ; USGS, 2011) during the test.

CONCLUSION The test substance is not harmful to fish up to its water solubility limit.

TEST FACILITY BASF (2016c)

### 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  
 EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia – Static

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent None

Water Hardness 2.57 mmol/L

Analytical Monitoring None

Remarks – Method No major deviations from the test guidelines were reported. A limit test was run based on preliminary test results. A loading rate of 100 mg/L was prepared in a glass bottle and stirred for 1 day before the Water Accommodated Fraction (WAF) was removed from the bottom port for testing. A reference test with sodium chloride was run.

#### RESULTS

Nominal Loading (mg /L WAF)	Number of <i>D. magna</i>	Number Immobilised 48 h
Control	20	0
100	20	0

EL50 > 100 mg/L (WAF) at 48 hours (nominal concentration)

Remarks – Results All validity criteria for the test were satisfied. The DO concentration was  $\geq 8.7$  mg/L at 20°C ( $\geq 96\%$ ; USGS, 2011) during the test. The 48 h EC50 for *D. magna* exposed to sodium chloride was 5.04 g/L which was within the range of expected responses.

CONCLUSION The test substance is not harmful to aquatic invertebrates up to its water solubility limit.

TEST FACILITY BASF (2016d)

### 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*

Exposure Period 72 hours

Nominal Loading Control, 4.6, 10, 22, 46, 100 mg/L

Auxiliary Solvent None

Water Hardness Not determined

Analytical Monitoring None

Remarks – Method The test loading rates were selected based on preliminary test results. No

major deviations from the test guidelines were reported. Each nominal loading rate was prepared in a glass bottle and stirred for 1 day before the Water Accommodated Fraction (WAF) was removed from the bottom port for testing. A reference test with potassium dichromate was run.

## RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>EyL50</i> (mg/L at 72 h)	<i>NOEyL</i> (mg/L)	<i>ErL50</i> (mg/L at 72 h)	<i>NOErL</i> (mg/L)
28.4	22	34	22

## Remarks – Results

All validity criteria for the test were satisfied. The mean cell density in the control increased 224 times after 72 hours. The 72 h ErC50 for *D. magna* exposed to potassium dichromate was 1.30 mg/L which was within the range of expected responses.

## CONCLUSION

The test substance is harmful to algae.

## TEST FACILITY

BASF (2016e)

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