File No: STD/1682

June 2019

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:

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

Director
NICNAS

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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.

Hazard Classification	*Hazard Statement*
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.

Hazard Classification	*Hazard Statement*
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 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 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

Property	*Value*	*Data Source/Justification*
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^3 at 20 °C	Measured
Viscosity	863 mPa*s at 20 °C 204 mPa*s at 40 °C	Measured
Vapour Pressure	< 1 × 10^{-7} kPa at 20 or 25 °C (extrapolated) 7.6 × 10^{-7} 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

Property	*Value*	*Data Source/Justification*
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 ºC 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

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

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
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 (< 1×10^{-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 ≤ 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 ≤ 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.

Endpoint	***Result and Assessment Conclusion***
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

Endpoint	*Result and Assessment Conclusion*
Genotoxicity – *in vitro* chromosome aberration test	non genotoxic

Toxicokinetics
No information on toxicokinetics of the notified chemical was provided. Based on the water solubility (5 – 34 × 10^{-3} g/L at 20 °C), partition coefficient (log Pow ≥ 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 sensitiser 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.

Hazard Classification	*Hazard Statement*
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 sensitiser, 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.

	Result	*Assessment Conclusion*
Fish Toxicity	96 h LL50 >100 mg/L (WAF)	Not harmful to fish up to its water solubility limit
Daphnia Toxicity	48 h EL50 >100 mg/L (WAF)	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	72 h 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

Melting Point/Freezing Point 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)

Boiling Point 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)

Density 949.3 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids
Remarks Determined by a oscillating density meter
Test Facility BASF (2015a)

Viscosity 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)

Vapour Pressure $< 1 \times 10^{-7}$ kPa at 20 and 25 °C (extrapolated)
7.6×10^{-7} kPa at 50 °C

Method OECD TG 104 Vapour Pressure
Remarks Effusion method
Test Facility BASF (2015a)

Water Solubility 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)

Hydrolysis as a Function of pH

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)

Surface Tension 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)

Adsorption/Desorption 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, 5th 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

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
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

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
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 form 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	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks – Results	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

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* Animal No.*			*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* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	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 α-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 tropical 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 tropical 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

absolute (+ 18%) and relative (+ 18%) liver weight in female animals, statistically significant increase in absolute (+ 33%) and relative (+ 33%) spleen weight in female animals and relative (+ 34%) spleen weight in male animals, granulomatous inflammation in the mesenteric lymph nodes in all male and female animals, granuloma in the liver of 4/5 male and 3/5 female animals, granuloma in the submucosa of the ileum in 2/5 male and 2/5 female animals, myeloid hyperplasia in the bone marrow of the femur in 4/5 male animals and 3/5 female animals, myeloid hyperplasia in the bone marrow of the sternum in 3/5 male and 3/5 female animals, and extramedullary hematopoiesis in the spleen of 2/5 male and 1/5 female animals.

Pathological findings in the group treated at 150 mg/kg bw/day included granulomatous inflammation in the mesenteric lymph nodes in all male and female animals, granuloma in the liver of 5/5 male and 2/5 female animals, myeloid hyperplasia in the bone marrow of the femur in 2/5 male and 1/5 female animals, myeloid hyperplasia in the bone marrow of the sternum in 1/5 male and 2/5 female animals, and extramedullary hematopoiesis in the spleen of 1/5 female animal.

Pathological findings in the group treated at 50 mg/kg bw/day included granulomatous inflammation in the mesenteric lymph nodes in 3/5 male and 4/5 female animals and granuloma in the liver of all male animals.

Remarks – Results
No test substance-related adverse changes with regard to food/water consumption, body weight, functional observational battery and motor activity.

CONCLUSION
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 noted at each of the doses tested.

TEST FACILITY BASF (2016)

B.7. Genotoxicity – Bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test
Plate incorporation procedure (Test 1)/Pre incubation procedure (Test 2)

Species/Strain *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100
Escherichia coli: WP2uvrA

Metabolic Activation System S9 mix from phenobarbital/β-naphthoflavone induced rat liver

Concentration Range in Main Test
Test 1
a) With metabolic activation: 3-5000 µg/plate
b) Without metabolic activation: 3-5000 µg/plate
Test 2
a) With metabolic activation: 33 – 5000 µg/plate
b) Without metabolic activation: 33 – 5000 µg/plate

Vehicle Ethanol

Remarks – Method The dose selection for Test 2 was based on the toxicity observed in a preliminary test (reported as Test 1) carried out at 3 – 5000 µg/mL.

Positive controls:
With metabolic activation: 2-aminoanthracene
Without metabolic activation: methyl methane sulfonate (WP2 *uvrA*); sodium azide (TA1535, TA100); 4-nitro-o-phenylene-diamine (TA1537, TA98)

RESULTS

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

Present				
Test 1	> 5000	> 5000	≥ 5000	negative
Test 2		> 5000	> 5000	negative

Remarks – Results: 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 *In vitro* 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.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
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
Present			
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

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

^ 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	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. The positive and negative controls gave a satisfactory response confirming the validity of the test system.
CONCLUSION	The notified chemical was not clastogenic to Chinese hamster V79 cells treated *in vitro* under the conditions of the test.
TEST FACILITY	Harlan (2015b)

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 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

Test Substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
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 (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/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

Nominal Loading (mg/L WAF)	*Number of Fish*	*Mortality 96 h*
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 ≥ 8.2 mg/L at 23°C (≥ 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 D. magna*	*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 ≥ 8.7 mg/L at 20°C (≥ 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

Biomass		*Growth*	
EyL50 (mg/L at 72 h)	*NOEyL (mg/L)*	*ErL50 (mg/L at 72 h)*	*NOErL (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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