

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 **Revision Number** 1

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

MM3602.00 Product Code(s)

**Product Name** Ketoprofen Lysinate

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

**EC No** 643-003-8

**CAS No** 57469-78-0

Pure substance/mixture Substance

C16H14O3 C6H14N2O2 **Formula** 

400.47 Molecular weight

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

#### **Supplier**

LGC Limited Queens Road Teddington Middlesex TW11 0LY UNITED KINGDOM :+44 (0) 20 8943 7000 Fax:+44(0)2089432767

eMail: gb@lgcstandards.com

Web: www.lgcstandards.com

For further information, please contact

E-mail address sds-request@lgcgroup.com

1.4. Emergency telephone number

EGHS / EN Page 1/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

### MM3602.00 - Ketoprofen Lysinate

Emergency Telephone For Hazardous Materials or Dangerous Goods Incident

Spill, Leak, Fire Exposure, or Accident

Call CHEMTREC:

USA & Canada 1-800-424-9300 Rest of the world +1 703-741-5970

Emergency Telephone - §45 - (EC)	1272/2008			
Europe	112			
Austria	No information available			
Bulgaria				
Croatia				
Cyprus				
Czech Republic				
Denmark				
France				
Hungary				
Ireland				
Italy				
Lithuania				
Luxembourg	(+352) 8002 5500 Free telephone number with a 24/7 access in French, Dutch and English.			
Netherlands				
Norway				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden				
Switzerland				

## **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 3 - (H301)
Skin corrosion/irritation	Category 2 - (H315)
Reproductive toxicity	Category 1B - (H360)
Specific target organ toxicity — repeated exposure	Category 1 - (H372)

#### 2.2. Label elements

Contains Ketoprofen Lysinate

EGHS / EN Page 2/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

### MM3602.00 - Ketoprofen Lysinate



#### Signal word Danger

#### **Hazard statements**

H301 - Toxic if swallowed

H315 - Causes skin irritation

H360 - May damage fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

#### Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P308 + P313 - IF exposed or concerned: Get medical advice/attention

#### 2.3. Other hazards

No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very	,
	High Concern (SVHC) for Authorisation	Substances
Ketoprofen Lysinate	-	-

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Ketoprofen Lysinate 57469-78-0	100	-	643-003-8	Acute Tox. 3 (H301) Skin Irrit. 2 (H315)			

EGHS / EN Page 3/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

#### MM3602.00 - Ketoprofen Lysinate

	F S1	Repr. 1B (H360) FOT RE 1 (H372)		

#### Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

**General advice** Show this safety data sheet to the doctor in attendance.

**Inhalation** Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a doctor.

**Skin contact** Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

attention if irritation develops and persists.

**Ingestion** Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. Get medical attention.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors Treat symptomatically.

### SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

EGHS / EN Page 4/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

MM3602.00 - Ketoprofen Lysinate

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

### **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate

personnel to safe areas. Avoid contact with skin, eyes or clothing.

**Other information** Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

### SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove

EGHS / EN Page 5/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

MM3602.00 - Ketoprofen Lysinate

contaminated clothing and shoes. Ensure adequate ventilation. Take off contaminated clothing and wash it before reuse.

clothing and wash it before red

General hygiene considerations Wash hands before breaks and immediately after handling the product. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands

before breaks and after work. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children. Store locked up. Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless

other advice is given on the CoA.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

#### SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific

regulatory bodies

Derived No Effect Level (DNEL)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

8.2. Exposure controls

Personal protective equipment

**Eye/face protection** Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves. Impervious gloves. The protective gloves to be used must comply

with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear

EGHS / EN Page 6/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

### MM3602.00 - Ketoprofen Lysinate

protective nitrile rubber gloves.

Skin and body protection Long sleeved clothing. Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

Wash hands before breaks and immediately after handling the product. Avoid contact with General hygiene considerations

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands

before breaks and after work. Wear suitable gloves and eye/face protection.

**Environmental exposure controls** Do not allow into any sewer, on the ground or into any body of water.

## **SECTION 9: Physical and chemical properties**

9.1. Information on basic physical and chemical properties

**Physical state** Solid **Appearance** Solid Colour white

Odour No information available. **Odour threshold** No information available

Remarks • Method Property Values

Melting point / freezing point 159 °C None known Initial boiling point and boiling No data available None known

range

**Flammability** No data available None known None known

Flammability Limit in Air

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

**Bulk density** 

Flash point No data available None known No data available **Autoignition temperature** None known **Decomposition temperature** None known

pН No data available None known

pH (as aqueous solution) No data available No information available

Kinematic viscosity No data available None known Dynamic viscosity No data available None known Water solubility No data available None known No data available Solubility(ies) None known No data available Partition coefficient None known Vapour pressure No data available None known No data available Relative density None known

No data available

EGHS / EN Page 7 / 15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

None known

MM3602.00 - Ketoprofen Lysinate

Liquid Density

Relative vapour density

No data available

No data available

Particle characteristics

Particle Size No information available
Particle Size Distribution No information available

9.2. Other information

Molecular weight 400.47

Molecular formula C16H14O3 C6H14N2O2

9.2.1. Information with regards to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

## SECTION 10: Stability and reactivity

10.1. Reactivity

**Reactivity** No information available.

10.2. Chemical stability

**Stability** Stable under normal conditions.

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

**Incompatible materials** Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

# SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

EGHS / EN Page 8/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

MM3602.00 - Ketoprofen Lysinate

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#### Information on likely routes of exposure

#### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

**Skin contact** Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

**Ingestion** Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhoea. Toxic if swallowed. (based on

components).

#### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity

No information available

**Acute toxicity** 

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation**Classification based on data available for ingredients. Causes skin irritation.

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitisation** No information available.

Germ cell mutagenicity No information available.

**Carcinogenicity** No information available.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

EGHS / EN Page 9/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

MM3602.00 - Ketoprofen Lysinate

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for ingredients. May damage fertility or the unborn child.

**STOT - single exposure** No information available.

**STOT - repeated exposure**Causes damage to organs through prolonged or repeated exposure.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

EGHS / EN Page 10/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Number 1 Revision date 09-Jun-2022

MM3602.00 - Ketoprofen Lysinate

12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

12.7. Other adverse effects

No information available.

## **SECTION 13: Disposal considerations**

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

### **SECTION 14: Transport information**

IATA

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Ketoprofen Lysinate)

14.3 Transport hazard class(es) 14.4 Packing group Ш

Description UN2811, Toxic solid, organic, n.o.s. (Ketoprofen Lysinate), 6.1, III

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

**Special Provisions** A3, A5

**ERG Code** 

IMDG

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Ketoprofen Lysinate)

14.3 Transport hazard class(es) 6.1 14.4 Packing group

Description UN2811, Toxic solid, organic, n.o.s. (Ketoprofen Lysinate), 6.1, III

14.5 Marine pollutant NΡ

14.6 Special precautions for user

**Special Provisions** 223, 274

EmS-No F-A, S-A No information available

14.7 Maritime transport in bulk according to IMO instruments

No information available

RID

EGHS / EN Page 11/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

#### MM3602.00 - Ketoprofen Lysinate

14.1 UN number or ID number UN2811

**14.2 UN proper shipping name** Toxic solid, organic, n.o.s. (Ketoprofen Lysinate)

**14.3 Transport hazard class(es)** 6.1 **14.4 Packing group** III

Description UN2811, Toxic solid, organic, n.o.s. (Ketoprofen Lysinate), 6.1, III

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions 274, 614 Classification code T2

ADR

14.1 UN number or ID number UN2811

**14.2 UN proper shipping name** Toxic solid, organic, n.o.s. (Ketoprofen Lysinate)

14.3 Transport hazard class(es) 6.1
14.4 Packing group

Description UN2811, Toxic solid, organic, n.o.s. (Ketoprofen Lysinate), 6.1, III, (E)

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions 274, 614
Classification code T2
Tunnel restriction code (E)

### **SECTION 15: Regulatory information**

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water hazard class (WGK) slightly hazardous to water (WGK 1)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended, Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor

EGHS / EN Page 12/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

### MM3602.00 - Ketoprofen Lysinate

and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

#### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors Not applicable

### **Persistent Organic Pollutants**

Not applicable

#### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

#### **International Inventories**

**TSCA** Contact supplier for inventory compliance status **DSL/NDSL** Contact supplier for inventory compliance status Contact supplier for inventory compliance status **EINECS/ELINCS** Contact supplier for inventory compliance status **ENCS** Contact supplier for inventory compliance status **IECSC KECL** Contact supplier for inventory compliance status **PICCS** Contact supplier for inventory compliance status Contact supplier for inventory compliance status AIIC

Legend:

EGHS / EN Page 13/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022 Revision Number 1

#### MM3602.00 - Ketoprofen Lysinate

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

#### 15.2. Chemical safety assessment

**Chemical Safety Report** 

A Chemical Safety Assessment has been carried out for this substance

### **SECTION 16: Other information**

#### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

H301 - Toxic if swallowed

H315 - Causes skin irritation

H360 - May damage fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value \* Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method

EGHS / EN Page 14/15



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Jun-2022

Revision Number 1

#### MM3602.00 - Ketoprofen Lysinate

Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date

09-Jun-2022

# This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

**End of Safety Data Sheet** 

EGHS / EN Page 15/15