

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

Revision date 19-Feb-2024 Revision Number 1.01

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

1.1. Product identifier

Product Code(s) MM0079.00-0250

Product Name Nortriptyline Hydrochloride

Form Not applicable

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 (EU Index No) 212-973-0

**CAS No.** 894-71-3

Pure substance/mixture Substance

Formula C19H21N·HCI

Molecular weight 299.84

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) 20 8943 2767 eMail : gb@lgcstandards.com

Web: www.lgcstandards.com

For further information, please contact

E-mail address sds-request@lgcgroup.com

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### 1.4. Emergency telephone number

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			
Netherlands			
Norway			
Portugal			
Romania			
Slovakia			
Slovenia			
Spain			
Sweden			
Switzerland			

## **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Classification according to

Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity - Oral Category 4 - (H302)

## 2.2. Label elements

Contains Nortriptyline hydrochloride

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# Warning

#### **Hazard statements**

H302 - Harmful if swallowed

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

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents/ container to an approved waste disposal plant

#### 2.3. Other hazards

No information available.

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

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

	2 do 1 do 2 do 11 de 1 de 11 d	0.00 0.1.00 0.11.0 0.10.
Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine
	- Candidate List of Substances of Very	Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	Substances
Nortriptyline hydrochloride	-	-

## SECTION 3: Composition/information on ingredients

#### 3.1 Substances

	Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor
			number	Index No)	to Regulation (EC) No.	concentration		(long-term)
					1272/2008 [CLP]	limit (SCL)		
Γ	Nortriptyline	100	-	212-973-0	Acute Tox. 4 (H302)			
	hydrochloride							
L	894-71-3							

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

#### **Acute Toxicity Estimate**

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Nortriptyline hydrochloride 894-71-3	405	No data available	No data available	No data available	No data 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.

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

Consult a doctor.

**Skin contact**Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

doctor.

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

person. Call a doctor.

#### 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.

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### SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

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

**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.

6.2. Environmental precautions

**Environmental precautions**See Section 12 for additional Ecological Information.

#### 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.

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## **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

**General hygiene considerations** 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 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. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children.

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

No information available. No information available.

(PNEC)

8.2. Exposure controls

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Personal protective equipment

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

**Hand protection** The protective gloves to be used must comply with the specifications of EC Directive

89/686/EEC and the related standard EN374.

Gloves				
Duration of contact	PPE - Glove material	Glove thickness	Break through time	
	Wear protective nitrile	0.11 mm	480 minutes	
	rubber gloves			

**Skin and body protection** 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.

**General hygiene considerations** 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.

**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

Colourwhite to off-whiteOdourNo information available.Odour thresholdNo information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing point > 215 °C None known Initial boiling point and boiling rangeNo data available None known Flammability No data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash pointNo data availableNone knownAutoignition temperatureNo data availableNone known

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 Decomposition temperature
 No data available
 None known

 No data available
 None known

PH (as aqueous solution)

No data available

No information available

None known

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

Bulk density
No data available
Liquid Density
No data available

Relative vapour density No data available None known

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

9.2. Other information

Molecular weight 299.84 Molecular formula C19H21N·HCl

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

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Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

**Incompatible materials**None known based on information supplied.

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

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.

Ingestion Specific test data for the substance or mixture is not available. Harmful if swallowed. (based

on components).

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

Numerical measures of toxicity

**Acute toxicity** 

#### **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Nortriptyline hydrochloride	= 405 mg/kg (Rat)		

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

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**Skin corrosion/irritation**Based on available data, the classification criteria are not met.

**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 No information available.

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

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

**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.

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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 This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This

substance is not considered to be very persistent nor very bioaccumulating (vPvB). The

product contains substance(s) classified as PBT or vPvB.

Chemical name	PBT and vPvB assessment
Nortriptyline hydrochloride	The substance is not PBT / vPvB

#### 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**

### <u>IATA</u>

14.1 UN number or ID number Not regulated

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14.2	UN proper shipping name	Not regulated
14.3	Transport hazard class(es)	Not regulated
14.4	Packing group	Not regulated
14.5	Environmental hazards	Not applicable

14.6 Special precautions for user

Special Provisions None

**IMDG** 

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Marine pollutantNot applicable

14.6 Special precautions for user

according to IMO instruments

Special Provisions
None No information available
No information available

RID

14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

<u>ADR</u>

14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

## SECTION 15: Regulatory information

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

National regulations

Germany

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

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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 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

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

Not applicable

**International Inventories** 

TSCA Complies under research and development exemption or is regulated by a different

government agency.

DSL/NDSL
Contact supplier for inventory compliance status

Legend:

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 is not required 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

H302 - Harmful if swallowed

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

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Legend Section 8: Exposure controls/personal protection

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

Ceiling Maximum limit value Sk\* 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		
Reproductive toxicity	Calculation method		
STOT - single exposure	Calculation method		
STOT - repeated exposure	Calculation method		
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

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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

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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** 

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