

1-phenylethan-1-amine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : 1-phenylethan-1-amine hydrochloride
Product code : 202100377
Synonyms : Levetiracetam impurity E CRS

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

1.2.1. Relevant identified uses

No additional information available

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe 7, Allée Kastner, CS30026
F- 67081 Strasbourg
France
T +33(0)388412035 - F +33(0)388412771
sds@edqm.eu - www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

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
Acute toxicity (dermal), Category 4	H312
Skin corrosion/irritation, Category 1	H314

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)



GHS05

GHS07

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302+H312 - Harmful if swallowed or in contact with skin.
H314 - Causes severe skin burns and eye damage.

Precautionary statements (CLP)

: P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

1-phenylethan-1-amine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

P302+P352 - IF ON SKIN: Wash with plenty of water.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor.
P312 - Call a POISON CENTRE or doctor if you feel unwell.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P330 - Rinse mouth.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP)



GHS05

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
1-phenylethan-1-amine hydrochloride	-	100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) Skin Corr. 1, H314

Full text of H- and EUH-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

No additional information available

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

No additional information available

1-phenylethan-1-amine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

No additional information available

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

1-phenylethan-1-amine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

1-phenylethan-1-amine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Harmful in contact with skin.
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Causes severe skin burns.
Serious eye damage/irritation	: Assumed to cause serious eye damage
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified
Not rapidly degradable	

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

1-phenylethan-1-amine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878




SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 1759	UN 1759	UN 1759	Not applicable	Not applicable
14.2. UN proper shipping name				
CORROSIVE SOLID, N.O.S.	CORROSIVE SOLID, N.O.S.	Corrosive solid, n.o.s.	Not applicable	Not applicable
Transport document description				
UN 1759 CORROSIVE SOLID, N.O.S., 8, III, (E)	UN 1759 CORROSIVE SOLID, N.O.S., 8, III	UN 1759 Corrosive solid, n.o.s., 8, III	Not applicable	Not applicable
14.3. Transport hazard class(es)				
8	8	8	Not applicable	Not applicable
			Not applicable	Not applicable
14.4. Packing group				
III	III	III	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

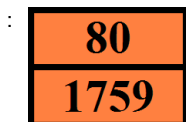
Classification code (ADR)	: C10
Special provisions (ADR)	: 274
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, L4BN
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Bulk (ADR)	: VC1, VC2, AP7
Hazard identification number (Kemler No.)	: 80

1-phenylethan-1-amine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Orange plates



Tunnel restriction code (ADR)

: E

Transport by sea

Special provisions (IMDG)	: 223, 274
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: P002, LP02
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: T1
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-B
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: Causes burns to skin, eyes and mucous membranes.

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y845
PCA limited quantity max net quantity (IATA)	: 5kg
PCA packing instructions (IATA)	: 860
PCA max net quantity (IATA)	: 25kg
CAO packing instructions (IATA)	: 864
CAO max net quantity (IATA)	: 100kg
Special provisions (IATA)	: A3, A803
ERG code (IATA)	: 8L

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

1-phenylethan-1-amine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

Classification of the substance or mixture.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
Skin Corr. 1	Skin corrosion/irritation, Category 1

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.