

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: VENLAFAXINE HYDROCHLORIDE
Chemical name	: 1-[2-dimethylamino-1-(4-methoxyphenyl)ethyl]cyclohexan-1-ol Hydrochloride
IUPAC name	: 1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexan-1-ol;hydrochloride
CAS-No.	: 99300-78-4
Product code	: 79020
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C17H28ClNO2
Synonyms	: (+-)-1-(alpha-((Dimethylamino)methyl)-p-methoxybenzyl)ciclohexanol hydrochloride;Venlafaxine Hydrochloride
Product group	: API
Other means of identification	: SMILE: COC1=CC=C(C=C1)C(CN(C)C)C1(O)CCCC1 (Free Venlafaxine base)

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: API,Industrial use,Medicinal use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use For professional use only
Use of the substance/mixture	: Chemical Intermediate
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Head office**

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1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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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 (inhalation:dust,mist) Category 4	H332
Serious eye damage/eye irritation, Category 2	H319
Full text of H- and EUH-statements: see section 16	

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Adverse physicochemical, human health and environmental effects

Harmful if inhaled. Harmful if swallowed.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302+H332 - Harmful if swallowed or if inhaled.

H319 - Causes serious eye irritation.

Precautionary statements (CLP)

: P261 - Avoid breathing vapours, mist, dust, fume, gas, spray.

P264 - Wash hands, forearms and face thoroughly after handling.

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

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective clothing, eye protection, face protection.

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

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.

P312 - Call a POISON CENTER, a doctor if you feel unwell.

P330 - Rinse mouth.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions.

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
VENLAFAXINE HYDROCHLORIDE	CAS-No.: 99300-78-4	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

: Never give anything by mouth to an unconscious person.

First-aid measures after inhalation

: Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact

: Wash skin with plenty of water. Take off contaminated clothing.

First-aid measures after eye contact

: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion

: Rinse mouth. Call a POISON CENTER/doctor if you feel unwell.

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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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Foam. Dry powder. Carbon dioxide. Sand. Do not use a solid water stream as it may scatter and spread fire.
- Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire. Apply water spray or fog to cool nearby equipment.

5.2. Special hazards arising from the substance or mixture

- Explosion hazard : Avoid raising powdered material due to explosion hazard.
- Hazardous decomposition products in case of fire : Do not breathe gas/fumes. Carbon monoxide. Nitrogen oxides. Carbon dioxide.

5.3. Advice for firefighters

- Precautionary measures fire : Keep away from combustible materials. Minimize generation of dust which may be combustible.
- Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Emergency procedures : Ventilate confined spaces before entering.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Collect spillage.
- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust.

6.4. Reference to other sections

Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store at room temperature. Keep only in the original container in a cool, well ventilated place away from : Direct sunlight, Heat sources. Keep container closed when not in use.
- Incompatible products : Strong acids. Strong bases. Oxidizing agent.
- Incompatible materials : Sources of ignition. Direct sunlight. Oxidizing agents.

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Storage area : Store in a well-ventilated place. Store away from heat.
Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use.

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

Control banding : MOEHS occupational exposure band: 1 (> 1 mg/m3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Breathing equipment. Ensure good ventilation of the work station. Dust extraction (suction). Local exhaust or breathing protection.

8.2.2. Personal protection equipment

Personal protective equipment:

Safety glasses. Gloves.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection		
Type	Field of application	Standard
Safety glasses	Dust	EN 166

8.2.2.2. Skin protection

Skin and body protection	
Type	Standard
Disposable gowns, Reusable gowns, Tyvek® Gown/Coveralls	EN 13034, EN 1149-1

Hand protection

Type	Material	Standard
Disposable gloves	Nitrile rubber (NBR), Butyl rubber, Natural rubber, Latex, Polyvinylchloride (PVC), Neoprene rubber (HNBR), Fluoroelastomer (FKM)	EN 374-2

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Other skin protection Materials for protective clothing		
Condition	Material	Standard
Good resistance:	Synthetic material, Polyethylene, Tyvek®	EN 13034, EN ISO 13982-1

8.2.2.3. Respiratory protection

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	High dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Molecular mass	: 313.8 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 215 – 217 °C [SciFinder, accessed October 2020]
Freezing point	: Not available
Boiling point	: 397.6 [(ACD/Labs) Software V11.02]; Venlafaxine
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	: Soluble in ethanol. Water: 572 mg/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 0.3
Vapour pressure	: < 0.0000001 kPa (25oC) (US Pharmacopoeia, 2013)
Vapour pressure at 50°C	: Not available
Density	: 1.060 ± 0.06 g/cm (20°C, 760 Torr) [(ACD/Labs) Software V11.02] ; Venlafaxine
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

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9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy : < 1 mJ
Additional information : Layer Minimum flammability Temperature : Melt.
Dust Cloud minimum Flammability Temperature : 380 °C.
Explosion Class : st3.
Explosivity Pmax : 8.
Explosion Severity Factor Kmax (bar.m/s) : 324

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Extremely high or low temperatures. Direct sunlight.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Carbon dioxide. Toxic gases. Carbon monoxide. Nitrogen oxides. fume.

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) : Not classified
Acute toxicity (inhalation) : Harmful if inhaled.

VENLAFAXINE HYDROCHLORIDE (99300-78-4)	
LD50 oral rat	673 mg/kg (US Pharmacopoeia, 2013)
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified

VENLAFAXINE HYDROCHLORIDE (99300-78-4)	
NOAEL (animal/male, F0/P)	(2 years): 35 mg/kg/day on rats [Venlafaxine]
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

: The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

11.2.2. Other information

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

VENLAFAXINE HYDROCHLORIDE (99300-78-4)

LC50 - Fish [1]	≥ 100 mg/kg trucha arcoiris
EC50 - Crustacea [1]	38 mg/l
EC50 96h - Algae [1]	4.8 mg/l

12.2. Persistence and degradability

VENLAFAXINE HYDROCHLORIDE (99300-78-4)

Persistence and degradability : Not established.

12.3. Bioaccumulative potential

VENLAFAXINE HYDROCHLORIDE (99300-78-4)

Partition coefficient n-octanol/water (Log Pow)	0.3
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

VENLAFAXINE HYDROCHLORIDE (99300-78-4)

vPvB: not relevant – no registration required

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties

: The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information

: Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods

: Dispose of contents/container in accordance with licensed collector's sorting instructions.

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Sewage disposal recommendations : Disposal must be done according to official regulations.

SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not applicable

IMDG
Transport hazard class(es) (IMDG) : Not applicable

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN
Transport hazard class(es) (ADN) : Not applicable

RID
Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

Overland transport
Not applicable

Transport by sea
Not applicable

Air transport
Not applicable

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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 listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

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

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen –

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Switzerland

Storage class (LK) : LK 11/13 - Solids

15.2. Chemical safety assessment

No additional information available

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SECTION 16: Other information

Full text of H- and EUH-statements:	
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.