

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

- **1.1 Product identifier**
- **Trade name:** Sertraline Hydrochloride
- **Article number:** 103474
- **CAS Number:**  
79559-97-0
- **EC number:**  
616-702-0
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
FAGRON a.s.  
Holická 1098/31m  
779 00 Olomouc  
Česká republika
- **Further information obtainable from:**  
Tel.: +420 585 222 590  
info@fagron.cz
- **1.4 Emergency telephone number:**  
Toxikologické informační středisko,  
Na Bojišti 1,  
128 08 Praha 2  
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),  
e-mail:tis.cuni@cesnet.cz

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Acute Tox. 4      H302 Harmful if swallowed.  
STOT RE 2      H373 May cause damage to organs through prolonged or repeated exposure.  
Aquatic Acute 1      H400 Very toxic to aquatic life.  
Aquatic Chronic 1      H410 Very toxic to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07   GHS08   GHS09

- **Signal word** Warning

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· **Hazard statements**

H302 Harmful if swallowed.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.  
P264 Wash thoroughly after handling.  
P273 Avoid release to the environment.  
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.  
P330 Rinse mouth.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

· **3.1 Substances**

· **CAS No. Description**

CAS: 79559-97-0 Sertraline Hydrochloride

· **Identification number(s)**

· **EC number:** 616-702-0

## SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:**

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Call a doctor immediately.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

Call for a doctor immediately.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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## SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
Use fire extinguishing methods suitable to surrounding conditions.  
Carbon dioxide  
Fire-extinguishing powder  
Water spray
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
In case of fire, the following can be released:  
Carbon monoxide (CO)  
Nitrogen oxides (NO<sub>x</sub>)  
Hydrogen chloride (HCl)
- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

## SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Dispose of the material collected according to regulations.  
Dispose contaminated material as waste according to section 13.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Prevent formation of dust.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:**  
Dust can combine with air to form an explosive mixture.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store receptacle in a well ventilated area.

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- **7.3 Specific end use(s)** No further relevant information available.

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## SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Store protective clothing separately.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection**



Tightly sealed goggles

- **Body protection:** Protective work clothing

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** Whitish
- **Odour:** Odourless

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|  |                           |
|--|---------------------------|
| · Odour threshold:   | Not determined.           |
| · Melting point/freezing point:                            | 243–245°C                 |
| · Boiling point or initial boiling point and boiling range | Undetermined.             |
| · Flammability   | Product is not flammable. |
| · Lower and upper explosion limit                          |                           |
| · Lower:   | Not determined.           |
| · Upper:   | Not determined.           |
| · Flash point:   | Not applicable.           |
| · Decomposition temperature:                               | Not determined.           |
| · pH   | 4–7                       |
| · Viscosity:   |                           |
| · Kinematic viscosity                                      | Not applicable.           |
| · Dynamic:   | Not applicable.           |
| · Solubility   |                           |
| · water:   | Not determined.           |
| · Partition coefficient n-octanol/water (log value)        | Not determined.           |
| · Vapour pressure:   | Not applicable.           |
| · Density and/or relative density                          |                           |
| · Density:   | Not determined.           |
| · Relative density   | Not determined.           |
| · Vapour density   | Not applicable.           |
| · Particle characteristics                                 |                           |
| See section 3.   |                           |

|   |   |
|---|---|
| · 9.2 Other information   |   |
| · Appearance:   |   |
| · Form:   | Crystalline powder                            |
| · Important information on protection of health and environment, and on safety. |   |
| · Ignition temperature:   | Not determined.                               |
| · Explosive properties:   | Product does not present an explosion hazard. |
| · Molecular weight  | 342,69 g/mol                                  |
| · Change in condition   |   |
| · Evaporation rate  | Not applicable.                               |

|  |      |
|--|------|
| · Information with regard to physical hazard classes |      |
| · Explosives   | Void |
| · Flammable gases                                    | Void |
| · Aerosols   | Void |
| · Oxidising gases                                    | Void |
| · Gases under pressure                               | Void |
| · Flammable liquids                                  | Void |
| · Flammable solids                                   | Void |
| · Self-reactive substances and mixtures              | Void |
| · Pyrophoric liquids                                 | Void |
| · Pyrophoric solids                                  | Void |

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|   |      |
|---|------|
| · Self-heating substances and mixtures                                      | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids   | Void |
| · Oxidising solids  | Void |
| · Organic peroxides   | Void |
| · Corrosive to metals   | Void |
| · Desensitised explosives   | Void |

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**  
Risk of dust explosion if enriched with fine dust in the presence of air.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**  
Poisonous gases/vapours  
Carbon monoxide and carbon dioxide  
Nitrogen oxides (NO<sub>x</sub>)  
Hydrogen chloride (HCl)  
Chlorine compounds

## SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Harmful if swallowed.

### LD/LC50 values relevant for classification:

|      |      |                   |
|------|------|-------------------|
| Oral | LD50 | >2000 mg/kg (rat) |
|------|------|-------------------|

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Aquatic toxicity:

LC50 (96h) | 0,03 mg/l (fish)

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

#### 12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

#### 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

#### 12.7 Other adverse effects

Remark: Very toxic for fish

#### Additional ecological information:

##### General notes:

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

#### European waste catalogue

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

HP6 Acute Toxicity

HP14 Ecotoxic

#### Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

## SECTION 14: Transport information

### 14.1 UN number or ID number

#### ADR, IMDG, IATA

UN3077

### 14.2 UN proper shipping name

#### ADR, IMDG

ENVIRONMENTALLY HAZARDOUS SUBSTANCE,  
SOLID, N.O.S. (Sertraline Hydrochloride)

#### IATA


Environmentally hazardous substance, solid, n.o.s.  
(Sertraline Hydrochloride)

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|   |   |
|---|---|
| <ul style="list-style-type: none"> <li>· 14.3 Transport hazard class(es)</li> <li>· ADR, IMDG, IATA</li> </ul>  |    |
| <ul style="list-style-type: none"> <li>· Class</li> <li>· Label</li> </ul>  | 9 Miscellaneous dangerous substances and articles.<br>9   |
| <ul style="list-style-type: none"> <li>· 14.4 Packing group</li> <li>· ADR, IMDG, IATA</li> </ul>   | III   |
| <ul style="list-style-type: none"> <li>· 14.5 Environmental hazards:</li> <li>· Marine pollutant:</li> <li>· Special marking (ADR):</li> <li>· Special marking (IATA):</li> </ul>                                       | Symbol (fish and tree)<br>Symbol (fish and tree)<br>Symbol (fish and tree)  |
| <ul style="list-style-type: none"> <li>· 14.6 Special precautions for user</li> <li>· Hazard identification number (Kemler code):</li> <li>· EmS Number:</li> <li>· Stowage Category</li> <li>· Stowage Code</li> </ul> | Warning: Miscellaneous dangerous substances and articles.<br>90<br>F-A,S-F<br>A<br>SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9. |
| <ul style="list-style-type: none"> <li>· 14.7 Maritime transport in bulk according to IMO instruments</li> </ul>  | Not applicable.   |
| <ul style="list-style-type: none"> <li>· Transport/Additional information:</li> </ul>   |   |
| <ul style="list-style-type: none"> <li>· ADR</li> <li>· Limited quantities (LQ)</li> <li>· Excepted quantities (EQ)</li> <li>· Transport category</li> <li>· Tunnel restriction code</li> </ul>                         | 5 kg<br>Code: E1<br>Maximum net quantity per inner packaging: 30 g<br>Maximum net quantity per outer packaging: 1000 g<br>3<br>(-)                        |
| <ul style="list-style-type: none"> <li>· IMDG</li> <li>· Limited quantities (LQ)</li> <li>· Excepted quantities (EQ)</li> </ul>   | 5 kg<br>Code: E1<br>Maximum net quantity per inner packaging: 30 g<br>Maximum net quantity per outer packaging: 1000 g                                    |
| <ul style="list-style-type: none"> <li>· UN "Model Regulation":</li> </ul>  | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (SERTRALINE HYDROCHLORIDE), 9, III   |

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## SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Directive 2012/18/EU**
  - **Named dangerous substances - ANNEX I** Substance is not listed.
  - **Seveso category E1** Hazardous to the Aquatic Environment
  - **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
  - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
  - **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**  
Substance is not listed.
  - **REGULATION (EU) 2019/1148**
  - **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**  
Substance is not listed.
  - **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
  - **Regulation (EC) No 273/2004 on drug precursors** Substance is not listed.
  - **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**  
Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Fagron Česká republika
- **Contact:** msds@fagron.cz
- **Abbreviations and acronyms:**
  - ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - IATA: International Air Transport Association
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Acute Tox. 4: Acute toxicity – Category 4
  - STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
  - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
  - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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