

## 1 Identification

- **Product identifier**
- **Trade name:** Sertraline Hydrochloride
- **Article number:** 103474
- **CAS Number:**  
79559-97-0
- **EC number:**  
616-702-0
- **Application of the substance / the mixture** Pharma Active ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Inc  
2400 Pilot Knob Road  
St. Paul, MN 55120  
www.fagron.us  
QA@fagron.us
- **Information department:**  
Tel.: 800-423-6967  
Fax: 800-339-1596
- **Emergency telephone number:**  
Emergency Telephone:  
US: 1-800-535-5053  
International: 1-352-323-3500

## 2 Hazard(s) identification

- **Classification of the substance or mixture**  
Acute Toxicity - Oral 4 H302 Harmful if swallowed.  
Specific Target Organ Toxicity - Repeated Exposure H373 May cause damage to organs through  
2 prolonged or repeated exposure.

- **Label elements**
- **GHS label elements**  
The substance is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning
- **Hazard statements**  
Harmful if swallowed.  
May cause damage to organs through prolonged or repeated exposure.
- **Precautionary statements**  
Do not breathe dust/fume/gas/mist/vapors/spray.  
Wash thoroughly after handling.  
Do not eat, drink or smoke when using this product.  
If swallowed: Call a poison center/doctor if you feel unwell.  
Rinse mouth.

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Get medical advice/attention if you feel unwell.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 1  
Fire = 0  
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1  
Fire = 0  
Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

## 3 Composition/information on ingredients

· **Chemical characterization: Substances**

· **CAS No. Description**

CAS: 79559-97-0 Sertraline Hydrochloride

· **Identification number(s)**

· **EC number:** 616-702-0

## 4 First-aid measures

· **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.

Immediately call a doctor.

· **Information for doctor:**

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

No further relevant information available.

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

No further relevant information available.

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## 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Use fire fighting measures that suit the environment.  
Carbon dioxide  
Fire-extinguishing powder  
Water spray
- **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 (NOx)  
Hydrogen chloride (HCl)
- **Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Wear protective equipment. Keep unprotected persons away.
- **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.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Dispose of the collected material according to regulations.  
Dispose contaminated material as waste according to section 13.
- **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.
- **Protective Action Criteria for Chemicals**
- **PAC-1:** Substance is not listed.
- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Prevent formation of dust.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:**  
Dust can combine with air to form an explosive mixture.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.

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- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:**
  - Keep receptacle tightly sealed.
  - Store receptacle in a well ventilated area.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **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.
- **Breathing equipment:**
  - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



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 protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

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## 9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Crystalline powder
Color:	Whitish
· Odor:	Odorless
· Odor threshold:	Not determined.
· pH-value:	4–7
· Change in condition	
Melting point/Melting range:	243–245°C (469.4–473°F)
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Product is not flammable.
· Decomposition temperature:	Not determined.
· Ignition temperature:	Not determined.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
Water:	Not determined.
· Partition coefficient (n-octanol/water): Not determined.	
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Other information	No further relevant information available.

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **Possibility of hazardous reactions**  
Risk of dust explosion if enriched with fine dust in the presence of air.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.

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- **Hazardous decomposition products:**  
Poisonous gases/vapors  
Carbon monoxide and carbon dioxide  
Nitrogen oxides (NO<sub>x</sub>)  
Hydrogen chloride (HCl)  
Chlorine compounds

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

Oral	LD50	>2000 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** Substance is not listed.
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

## 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

LC50 (96h)	0.03 mg/l (fish)
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- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological 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 (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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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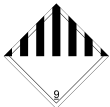
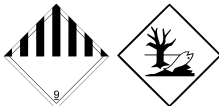
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## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

<ul style="list-style-type: none"> <li>• UN-Number</li> <li>• DOT, IMDG, IATA</li> </ul>	UN3077
<ul style="list-style-type: none"> <li>• UN proper shipping name</li> <li>• DOT, IATA</li> <li>• IMDG</li> </ul>	Environmentally hazardous substance, solid, n.o.s. (Sertraline Hydrochloride) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sertraline Hydrochloride)
<ul style="list-style-type: none"> <li>• Transport hazard class(es)</li> <li>• DOT</li> </ul> 	
<ul style="list-style-type: none"> <li>• Class</li> <li>• Label</li> </ul>	9 Miscellaneous dangerous substances and articles 9
<ul style="list-style-type: none"> <li>• IMDG, IATA</li> </ul> 	
<ul style="list-style-type: none"> <li>• Class</li> <li>• Label</li> </ul>	9 Miscellaneous dangerous substances and articles 9
<ul style="list-style-type: none"> <li>• Packing group</li> <li>• DOT, IMDG, IATA</li> </ul>	III
<ul style="list-style-type: none"> <li>• Environmental hazards:</li> <li>• Marine pollutant:</li> <li>• Special marking (IATA):</li> </ul>	Symbol (fish and tree) Symbol (fish and tree)
<ul style="list-style-type: none"> <li>• Special precautions for user</li> <li>• Hazard identification number (Kemler code):</li> <li>• EMS Number:</li> <li>• Stowage Category</li> </ul>	Warning: Miscellaneous dangerous substances and articles 90 F-A,S-F A

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· <b>Stowage Code</b>	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>DOT</b>	
· <b>Quantity limitations</b>	On passenger aircraft/rail: 400 kg On cargo aircraft only: 400 kg
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· <b>UN "Model Regulation":</b>	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (SERTRALINE HYDROCHLORIDE), 9, III

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **Sara**
- **Section 355 (extremely hazardous substances):** Substance is not listed.
- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
- **TSCA (Toxic Substances Control Act):** Substance is not listed.
- **Hazardous Air Pollutants** Substance is not listed.
- **Proposition 65**
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
- **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value)** Substance is not listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 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 US  
Quality Assurance
- **Contact:** QA@fagron.us
- **Date of preparation / last revision** 01/19/2024

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· **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  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
EINECS: European Inventory of Existing Commercial Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
NIOSH: National Institute for Occupational Safety  
OSHA: Occupational Safety & Health  
TLV: Threshold Limit Value  
PEL: Permissible Exposure Limit  
REL: Recommended Exposure Limit  
Acute Toxicity - Oral 4: Acute toxicity – Category 4  
Specific Target Organ Toxicity - Repeated Exposure 2: Specific target organ toxicity (repeated exposure) – Category 2

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