

1 Identification

- **Product identifier**
- **Trade name:** Sertraline Hydrochloride
- **Article number:** 103474
- **CAS Number:**
79559-97-0
- **EC number:**
616-702-0
- **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
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Services B.V.
Molenwerk 13, UITGEEEST, 1911DB
Netherlands
Phone: +31251361400

- Supplier
Azelis Australia
Suite 217
117 Old Pittwater Road
Brookvale
NSW 2100
Australia
Phone: +61 0299392188
Fax: +61 0299392799
e-mail: info@azelis.com.au
- **Further information obtainable from:** info@fagron.com.au
- **Emergency telephone number:**
In case of emergency, please call your local poisons:
Emergency Australia: 13 11 26
Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only)

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Acute Tox. 4 H302 Harmful if swallowed.
STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

- **Label elements**
- **GHS label elements**
The substance is classified and labelled according to the Globally Harmonised System (GHS).

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· **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/vapours/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.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Substances**
- **CAS No. Description**
CAS: 79559-97-0 Sertraline Hydrochloride
- **Identification number(s)**
- **EC number:** 616-702-0

4 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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:**
Use fire extinguishing methods suitable to surrounding conditions.
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 (NO_x)
Hydrogen chloride (HCl)
- **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 material collected 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.

7 Handling and Storage

- **Handling:**
- **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.
- **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.

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- Store receptacle in a well ventilated area.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **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.
- **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

9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Crystalline powder
- **Colour:** Whitish
- **Odour:** Odourless
- **Odour threshold:** Not determined.

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· pH-value:	4–7
· Change in condition	
· Melting point/freezing point:	243–245°C
· Initial boiling point and boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Product is not flammable.
· Decomposition temperature:	Not determined.
· Ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
· Lower:	Not determined.
· Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour 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.
- **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.
- **Hazardous decomposition products:**
Poisonous gases/vapours
Carbon monoxide and carbon dioxide
Nitrogen oxides (NO_x)
Hydrogen chloride (HCl)
Chlorine compounds

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

Oral	LD50	>2000 mg/kg (rat)
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- **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.

12 Ecological Information

- **Toxicity**

- **Aquatic toxicity:**

LC50 (96h) 0.03 mg/l (fish)

- **Persistence and degradability** No further relevant information available.
- **Behaviour 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 (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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

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

14 Transport information

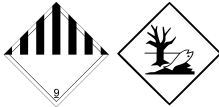
- | | |
|--------------------------|--------|
| · UN-Number | UN3077 |
| · ADG, IMDG, IATA | |

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<ul style="list-style-type: none"> · UN proper shipping name · ADG, IMDG · IATA 	<p>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sertraline Hydrochloride) Environmentally hazardous substance, solid, n.o.s. (Sertraline Hydrochloride)</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · ADG, IMDG, IATA 	
<ul style="list-style-type: none"> · Class · Label 	<p>9 Miscellaneous dangerous substances and articles. 9</p>
<ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA 	<p>III</p>
<ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: · Special marking (ADG): · Special marking (IATA): 	<p>Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree)</p>
<ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · EmS Number: · Stowage Category · Stowage Code 	<p>Warning: Miscellaneous dangerous substances and articles. 90 F-A,S-F A SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.</p>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: 	
<ul style="list-style-type: none"> · ADG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g</p>
<ul style="list-style-type: none"> · Transport category · Tunnel restriction code 	<p>3 (-)</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g</p>

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- **UN "Model Regulation":** 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**
- **Australian Inventory of Industrial Chemicals** Substance is not listed.
- **Standard for the Uniform Scheduling of Medicines and Poisons** Substance is not listed.
- **Australia: Priority Existing Chemicals** Substance is not listed.
- **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
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
Therapeutic goods are listed on the Australian Register of Therapeutic Goods (ARTG)
- **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:** Product Safety Department

- **Contact:**

- **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

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

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