

SERTRALINE HYDROCHLORIDE

ChemWatch Review SDS

Chemwatch: 59370-4
Version No: 7.1
Safety Data Sheet

Chemwatch Hazard Alert Code: 2

Initial Date: 17/06/2001
Revision Date: 08/07/2023
Print Date: 21/07/2025
S.GHS.IND.EN

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

Product Identifier

Product name	SERTRALINE HYDROCHLORIDE
Chemical Name	Not Available
Synonyms	C17-H17-Cl2-N.HCl; 1-napthalenamine, 4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-, hydrochloride, (1S-cis); (1S-cis)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-naphthaleneamine hydrochloride; (1S,4S)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-naphthylamine hydrochloride; CP-51974-1 Lustral Zolof; antidepressant
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains sertraline hydrochloride)
Chemical formula	C17H17Cl2N.CIH
Other means of identification	Not Available
CAS number	79559-97-0

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

Relevant identified uses	<p>An antidepressant used in the treatment of depression. Inhibits uptake of serotonin selectively. CAUTION: May modify behaviour and state of alertness; exposed individuals taking charge of vehicles or machinery should be warned of the hazards. Therapeutic or pharmacologically-active agent.</p> <p>A sigma receptor ligand, modulator, agonist, antagonist.</p> <p>Sigma receptors are protein cell surface receptors that bind ligands such as 4-PPBP (4-phenyl-1-(4-phenylbutyl) piperidine), SA 4503 (cutamesine), ditolylguanidine, dimethyltryptamine and siramesine. There are two subtypes, sigma-1 receptors and sigma-2 receptors, which are classified as sigma receptors for their pharmacological similarities, even though they are evolutionarily unrelated.</p>
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Details of the manufacturer or importer of the safety data sheet

Registered company name	ChemWatch
Address	Australia
Telephone	Not Available
Fax	Not Available
Website	Not Available
Email	Not Available

Emergency telephone number

Association / Organisation	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone number(s)	+918000403230 (ID#: 59370-4)
Other emergency telephone number(s)	+61 3 9573 3188

SECTION 2 Hazards identification

Classification of the substance or mixture



Chemwatch Hazard Ratings

	Min	Max
Flammability	1	1
Toxicity	1	1
Body Contact	1	1
Reactivity	1	1
Chronic	2	2

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Classification	Acute Toxicity (Oral) Category 5, Acute Toxicity (Dermal) Category 5, Skin Corrosion/Irritation Category 3, Reproductive Toxicity Category 2, Hazardous to the Aquatic Environment Long-Term Hazard Category 1
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Label elements

Hazard pictogram(s)	 
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Signal word	Warning
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Hazard statement(s)	
H303	May be harmful if swallowed.
H313	May be harmful in contact with skin.
H316	Causes mild skin irritation.
H361	Suspected of damaging fertility or the unborn child.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statement(s) Prevention	
P280	Wear protective gloves and protective clothing.
P273	Avoid release to the environment.
P202	Do not handle until all safety precautions have been read and understood.

Precautionary statement(s) Response	
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.
P302+P312	IF ON SKIN: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.
P308+P313	IF exposed or concerned: Get medical advice/ attention.
P332+P313	If skin irritation occurs: Get medical advice/attention.

Precautionary statement(s) Storage	
P405	Store locked up.

Precautionary statement(s) Disposal	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3 Composition / information on ingredients

Substances		
CAS No	%[weight]	Name
79559-97-0	>98	sertraline hydrochloride

Mixtures
See section above for composition of Substances

SECTION 4 First aid measures

Description of first aid measures	
Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none">▶ Wash out immediately with fresh running water.▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.▶ Seek medical attention without delay; if pain persists or recurs seek medical attention.▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none">▶ Immediately remove all contaminated clothing, including footwear.▶ Flush skin and hair with running water (and soap if available).▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none">▶ If dust is inhaled, remove from contaminated area.▶ Encourage patient to blow nose to ensure clear passage of breathing.▶ If irritation or discomfort persists seek medical attention.
Ingestion	<ul style="list-style-type: none">▶ If swallowed do NOT induce vomiting.▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.▶ Observe the patient carefully.▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.▶ Seek medical advice.

Indication of any immediate medical attention and special treatment needed

For sertraline: Establish and maintain an airway; insure adequate oxygenation and ventilation. Activated charcoal, which may be used with sorbitol, may be more effective than emesis or lavage. Cardiac and vital signs monitoring is recommended along with general symptomatic and supportive measures. There is no specific antidote. Due to the large volume of distribution of the drug, forced diuresis, dialysis, haemoperfusion, and exchange transfusion are unlikely to be of benefit. In managing overdose, consider the possibility of multiple drug involvement.

Treat symptomatically.

For selective serotonin reuptake inhibitors (SSRIs):

Serotonin toxicity is more pronounced following supra-therapeutic doses and overdoses, and they merge in a continuum with the toxic effects of overdose. The serotonergic toxicity of SSRIs increases with dose, but even in over-dose it is insufficient to cause fatalities from serotonin syndrome in healthy adults. The syndrome occurs in approximately 14 to 16 percent of persons who overdose on SSRIs.

It is usually only when drugs with different mechanisms of action are mixed together that elevations of central nervous system serotonin reach potentially fatal levels.

The symptoms are often described as a clinical triad of abnormalities:

- **Cognitive effects:** mental confusion, hypomania, hallucinations, agitation, headache, coma.
- **Autonomic effects:** shivering, sweating, fever, hypertension, tachycardia, nausea, diarrhea.
- **Somatic effects:** myoclonus/clonus (muscle twitching), hyperreflexia, tremor.

Symptom onset is usually rapid, often occurring within minutes after self-poisoning or a change in medication. Serotonin syndrome encompasses a wide range of clinical findings. Mild symptoms may only consist of tachycardia, shivering, diaphoresis (sweating), mydriasis (dilated pupils), myoclonus (intermittent tremor or twitching), as well as

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overactive or over-responsive reflexes. Moderate intoxication includes additional abnormalities such as hyperactive bowel sounds, hypertension and hyperthermia; a temperature as high as 40 C (104 F) is common in moderate intoxication. The overactive reflexes and clonus in moderate cases may be greater in the lower limbs than in the upper limbs. Mental status changes include hyper-vigilance and agitation. Severe symptoms include severe hypertension and tachycardia that may lead to shock. Severe cases often have agitated delirium as well as muscular rigidity and high muscular tension. Temperature may rise to above 41.1 C (106.0 F) in life-threatening cases. Other abnormalities include metabolic acidosis, rhabdomyolysis, seizures, renal failure, and disseminated intravascular coagulation, these effects usually arise as a consequence of hyperthermia.

SSRIs appear to be safer in overdose when compared with traditional antidepressants such as the tricyclic antidepressants. This relative safety is supported both by case series and studies of deaths per numbers of prescriptions. However, case reports of SSRI poisoning have indicated that severe toxicity can occur and deaths have been reported following massive single ingestions, although this is exceedingly uncommon when compared to the tricyclic antidepressants.

Because of the wide therapeutic index of the SSRIs, most patients will have mild or no symptoms following moderate overdoses. The most commonly reported severe effect following SSRI overdose is serotonin syndrome; serotonin toxicity is usually associated with very high overdoses or multiple drug ingestion. Other reported significant effects include coma, seizures, and cardiac toxicity.

Treatment for SSRI overdose is mainly based on symptomatic and supportive care. Medical care may be required for agitation, maintenance of the airways, and treatment for serotonin syndrome. ECG monitoring is usually indicated to detect any cardiac abnormalities.

Supportive care includes:

- the control of agitation,
- the administration of serotonin antagonists (cyproheptadine or methysergide),
- the control of autonomic instability, and the control of hyperthermia.

The intensity of therapy depends on the severity of symptoms.

If the symptoms are mild, treatment may only consist of:

- discontinuation of the offending medication or medications,
- offering supportive measures,
- giving benzodiazepines for myoclonus, and waiting for the symptoms to resolve.

Moderate cases should have:

- all thermal and cardiorespiratory abnormalities corrected and
- can benefit from serotonin antagonists such as cyproheptadine.

Critically ill patients should receive the above therapies as well as:

- sedation, neuromuscular paralysis, and
- intubation with artificial ventilation.

Upon initiation of therapy and the discontinuation of serotonergic drugs most cases of serotonin syndrome resolve within 24 hours. although delirium may persist for a number of days. Cases have reported muscle pain and weakness persisting for months although antidepressant withdrawal may contribute to ongoing features. Following appropriate medical management, serotonin syndrome is generally associated with a favorable prognosis.

Many SSRIs are also monoamine oxidase inhibitors (MAOIs):

Special care should be taken with any drug therapy in view of the many hazards of monoamine oxidase inhibitor interactions. In particular metaraminol and other sympathomimetic agents are not suitable for the treatment of hypotension, which should be managed with intravenous fluids and, in severe shock, intravenous hydrocortisone.

SECTION 5 Firefighting measures

Extinguishing media

- ▶ Water spray or fog.
- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).

Special hazards arising from the substrate or mixture

Fire Incompatibility

- ▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use water delivered as a fine spray to control fire and cool adjacent area.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. ▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). ▶ Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion. <p>Combustion products include: carbon monoxide (CO) carbon dioxide (CO2) hydrogen chloride phosgene nitrogen oxides (NOx) other pyrolysis products typical of burning organic material.</p>

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	Environmental hazard - contain spillage. <ul style="list-style-type: none"> ▶ Clean up waste regularly and abnormal spills immediately. ▶ Avoid breathing dust and contact with skin and eyes. ▶ Wear protective clothing, gloves, safety glasses and dust respirator. ▶ Use dry clean up procedures and avoid generating dust.
Major Spills	Environmental hazard - contain spillage. Moderate hazard. <ul style="list-style-type: none"> ▶ CAUTION: Advise personnel in area.

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- ▶ Alert Emergency Services and tell them location and nature of hazard.
- ▶ Control personal contact by wearing protective clothing.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	<ul style="list-style-type: none">▶ Avoid all personal contact, including inhalation.▶ Wear protective clothing when risk of exposure occurs.▶ Use in a well-ventilated area.▶ Prevent concentration in hollows and sumps.▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.▶ Establish good housekeeping practices.▶ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
Other information	<ul style="list-style-type: none">▶ Store in original containers.▶ Keep containers securely sealed.▶ Store in a cool, dry area protected from environmental extremes.▶ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none">▶ Glass container is suitable for laboratory quantities▶ Polyethylene or polypropylene container.▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none">▶ Avoid reaction with oxidising agents

SECTION 8 Exposure controls / personal protection

Control parameters


Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Ingredient	Original IDLH	Revised IDLH
sertraline hydrochloride	Not Available	Not Available

Exposure controls

Appropriate engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.
Individual protection measures, such as personal protective equipment	
Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: <ul style="list-style-type: none">▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.
Skin protection	See Hand protection below
Hands/feet protection	The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care. <ul style="list-style-type: none">▶ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.▶ Double gloving should be considered.▶ PVC gloves. Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present. <ul style="list-style-type: none">▶ polychloroprene.▶ nitrile rubber.▶ butyl rubber.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none">▶ For quantities up to 500 grams a laboratory coat may be suitable.▶ For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.▶ For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

Respiratory protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1	-	PAPR-P1

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	Air-line*	-	-
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

Class P2 particulate filters are used for protection against mechanically and thermally generated particulates or both.

P2 is a respiratory filter rating under various international standards, Filters at least 94% of airborne particles

Suitable for:

- Relatively small particles generated by mechanical processes eg. grinding, cutting, sanding, drilling, sawing.
- Sub-micron thermally generated particles e.g. welding fumes, fertilizer and bushfire smoke.
- Biologically active airborne particles under specified infection control applications e.g. viruses, bacteria, COVID-19, SARS

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	White powder; does not mix with water.		
Physical state	Divided Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Applicable	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	243-245	Viscosity (cSt)	Not Applicable
Initial boiling point and boiling range (°C)	Not Applicable	Molecular weight (g/mol)	342.69
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Applicable	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Negligible
Vapour pressure (kPa)	Negligible	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Applicable	VOC g/L	Not Applicable
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

a) Acute Toxicity	There is sufficient evidence to classify this material as acutely toxic.
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b) Skin Irritation/Corrosion	There is sufficient evidence to classify this material as skin corrosive or irritating.
c) Serious Eye Damage/Irritation	Based on available data, the classification criteria are not met.
d) Respiratory or Skin sensitisation	Based on available data, the classification criteria are not met.
e) Mutagenicity	Based on available data, the classification criteria are not met.
f) Carcinogenicity	Based on available data, the classification criteria are not met.
g) Reproductivity	There is sufficient evidence to classify this material as toxic to reproductivity
h) STOT - Single Exposure	Based on available data, the classification criteria are not met.
i) STOT - Repeated Exposure	Based on available data, the classification criteria are not met.
j) Aspiration Hazard	Based on available data, the classification criteria are not met.

Inhaled	<p>The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.</p> <p>Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.</p> <p>If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.</p>
Ingestion	<p>Treatment-associated side-effects of sertraline include: Autonomic nervous system disorders: impotence, flushing, increased saliva, cold clammy skin, mydriasis, pallor, glaucoma, priapism, vasodilation; Body as a whole - general disorders: allergy; Cardiovascular disorders: palpitations, chest pains, hypertension, tachycardia, postural dizziness, postural hypotension, periorbital oedema, peripheral oedema, hypotension, peripheral ischaemia, syncope, oedema, dependent oedema, precordial chest pain, substernal chest pain, aggravated hypertension, myocardial infarction, cerebrovascular disorder; Central and peripheral nervous system disorders: hypertonia, hypoesthesia, twitching, confusion, hyperkinesia, vertigo, ataxia, migraine, abnormal coordination, hyperesthesia, leg cramps, abnormal gait, nystagmus, hypokinesia, dysphonia, coma, dyskinesia, hypotonia, ptosis, choreoathetosis, hyporeflexia; Disorders of the skin and appendages: pruritus, acne, urticaria, alopecia, dry skin, erythematous rash, photosensitivity reaction, maculopapular rash, follicular rash, eczema, dermatitis, contact dermatitis, bullous eruptions, hypertrichosis, skin discolouration, pustular rash; Endocrine disorders: exophthalmos, gynaecomastia; Gastrointestinal disorders: increased appetite, dysphagia, aggravated tooth caries, eructation, oesophagitis, gastroenteritis, melena, glossitis, gum hyperplasia, hiccup, stomatitis, tenesmus, colitis, diverticulitis, faecal incontinence, gastritis, rectum haemorrhage, haemorrhagic peptic ulcer, proctitis, ulcerative stomatitis, tongue oedema, tongue ulceration; General disorders: back pain, asthenia, malaise, weight increase, fever, rigors, generalised oedema, facial oedema, aphthous stomatitis; Hearing and vestibular disorders: hyperacusis, labyrinth disorder; Haemopoietic and lymphatic disorders: anaemia, anterior chamber eye haemorrhage; Liver and biliary system disorders: abnormal hepatic function; Metabolic and nutritional disorders: thirst, hypoglycaemia; Musculoskeletal disorders: myalgia, arthralgia, dystonia, arthrosis, muscle cramps, muscle weakness; Psychiatric disorders: yawning, sexual dysfunction, depression, amnesia, paroniria, teeth-grinding, emotional lability, apathy, abnormal dreams, euphoria, paranoid reaction, hallucination, aggressive reaction, aggravated depression, delusions, withdrawal syndrome, suicide ideation, libido increased, somnambulism, illusion; Reproductive disorders: menstrual disorder, dysmenorrhea, intermenstrual bleeding, vaginal haemorrhage, amenorrhoea, leukorrhea, female breast pain, menorrhagia, balanoposthitis, breast enlargement, atrophic vaginitis, female mastitis; Respiratory system disorders: rhinitis, coughing, dyspnea, upper respiratory tract infection, epistaxis, bronchospasm, sinusitis, hyperventilation, bradypnea, stridor, apnea, bronchitis, haemoptysis, hypoventilation,, laryngismus, laryngitis; Special senses disorders: tinnitus, conjunctivitis, earache, eye pain, abnormal accommodation, xerophthamia, photophobia, diplopia, abnormal lachrymation, scotoma, visual field defect; Urinary system disorders: micturition frequency, polyuria, urinary retention, dysuria, nocturia, urinary incontinence, cystitis, oliguria, pyelonephritis, haematuria, renal pain, strangury. Symptoms of overdose include somnolence, nausea, vomiting, tachycardia, ECG changes, anxiety and dilated pupils. Accidental ingestion of the material may be damaging to the health of the individual.</p> <p>Treatment with selective serotonin reuptake inhibitors (SSRIs) can cause serotonin syndrome, a serious condition affecting the brain, muscles and digestive system. Signs and symptoms of serotonin syndrome include restlessness, fast heart rate, rapid changes in blood pressure, diarrhoea, nausea and vomiting, hallucinations, fever, coma, loss of co-ordination and overactive reflexes.</p> <p>General side effects usually occur in the first month of treatment while the body adapts to the drug (with the exception of sexual side effects, which occur later). The efficacy of SSRIs does not usually peak until 6-8 weeks after commencement of treatment.</p>
Skin Contact	<p>Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.</p> <p>There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.</p> <p>This material is a photosensitiser. Certain individuals working with this substance may show allergic reaction of the skin under sunlight.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
Eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.
Chronic	<p>Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.</p> <p>Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung.</p>

SERTRALINE HYDROCHLORIDE	TOXICITY	IRRITATION
	Not Available	Not Available

Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances
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SERTRALINE HYDROCHLORIDE	<p>Headache, changes in teeth and supporting structures, sweating, excitement, hallucinations, nausea, vomiting, convulsions, changes in liver weight, mydriasis, muscle weakness, maternal effects recorded. Sertraline shares the common side effects and contraindications of other SSRIs, with high rates of diarrhea, nausea, insomnia, and sexual dysfunction, but it appears not to lead to much weight gain, and its effects on cognitive performance are mild. Similar to other antidepressants, the use of sertraline for depression may be associated with a mildly elevated rate of suicidal thoughts in people under the age of 25 years old. It should not be used together with MAO inhibitor medication: this combination may cause serotonin syndrome, which can be life-threatening in some cases. Sertraline taken during pregnancy is associated with an increase in congenital heart defects in newborns</p> <p>No significant acute toxicological data identified in literature search.</p> <p>Neonates exposed to dual reuptake inhibitors of serotonin and norepinephrine, or selective serotonin reuptake inhibitors late in the third trimester have developed complications that can arise immediately upon delivery and require prolonged hospitalisation, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Monitor neonates for reported clinical findings such as respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of these classes of drugs or, possibly, a drug discontinuation syndrome.</p>
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The substance binds to sigma receptors on nerve endings

Physiologic effects when the sigma receptor is activated include hypertonia, tachycardia, tachypnea, antitussive effects, and mydriasis. Some sigma receptor activators (agonists) - such as cocaine, a weak sigma agonist- -exert convulsant effects in animals. Behavioral reactions to sigma agonists are rather heterogeneous: some individuals find sigma receptor agonists euphoric with significant anti-depressive effects. Other individuals, however, experience dysphoria and often report feelings of malaise or anxiety.

Selective sigma-receptor agonists have been shown to produce antidepressant effects in mice

Activation of sigma receptors may induce hallucinogenic effects and also may be responsible for the paradoxical convulsions sometimes seen in opiate overdose.

Cytochrome P450 enzymes are essential for the metabolism of many medications. Although this class has more than 50 enzymes, six of them metabolize 90 percent of drugs, with the two most significant enzymes being CYP3A4 and CYP2D6. Genetic variability (polymorphism) in these enzymes may influence a patient's response to commonly prescribed drug classes, including beta blockers and antidepressants. Cytochrome P450 enzymes can be inhibited or induced by drugs, resulting in clinically significant drug-drug interactions that can cause unanticipated adverse reactions or therapeutic failures.

Acute Toxicity	✓	Carcinogenicity	✗
Skin Irritation/Corrosion	✓	Reproductivity	✓
Serious Eye Damage/Irritation	✗	STOT - Single Exposure	✗
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

Legend: ✗ – Data either not available or does not fill the criteria for classification
✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

SERTRALINE HYDROCHLORIDE	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	0.118-0.135mg/L	4
	EC20(ECx)	336h	Crustacea	<0.001mg/L	4
Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data					

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

For Selective Serotonin Reuptake Inhibitors (SSRIs): Selective serotonin reuptake inhibitors (SSRIs) are a major class of widely prescribed antidepressants and obsessive-compulsive regulators that includes Prozac, Zoloft, Luvox, and Paxil. Serotonin is found in both vertebrate and invertebrate nervous systems. Additionally, serotonin is involved in a wide array of physiologic regulatory roles in molluscs, among most other creatures.

Ecotoxicity: The function of serotonin in a wide array of aquatic creatures could prove highly significant in any discussion of the importance of low levels of pharmaceuticals in the environment.

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

Bioaccumulative potential

Ingredient	Bioaccumulation
sertraline hydrochloride	LOW (LogKOW = 2.18)

Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients



SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	<p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none">▶ Reduction▶ Reuse▶ Recycling▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.</p> <ul style="list-style-type: none">▶ DO NOT allow wash water from cleaning or process equipment to enter drains.▶ It may be necessary to collect all wash water for treatment before disposal.▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.▶ Where in doubt contact the responsible authority.
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SECTION 14 Transport information

Labels Required

	
Marine Pollutant	

Land transport (UN)

14.1. UN number or ID number	3077	
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains sertraline hydrochloride)	
14.3. Transport hazard class(es)	Class	9
	Subsidiary Hazard	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Special provisions	274; 331; 335; 375
	Limited quantity	5 kg

Air transport (ICAO-IATA / DGR)

14.1. UN number	3077	
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (contains sertraline hydrochloride)	
14.3. Transport hazard class(es)	ICAO/IATA Class	9
	ICAO / IATA Subsidiary Hazard	Not Applicable
	ERG Code	9L
14.4. Packing group	III	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Special provisions	A97 A158 A179 A197 A215
	Cargo Only Packing Instructions	956
	Cargo Only Maximum Qty / Pack	400 kg
	Passenger and Cargo Packing Instructions	956
	Passenger and Cargo Maximum Qty / Pack	400 kg
	Passenger and Cargo Limited Quantity Packing Instructions	Y956
	Passenger and Cargo Limited Maximum Qty / Pack	30 kg G

Sea transport (IMDG-Code / GGVSee)

14.1. UN number	3077	
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains sertraline hydrochloride)	
14.3. Transport hazard class(es)	IMDG Class	9
	IMDG Subsidiary Hazard	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Marine Pollutant	
14.6. Special precautions for user	EMS Number	F-A , S-F
	Special provisions	274 335 966 967 969
	Limited Quantities	5 kg

14.7. Maritime transport in bulk according to IMO instruments

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code
Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
sertraline hydrochloride	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
sertraline hydrochloride	Not Available

SECTION 15 Regulatory information

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

sertraline hydrochloride is found on the following regulatory lists
Not Applicable

Additional Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIC / Australia Non-Industrial Use	No (sertraline hydrochloride)
Canada - DSL	No (sertraline hydrochloride)
Canada - NDSL	No (sertraline hydrochloride)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	No (sertraline hydrochloride)
Japan - ENCS	No (sertraline hydrochloride)
Korea - KECI	No (sertraline hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (sertraline hydrochloride)
USA - TSCA	No (sertraline hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	No (sertraline hydrochloride)
Vietnam - NCI	Yes
Russia - FBEPH	No (sertraline hydrochloride)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	08/07/2023
Initial Date	17/06/2001

SDS Version Summary

Version	Date of Update	Sections Updated
6.1	15/03/2021	Toxicological information - Chronic Health, Hazards identification - Classification, Disposal considerations - Disposal, Exposure controls / personal protection - Exposure Standard, Exposure controls / personal protection - Personal Protection (hands/feet), Toxicological information - Toxicity and Irritation (Other), Identification of the substance / mixture and of the company / undertaking - Use
7.1	08/07/2023	Toxicological information - Acute Health (swallowed), First Aid measures - Advice to Doctor, CAS Number, Toxicological information - Chronic Health, Hazards identification - Classification, Firefighting measures - Fire Fighter (extinguishing media), Toxicological information - Toxicity and Irritation (Other), Identification of the substance / mixture and of the company / undertaking - Use

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

- PC - TWA: Permissible Concentration-Time Weighted Average
- PC - STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit,
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level

SERTRALINE HYDROCHLORIDE

- PNEC: Predicted no-effect concentration
- MARPOL: International Convention for the Prevention of Pollution from Ships
- IMSBC: International Maritime Solid Bulk Cargoes Code
- IGC: International Gas Carrier Code
- IBC: International Bulk Chemical Code

- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- NDSSL: Non-Domestic Substances List
- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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