



# SAFETY DATA SHEET

Revision date: 09-Mar-2015

Version: 6.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Sertraline hydrochloride film coated tablets

**Trade Name:** ZOLOFT; ALTRULINE; GLADEM; TATIQ; XYDEP; SERLAIN; INIVON; DAXID; LUSTRAL;  
ENORE; BESITRAN; SERTRALIN; TRESLEEN

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as antidepressant

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4  
Specific target organ systemic toxicity (repeated exposure): Category 2  
Acute aquatic toxicity: Category 1  
Chronic aquatic toxicity: Category 1

#### EU Classification:

EU Indication of danger: Harmful  
Dangerous for the Environment

#### EU Risk Phrases:

R22 - Harmful if swallowed.  
R50 - Very toxic to aquatic organisms.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H302 - Harmful if swallowed  
H373 - May cause damage to organs through prolonged or repeated exposure  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects

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**Precautionary Statements:**

- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P314 - Get medical attention/advice if you feel unwell
- P330 - Rinse mouth
- P273 - Avoid release to the environment
- P391 - Collect spillage
- P501 - Dispose of contents/container in accordance with all local and national regulations



**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
 Hazardous Substance. Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sertraline hydrochloride	79559-97-0	Not Listed	N;R50 Xn;R22	Acute Tox.4 (H302) STOT RE.2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	37
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	Not Listed	*
Dibasic calcium phosphate, dihydrate USP	7789-77-7	Not Listed	Not Listed	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	Not Listed	*

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**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

**Fire / Explosion Hazards:** Not determined

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Sertraline hydrochloride  
Pfizer OEL TWA-8 Hr:

500µg/m<sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)

10 mg/m<sup>3</sup>

Lithuania OEL - TWA

5 mg/m<sup>3</sup>

Sweden OEL - TWAs

5 mg/m<sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)

10 mg/m<sup>3</sup>

Australia TWA

10 mg/m<sup>3</sup>

Belgium OEL - TWA

10 mg/m<sup>3</sup>

Estonia OEL - TWA

10 mg/m<sup>3</sup>

France OEL - TWA

10 mg/m<sup>3</sup>

Ireland OEL - TWAs

10 mg/m<sup>3</sup>

Latvia OEL - TWA

4 mg/m<sup>3</sup>

Latvia OEL - TWA

2 mg/m<sup>3</sup>

OSHA - Final PELs - TWAs:

15 mg/m<sup>3</sup>

Portugal OEL - TWA

10 mg/m<sup>3</sup>

Romania OEL - TWA

10 mg/m<sup>3</sup>

Russia OEL - TWA

6 mg/m<sup>3</sup>

Spain OEL - TWA

10 mg/m<sup>3</sup>

Switzerland OEL - TWAs

3 mg/m<sup>3</sup>

Vietnam OEL - TWAs

10 mg/m<sup>3</sup>

5 mg/m<sup>3</sup>

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

#### Analytical Method:

Analytical method available for Sertraline HCl. Contact Pfizer Inc for further information.

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
<b>Eyes:</b>	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
<b>Respiratory protection:</b>	Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablet	<b>Color:</b>	Light green, Light blue, or Light yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

#### Hydroxypropyl cellulose

No data available

#### Microcrystalline cellulose

No data available

#### Sodium starch glycolate

No data available

#### Magnesium stearate

No data available

#### Sertraline hydrochloride

Predicted 7.0 Log D 2.39

#### Dibasic calcium phosphate, dihydrate USP

No data available

<b>Decomposition Temperature (°C):</b>	No data available.
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<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

**Polymerization:** Will not occur

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Partition Coefficient (n-octanol/water - Log P): 2.9 (pH 7) (Sertraline HCl)

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on : liver.  
**Known Clinical Effects:** Ingestion of this material may cause effects similar to those seen in clinical use including suicidal behavior, nausea, diarrhea, insomnia, and headache. Signs and symptoms associated with non-fatal overdosage were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### Sertraline hydrochloride

Mouse Oral LD50 419 - 548 mg/kg  
Rat Oral LD50 1327 - 1591mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Sertraline hydrochloride

3 Month(s) Rat Oral 80 mg/kg/day LOAEL Liver  
3 Month(s) Dog Oral 80 mg/kg/day LOAEL Liver  
1 Year(s) Dog Oral 30 mg/kg/day LOAEL Central Nervous System  
2 Year(s) Rat Oral 40 mg/kg/day LOAEL Liver

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### 11. TOXICOLOGICAL INFORMATION

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Sertraline hydrochloride**

Peri-/Postnatal Development	Rat	Oral	20 mg/kg/day	LOAEL	Early embryonic development, Developmental toxicity
Reproductive & Fertility	Rat	Oral	80 mg/kg/day	LOAEL	Fertility
Reproductive & Fertility	Rat	Oral	10 mg/kg/day	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rabbit	Oral	40 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	80 mg/kg/day	NOAEL	Not Teratogenic

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Sertraline hydrochloride**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
Bone Marrow Metaphase Analysis	Mouse	Negative
<i>In Vitro</i> Cytogenetics	Mouse Bone Marrow	Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Sertraline hydrochloride**

2 Year(s)	Rat	Oral	40 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral	40 mg/kg/day	LOAEL	Benign tumors, Liver, Lungs

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

#### **Environmental Overview:**

The environmental characteristics of this mixture have not been fully evaluated. In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.

#### **Toxicity:**

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### **Sertraline hydrochloride**

<i>Daphnia magna</i> (Water Flea)	EC50	1.25 Hours	2.14 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	TAD LC50	96 Hours	0.30 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	NPDES EC50	96 Hours	0.03 mg/L
<i>Skeletonema costatum</i> (Marine Diatom)	NPDES EC50	96 Hours	0.03 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	TAD NOEC	12 Days	0.033 mg/L

**Persistence and Degradability:** No data available

#### **Bio-accumulative Potential:**

##### **Sertraline hydrochloride**

Predicted 7.0 Log D 2.39

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Mobility in Soil: No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

**UN number:** UN 3077  
**UN proper shipping name:** Environmentally Hazardous Substance, Solid, n.o.s (substituted naphthalenamine, hydrochloride salt)  
**Transport hazard class(es):** 9  
**Packing group:** III  
**Environmental Hazard(s):** Marine Pollutant

**5 kg/5L Exception:**

Effective January 1, 2015, UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:

\* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

\* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

**Sertraline hydrochloride**

**CERCLA/SARA 313 Emission reporting**

Not Listed

**California Proposition 65**

Not Listed

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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed
<b>Hydroxypropyl cellulose</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Dibasic calcium phosphate, dihydrate USP</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Sodium starch glycolate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Magnesium stearate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3
<b>Microcrystalline cellulose</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

N - Dangerous for the environment  
Xn - Harmful

R22 - Harmful if swallowed.  
R50 - Very toxic to aquatic organisms.

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**Data Sources:** Publicly available toxicity information. Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 14 - Transport Information.

**Revision date:** 09-Mar-2015  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**