
Safety Data Sheet

Tamsulosin hydrochloride

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1. Identification of the substance and the company	
<u>1.1 Product identifier</u>	Tamsulosin hydrochloride (TSL.hcl). CAS no.: 106463-17-6 EC / List no.: 629-756-5
<u>1.2.a Uses</u>	TSL.hcl is used as an active ingredient in pharmaceutical formulations, indicated for the treatment of Lower Urinary Tract Symptoms associated with benign prostatic hyperplasia. TSL.hcl blocks alpha1 adrenoreceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra, and bladder neck which can cause smooth muscles in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in symptoms of benign prostatic hyperplasia.
<u>1.2.b Uses advised against</u>	All uses not specified under section 1.2.a.
<u>1.3 Details of SDS supplier</u>	Synthon BV, Microweg 22, 6545 CM, Nijmegen, The Netherlands.
<u>1.4 Emergency Telephone</u>	+31-(0)24-3727700
2. Hazards identification	
<u>2.1 Classification</u>	Acute toxicity, Cat. 4
<u>2.2 Label elements</u>	
<u>2.2.1 Hazard Pictogram(s)</u>	
<u>2.2.2 Signal word(s)</u>	Warning.
<u>2.2.3 Hazard statement(s)</u>	H302: Harmful if swallowed
<u>2.2.4 Precautionary statement(s)</u>	P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P501: Dispose of contents/container to suitable waste streams in accordance with local/regional/national/international regulations.
<u>2.3 Other hazards</u>	See section 9, 11 and 12.
3. Composition/information on ingredients	
<u>3.1 Chemical names</u>	(-)-(R)-5-[2-[[2-(o-Ethoxyphenoxy) ethyl]amino]propyl]-2-methoxybenzenesulfonamide monohydrochloride
<u>3.2 Assay/purity</u>	98-100%
<u>3.3 Molecular formula</u>	C ₂₀ H ₂₈ N ₂ O ₅ S.HCl
<u>3.4 Molecular weight</u>	444.98
<u>3.5 CAS number</u>	106463-17-6
<u>3.6 EC/REACH registration number</u>	EC / List no.: 629-756-5

4. First aid measures	
4.1 Description of first aid measures	
4.1.1 Inhalation	If symptoms are experienced remove source of contamination or move victim to fresh air. Obtain medical advice (show this SDS).
4.1.2 Skin	No health effects expected. If irritation does occur, flush with lukewarm, gently flowing water for 5 minutes. If irritation persists, obtain medical advice. (show this SDS).
4.1.3 Eyes	Do not allow victim to rub eye(s). Let the eye(s) water naturally for a few minutes. Have victim look right and left, then up and down. If particle/dust does not dislodge, flush with lukewarm, gently flowing water for 5 minutes or until particle/dust is removed, while holding eyelid(s) open. If irritation persists, immediately obtain medical attention. DO NOT attempt to manually remove anything stuck to the eye (show this SDS).
4.1.4 Ingestion	If irritation or discomfort occur, obtain medical advice (show this SDS).
4.2 Most important symptoms and effects, both acute and delayed	– <u>Acute</u>: acute hypotension, headache, vomiting and diarrhoea were observed with overdosage of up to 30 times the recommended human dose. – <u>Delayed</u>: most common adverse events were headache, dizziness, rhinitis, infection, abnormal ejaculation, asthenia, back pain, diarrhea, pharyngitis, chest pain, cough increased, somnolence, nausea, sinusitis, insomnia, libido decreased, tooth disorder, and blurred vision. Rarely, fainting can occur. At the first signs of dizziness or weakness you should sit or lie down until they have disappeared. – Consider effects related to the classification of the compound (see section 11).
4.3 Indication of any immediate medical attention and special treatment needed	Medical advice may be required (show this SDS). – Should overdosage lead to hypotensive effects, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, then administration of intravenous fluids should be considered. If necessary, vasopressors should then be used and renal function should be monitored and supported as needed. Dialysis is unlikely to be of benefit. When large quantities are involved, gastric lavage can be applied and activated charcoal and an osmotic laxative, such as sodium sulphate can be administered. – When feeling dizzy or weak (signs of fainting), sit or lie down until they disappear.

5. Fire-fighting measures	
5.1 Extinguishing media	
<i>5.1.1 Suitable extinguishing media</i>	Use water, dry chemical powder (ABC) or appropriate foam.
<i>5.1.2 Unsuitable extinguishing media</i>	None known.
5.2 Special hazards arising from the substance or mixture	When heated to decomposition it emits toxic fumes and flammable vapours.
5.3 Advice for firefighters	Avoid exposure to the compound. Fire fighters should use self-containing breathing apparatus and protective clothing to prevent contact with skin and eyes.
6. Accidental release measures	
6.1 Personal precautions, protective equipment and emergency procedures	
<i>6.1.1. For non-emergency personnel</i>	Take immediate action if necessary and considered safe. Use an (FF)P3 filter (USA: N100 or P100). Wear suitable protective clothing (e.g. made from Tyvek material) and safety goggles. Wear gloves, for dust any glove is suitable, check solvent compatibility of gloves where relevant. For major spills involvement of the fire brigade or other local authorities should be considered.
<i>6.1.2. For emergency responders</i>	See row above and/or section 8.
6.2 Environmental precautions	Keep away from drains, surface- and groundwater, and soil.
6.3 Methods and material for containment and cleaning up	Wear protective clothing. See section 6.1
<i>6.3.1. Containment of spill</i>	Try to moisten the compound without raising dust.
<i>6.3.2. Clean-up</i>	Clean the spill with universal sorbent sheets, towels/tissues, a HEPA-filtered vacuum cleaner etc. Work from the surrounding area towards the location of the actual spill. Dispose the spill into containers labelled as hazardous material if required. Repeat cleaning if required with a proper soap or solvent solution.
6.4 Reference to other sections	Refer to section 8, 11, 12 and 13 for additional information.
7. Handling and storage	
7.1 Precautions for safe handling	Work in an area with general and local ventilation, if possible in a contained area. Prevent aerosol and dust generation.
<i>7.1.1. Protective measures</i>	– Measures to prevent fire: This material is assumed to be combustible. It is advisable to dissipate the potential build-up of static electricity by grounding mechanical equipment in contact with the dry material (as with all dry powders). – Measures to prevent aerosol/dust generation: See section 8.2. – Measures to protect the environment: Keep away from drains, surface- and groundwater, and soil.
<i>7.1.2. Advice on general occupational hygiene</i>	Wear protective clothing (e.g. lab coat) and safety goggles, apply hygienic working habits (e.g. no drinking, eating or smoking at the workplace).

<u>7.2 Conditions for safe storage</u>	– Store at room temperature in the dark, in sealed containers and protected from moisture. – Also see supplementary information, e.g. shipping documentation, CoA or contact Synthon. – Select storage locations and packaging material in line with relevant local chemical storage guidelines where relevant.
<u>7.3 Specific end use(s)</u>	TSL.hcl is used as an active ingredient in pharmaceutical formulations.
8. Exposure controls/personal protection	
<u>8.1 Control parameters</u>	
<u>8.1.1. Exposure limit values</u>	OEL: 0.003 mg/m³ Time Weighted Average for 8 hours (originator OEL, also implemented by Synthon). <i>Note that OELs do not represent a definitive borderline between safe and hazardous conditions; working environments where OELs are temporarily exceeded do not necessarily result in, or are the direct and sole cause of, health impairment in workers, or vice versa.</i> No OELs set by competent authorities available.
<u>8.1.2. Currently recommended monitoring procedures</u>	Please refer to local legislation. Alternatively reference to the ISPE good practice guide, ISBN 978-1-936379-35-4 is advised.
<u>8.1.3. Occupational Exposure Band</u>	Synthon OEB: C (deviation from default based on overall compound properties). OEB context and limitations: A Synthon OEB value is primarily the result of a toxicological hazard driven classification including the OEL value and hazard statements. In general, the following containment strategies are considered possibly suitable for use with the assigned OEB depending on scale, dustiness and task duration: <i>Open handling within isolator or High-integrity closed coupling without external containment.</i> <i>or</i> <i>Local exhaust ventilation +/- personal protective equipment (see below).</i> <i>or</i> <i>Controlled general ventilation supplemented with personal protective equipment (see below).</i> Also see section 8.2.1. Please contact a EHS representative or Synthon for additional information.

8.2 Exposure controls	TSL.hcl can possibly enter the body through inhalation, ingestion and via the skin.
8.2.1 Appropriate engineering controls	Work in an area with general and local ventilation, if possible in a contained area. The use of weighing cabinets or fumehoods is preferred. If open manufacturing systems are used or dust is generated while transferring, weighing or pelletising, enclosed equipment and high integrity closed coupling systems should be applied when available and feasible. Otherwise, flexible local exhaust ventilation should be used. Where necessary, safety measures should be supplemented with respiratory protection equipped with a (FF)P3 filter (USA: N100 or P100). For appropriate handling precautions in specific settings consult with a health and safety representative.
8.2.2. Individual protection measures, such as personal protective equipment	
- Respiratory control	If required: Use a (FF)P3 filter (USA: N100 or P100).
- Hand protection	Wear gloves, for dust any glove is suitable, check liquid compound or solvent compatibility of gloves where relevant.
- Eye protection	Wear safety goggles.
- Skin protection	Wear suitable protective clothing (e.g. lab coat).
- Other	None.
8.3 Environmental exposure controls	Keep away from drains, surface- and groundwater, and soil. Avoid raising dust. Moisten spilled product with water and collect in containers for disposal. Rinse remnant with plenty of water and soap.
9. Physical and chemical properties	
9.1 General information	
Appearance	White or almost white crystalline powder
Odour	No data (publically) available or generated.
Odour threshold	No data (publically) available or generated.
pH	5.20 (7.5 mg/mL)
Melting point	230°C (with decomposition)
Initial boiling point and range	No data (publically) available or generated.
Flash point	No data (publically) available or generated.
Evaporation rate	No data (publically) available or generated.
Flammability (solid/gas)	No data (publically) available or generated.
Upper/lower Flammability or explosive limits	No data (publically) available or generated.
Vapour pressure	No data (publically) available or generated.
Vapour density	No data (publically) available or generated.
Relative density	No data (publically) available or generated.
Solubility(ies)	Sparingly soluble in water and in methanol, slightly soluble in glacial acetic acid and in ethanol, and practically insoluble in ether.
Partition coefficient: n-octanol/water	log P _{ow} = 0.5 (37°C)
Auto-ignition temperature	No data (publically) available or generated.
Decomposition temperature	No data (publically) available or generated.

<i>Viscosity</i>	No data (publically) available or generated.
<i>Explosive properties</i>	No data (publically) available or generated.
<i>Oxidising properties</i>	No data (publically) available or generated.
9.2 Other information	pKa = 8.37 (secondary amine); 10.23 (sulfonamide)
10. Stability and Reactivity	
10.1 Reactivity	Not considered to be a reactive compound.
10.2 Chemical stability	Stable (for 4 years) when stored under the storage conditions given in section 7 of this SDS.
10.3 Possibility of hazardous reactions	No hazardous reactions are expected to occur.
10.4 Conditions to avoid	None known. For general advice see section 7.
10.5 Incompatible materials	None known.
10.6 Hazardous decomposition products	When heated to decomposition it emits toxic fumes and flammable vapors.
11. Toxicological information	
11.1 Acute toxicity	
11.1.1 Inhalation	No data (publically) available or generated.
11.1.2 Oral	Acute toxicity, Cat. 4 Rat LD ₅₀ = 650 mg/kg.
11.1.3 Dermal	No data (publically) available or generated.
11.2 Skin corrosion/irritation	Based on available data the classification criteria are not met. Not irritating to rabbit skin
11.3 Serious eye damage/irritation	No data (publically) available or generated.
11.4 Respiratory sensitisation	No data (publically) available or generated.
11.5 Skin sensitisation	Based on available data the classification criteria are not met. Not sensitizing to guinea pig skin.
11.6 Germ cell mutagenicity	Based on available data the classification criteria are not met. TSL.hcl was not mutagenic <i>in vitro</i> in Ames reverse mutation test, mouse lymphoma thymidine kinase assay, and chromosomal aberration assays in Chinese hamster ovary cells or human lymphocytes. There were no mutagenic effects in the <i>in vivo</i> sister chromatid exchange and mouse micronucleus assay.
11.7 Carcinogenicity	Based on available data the classification criteria are not met. Increased incidences of prolactin-mediated endocrine tumours in rodents. It is not known if TSL.hcl elevates prolactin in humans. Relevance for human risk of the findings is not known.
11.8 Reproductive toxicity	Based on available data the classification criteria are not met. Males: reversible reduced fertility at doses 50 times the max. human exposure (no effect up to 16 times), possibly due to changes of semen content or impairment of ejaculation. Females: – Fertility: significant reductions in fertility associated with impairments in fertilization (no effect up to 16 times the max. human exposure). – Pregnancy: in rats and rabbits, TSL.hcl revealed no evidence of harm to the fetus. TSL.hcl is not indicated for use in women.

	– Lactation: no data (publically) available or generated. TSL.hcl is not indicated for use in women. Exercise caution.
11.9 STOT-single exposure	Based on available data the classification criteria are not met.
11.10 STOT-repeated exposure	Based on available data the classification criteria are not met.
11.11 Aspiration hazard	No data (publically) available or generated.
11.12 Other	See section 4.2.
12. Ecological information	
12.1 Toxicity	
12.1.1 <i>LC₅₀ (96 h, fish)</i>	750 mg/l
12.1.2 <i>E(L)C₅₀ (48 h, crustacea)</i>	Daphnia (water flea) = 180 mg/l
12.1.3 <i>ErC₅₀ (72 or 96 h, for algae or other aquatic plants)</i>	No data (publically) available or generated.
12.1.4 <i>Other</i>	-
12.2 <u>Persistence and degradability</u>	No data (publically) available or generated.
12.3 Bioaccumulative potential	
12.3.1. <i>Octanol/water partition coefficient.</i>	log P _{ow} = 0.5 (37°C)
12.3.2. <i>Bioconcentration factor</i>	No data (publically) available or generated.
12.3.3. <i>Other information</i>	No relevant data available.
12.4 <u>Mobility in soil</u>	No data (publically) available or generated.
12.5 <u>Results of PBT and vPvB assessment</u>	Not required/available.
12.6 <u>Other adverse effects</u>	No relevant data (publically) available or generated.
13 Disposal considerations	
13.1 <u>Waste treatment methods</u>	Handle as chemical waste. Dispose according to Federal-, State- or Local laws. Keep away from drains, surface- and ground-water, and soil. Please contact a EHS representative for additional information.
14 Transport information	
14.1 <u>UN number</u>	Not relevant/required.
14.2 <u>UN Proper shipping name</u>	Tamsulosin hydrochloride
14.3 <u>Transport hazard class(es)</u>	1] TSL.hcl, drug substance: ADR/RID: Not subject to ADR/RID. ICAO/IATA: Not subject to ICAO/IATA. TARIC: 2935 90 90 99 (CN code: 29359090) 2] Finished product (in bulk, non-retail): ADR/RID: Not subject to ADR/RID. ICAO/IATA: Not subject to ICAO/IATA. TARIC: 3004 90 00 00.
14.4 <u>Packing Group</u>	Not relevant/required.
14.5 <u>Environmental hazards</u>	Not environmentally hazardous. See section 12.
14.6 <u>Special precautions for user</u>	None known.
14.7 <u>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</u>	Not relevant.

<u>14.8 Other information</u>	LD₅₀ acute oral toxicity (LD(o)): 650 mg/kg. LD₅₀ acute dermal toxicity (LD(d)): no data available. LC₅₀ acute inhalatory toxicity (LD(i)): no data available. Although classified as described in section 2 of this SDS, the compound is not regulated for transport under ADR/RID (see ADR 2021, section 2.2.61.1.6) or ICAO/IATA (see 61st edition, section 3.6.1.3.2).
15 Regulatory information	
<u>15.1 Safety, health and environmental regulations/legislation specific for the substance</u>	No specific information available/required.
<u>15.2 Chemical safety assessment (as part of EU-REACH, (EC) No 1907/2006).</u>	To our knowledge, no CSA is required for this compound.
16 Other information	
<u>16.1 Revisions</u>	Supersedes: SDS.NL01.16740 (4.0) Minor changes sections 2, 11, and 12
<u>16.2 Abbreviations</u>	CLP: Classification, Labelling & Packaging OEB: Occupational Exposure Band OEL: Occupational Exposure limit STOT: Specific Target Organ Toxicity
<u>16.3 Key data sources</u>	Boehringer Ingelheim SDS V.1. 29-10-2019 Boehringer Ingelheim product monograph # 229213. 28-08-2019 FDA label NDA 21-319
<u>16.4 Training advice</u>	Distribute this SDS and relevant additional information to appropriate employees. If necessary, provide sufficient training to personnel with regard to safe working with hazardous materials.
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