according to Regulation (EC) No. 1907/2006



# Tamsulosin hydrochloride

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

1.1 Product identifier

Trade name : Tamsulosin hydrochloride

REACH Registration Number : -

CAS-No. : 106463-17-6

Unique Formula Identifier : -

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

Use of the Sub- : Active pharmaceutical ingredients

stance/Mixture

Recommended restrictions

on use

: No data available

1.3 Details of the supplier of the safety data sheet

Company : Fermion Oy

Street address : Koivu-Mankkaan tie 6 A

Post-office box: P.O. Box 28

Postcode : 02101 Espoo, Finland

Telephone : +358 10 4261

E-mail address of person : chemicalsafety@orion.fi

responsible for the SDS

VAT Reg. No: : FI18552129

1.4 Emergency telephone number

Poison Center : +358 800 147111

+358 9 471 977

# **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

### Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4 H332: Harmful if inhaled.

Acute toxicity, Category 4 H312: Harmful in contact with skin.

Acute toxicity, Category 4 H302: Harmful if swallowed.

For explanation of abbreviations see section 16.

#### 2.2 Label elements

#### Labeling (REGULATION (EC) No 1272/2008)

Hazard pictograms

**(!**>

Signal Word : Warning

**Hazard Statements** 

H302 Harmful if swallowed.

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H312 Harmful in contact with skin.

H332 Harmful if inhaled.

# **Precautionary Statements**

General:

P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.

Disposal:

P501 Dispose of contents according to national and local law.

2.3 Other hazards

Other hazards : No data available

PBT : No data available

vPvB : No data available

Endocrine disrupting pro-

perties

Ecological information: No data available

Toxicological information: No data available

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Chemical name	CAS-No. EC-No. Registration-No	Concentration (% w/w)	M-Factor, SCL, ATE
Tamsulosin hydrochloride	106463-17-6		

Other information : No data available

#### 3.2 Mixtures

Not applicable

#### **SECTION 4: First aid measures**

# 4.1 Description of first-aid measures

General advice : No data available

If inhaled : IF INHALED: Remove victim to fresh air and keep at rest in a

position comfortable for breathing. Get medical advice/attention.

In case of skin contact : Remove/ Take off immediately all contaminated clothing.

IF ON SKIN: Wash with soap and water.

In case of eye contact : IF IN EYES: Rinse continuously with water for several minu-

tes. Get medical advice/attention.

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If swallowed : Do NOT induce vomiting.

If the patient is conscious, give plenty of water (2 - 4 glasses), and let the charcoal (approximately 20 tablets), or give acti-

vated charcoal slurry (2 - 4 glasses).

Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No data available

Risks : No data available

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No data available

**SECTION 5: Firefighting measures** 

5.1 Extinguishing media

Suitable extinguishing media : Carbon dioxide (CO2)

Foam Water Powder

Unsuitable extinguishing

media

No data available

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire

fighting

May emit toxic fumes of oxides of carbon, nitrogen and

sulphur during heating or fire.

May emit toxic fumes of hydrogen chloride during heating or

fire.

Hazardous combustion pro-

ducts

No data available

5.3 Advice for firefighters

Special protective equipment:

for fire-fighters

Isolating breathing apparatus eg. compressed breathing appa-

ratus and protective clothing against chemicals.

Specific extinguishing me-

thods

No data available

Further information : No data available

**SECTION 6: Accidental release measures** 

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment as required.

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

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Methods for cleaning up : Collect spilled powder without dusting into tight closed contai-

ner.

6.4 Reference to other sections

See Section 8 and 13

**SECTION 7: Handling and storage** 

7.1 Precautions for safe handling

Advice on safe handling : Handle in well-ventilated space.

All exposure must be avoided.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep container tightly closed.

Protect from sunlight.

Store in a well ventilated place.

See incompatible materials in section 10.5.

Packaging material : Suitable material: No data available

Unsuitable material: No data available

7.3 Specific end use(s)

Specific use(s) : No information identified.

**SECTION 8: Exposure controls/personal protection** 

8.1 Control parameters

8.2 Exposure controls

Engineering measures : Do not get in eyes, on skin, or on clothing.

Handle in closed systems or use an efficient local exhaust if dust, vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal

protective equipment.

Personal protective equipment

Respiratory protection : In open handling use respirator (P3) with a minimum protec-

tion factor of 200.

See standard working procedures/instructions or department's

instructions for more detailed protection measures.

Eye/face protection : Use protective goggles.

Hand protection

Remarks : Use protective gloves (e.g. nitrile or neopren gloves).

Skin and body protection : Use normal working clothes.

Protective measures : No data available

Environmental exposure

controls

No data available

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## **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Form : powder

Physical state : solid

Color : white

Odor : odorless

Odor Threshold : No data available

Melting point/range : 226 - 228 °C

Boiling point/boiling range : No data available

Flammability : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Self-Accelerating decomposi-

tion temperature (SADT)

No data available

pH : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Flow time : No data available

Solubility(ies)

Water solubility : soluble

Solubility in other solvents : No data available

Dissolution Rate : No data available

Partition coefficient: n-

octanol/water

No data available

Dispersion Stability : No data available

Vapor pressure : No data available

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Relative density : No data available

Density : No data available

Bulk density : No data available

Relative vapor density : No data available

Dissociation constant : No data available

Particle characteristics : No data available

9.2 Other information

Self-ignition : No data available

Hygroscopic properties : No data available

Henry's Constant : No data available

Further information : No data available

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Stable in normal conditions.

# 10.2 Chemical stability

Stable when stored and handled according to instructions of use.

# 10.3 Possibility of hazardous reactions

Hazardous reactions : No data available

10.4 Conditions to avoid

Conditions to avoid : moisture

Light

10.5 Incompatible materials

Materials to avoid : Alkalis

#### 10.6 Hazardous decomposition products

May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.

# May emit toxic fumes of hydrogen chloride during heating or fire.

#### **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

**Acute toxicity** 

Health hazard information : Harmful if swallowed.

Acute oral toxicity : LD50 (Rat): 650 mg/kg

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Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

Acute toxicity (other routes of : No data available

administration)

Skin corrosion/irritation

Result May irritate the skin.

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Genotoxicity in vitro : No data available

: No data available Genotoxicity in vivo

Carcinogenicity

No data available

Reproductive toxicity

Effects on fertility : No data available

Effects on fetal development : No data available

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Repeated dose toxicity

No data available

**Aspiration toxicity** 

No data available

11.2 Information on other hazards

**Endocrine disrupting properties** 

No data available

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**Experience with human exposure** 

**General Information** No data available

Inhalation No data available

Skin contact No data available

Eye contact No data available

Ingestion No data available

Toxicology, Metabolism, Distribution

Remarks No data available

**Neurological effects** 

Remarks No data available

**Further information** 

Remarks May cause respiratory irritation.

**Other Health Hazards** 

No data available

# **SECTION 12: Ecological information**

12.1 Toxicity

Toxicity to fish No data available

Toxicity to daphnia and other :

aquatic invertebrates

No data available

Toxicity to algae/aquatic

plants

: No data available

Toxicity to fish (Chronic toxi:

No data available

Toxicity to daphnia and other : No data available

aquatic invertebrates (Chro-

nic toxicity)

Toxicity to microorganisms No data available

Toxicity to soil dwelling orga:

nisms

No data available

No data available Plant toxicity

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Sediment toxicity : No data available

Toxicity to terrestrial orga-

nisms

No data available

**Ecotoxicology Assessment** 

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

Toxicity Data on Soil : No data available

Other organisms relevant to

the environment

No data available

12.2 Persistence and degradability

Biodegradability : No data available

Biochemical Oxygen De-

mand (BOD)

No data available

Chemical Oxygen Demand

(COD)

No data available

BOD/COD : No data available

ThOD : No data available

BOD/ThOD : No data available

Dissolved organic carbon

(DOC)

No data available

Physico-chemical removabili: :

ty

No data available

Stability in water : No data available

Impact on Sewage Treat-

ment

No data available

Photodegradation : No data available

12.3 Bioaccumulative potential

Bioaccumulation : No data available

Partition coefficient: n-

octanol/water

No data available

12.4 Mobility in soil

Mobility : No data available

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Distribution among environ:

mental compartments

No data available

: No data available Stability in soil

12.5 Results of PBT and vPvB assessment

Assessment : No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

Environmental fate and pa-

thways

: No data available

Adsorbed organic bound

halogens (AOX)

: No data available

Ozone-Depletion Potential : No data available

Additional ecological informa: No data available

tion

# **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

#### **SECTION 14: Transport information**

14.1 UN number

ADR/RID: -IMDG: -IATA: -

14.2 UN proper shipping name

14.3 Transport hazard class(es) (ADR/RID, IMDG, ICAO/IATA)

ADR/RID: This product is not regulated under the

transport regulations.

IMDG: This product is not regulated under the trans-

port regulations.

IATA: This product is not regulated under the transport

regulations.

14.4 Packing group

ADR/RID: -IMDG: -IATA: -

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14.5 Environmental hazards

ADR/RID: - IMDG: - IATA: -

14.6 Special precautions for user

Tunnel restriction code : No data available

Further information for trans-

port

: No data available

# 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable

#### **SECTION 15: Regulatory information**

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

The product has not been fully tested.

#### 15.2 Chemical Safety Assessment

No

#### **SECTION 16: Other information**

#### **Full text of H-Statements**

H302 Harmful if swallowed. H312 Harmful in contact with skin.

H332 Harmful if inhaled.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity
Acute Tox. : Acute toxicity
Acute Tox. : Acute toxicity

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

AIIC - Australian Inventory of Industrial Chemicals

ASTM - American Society for the Testing of Materials

bw - Body weight

CLP - Classification Labelling Packaging Regulation

Regulation (EC) No 1272/2008

CMR - Carcinogen, Mutagen or Reproductive Toxicant

DIN - Standard of the German Institute for Standardisation

DSL - Domestic Substances List (Canada)

ECHA - European Chemicals Agency

EC-Number - European Community number

ECx - Concentration associated with x% response

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ELx - Loading rate associated with x% response

EmS - Emergency Schedule

ENCS - Existing and New Chemical Substances (Japan)

ErCx - Concentration associated with x% growth rate response

GHS - Globally Harmonized System

**GLP - Good Laboratory Practice** 

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC50 - Half maximal inhibitory concentration

ICAO - International Civil Aviation Organization

IECSC - Inventory of Existing Chemical Substances in China

IMDG - International Maritime Dangerous Goods

IMO - International Maritime Organization

ISHL - Industrial Safety and Health Law (Japan)

ISO - International Organisation for Standardization

**KECI - Korea Existing Chemicals Inventory** 

LC50 - Lethal Concentration to 50 % of a test population

LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)

MARPOL - International Convention for the Prevention of Pollution from Ships

n.o.s. - Not Otherwise Specified

NO(A)EC - No Observed (Adverse) Effect Concentration

NO(A)EL - No Observed (Adverse) Effect Level

NOELR - No Observable Effect Loading Rate

NZIoC - New Zealand Inventory of Chemicals

OECD - Organization for Economic Co-operation and Development

OPPTS - Office of Chemical Safety and Pollution Prevention

PBT - Persistent, Bioaccumulative and Toxic substance

PICCS - Philippines Inventory of Chemicals and Chemical Substances (Q)SAR - (Quantitative) Structure Activity Relationship

REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

RID - Regulations concerning the International Carriage of Dangerous Goods by Rail

SADT - Self-Accelerating Decomposition Temperature

SDS - Safety Data Sheet

SVHC - substance of very high concern

TCSI - Taiwan Chemical Substance Inventory

TECI - Thailand Existing Chemicals Inventory

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TRGS - Technical Rule for Hazardous Substances

TSCA - Toxic Substances Control Act (United States)

**UN - United Nations** 

vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Other information : The above information is believed to be correct but does not

purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Orion Diagnostica Oy shall not be held liable for any damage resulting from

handling or from contact with the above product.

Sources of key data used to compile the Material Safety

**Data Sheet** 

Information provided by the supplier

Information which has been

added, deleted or revised

Updated section / sections:

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.